Quick Reference to QUALITY SYSTEM PROCEDURE

AS PER ISO 15189:2022

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Table of Contents

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Master Copy				
Copy-1				

Gap analysis comparing ISO 15189:2012 and ISO 15189:2022, highlighting the key differences based on different aspects

Aspect	ISO 15189:2012	ISO 15189:2022	Gap/Change
Scope	Focuses on quality and competence of medical laboratories	Updated to address risk-based thinking and broader management changes	Emphasis on risk management and broader scope of management practices in the new version.
Quality Management System (QMS)	Requires a QMS based on the laboratory's operations	Strengthened focus on risk-based approach to QMS	More comprehensive approach to risk management and continuous improvement processes.
Risk Management	Not explicitly addressed in detail	Requires a systematic approach to risk management, including risk assessment and mitigation	Major addition to emphasize risk management at all levels.
Quality Indicators	Focus on monitoring quality through key performance indicators	Includes more explicit requirements for monitoring and assessing quality performance, with added focus on corrective actions	Expanded guidance on the assessment of performance and more detailed documentation required.
Internal Audit	Internal audits are required as part of QMS	Internal audits required, with more emphasis on assessing effectiveness and risk-based auditing	Enhanced focus on auditing and assessing the effectiveness of the system.
Management Responsibility	Focus on management roles and responsibilities in maintaining quality standards	Broader responsibilities for management, including the integration of risk management into leadership activities	Greater focus on leadership and the integration of risk management across all levels of management.
Documentation Control	Requires documentation control for laboratory processes	Explicitly requires documentation to cover risk management, corrective actions, and performance reviews	Broader documentation requirements, including those related to risk and corrective actions.
Calibration and Equipment Management	Equipment calibration and maintenance are addressed	Updated requirements for equipment calibration with more detailed procedures for ensuring equipment reliability	More detailed and clearer procedures on equipment reliability and calibration processes.

Non-conformity Management	Requires the management of non-conformities and corrective actions	Requires more explicit and structured management of non-conformities, with an emphasis on root cause analysis and risk-based corrective actions	Enhanced requirements for the documentation of non-conformities and the incorporation of root cause analysis.
Competence and Training	Requires staff training and competence verification	Training programs need to be more aligned with risk management practices and changes in laboratory operations	Training now needs to include risk management and related competencies.
Accreditation Process	Focused on regular assessments and audits by accrediting bodies	Includes more emphasis on the transition to ISO 15189:2022 with updated processes for accreditation	Transition audit requirement for the update to ISO 15189:2022.

Gap analysis comparing ISO 15189:2012 and ISO 15189:2022, highlighting the key differences based on Area

Area	ISO 15189:2012	ISO 15189:2022	Key Changes
Structure & Alignment	Based on ISO/IEC 17025:2005 and ISO 9001:2008	Aligned with ISO/IEC 17025:2017 and ISO 9001:2015	Enhanced alignment with updated standards for consistency across management systems.
Risk Management	Limited references to risk management.	Emphasizes risk-based thinking throughout the standard.	Laboratories are required to identify and manage risks to patient safety and laboratory operations.
Point-of-Care Testing (POCT)	Addressed separately in ISO 22870:2016.	Integrated into the main standard.	POCT requirements are now part of ISO 15189:2022, leading to the withdrawal of ISO 22870:2016.
Quality Manual	Mandatory requirement.	Optional; not explicitly required.	Laboratories have flexibility in documenting their quality management systems.
Quality Manager Role	Specific appointment required.	Role is not specifically mandated.	Emphasis on shared responsibility among competent personnel.
Patient Focus	Implicit focus on patient care.	Explicit emphasis on patient safety and rights.	Laboratories must consider patient impact in all processes.
Impartiality and Confidentiality	General requirements.	Detailed requirements for impartiality and confidentiality, including legally enforceable agreements.	Strengthened measures to prevent conflicts of interest and protect patient information.
Competence and Personnel Authorization	General competence requirements.	Detailed processes for personnel authorization and competence assessment.	Laboratories must ensure personnel are authorized for specific activities and maintain competence records.
Information Management	Basic requirements for information systems.	Enhanced focus on information management, including cybersecurity considerations.	Laboratories must ensure the security and integrity of data, with attention to cybersecurity risks.
Management System Documentation	Prescriptive documentation requirements.	Less prescriptive; allows for flexibility in documentation.	Laboratories can tailor documentation to their specific needs while ensuring compliance.
Internal Audits	Scheduled audits without specific risk-based approach.	Requires risk-based audit planning.	Audit schedules must prioritize areas with higher risks to patient safety and laboratory quality.

Area	ISO 15189:2012	ISO 15189:2022	Key Changes
Nonconforming Work	Procedures for handling nonconformities.	Emphasizes evaluation of the clinical impact of nonconforming work.	Laboratories must assess the potential patient impact of nonconformities and take appropriate actions.
Terminology and Definitions	Limited definitions provided.	Expanded and clarified definitions, including terms like "impartiality," "laboratory user," and "consultant."	Improved clarity to reduce misinterpretation and enhance understanding.

Gap analysis Amendments incorporated in Quality System Procedure Version 2.0 to suite as per ISO 15189:2022 in QSP version 3.0

Clause	ISO 15189:2012 Sub-clause	ISO 15189:2022 Sub-clause	Key Changes
Management Requirements			
Organization and Management Responsibility	4.1	5.1, 5.2	Enhanced emphasis on governance and leadership responsibilities.
Quality Management System	4.2	8.1, 8.2	Shift towards a risk-based approach and integration with ISO 9001:2015 principles.
Document Control	4.3	8.3	Streamlined requirements for document management.
Service Agreements	4.4	6.7	Expanded to include agreements with POCT operators.
Examination by Referral Laboratories	4.5	6.8.2	More detailed requirements for managing referral laboratories.
External Services and Supplies	4.6	6.8	Broader scope covering all externally provided products and services.
Advisory Services	4.7	5.3.3	Clarified expectations for advisory activities.
Resolution of Complaints	4.8	7.7	More structured approach to handling complaints.
Identification and Control of Nonconformities	4.9	8.7	Emphasis on evaluating the impact of nonconformities on patient care.
Corrective Action	4.1	8.7.2	Integrated into a broader nonconformity management process.
Preventive Action	4.11	8.5	Replaced with a proactive approach to risk management.
Continual Improvement	4.12	8.6	Focus on systematic improvement based on data analysis.
Control of Records	4.13	8.4	Enhanced requirements for record management and retention.
Evaluation and Audits	4.14	8.8	Introduction of quality indicators and expanded audit processes.

Management Review	4.15	8.9	Broadened scope to include strategic direction and risk management.
Technical Requirements			
Personnel	5.1	6.2	Detailed competence requirements and authorization processes.
Accommodation and Environmental Conditions	5.2	6.3	Specific controls for facilities, including sample collection areas.
Laboratory Equipment, Reagents, and Consumables	5.3	6.4, 6.5, 6.6	Segregated into detailed subclauses for equipment and materials management.
Pre-examination Processes	5.4	7.2	Expanded to cover patient information and sample handling procedures.
Examination Processes	5.5	7.3	Inclusion of method validation and measurement uncertainty evaluation.
Ensuring Quality of Examination Results	5.6	7.3.7	Enhanced focus on internal quality control and result validation.
Post-examination Processes	5.7	7.4	Detailed requirements for result reporting and sample storage.
Reporting of Results	5.8	7.4.1	Clarified reporting protocols, including electronic reporting considerations.
Laboratory Information Management	5.9	7.6	Comprehensive requirements for information systems and data integrity.
Additional Requirements			
Risk Management	Not explicitly defined	5.6, 8.5	Introduction of risk-based thinking throughout the standard.
Point-of-Care Testing (POCT)	Covered under ISO 22870	Annex A	Integrated POCT requirements into the main standard, leading to withdrawal of ISO 22870.

Sl. No	Clause No.	Date of Amendment	Amendment made	Reasons	Signature of Section-in-charge	Signature of Lab Director

1. Scope

This document specifies requirements for quality and competence in medical laboratories.

This document is applicable to medical laboratories in developing their management systems and assessing their competence. It is also applicable for confirming or recognizing the competence of medical laboratories by laboratory users, regulatory authorities and accreditation bodies.

2. Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

1. ISO/IEC Guide 99:2007, International vocabulary of metrology — Basic and general concepts and associated terms (VIM)
2. ISO/IEC Guide 99 is also known as the Joint Committee for Guides in Metrology (JCGM) 200.
3. ISO/IEC 17000:2020, Conformity assessment Vocabulary and general principles
4. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories

3 Terms and definitions

3.1 Bias measurement bias

estimate of a systematic measurement error

3.2 Biological reference interval reference interval

Specified interval of the distribution of values taken from a biological reference population

- A reference interval is commonly defined as the central 95% interval. Another size or an asymmetrical location of the reference interval could be more appropriate in particular cases.
- A reference interval can depend upon the type of *primary sample* and the *examination procedure* used.

- In some cases, only one biological reference limit is important, usually an upper limit, “x”, so that the corresponding biological reference interval would be less than or equal to “x”.
- Terms such as ‘normal range’, ‘normal values’, and ‘clinical range’ are ambiguous and therefore discouraged.

3.3 Clinical decision limit

Examination result that indicates a higher risk of adverse clinical outcomes, or is diagnostic for the presence of a specific disease

Clinical decision limits for therapeutic drugs are called "therapeutic range". It is used to determine risk of disease, to diagnose or to treat.

3.4 Commutability of a reference material

The commutability property of reference material, demonstrated by the closeness of agreement between the relation among the measurement results for a stated quantity in this material, obtained according to two given measurement procedures and the relation obtained among the measurement results for other specified materials

- The reference material in question is usually a calibrator and the other specified materials are usually routine samples.
- It is typical that there are more than two measurement procedures available and comparison among all applicable measurement procedures is desirable.
- Closeness of agreement of measurement results is defined in terms of fitness for purpose as appropriate for the intended use of the reference material.
- A commutability statement is restricted to the measurement procedures as specified in a particular comparison.

3.5 Competence

Demonstrated ability to apply knowledge and skills to achieve intended results

3.6 Complaint

Expression of dissatisfaction by any person or organization to a *laboratory*, relating to the activities or results of that laboratory, where a response is expected

3.7 Consultant

The person who provides expert advice professionally

3.8 Examination

Set of operations having the objective of determining the numerical value, text value, or characteristics of a property

- An examination may be the total of number of activities, observations, or measurements required to determine a value or characteristic.
- Laboratory examinations that determine a numerical value of a property are called "quantitative examinations"; those that determine the characteristics of a property are called "qualitative examinations".
- Laboratory examinations are also called "assays" or "tests".

3.9 Examination procedure

Specifically described a set of operations used in the performance of an *examination* according to a given method. In the IVD medical device industry and in many laboratories that use IVD medical devices, an examination procedure for an analyte in a biological sample is commonly referred to as an analytical method, analytical procedure, or test procedure.

3.10 External quality assessment

Evaluation of participant performance against pre-established criteria by means of inter-laboratory Comparison

3.11 Impartiality

Objectivity with regard to the outcome of tasks performed by the *medical laboratory*

- Objectivity can be understood as freedom from bias or freedom from conflicts of interest.
- Other terms that are useful in conveying the element of impartiality include “independence”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.

3.12 Inter-laboratory comparison

Organization, performance and evaluation of measurements or *examinations* on the same or similar materials by two or more independent laboratories in accordance with pre-determined conditions

3.13 Internal quality control IQC

Quality control QC

Internal procedure which monitors the testing process to verify the system is working correctly and gives confidence that the results are reliable enough to be released

3.14 In-vitro diagnostic medical device

IVD medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring, or compatibility purposes and including reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles

3.15 Laboratory management

Person(s) with responsibility for, and authority over a *laboratory*

- Laboratory management can delegate authority and provide resources within the laboratory.
- The laboratory management includes the laboratory director(s) and delegates together with individuals specifically assigned to ensure the quality of the activities of the laboratory.

3.16 Laboratory user

Individual or entity requesting services of the *medical* users can include patients, clinicians, and, other laboratories or institutions that send samples for examination.

3.17 Management system

Set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve those objectives

- This was formerly referred to and is synonymous with “quality management system”.
- The management system elements establish the organization’s structure, roles and responsibilities, planning, operation, policies, practices, rules, beliefs, objectives, and processes to achieve those objectives.

3.18 Measurement accuracy

Accuracy: Closeness of agreement between a measured quantity value and a true quantity value of a measured

- The concept 'measurement accuracy' is not a quantity and is not given a numerical quantity value. A measurement is said to be more accurate when it offers a smaller measurement error.
- The term "measurement accuracy" should not be used for measurement trueness and the term measurement precision should not be used for 'measurement accuracy', which, however, is related to both these concepts.
- Measurement accuracy' is sometimes understood as the closeness of agreement between measured quantity values that are being attributed to the measurand.

3.19 Measurement uncertainty (MU)

Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

- MU includes components arising from systematic effects, as in the case of corrections to the assigned quantity values of measurement standards. Sometimes estimated systematic effects are not corrected for, but instead, the associated MU components are incorporated.
- The parameter may be, for example, a standard deviation (SD) called standard MU (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.
- MU comprises, in general, of many components. Some of these may be evaluated by Type A evaluation of MU from the statistical distribution of the quantity values from series of measurements and can be characterized by SD. The other components, which may be evaluated by Type B evaluation of MU, can also be characterized by SD or evaluated from probability density functions based on experience or other information.
- In general, for a given set of information, it is understood that the MU is associated with a stated quantity value attributed to the measurand. A modification of this value may result in a modification of the associated uncertainty.
- All measurements have *bias* and imprecision. For example, replicate measurements of a sample performed under repeatability conditions generally produce different values for the same measurand. Because the different values could all be reasonably attributed to the same amount of measurand, there is uncertainty as to which value should be reported as the value of the measurand.

- Based on available data about the analytical performance of a given measurement procedure, an estimation of MU provides an interval of values that is believed to include the actual value of the measurand, with a stated level of confidence.
- Available data about the analytical performance of a given measurement procedure typically comprise uncertainty of calibrator assigned values and long-term imprecision of IQC materials.
- In medical laboratories, most measurements are performed in singleton, and are taken to be an acceptable estimate of the value of the measurand, while the MU interval indicates other results that are also possible.

3.20 Medical Laboratory

Laboratory

entity for the *examination* of materials derived from the human body for the purpose of providing information for the diagnosis, monitoring, management, prevention and treatment of disease, or assessment of health. The laboratory can also provide advice covering all aspects of examinations including appropriate selection, the interpretation of results, and advice on further examinations. Laboratory activities include *pre-examination*, *examination,* and *post-examination processes*. Materials for *examination* include but are not limited to, microbiological, immunological, biochemical, immune-haematological, hematological, biophysical, cytological, tissue and cells, and genetic material.

3.21 Patient

A person who is the source of material for an *examination*

3.22 Point-of-care testing

POCT examination is performed near or at the site of a patient.

3.23 Post-examination processes

Processes following the examination include review of results, formatting, releasing, reporting, and retention of examination results, retention and storage of clinical material, samples, and waste disposal

3.24 Pre-examination processes

Processes that start, in chronological order, from the user's request and include the *examination* request, preparation, and identification of the *patient*, collection of the *primary sample(s)*, transportation to and within the *laboratory*, ending when the *examination* begins

3.25 Primary sample

Specimen

Discrete portion of a body fluid or tissue or other sample associated with the human body taken for examination, study or analysis of one or more quantities or characteristics to determine the character of the whole. The International Medical Device Regulators Forum (IMDRF) uses the term specimen in its harmonized guidance documents to mean a sample of biological origin intended for examination by a medical laboratory.

3.26 Quality indicator

Measure of the degree to which a large number of characteristics of an object fulfills requirements Measure can be expressed, for example, as % yield (% within specified requirements), % defects (% outside specified requirements), defects per million occasions (DPMO) or on the Six Sigma scale. Quality indicators can measure how well an organization meets the needs and requirements of users and the quality of all operational processes.

3.27 Referral laboratory

External *laboratory* to which a sample or data is submitted for *examination*. A referral laboratory is one to which laboratory management chooses to submit a sample or sub- sample for examination, data for analysis or interpretation, or when routine examinations cannot be carried out. This differs from a laboratory to which submission of samples is required by regulation, or a so called reference laboratory, e.g. public health, forensic, tumour registry, or a central (parent) facility to which submission of samples is required by structure.

3.28 Sample

One or more parts taken from a *primary sample*

3.29 Trueness

Measurement trueness

The closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value. Measurement trueness is not a quantity and thus cannot be expressed numerically, but measures for closeness of agreement are given in ISO 5725-1. Measurement trueness is inversely related to systematic measurement error, but is not related to random measurement error. Measurement accuracy" should not be used for 'measurement trueness'. For qualitative examinations, trueness of measurement (closeness of agreement) can be expressed in terms of concordance (i.e. percent agreement with a reference examination). Trueness is a property of the *examination procedure* that reflects the *bias* of the measurements from the

expected or target value. It is described qualitatively as good or bad. An *examination procedure* has good trueness if the *bias* of the measurements is acceptable.

3.30 Turnaround time

Elapsed time between two specified points through pre-examination, examination, and post-examination processes

3.31 Validation

Confirmation of plausibility for a specific intended use or application through the provision of objective evidence that specified requirements have been fulfilled. Objective evidence can be obtained through observation, measurement, examination or by other means. The word "validated" is used to designate the corresponding status. Specified requirements of an examination method may include the following performance specifications: measurement trueness, measurement precision including measurement repeatability, and measurement intermediate precision, analytical specificity, including interfering substances, detection limit and quantitation limit, measuring interval, clinical relevance, diagnostic specificity and diagnostic sensitivity.

3.32 Verification

Confirmation of truthfulness, through the provision of objective evidence that specified requirements have been fulfilled. Verification is the process by which the laboratory confirms that the established performance claims of a measuring system, e.g. trueness, precision, reportable range, can be replicated in the laboratory before human sample examination is performed. The objective evidence needed for a verification can be the results of an inspection, or other forms of determination, such as performing alternative calculations or reviewing documents. Verification may be sufficient to implement a new IVD device under circumstances where the *examination* is performed and used in the manner as directed in the package insert. The word "verified" is used to designate the corresponding status.

4.0 General Requirements

4.1 Impartiality (QSP Number: ML/QSP-01/IMP)

1. Purpose

This procedure aims to uphold the **competence, impartiality, judgment, and operational integrity** of the Molecular Laboratory (ML), ensuring that all activities align with ethical and professional standards. The laboratory is committed to avoiding any actions that could compromise the **trust and confidence** of patients, stakeholders, and regulatory bodies in its operations.

2. Responsibility

- All **laboratory staff** are responsible for adhering to this procedure.
- **Laboratory management** is responsible for monitoring, implementing, and enforcing compliance with ethical and quality standards.
- **Section In-Charges** oversee employees' adherence to integrity, confidentiality, and professional conduct.

3. Scope

This procedure defines the **impartiality, ethical, and professional responsibilities** of all laboratory personnel, ensuring that operations are carried out with the highest level of **integrity, transparency, and ethical compliance**. It applies to:

- Patient-related activities
- Confidentiality and impartiality in decision-making
- Laboratory processes and operational ethics
- Employee conduct and responsibilities

4. Procedure

a) The **Molecular Laboratory** ensures that all employees maintain **impartiality and integrity** when handling **patient samples, data, and related activities**. Employees are expected to perform their duties without bias or favoritism.

b) Laboratory management has a strict policy to **shield employees from any commercial, financial, or external pressures** that could impact the quality, accuracy, or reliability of laboratory work. Employees must report any undue influences to management immediately.

c) A **Quality Policy** has been established to **monitor and supervise** employee conduct, ensuring strict adherence to laboratory guidelines, ethical responsibilities, and professional standards.

d) The laboratory ensures **hiring and role allocation** are based on **qualification and competency**, preventing any compromise in service quality. **Job responsibilities are assigned in alignment with employees' expertise, ensuring high-quality performance.**

e) Employees are provided with **continuous professional training** to enhance their **technical skills, knowledge, and competency**. Regular workshops, refresher courses, and hands-on training sessions are conducted to keep employees updated on the latest advancements in molecular laboratory practices.

f) **Section In-Charges** conduct **regular interactions, reviews, and performance assessments** to ensure employees **uphold ethical standards** and maintain a high level of integrity in their professional conduct.

g) Employees are **guided and supported** to maintain **precision, accuracy, and reliability** in laboratory testing. Additionally, they are strictly advised to **handle test results as confidential information** and to prevent any unauthorized disclosure to third parties.

h) All employees **undergo an induction program** where they receive comprehensive training on:

- Confidentiality of patient information
- Impartiality in laboratory procedures
- Judgment and decision-making ethics
- **Operational integrity and compliance with legal regulations**
  At the end of the induction program, employees **sign a confidentiality agreement**, reinforcing their commitment to maintaining discretion and professional ethics.

i) Employees and consultants are **encouraged to report concerns** related to professional ethics, performance, or external influences that may affect their duties. Section In-Charges promptly **initiate corrective and preventive actions** to eliminate any issues that could impact employee performance and laboratory standards.

j) **Acceptance of favors, gifts, or personal benefits** from patients, their attendants, or any external parties is strictly **prohibited**. Employees are expected to adhere to the **highest standards of ethical conduct** and avoid engaging in any actions that could compromise the integrity of the laboratory.

k) The laboratory ensures **no involvement in activities** that could undermine **public trust and confidence** in its **competence, impartiality, judgment, or operational integrity**. Any potential conflicts of interest must be reported and resolved transparently.

l) In cases where **competing interests** arise, they must be **openly declared and appropriately managed** to ensure that they do not influence laboratory decisions, results, or operations.

m) The laboratory has implemented **strict protocols** to ensure that **human samples, tissues, or remains** are handled in **compliance with legal and ethical guidelines**. Employees are required to follow all relevant regulatory requirements to ensure **respect, dignity, and professionalism** in handling biological materials.

5. Commitment to Continuous Improvement

To ensure the continued effectiveness of this policy:

- Regular internal audits and quality control assessments are conducted.
- Employees receive ongoing ethics and integrity training.
- The Quality Policy is periodically reviewed and updated to align with new regulations, technological advancements, and best practices in laboratory management.

This procedure serves as the foundation for maintaining **high ethical and professional standards** within the Molecular Laboratory. Employees are expected to **uphold these principles** in all aspects of their work.

Annexures

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/F/1	Confidentiality and Ethical conduct agreement	Form	Laboratory Director	Personnel File-Laboratory office	Continuous

4.2 Confidentiality (QSP Number: ML/QSP-02/CONF)

1. **Purpose**

This procedure ensures that the **Molecular Laboratory** upholds the **highest standards of confidentiality and data protection** when handling patient information. The laboratory is committed to **preventing any unauthorized access, disclosure, or misuse** of patient data, thereby safeguarding **patient privacy, dignity, and trust**.

2. Responsibility

All laboratory staff are responsible for maintaining patient confidentiality and adhering to established privacy policies.

Laboratory management must enforce confidentiality policies and ensure staff compliance.

Section In-Charges oversee the proper handling of patient information and address any breaches.

3. Scope

This **Quality System Procedure (QSP)** applies to:

- **All patient data, including personal, medical, and test-related information.**
- **The ethical and professional responsibility of every laboratory staff member** in maintaining confidentiality.
- **The handling, processing, storage, and transmission of patient records.**
- **Legal and regulatory compliance in protecting patient information.**

4. Procedure

a) Respect for Patient Confidentiality

All **laboratory personnel** must uphold and respect **patient privacy** by ensuring that all personal and medical information is handled **with the highest level of discretion and security**.

b) Protection of Patient Information

- All details related to **patients, their medical history, test results, and health conditions** are treated as **highly confidential information**.
- **Health insurance claims** and other sensitive data are processed securely and shared **only with the relevant employer or insurer**.

c) Controlled Access and Restrictions on Information Disclosure

- The **Molecular Laboratory does not share patient personal or medical information** with any **unauthorized individuals, external organizations, or third parties** unless:
  - The patient provides **explicit written consent** for disclosure.
  - Disclosure is **required by law** for reporting to regulatory or statutory authorities.
  - Confidentiality is **a shared responsibility** between the **patient and the caregiver**, ensuring that patient information remains secure and private.

d) Confidentiality Agreement for Staff

- Upon employment, **all laboratory staff are required to sign a Confidentiality and Responsibility Agreement** (**ML/F/001**), which legally binds them to maintain patient confidentiality.
- This signed agreement is **stored securely in the personnel records** of the employee.
- Employees who violate confidentiality policies may be subject to **disciplinary action**, which could include **warnings, suspension, or termination**, depending on the severity of the breach.

e) Secure Handling and Storage of Patient Records

- All patient records are maintained **securely in a controlled environment** to prevent unauthorized access, tampering, or loss.
- **Electronic medical records** (if applicable) are **protected through secure login credentials, encrypted databases, and restricted access** based on employee roles.
- Printed records are **stored in locked cabinets** with limited access to authorized personnel only.

f) Employee Training and Awareness

- Laboratory staff **receive regular training** on data protection laws, patient confidentiality, and ethical handling of sensitive information.
- Awareness programs reinforce the importance of **ethical responsibility** and help staff **recognize potential confidentiality breaches** before they occur.

g) Compliance with Legal and Regulatory Standards

- The Molecular Laboratory follows **ISO 15189:2022** standards, which set international requirements for **medical laboratory quality and competence**.
- The laboratory also adheres to **national and institutional guidelines** on data privacy and security.

5. Monitoring and Enforcement

- **Routine audits** and inspections are conducted to assess compliance with confidentiality policies.
- Any **breaches of patient confidentiality** are investigated, and corrective actions are implemented to prevent recurrence.
- Employees are encouraged to report any concerns about **data security or confidentiality violations** to their Section In-Charge or management.

This procedure ensures that patient information is handled **with the highest level of security, professionalism, and integrity**. The **Molecular Laboratory remains committed to protecting patient confidentiality**, maintaining compliance with ethical and legal standards, and fostering **trust among patients, caregivers, and regulatory authorities**.

4.2.2 Release of Information

The Molecular Laboratory is committed to maintaining **the confidentiality of patient information** while ensuring compliance with **legal and contractual obligations** regarding data disclosure. The following principles guide the controlled release of patient information:

1. Legal and Contractual Disclosure

- If the laboratory is **legally required** or **contractually obligated** to disclose confidential patient information, the **concerned patient will be informed** about the details of the disclosure during registration, and consent will be taken during registration in the software.
- Such disclosures may be mandated by **statutory authorities, court orders, public health regulations, or insurance agreements** that require patient data for lawful purposes.

2. Handling Third-Party Information Requests

- If patient-related information is obtained from a **source other than the patient** (e.g., a **regulatory body, complainant, or legal authority**), the laboratory will:
  - **Ensure that the information remains confidential** and is only used for its intended purpose.
  - **Protect the identity of the source** and do **not disclose it to the patient** unless the source has provided **explicit consent** for such disclosure.

3. Confidentiality Measures for Disclosures

- All disclosures of patient information must be **carefully documented**, including:
  - **The reason for disclosure**
  - **The recipient of the information**

- **Legal or contractual justification**
- **Whether the patient was notified** (unless prohibited)

- The laboratory will **only disclose the minimum necessary information** required by law or agreement to protect patient privacy as much as possible.

4. Patient Notification and Rights

- In cases where notification is **not legally restricted**, the patient will be:
  - Informed about what information was released
  - Told why the information was disclosed
  - Provided with details about the recipient of the data
- If a patient has concerns regarding the disclosure of their information, they have the right to seek **clarification or legal guidance**.

5. Compliance and Ethical Considerations

- The Molecular Laboratory follows **ISO 15189:2022** and **institutional regulations** to ensure confidentiality and ethical handling of patient data.
- Employees involved in handling or releasing confidential information receive **training on privacy laws, ethical responsibilities, and best practices**.
- Any **unauthorized or improper disclosure** of patient information is taken **seriously** and may result in **corrective actions, disciplinary measures, or legal consequences**.

By adhering to these guidelines, the laboratory ensures that patient data remains **secure, confidential, and disclosed only when absolutely necessary**, maintaining **trust and compliance** with all applicable regulations.

4.2.3 Personnel Responsibility

All laboratory personnel, including committee members, contractors, representatives of external bodies, and any individuals acting on behalf of the laboratory, are strictly required to maintain confidentiality regarding all information accessed, obtained, or created during laboratory operations.

This responsibility ensures the **protection of sensitive data**, including:

- **Patient information** (personal details, test results, medical history)
- **Research and diagnostic findings**
- **Laboratory procedures, methodologies, and protocols**
- **Proprietary or institutional information**
- **Any data related to contractual, legal, or regulatory matters**

Key Confidentiality Obligations:

- Personnel must **not share laboratory-related information** with unauthorized individuals, including colleagues not involved in specific tasks, external parties, or the public.
- Disclosure is permitted **only when legally required or explicitly authorized by laboratory management**.

1. **Secure Handling of Information:**
    - Laboratory records, reports, and digital files must be stored securely to prevent **unauthorized access, modification, or misuse**.
    - Electronic information must be **password-protected, encrypted (if applicable), and accessible only to authorized personnel**.
    - Physical documents must be stored in **locked cabinets or controlled-access areas**.
2. **Confidentiality Agreement:**
    - Upon joining, all personnel are required to **sign a confidentiality and non-disclosure agreement** that legally binds them to uphold these responsibilities.
    - Breach of confidentiality may result in **disciplinary actions, contract termination, or legal consequences**, depending on the severity of the violation.
3. **Handling Third-Party Information Requests:**
    - Any external request for laboratory data must be **formally reviewed and approved by laboratory management** before disclosure.
    - Personnel must **not respond to informal inquiries** regarding laboratory activities or patient information.

4. **Legal and Ethical Compliance:**
    - All personnel must comply with **ISO 15189:2022** and other relevant regulations governing **medical laboratory confidentiality and ethical conduct**.
    - Regular training sessions on **data protection, ethical responsibility, and confidentiality policies** are conducted to ensure ongoing compliance.

By adhering to these principles, the laboratory safeguards **data security, patient trust, and operational integrity**, ensuring compliance with ethical, professional, and legal standards.

Annexures

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/F/1	Confidentiality and Ethical Conduct Agreement	Form	Laboratory Director	Personnel File-Laboratory office	Continuous

4.3 Requirements regarding patients (QSP Number: ML/QSP-03/REQRP)

The **Molecular Laboratory** is dedicated to upholding the **well-being, safety, and rights** of all patients by ensuring **ethical, professional, and legally compliant practices**. Laboratory management is responsible for **establishing, implementing, and monitoring** processes that protect patient interests while maintaining **high standards of diagnostic accuracy, confidentiality, and patient care**.

To achieve these objectives, the laboratory has implemented the following measures:

a) Facilitating Patient and User Input

- The laboratory encourages **patients and laboratory users** to provide information that may assist in:
  - **Selecting appropriate examination methods** tailored to the patient's medical needs.
  - **Interpreting test results accurately**, considering patient history and relevant clinical details.
- Mechanisms such as **pre-test consultations, request forms, and follow-up discussions** are provided to enable patient input.

b) Transparent Communication About Testing

- The laboratory ensures that patients and users have **clear, publicly accessible information** regarding:
  - **Examination procedures** – what to expect during testing.
  - **Turnaround times** – when results will be available.
  - **Costs and financial policies** (if applicable).
  - **Any pre-test or post-test requirements** (e.g., fasting, sample collection guidelines).
- Information is made available through **patient information brochures, laboratory websites, and direct communication with healthcare providers**.

c) Periodic Review of Laboratory Examinations

- The laboratory conducts **regular reviews of all tests offered** to ensure they:
  - Remain **clinically relevant** and **medically necessary**.
  - Align with **current best practices, research, and guidelines**.
  - Meet the **changing needs of patients, physicians, and healthcare systems**.
- If any test is **outdated, ineffective, or redundant**, it may be revised, replaced, or discontinued in consultation with **medical professionals and laboratory specialists**.

d) Incident Reporting and Patient Disclosure

- The laboratory maintains a **systematic approach** to managing incidents that **resulted in, or could have resulted in, patient harm**. This includes:
  - **Identifying and recording incidents** such as misdiagnosis, delayed results, or sample mishandling.
  - **Informing affected patients, laboratory users, or healthcare providers** when legally or ethically required.
  - **Investigating root causes** and implementing **corrective and preventive actions (CAPA)** to avoid recurrence.
- The laboratory ensures **transparency in communication** while adhering to **confidentiality laws and ethical disclosure guidelines**.

e) Ethical Handling of Patients, Samples, and Human Remains

- Patients, **biological samples**, and **human remains** are handled with **utmost respect, dignity, and care**.
- All laboratory personnel are trained to:
  - Follow **ethical guidelines for sample collection, storage, and disposal**.
  - Ensure **proper documentation and traceability** of each sample.
  - Prevent **sample contamination, misidentification, or loss**.
- When handling **human remains or post-mortem samples**, strict **regulatory and ethical standards** are followed to ensure **respect for the deceased and their families**.

f) Obtaining Informed Consent

- Informed consent is **obtained from patients** whenever required by law or laboratory policy, particularly for:
  - **Genetic testing** or tests involving **sensitive medical information**.
  - **Experimental, research-based, or high-risk examinations**.
  - **Storage or secondary use of patient samples for future studies**.
- Patients are fully informed of:
  - The **purpose, risks, and benefits** of the examination.
  - Their **right to refuse** or withdraw consent at any time.
  - How their **samples and data** will be used.
- Consent is documented and securely stored for compliance and legal protection.

g) Safeguarding Patient Records and Samples

- The laboratory has **protocols in place** to ensure the **long-term security and integrity** of retained patient samples and records, particularly in cases of:
  - **Laboratory closure, acquisition, or merger**.
  - **Regulatory investigations or legal inquiries**.
  - **Long-term patient follow-up and research purposes** (when permitted).
- Confidentiality and data security measures include:
  - **Encryption and password protection** for electronic records.
  - **Restricted access policies** for authorized personnel only.
  - **Secure storage facilities** for physical samples and documents.
- In case of laboratory transition, **patient records and samples are either transferred securely to an appropriate facility** or disposed of in accordance with **legal and ethical standards**.

h) Providing Patient Information to Healthcare Providers

- Upon request, **relevant laboratory information** is made available to:
  - **The patient directly**.
  - **Their authorized healthcare provider**.
- Information is shared in a **timely, secure, and confidential manner** to support **clinical decision-making** and continuity of care.
- Requests are processed in compliance with:
  - **Patient consent requirements**.
  - **Data protection laws** and **institutional policies**.

i) Ensuring Non-Discriminatory Patient Care

- The laboratory is committed to providing services without discrimination based on:
  - Gender, race, ethnicity, religion, disability, socioeconomic status, or any other personal characteristic.
- All staff are trained to:
  - Respect cultural diversity and individual patient needs.
  - Provide equal access to laboratory services for all patients.
  - Ensure unbiased, ethical, and professional conduct at all times.

- Any discrimination-related complaints are taken seriously and addressed through internal investigations and corrective actions.

Conclusion

By implementing these measures, the Molecular Laboratory ensures:

- **Patient safety, well-being, and confidentiality** are always prioritized.
- **Ethical and professional standards** are upheld in every laboratory process.
- **Compliance with legal, regulatory, and accreditation requirements** such as **ISO 15189:2022** is maintained.

5.0 Structure and Governance Requirements

5.1 Legal entity (QSP Number: ML/QSP-04/LEGENT)

1. Purpose of a Legal Entity in a Molecular Laboratory

- **Regulatory Compliance**: To meet the statutory requirements laid out by authorities such as NABL, ICMR, CDSCO, DBT, and other national/international regulatory bodies.
- **Operational Legitimacy**: Enables lawful functioning including signing MoUs, applying for accreditations, licenses, and tenders.
- **Financial Transactions**: Allows opening and operating bank accounts, receiving grants/funding, and handling commercial transactions.
- **Intellectual Property**: Facilitates patent applications, licensing, and ownership of research outcomes.
- **Liability Management**: Protects individual stakeholders from personal liability in case of legal issues.

2. Responsibilities of the Legal Entity

- Principal
- Laboratory Director
- Administrative Manager

3. Scope of the Legal Entity

The laboratory or the organization of which the laboratory is a part will be an entity that can be held legally responsible for its activities (Diagnostic Services, Research and Development, Training and Education, Technology Transfer and Commercialization: Accreditation and Certification)

The Molecular Laboratory is a legally recognized entity operating as an integral part of (Name of the Legal Entity), a registered society that oversees and governs multiple educational institutions.

In accordance with its legal standing, the (Name of the Laboratory), operates within the governance framework of (Name of the Legal entity), adhering to all applicable regulatory, ethical, and institutional guidelines. This ensures compliance with relevant legal and professional standards in its operations, including laboratory research, diagnostics, and other scientific activities.

5.2 Laboratory Director (QSP Number: ML/QSP-05/LADDIR)

The **Molecular Laboratory** operates under the leadership of a **Laboratory Director**, whose qualifications comply with **NABL-112** and whose duties align with the standards outlined in **ISO 15189:2022**. The **Laboratory Director** of the **Molecular Laboratory** must possess specialized training and expertise in all aspects relevant to the **laboratory's scope of services**. This includes advanced knowledge of **molecular diagnostics, laboratory management, quality assurance, regulatory compliance, and emerging technologies** in the field. The Laboratory Director must demonstrate proficiency in overseeing laboratory operations, ensuring adherence to industry standards, and maintaining the highest level of accuracy and reliability in test results. The Laboratory Director plays a crucial role in overseeing laboratory operations, ensuring quality and regulatory compliance, and maintaining high standards of scientific and medical services.

As per the established **organizational structure**, the Laboratory Director reports **directly to the Principal** and holds the ultimate authority in directing all laboratory activities. While the Laboratory Director may delegate specific tasks to qualified personnel, they remain **fully accountable** for the overall operation, quality management, and administrative oversight of the laboratory.

In the **absence of the Laboratory Director**, the **Section-In-Charge** assumes interim responsibility, ensuring continuity of leadership and laboratory operations while simultaneously fulfilling their primary duties.

Additionally, the Laboratory Director is responsible for **developing and implementing a contingency plan** to ensure uninterrupted essential services during **emergencies, system failures, or other unexpected circumstances**.

5.2.2 Responsibilities of the Laboratory Director

The **Laboratory Director's** responsibilities span multiple domains, including **leadership, scientific oversight, regulatory compliance, quality assurance, staff management, and research development**. These responsibilities are categorized as follows:

1. **Leadership & Management**

- Provide **strategic direction** and effective leadership in managing laboratory services.
- Ensure that the laboratory operates efficiently, adhering to established standards and institutional policies.
- Develop and oversee the **laboratory's budget**, including financial planning, cost control, and resource allocation.
- Foster a **collaborative and professional work environment**, promoting teamwork and continuous learning.

2. **Regulatory Compliance & Accreditation**

- Ensure the laboratory complies with all **local, national, and international regulatory requirements** (e.g., NABL, ISO 15189:2022).
- Act as a liaison with **accrediting bodies, regulatory agencies, healthcare administrators, and other stakeholders**.
- Maintain proper documentation and records to demonstrate compliance with accreditation standards.
- Review and update laboratory policies in accordance with **changing regulatory requirements**.

3. **Staffing, Training & Competency Development**

- Ensure the laboratory is **adequately staffed** with professionals who possess the required **education, training, and competency**.
- Define **roles and responsibilities** for laboratory personnel, ensuring clear job expectations.
- Implement **training programs and continuing education** to enhance staff competency and technical expertise.
- Promote staff engagement in **professional development activities**, including participation in scientific conferences, research, and laboratory organizations.
- Conduct **performance evaluations** and identify areas for skill enhancement and growth.

4. **Quality Assurance & Safety Management**

- Develop and enforce the **laboratory's quality policy**, ensuring adherence to ISO 15189:2022 guidelines.
- Monitor laboratory performance through **internal audits, quality indicators, and corrective action plans**.
- Establish and oversee **quality control procedures**, ensuring accurate and reliable test results.
- Implement **biosafety and biosecurity protocols**, ensuring a safe working environment for laboratory personnel.
- Ensure proper disposal of **biological, chemical, and hazardous waste** in accordance with safety regulations.

5. **Clinical & Scientific Advisory Role**

- Provide **scientific and technical guidance** in laboratory testing, ensuring high-quality diagnostic services.
- Advise healthcare professionals on the **selection, interpretation, and utilization of laboratory tests**.
- Collaborate with **medical teams, clinicians, and researchers** to support patient care and evidence-based medicine.
- Participate in hospital or institutional committees as a **scientific advisor** on laboratory-related matters.

6. **Supplier & Referral Laboratory Management**

- Oversee the **procurement and selection of laboratory suppliers**, ensuring the quality and reliability of materials and reagents.
- Monitor the performance of **external referral laboratories** to ensure they meet the required quality standards.
- Evaluate vendor contracts, negotiate agreements, and manage inventory control.

7. **Performance Monitoring & Quality Improvement**

- Define, implement, and monitor **key performance indicators (KPIs)** for laboratory services.
- Establish **quality improvement initiatives** and track their effectiveness in enhancing laboratory operations.
- Ensure laboratory processes align with **institutional quality management programs**.
- Identify and address any **gaps, inefficiencies, or discrepancies** in laboratory testing and reporting.

8. **Handling Complaints & User Feedback**

- Establish a **system for addressing complaints, requests, and feedback** from laboratory staff and service users.
- Investigate and resolve laboratory-related issues while ensuring transparent communication.
- Implement corrective and preventive actions (CAPA) for **continuous service improvement**.

9. **Contingency Planning & Emergency Preparedness**

- Develop and implement a **comprehensive contingency plan** to maintain laboratory operations during **emergencies, disasters, or critical system failures**.
- Conduct **periodic tests and drills** to assess the effectiveness of contingency measures.
- Ensure that laboratory personnel are trained on emergency response protocols.

10. **Research & Development (R&D)**

- Encourage **scientific research, innovation, and technological advancements** in laboratory medicine.
- Plan and direct **research projects, method validation, and the development of new diagnostic tests**.
- Collaborate with universities, research institutions, and other scientific bodies to enhance laboratory capabilities.

Interim Leadership in the Absence of the Laboratory Director

- In the event of the **Laboratory Director's absence**, the **Section-In-Charge** assumes interim leadership responsibilities.
- The **Section-In-Charge** will oversee laboratory operations **while continuing their existing duties**.
- The Laboratory Director must ensure that **a structured transition plan** is in place for smooth leadership continuity.

Delegation of Responsibilities

- While the Laboratory Director may **delegate specific duties** to qualified personnel, they retain **full accountability** for laboratory operations.
- Any delegated tasks must be assigned to individuals with **the necessary qualifications, skills, and experience**.
- The Laboratory Director is responsible for **monitoring delegated tasks** to ensure compliance and effectiveness.

5.3 Laboratory Activities (QSP Number: ML/QSP-06/LABA)

1. Purpose:

The laboratory will define and document its scope of activities, including off-site services like sample collection, ensuring compliance with this document. It will claim conformity only within this specified scope, excluding externally provided laboratory activities.

2. Responsibility:

- Laboratory Director
- Section in-charge
- Consultants
- Technical staff

3. Scope

- Conformance with Requirements.
- Advisory activities.
- Advisory services for test selection and any other information.

5.3.2 Conformance with Requirements

The laboratory is committed to ensuring that all activities comply with established regulatory, accreditation, and quality standards. To achieve this, the laboratory **defines, documents, and maintains a clearly specified scope of activities**, including those conducted at locations outside the main laboratory, such as sample collection sites. Conformance with this document is strictly limited to the laboratory's **defined range of activities** and does not extend to externally provided laboratory services.

1. Definition and Documentation of Laboratory Scope

To maintain compliance, the laboratory must:

- **Clearly define its range of activities** in an official document, specifying all laboratory services provided.
- **Include both on-site and off-site activities** that fall under its operational control, such as sample collection, transportation, testing, analysis, and reporting.
- **Ensure that all documented activities comply with regulatory requirements**, including ISO 15189:2022, NABL guidelines, and any applicable national or international standards.

By documenting its scope, the laboratory establishes a **transparent and structured framework** that outlines the **extent and limitations of its conformance claims**.

2. Compliance with Regulatory and Quality Standards

The laboratory ensures that all activities within its documented scope adhere to:

- **International and national laboratory standards** such as ISO 15189:2022 and NABL accreditation requirements.
- **Institutional policies and protocols** governing laboratory operations.
- **Quality management system (QMS) guidelines**, ensuring reliability, accuracy, and consistency in test results.
- **Biosafety and biosecurity regulations**, particularly for handling biological specimens and hazardous materials.

This commitment to compliance enhances the **credibility, accuracy, and reliability** of the laboratory's services.

3. Scope of Conformance Claims

The laboratory will **only claim conformity with this document** for activities that fall within its **defined and documented scope**. This includes:

- **Core laboratory functions**, such as testing, diagnostics, and result interpretation.
- **Off-site laboratory activities**, such as sample collection centers that operate under the laboratory's direct supervision.
- **Internal quality control and assurance measures** to ensure that testing meets the highest standards.

However, the laboratory **does not claim conformance for any activities that fall outside this defined scope**, ensuring **honest and accurate representation** of its services.

4. Exclusion of Externally Provided Laboratory Activities

While the laboratory may engage with external service providers or referral laboratories, **ongoing outsourced laboratory activities do not fall under the laboratory's claim of conformity**. This means:

- **Third-party testing facilities or outsourced diagnostic services** are not covered under the laboratory's documented scope of activities.
- The laboratory may collaborate with **external referral laboratories**, but these services remain separate from the laboratory's direct conformance claim.
- The laboratory must **ensure that external partners meet quality and accreditation standards**, even though their activities are not included in the laboratory's formal conformance documentation.

This exclusion ensures that the laboratory **maintains accountability only for the activities it directly controls**, reducing the risk of misrepresentation and ensuring transparency in its accreditation claims.

5. Implementation and Continuous Monitoring

To ensure ongoing conformance with the requirements, the laboratory must:

- **Regularly review and update its scope of activities** to reflect changes in operations or regulatory requirements.
- **Conduct internal and external audits** to verify compliance with documented standards.
- **Train laboratory personnel** on conformance requirements, ensuring that all staff members are aware of their roles in maintaining compliance.
- **Implement corrective and preventive actions (CAPA)** if any non-conformities are identified.

By **consistently monitoring and improving laboratory activities**, the laboratory ensures **long-term conformance, operational excellence, and regulatory compliance**.

The laboratory's commitment to **documenting its scope, ensuring compliance, and maintaining transparency** reinforces its **integrity, reliability, and trustworthiness** in providing laboratory services. By adhering to **ISO 15189:2022 and NABL standards**, the laboratory guarantees that its **conformance claims are accurate and limited to activities under its direct operational control**, excluding externally provided services. This structured approach upholds quality assurance, regulatory compliance, and accountability in all laboratory functions.

5.3.3 Advisory activities

1. The Molecular Laboratory has a team of qualified professionals who provide expert guidance on test selection, service utilization, and recommendations regarding sample type, collection frequency, and the need for repeat testing when necessary.
2. Laboratory staff also offer advice on the clinical indications, limitations, and appropriate frequency of requesting specific examinations.
3. When required, our molecular laboratory professionals provide case-specific consultations to support clinical decision-making.
4. If a laboratory user requires assistance in interpreting examination results, our staff delivers expert professional guidance to ensure accurate understanding.
5. All laboratory personnel, including receptionists, technical staff, and management, are trained to assist users in effectively utilizing laboratory services.
6. To uphold quality standards, any samples failing to meet acceptance criteria will be rejected, and the concerned users will be advised on proper sample collection procedures, as outlined in the Sample Collection Manual.
7. Samples may be rejected due to improper labelling, inadequate volume, contamination, incorrect transport conditions, or exceeding the stability period. Users will be notified promptly, and appropriate guidance will be provided for recollection.

5.4 Structure and authority (QSP Number: ML/QSP-07/STRAUT)

1. Purpose:

The laboratory shall establish and document its organizational structure and lines of authority, including the organogram, its placement within the parent organization, and clearly defined job descriptions and responsibilities for all stakeholders.

2. Responsibility:

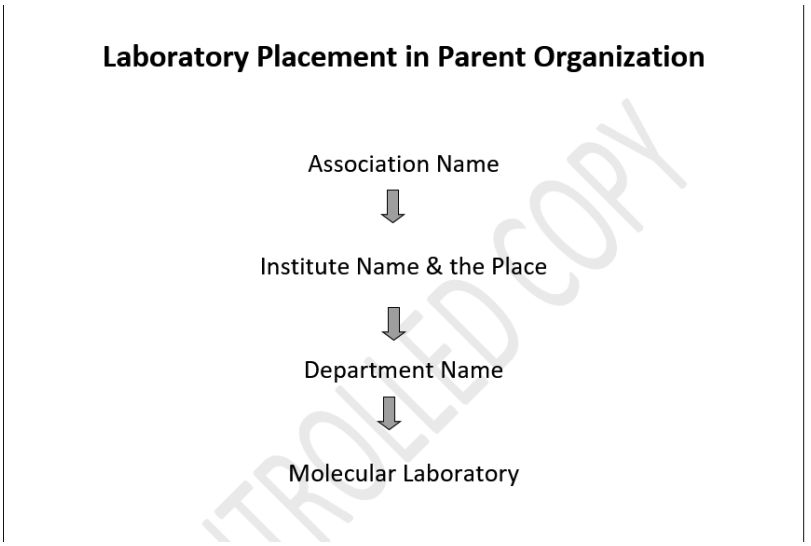
- Principal
- Laboratory Director

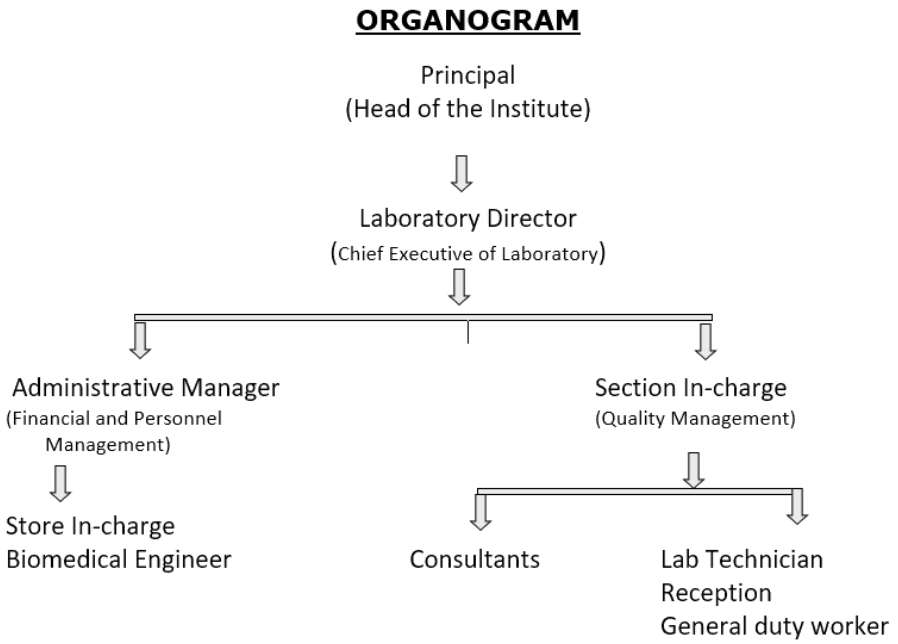
4. Scope

- Laboratory placement in the parent organization.
- Organogram
- Job description.
- Quality management

The laboratory will:

- Establish its **organizational and management structure**, including its position within any parent organization and the relationships between management, technical operations, and support services.
- Define **responsibilities, authority, communication channels**, and interrelationships among personnel involved in managing, performing, or verifying work that impacts laboratory results.
- Implement **standardized procedures** to ensure consistency in laboratory activities and the validity of results.





Responsibilities of the Principal

The Principal holds a key leadership role in overseeing the operations and administration of the molecular laboratory. Their responsibilities include:

- **Laboratory Administration:** Ensuring the efficient and effective management of the molecular laboratory, including compliance with institutional policies, regulatory standards, and best practices.
- **Resource Allocation:** Providing the necessary infrastructure, equipment, and personnel to facilitate the smooth functioning of the laboratory and support research and diagnostic activities.
- **Approval of Major Equipment:** Reviewing and approving the procurement of essential laboratory equipment, as recommended by the Management Review Meeting, to enhance laboratory capabilities and maintain operational efficiency.
- **Regulatory Compliance:** Ensuring that the laboratory adheres to all relevant regulations, quality control measures, and accreditation requirements.
- **Strategic Planning:** Contributing to the development of long-term strategies for the growth and advancement of the laboratory, including budgeting and resource planning.
- **Staff Supervision and Development:** Overseeing laboratory personnel, providing guidance, and facilitating professional development opportunities.

- **Collaboration and Communication:** Coordinating with institutional leadership, research teams, and external stakeholders to promote innovation and maintain high standards of laboratory operations.
- **Memorandums of Understanding (MoUs):** Establishing and maintaining MoUs with academic institutions, research organizations, and industry partners to foster collaboration, knowledge sharing, and technological advancements in molecular research.

Responsibilities of the Laboratory Director

The Laboratory Director is responsible for overseeing and managing all aspects of the medical laboratory service, ensuring high-quality performance, regulatory compliance, and efficient operations. Key responsibilities and authority include:

- Leading the medical laboratory service effectively, including budget planning and financial management, in alignment with institutional responsibilities.
- Establishing and maintaining effective relationships with accrediting and regulatory agencies, administrative officials, healthcare providers, and patient populations, as well as managing formal agreements when required.
- Ensuring the laboratory is adequately staffed with qualified personnel who possess the necessary education, training, and competencies to meet user needs.
- Overseeing the implementation of quality policies to maintain high standards of service.
- Maintaining a safe laboratory environment that adheres to best practices and regulatory requirements.
- Serving as an active member of the medical staff for affiliated facilities, when applicable.
- Providing clinical guidance on test selection, service utilization, and interpretation of laboratory results.
- Managing laboratory suppliers, including selection and ongoing monitoring.
- Selecting referral laboratories and evaluating the quality of their services.
- Facilitating professional development programs for laboratory staff and encouraging participation in scientific and professional organizations.
- Defining, implementing, and monitoring performance standards and quality improvement initiatives for laboratory services.
- Overseeing laboratory operations to ensure the generation of clinically relevant data.
- Addressing complaints, feedback, and requests from staff and users to enhance service quality.

- Developing and implementing contingency plans to maintain essential services during emergencies or disruptions.
- Planning and directing research and development initiatives, where applicable.

This role requires strong leadership, strategic planning, and collaboration to uphold excellence in laboratory operations and patient care.

Responsibilities of the Administrative Manager

The Administrative Manager is responsible for ensuring the efficient operation of the laboratory by overseeing daily activities, coordinating with key personnel, and optimizing processes. Key responsibilities include:

- Ensuring seamless laboratory operations in collaboration with the Laboratory Director.
- Coordinating with technicians on technical matters in consultation with the Laboratory Director.
- Managing daily operations and supervising non-technical staff within the laboratory.
- Overseeing outpatient specimen collection, processing, billing, and client service coordination.
- Working closely with the Section-in Charge to implement and maintain the Quality Management System and processes.
- Driving operational improvements to enhance efficiency and reduce costs.
- Overseeing material management in the lab, ensuring optimal resource utilization.
- Ensuring the maintenance and proper functioning of all laboratory equipment.
- Facilitating coordination with the engineering department for infrastructure and equipment-related needs.

This role requires strong organizational, management, and coordination skills to maintain high operational standards in the laboratory.

Responsibilities of the Section In-Charge

The Section In-Charge is responsible for overseeing the technical aspects of laboratory operations, ensuring quality control, and addressing any challenges related to sample processing and reporting. Key responsibilities include:

- Monitoring technical procedures related to sample processing, result interpretation, and report generation.
- Conducting induction and training programs for new employees.
- Handling complaints regarding test procedures, machine values, and reports.
- Overseeing internal quality control processes.

- Participating in External Quality Assessment Scheme (EQAS) and Internal Laboratory Quality Assessment (ILQA) programs.
- Providing technical support and troubleshooting issues for technicians.
- Coordinating with accreditation bodies (e.g., NABL)
- Managing complaints, implementing corrective actions, and ensuring compliance within the respective section.
- Reporting quality management system activities and findings to top management.
- Identifying and addressing nonconforming work at any stage of testing.
- Authorizing and releasing laboratory reports in the absence of consultants.

Responsibilities of the Consultant

This role requires strong technical expertise, leadership, and attention to quality standards to maintain laboratory efficiency and accuracy.

The Consultant is responsible for ensuring the accurate interpretation and reporting of test results while supporting laboratory operations, staff development, and workflow efficiency. Key responsibilities include:

- Analyzing, interpreting, and reporting test results with accuracy and precision.
- Conducting training sessions for technical staff to enhance their skills and knowledge.
- Monitoring the workflow of the laboratory to ensure smooth and efficient operations.
- Assessing the performance and competency of technical staff to maintain high standards of laboratory practice.
- Assisting with additional responsibilities assigned by the Section In-Charge as required.

This role requires strong expertise in diagnostics, quality assurance, and leadership to ensure efficient laboratory operations, staff development, and accurate test reporting.

Responsibilities of the Biomedical Engineer

The Biomedical Engineer plays a crucial role in ensuring the optimal functioning, maintenance, and advancement of medical equipment and technology within the molecular laboratory. Their key responsibilities include:

- **Equipment Management:** Overseeing the installation, calibration, maintenance, and repair of biomedical equipment to ensure accuracy and efficiency.
- **Technical Support:** Providing technical assistance to laboratory personnel in operating complex biomedical instruments and troubleshooting any malfunctions.

- **Regulatory Compliance:** Ensuring that all equipment meets regulatory and safety standards, including adherence to institutional policies and national/international guidelines.
- **Procurement and Evaluation:** Assisting in the selection, evaluation, and acquisition of biomedical equipment in coordination with the management and procurement teams.
- **Quality Assurance:** Implementing quality control measures to maintain the reliability and precision of laboratory instruments.
- **Training and Documentation:** Conducting training sessions for staff on the proper use and maintenance of biomedical equipment and maintaining accurate records of equipment performance and servicing.
- **Research and Innovation:** Collaborating with researchers and laboratory personnel to improve existing technologies and develop innovative biomedical solutions.
- **Budgeting and Cost Management:** Assisting in budget planning for equipment maintenance, repairs, and new acquisitions while ensuring cost-effective solutions.
- **Emergency Response:** Responding to equipment failures promptly to minimize downtime and ensure uninterrupted laboratory operations.

Responsibilities of the Senior Technician

The Senior Technician plays a key role in supporting technical operations, maintaining quality standards, and overseeing the work of laboratory staff. Key responsibilities include:

- Assisting the Section In-Charge with the technical operations of the lab.
- Implementing quality management procedures and adhering to established work instructions.
- Ensuring confidentiality, integrity, impartiality, and ethical practices are maintained in accordance with defined procedures.
- Overseeing that laboratory technicians properly maintain instruments, calibrators, controls, and reagents.
- Ensuring the implementation of corrective actions by laboratory staff when necessary.
- Performing technical tasks such as sample collection, processing, and analysis.
- Handling any additional tasks assigned by superiors.

This role requires technical expertise, attention to detail, and leadership to ensure high-quality laboratory operations and adherence to standards.

Responsibilities of the Laboratory Technician

The Laboratory Technician is responsible for performing diagnostic tests, handling samples, and supporting laboratory operations. Key responsibilities include:

- Assisting with patient registration processes.
- Collecting, labeling, and processing samples accurately.
- Conducting laboratory tests as per standard protocols.
- Maintaining registers for their assigned sections.
- Entering test results into the system and ensuring timely report dispatch.
- Delivering reports to wards, the Medical Records Department (MRD), or patients as needed.
- Conducting stock checks and preparing monthly stock statements.
- Managing correspondence and secretarial tasks as assigned by supervisors.
- Coordinating the referral of samples to external laboratories when required.
- Performing additional duties as assigned by superiors.

This role requires attention to detail, technical proficiency, and organizational skills to ensure efficient laboratory operations and accurate test processing.

Responsibilities of the Specimen Collection Nurse

The Specimen Collection Nurse is responsible for managing the sample collection process, educating patients, and ensuring proper handling and dispatch of specimens. Key responsibilities include:

- Registering, collecting, and labeling samples accurately.
- Educating patients on sample collection procedures and test methods.
- Segregating samples according to their categories.
- Dispatching reports to wards or the Medical Records Department (MRD) for patients.
- Maintaining adequate stock of materials necessary for specimen collection.
- Handling correspondence and other administrative tasks as assigned by superiors.
- Coordinating the transfer of samples to referral laboratories when required.
- Performing any other tasks as directed by superiors.

This role requires strong communication skills, attention to detail, and a commitment to ensuring proper specimen collection and patient care.

Responsibilities of the Clerk/Receptionist

The Clerk/Receptionist is responsible for managing sample registration, handling inquiries, and supporting administrative tasks in the laboratory. Key responsibilities include:

- Receiving, registering, and labeling samples accurately.
- Handling inquiries related to the molecular lab and answering phone calls professionally.
- Preparing and dispatching reports to patients.
- Drafting and managing documents, letters, and other communications.
- Performing additional tasks as assigned by superiors.

This role requires strong organizational skills, attention to detail, and effective communication to ensure smooth laboratory operations and patient service.

Responsibilities of the General Duty Worker

The General Duty Worker is responsible for supporting laboratory operations by maintaining cleanliness, handling waste, and assisting with sample and report management. Key responsibilities include:

- Ensuring cleanliness and hygiene in the laboratory.
- Performing fumigation as required.
- Handling biomedical waste safely and in compliance with regulations.
- Receiving samples and assisting patients as needed.
- Transporting specimens to the appropriate laboratory sections.
- Dispatching reports to patients, wards, or other designated areas.
- Carrying out messenger duties and other tasks as assigned by superiors.

This role requires diligence, adherence to safety protocols, and the ability to support daily laboratory operations efficiently.

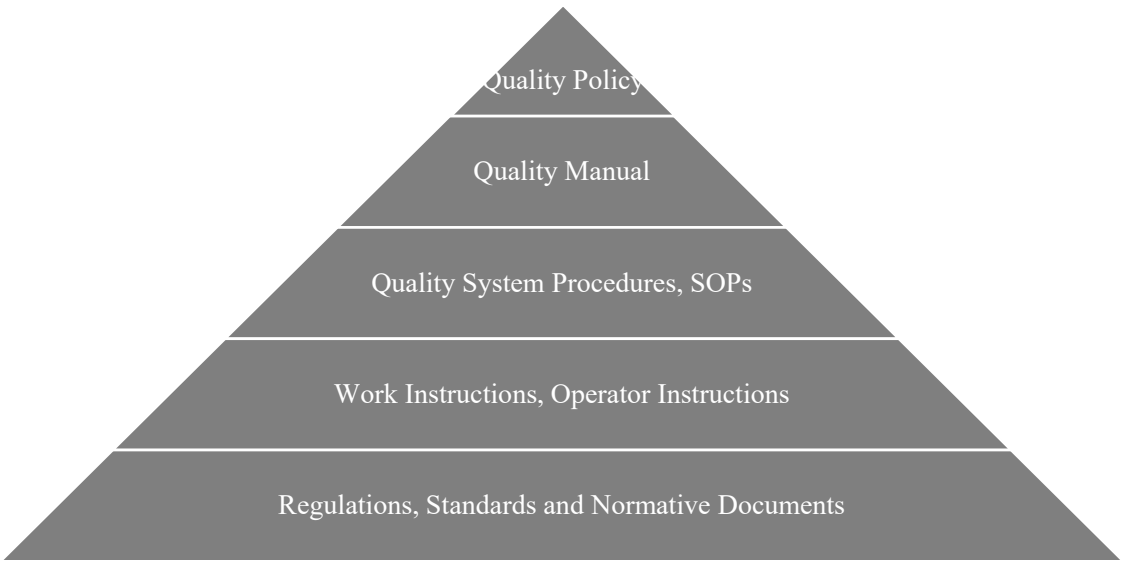
- Reporting quality management system activities and findings to top management.
- Identifying and addressing nonconforming work at any stage of testing.
- Authorizing and releasing laboratory reports in the absence of consultants.

5.4.2 Quality Management

General requirements

Molecular laboratory has established, documented, implemented and maintained a quality management system and the same is being continually improved upon for its effectiveness in accordance with the requirements of the International Standard ISO 15189-2022.

- Determine the processes needed for the quality management system and ensure their application throughout the laboratory.
- determine the sequence and interaction of these processes.
- determine criteria and methods needed to ensure that both the operation and control of these processes are effective.
- ensure the availability of resources and information necessary to support the operation and monitoring of these processes.
- monitor and evaluate these processes.
- implement actions necessary to achieve planned results and continual improvement of these processes.



Pyramidal Hierarchy in Quality Management System.

Documentation Requirements

The Molecular Laboratory's Quality Management System (QMS) documentation includes the following:

- The laboratory's **quality policy statements and quality objectives** are outlined in this Quality Manual (QM).

- **Quality system procedure** has been developed in compliance with the **ISO 15189:2022** standard.
- Documentation of **procedures and records** in accordance with **ISO 15189:2022**, including:
  - Standard Operating Procedures (SOPs)
  - Work instructions
  - Laboratory request forms
- Documents and records necessary for **effective planning, operation, and control** of laboratory processes, such as:
  - Equipment manufacturers' instructions and specifications
  - Reagent kit literature
  - Standard textbooks and journals
  - Regulatory body rules and guidelines
- Copies of applicable regulations, standards, and other normative documents, including:
  - **ISO 15189:2022** – Medical laboratories: Requirements for quality and competence
  - Accreditation body documents
  - Other relevant normative references

Quality System Procedure

The Molecular Laboratory has developed and maintains a **Quality System Procedure**

that includes:

- The **quality policy** or a reference to it.
- A **description of the scope** of the quality management system.
- An overview of the **organization and management structure** of the laboratory, including its position within any parent organization.
- A detailed outline of the **roles and responsibilities** of laboratory management.
- A description of the **structure and interrelationships** of the documentation used in the quality management system.
- The **documented policies** governing the quality management system, along with references to the **managerial and technical activities** that support them.
- All laboratory staff have access to the **QSP** and the referenced documents to ensure proper understanding and application of quality management principles.

Annexures

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/FL/19a	Staff training evaluation	File	Administrative manager	HR / Establishment Department	5 Years
ML/REG/6	Staff Training Records	Register	Laboratory Director	Laboratory office	Continuous
ML/F/13	Job Application	Form	Administrative manager	HR / Establishment Department	5 Years
ML/F/14	Staff Performance Evaluation Form	Form	Laboratory Director	Laboratory office	5 Years
ML/F/15	Staff Technical Competency / Skills Evaluation	Form	Laboratory Director	Laboratory office	5 Years
ML/FL/19b	Personnel Records	File	Administrative Manager	Laboratory office	Continuous
ML/F/16	Immunization form	Form	Laboratory Director	Laboratory office	Continuous
ML/F/24	Induction training form	Form	Laboratory Director	Laboratory office	Continuous

5.5 Objectives and Policies (ML/QSP-08/OBJPOL)

1. Purpose:

The laboratory shall establish, define, and document its quality objectives and quality policies.

2. Responsibility:

- Principal
- Laboratory Director
- Administrative manager
- Section-In-Charge
- Consultants
- Technicians

3. Scope

- Quality objectives.
- Quality policies
- Commitment of the laboratory.

The management of the Molecular Laboratory has defined quality objectives, formally approved by the Principal. These objectives are designed to address the needs and expectations of users across relevant functions and levels within the organization.

All quality objectives are measurable and aligned with the laboratory's quality policy.

Laboratory management ensures that the quality management system is planned and implemented in a manner that fulfills both the system's requirements and the established quality objectives. Additionally, it is ensured that the integrity of the quality management system is preserved during the planning and implementation of any changes.

The quality objectives of Molecular Lab are:

I.	To establish Laboratory Quality Indicators, audit its performance, and measure parameters that are consistent with the well-being of the patients and lab service users.
II.	To monitor the lab performance with other medical laboratories by way of participating in and evaluating the quality of results through PT and EQAS.
III.	Maintaining a stipulated turnaround time (TAT) in the delivery of test results for timely care of the patient.
IV.	To ensure that all personnel are trained and familiarized with the quality management system appropriate to individuals' degree of responsibility.
V.	To ensure the upgradation of technical knowledge and development of international and national perspectives in their areas of medical diagnostic services, to ensure comprehensive, appropriate, and cost-effective services.

- Establish measurable quality objectives such as:
  - Reducing turnaround time for test results by 10% annually.
  - Achieving 98% accuracy in molecular diagnostic tests.
  - Enhancing patient satisfaction scores by 15%.
- Regular review and update of objectives during management review meetings.

Quality Policy

The Molecular Laboratory is committed to delivering accurate, timely, and reliable laboratory results while upholding the highest standards of quality, professionalism, and integrity. Our commitment to quality is guided by the following principles:

- Customer Satisfaction: We prioritize meeting and exceeding customer expectations by providing high-quality laboratory services, ensuring accuracy in test results, and maintaining transparency in all processes.
- Regulatory and Compliance Standards: We strictly adhere to all applicable statutory, regulatory, and contractual requirements, ensuring that our laboratory operates in full compliance with national and international regulations governing medical laboratories.
- Adherence to National and International Standards: We are committed to maintaining the highest levels of quality and competence by complying with ISO 15189:2022 (International Standard for Medical Laboratories) and NABL (National Accreditation Board for Testing and Calibration Laboratories) requirements, ensuring standardization and reliability in our laboratory operations.

- Cost-Effective and Efficient Services: We strive to provide laboratory services in a cost-effective, proficient, and sustainable manner, ensuring accessibility to all users while maintaining the highest levels of quality and efficiency.

Our Commitment:

- Continuous improvement of our Quality Management System (QMS) to enhance laboratory processes, reduce errors, and improve service delivery.
- Ongoing training and skill development for laboratory personnel to ensure competence and adherence to best practices.
- Implementation of advanced technologies and quality control measures to ensure precision, accuracy, and reliability of test results.
- Fostering a culture of quality, ethics, and patient-centered care across all laboratory functions.

This Quality Policy is communicated to all laboratory personnel and stakeholders to ensure its effective implementation, and it is subject to periodic review for continuous improvement.

5.6 Risk Management (ML/QSP-09/RISKMANG)

1. Purpose:

Laboratory management will establish, implement, and maintain processes for identifying risks of harm to patients and opportunities for improved patient care associated with its examinations and activities, and develop actions to address both risks and opportunities for improvement

2. Responsibility:

- Laboratory Director
- Section-In-Charge
- Consultants
- Technicians

3. Scope

- Reduce risk at pre-examination, examination and post examination process

Procedure: The risk assessment and management process is detailed in the annexure-1

6.0 Resource requirements

6.1 General (ML/QSP-10/GEN)

The laboratory is well-equipped with adequate personnel, facilities, equipment, reagents, consumables, and support services to effectively manage and carry out its activities.

6.2 Personnel (ML/QSP-11/PERSON)

1. **Purpose**:

The purpose of this procedure is to ensure that the personnel performing specific operations related to testing are competent enough to carry out the operations.

2. **Responsibility**:

- Laboratory Director
- Administrative Manager

3. **Scope**:

- Competence requirements
- Authorization
- Continuing education and professional development
- Personnel records

6.2.2 Competence requirements:

- The laboratory has defined the competence requirements for each role that impacts laboratory activities, including the necessary education, qualifications, training, re-training, technical knowledge, skills, and experience.
- The laboratory ensures that all personnel possess the necessary competence to perform the laboratory activities they are assigned.
- The laboratory will implement a process for managing personnel competence, which includes established criteria for the frequency of competency assessments.
- The laboratory maintains documented records that demonstrate the competence of its personnel.

Job Description

1. Laboratory Director – The Laboratory Director is responsible for overseeing and managing all aspects of the medical laboratory service, ensuring high-quality performance, regulatory compliance, and efficient operations. Key responsibilities and authority include:

- Leading the medical laboratory service effectively, including budget planning and financial management, in alignment with institutional responsibilities.

- Establishing and maintaining effective relationships with accrediting and regulatory agencies, administrative officials, healthcare providers, and patient populations, as well as managing formal agreements when required.
- Ensuring the laboratory is adequately staffed with qualified personnel who possess the necessary education, training, and competencies to meet user needs.
- Overseeing the implementation of quality policies to maintain high standards of service.
- Maintaining a safe laboratory environment that adheres to best practices and regulatory requirements.
- Serving as an active member of the medical staff for affiliated facilities, when applicable.
- Providing clinical guidance on test selection, service utilization, and interpretation of laboratory results.
- Managing laboratory suppliers, including selection and ongoing monitoring.
- Selecting referral laboratories and evaluating the quality of their services.
- Facilitating professional development programs for laboratory staff and encouraging participation in scientific and professional organizations.
- Defining, implementing, and monitoring performance standards and quality improvement initiatives for laboratory services.
- Overseeing laboratory operations to ensure the generation of clinically relevant data. Addressing complaints, feedback, and requests from staff and users to enhance service quality.
- Developing and implementing contingency plans to maintain essential services during emergencies or disruptions.
- Planning and directing research and development initiatives, where applicable.

This role requires strong leadership, strategic planning, and collaboration to uphold excellence in laboratory operations and patient care.

2. Administrative Manager

The Administrative Manager is responsible for ensuring the efficient operation of the laboratory by overseeing daily activities, coordinating with key personnel, and optimizing processes. Key responsibilities include:

- Ensuring seamless laboratory operations in collaboration with the Laboratory Director.
- Coordinating with technicians on technical matters in consultation with the Laboratory Director.
- Managing daily operations and supervising non-technical staff within the laboratory.

- Overseeing outpatient specimen collection, processing, billing, and client service coordination.
- Working closely with the Section-in charge to implement and maintain the Quality Management System and processes.
- Driving operational improvements to enhance efficiency and reduce costs.
- Overseeing material management in the lab, ensuring optimal resource utilization.
- Ensuring the maintenance and proper functioning of all laboratory equipment.
- Facilitating coordination with the engineering department or infrastructure and equipment-related needs.

This role requires strong organizational, management, and coordination skills to maintain high operational standards in the laboratory.

3. Section In-Charge

The Section In-Charge is responsible for overseeing the technical aspects of laboratory operations, ensuring quality control, and addressing any challenges related to sample processing and reporting. Key responsibilities include:

- Monitoring technical procedures related to sample processing, result interpretation, and report generation.
- Conducting induction and training programs for new employees.
- Handling complaints regarding test procedures, machine values, and reports.
- Overseeing internal quality control processes.
- Participating in External Quality Assessment Scheme (EQAS) and Internal Laboratory Quality Assessment (ILQA) programs.
- Providing technical support and troubleshooting issues for technicians.
- Coordinating with accreditation bodies (e.g., NABL).
- Managing complaints, implementing corrective actions, and ensuring compliance within the respective section.
- Reporting quality management system activities and findings to top management.
- Identifying and addressing nonconforming work at any stage of testing.
- Authorizing and releasing laboratory reports in the absence of consultants.

4. Consultant

This role requires strong technical expertise, leadership, and attention to quality standards to maintain laboratory efficiency and accuracy.

The Consultant is responsible for ensuring the accurate interpretation and reporting of test results while supporting laboratory operations, staff development, and workflow efficiency. Key responsibilities include:

- Analyzing, interpreting, and reporting test results with accuracy and precision.
- Conducting training sessions for technical staff to enhance their skills and knowledge.
- Monitoring the workflow of the laboratory to ensure smooth and efficient operations.
- Assessing the performance and competency of technical staff to maintain high standards of laboratory practice.
- Assisting with additional responsibilities assigned by the Section In-Charge as required.

This role requires strong expertise in diagnostics, quality assurance, and leadership to ensure efficient laboratory operations, staff development, and accurate test reporting.

5. Senior Technician

The Senior Technician plays a key role in supporting technical operations, maintaining quality standards, and overseeing the work of laboratory staff. Key responsibilities include:

- Assisting the Section In-Charge with the technical operations of the lab.
- Implementing quality management procedures and adhering to established work instructions.
- Ensuring confidentiality, integrity, impartiality, and ethical practices are maintained in accordance with defined procedures.
- Overseeing that laboratory technicians properly maintain instruments, calibrators, controls, and reagents.
- Ensuring the implementation of corrective actions by laboratory staff when necessary.
- Performing technical tasks such as sample collection, processing, and analysis.
- Handling any additional tasks assigned by superiors.

This role requires technical expertise, attention to detail, and leadership to ensure high-quality laboratory operations and adherence to standards.

6. Laboratory Technician

The Laboratory Technician is responsible for performing diagnostic tests, handling samples, and supporting laboratory operations. Key responsibilities include:

- Assisting with patient registration processes.
- Collecting, labeling, and processing samples accurately.
- Conducting laboratory tests as per standard protocols.
- Maintaining registers for their assigned sections.
- Entering test results into the system and ensuring timely report dispatch.
- Delivering reports to wards, the Medical Records Department (MRD), or patients as needed.
- Conducting stock checks and preparing monthly stock statements.
- Managing correspondence and secretarial tasks as assigned by supervisors.
- Coordinating the referral of samples to external laboratories when required.
- Performing additional duties as assigned by superiors.

This role requires attention to detail, technical proficiency, and organizational skills to ensure efficient laboratory operations and accurate test processing.

7. Specimen Collection Nurse

The Specimen Collection Nurse is responsible for managing the sample collection process, educating patients, and ensuring proper handling and dispatch of specimens. Key responsibilities include:

- Registering, collecting, and labeling samples accurately.
- Educating patients on sample collection procedures and test methods.
- Segregating samples according to their categories.
- Dispatching reports to wards or the Medical Records Department (MRD) for patients.
- Maintaining adequate stock of materials necessary for specimen collection.
- Handling correspondence and other administrative tasks as assigned by superiors.
- Coordinating the transfer of samples to referral laboratories when required.
- Performing any other tasks as directed by superiors.

This role requires strong communication skills, attention to detail, and a commitment to ensuring proper specimen collection and patient care.

8. Clerk/Receptionist

The Clerk/Receptionist is responsible for managing sample registration, handling inquiries, and supporting administrative tasks in the laboratory. Key responsibilities include:

- Receiving, registering, and labeling samples accurately.
- Handling inquiries related to the molecular lab and answering phone calls professionally.
- Preparing and dispatching reports to patients.
- Drafting and managing documents, letters, and other communications.
- Performing additional tasks as assigned by superiors.

This role requires strong organizational skills, attention to detail, and effective communication to ensure smooth laboratory operations and patient service.

9. General Duty Worker

The General Duty Worker is responsible for supporting laboratory operations by maintaining cleanliness, handling waste, and assisting with sample and report management. Key responsibilities include:

- Ensuring cleanliness and hygiene in the laboratory.
- Performing fumigation as required.
- Handling biomedical waste safely and in compliance with regulations.
- Receiving samples and assisting patients as needed.
- Transporting specimens to the appropriate laboratory sections.
- Dispatching reports to patients, wards, or other designated areas.
- Carrying out messenger duties and other tasks as assigned by superiors.

This role requires diligence, adherence to safety protocols, and the ability to support daily laboratory operations efficiently.

Induction Training

Newly recruited employees undergo an induction training program within 30 days of joining, covering the following:

- Laboratory quality policy and objectives
- Employment terms, working conditions, and competency evaluation
- Performance appraisal process
- Security and confidentiality of patient test results
- Job responsibilities and authorities
- Quality Management System (QMS), quality documents, work processes, and procedures
- Laboratory Information System

- Health and safety, including emergency preparedness (fire, adverse incidents)
- Importance of proper QMS implementation and consequences of poor performance
- Occupational health services (annual health check-ups and vaccinations)
- Available staff facilities
- Introduction to the faculty, department, or section where they will work
- Post-training competence evaluation, conducted and recorded by the trainer

If the laboratory employs contracted or additional personnel, the Laboratory Director and Section-in-charge ensure they are supervised and competent per QMS requirements.

Employee Assessment for Technical Competency

- Employees are assessed in their core and related work areas to ensure continued competence.
- The Molecular Laboratory conducts annual competency assessments using a Competency Assessment Form.
- The Laboratory Director determines the assessment criteria, acceptance limits, frequency, and reassessment intervals based on the critical role of the individual in the process, as well as the results of the assessment. If the competency score falls below 90%, the individual will undergo retraining until they reach the acceptable competency level.
- Employees identified with poor performance are provided with retraining and support to help improve their performance.
- Competency assessments are conducted at least once a year, with additional evaluations or follow-ups as necessary based on the individual's performance and role within the laboratory.
- In the case of failing to meet the required competency level, a reassessment will be conducted after one week. During this period, the employee will receive additional training to address areas of weakness. The employee will continue to receive training and be reassessed until they reach the acceptable competency level. Until then, the employee will be assigned tasks that do not require the specific competencies they have yet to demonstrate.
- All assessment details and corrective actions are documented in the employee's Personnel File.

6.2.3 Authorization

The laboratory will authorize personnel to carry out specific tasks and responsibilities based on their roles and qualifications. The key activities are as follows:

- **Selection, Development, Modification, Validation, and Verification of Methods:** These tasks will be carried out by the Section-in-Charge in consultation with the Laboratory Director. This ensures that any new or modified methods are developed and verified to meet the laboratory's standards and regulatory requirements.
- **Review, Release, and Reporting of Results:** These tasks will be performed by Consultants. They will be responsible for reviewing test results, ensuring accuracy, and releasing the final reports to the appropriate stakeholders.
- **Use of Laboratory Information Systems:** Personnel involved in accessing patient data and entering examination results, such as data entry operators (Senior Technicians, Clerks, or Receptionists), will be authorized to perform these tasks.
- Changes to patient data or examination results will be managed by Consultants, in coordination with the Laboratory Director, to ensure that any alterations are done appropriately and in compliance with legal and regulatory standards.
- **Handling of Instruments:** The handling and operation of laboratory instruments will be carried out by designated technicians based on their demonstrated competency. Only technicians with the necessary skills and training will be authorized to operate specific instruments, ensuring accurate results and safe operation of equipment.
- **Management of Computers:** The management and maintenance of computers and related software used within the laboratory will be handled by the EDP (Electronic Data Processing) section. The EDP section will ensure that all systems are functioning properly, software is up-to-date, and data security protocols are followed to protect sensitive information.
- **Management of Instruments:** The management, calibration, and maintenance of laboratory instruments will be handled by the in-house biomedical engineer. The biomedical engineer will ensure that all instruments are functioning correctly, properly calibrated, and maintained according to the manufacturer's specifications to guarantee reliable performance.

These responsibilities ensure that the laboratory operates smoothly, with clear lines of authority and accountability for each task.

6.2.4 Continuing education and professional development

- Laboratory Director, Section in charge, and consultants identify and organize training for both new and existing employees to ensure competency.
- Continuing education / training is conducted based on:
    - Repeated non-conformities in a specific area
    - Introduction of new equipment
    - New recruitments

  - Laboratory Information System updates
  - Periodic assessments
  - Implementation of new technologies or methods
  - QMS updates and procedural changes
  - Health and safety, including laboratory safety, fire, and emergency protocols
  - Patient information confidentiality
- General training sessions on Biomedical Waste Management, Ethics, etc., are recorded in the Training Log.
- "On-the-job training" is documented in the Departmental Teaching Register.
- Training effectiveness is evaluated through periodic assessments.

Staff Performance Evaluation

The Molecular Laboratory conducts regular staff performance reviews, considering both laboratory needs and individual professional growth to enhance service quality.

The **objective evidence method** for evaluating staff competency involves the collection and analysis of tangible, measurable data that demonstrate a staff member's ability to perform specific tasks or meet defined standards. This method is particularly valuable because it relies on verifiable facts rather than subjective opinions or impressions. Here's how it can be applied in a molecular laboratory setting:

- **Standardized Testing and Assessments:** Staff may be required to complete written or practical assessments that test their knowledge and skills related to laboratory procedures, safety protocols, and the use of specific instruments or techniques. Results from these assessments provide objective evidence of their competency.
- **Review of Work Outputs:** Competency can be assessed by reviewing the staff member's work products, such as laboratory test results, reports, or documentation. The accuracy, completeness, and adherence to standard operating procedures (SOPs) in these outputs can serve as measurable indicators of competency.
- **Verification of Calibration and Maintenance Records:** For staff responsible for maintaining and calibrating equipment, records of instrument calibration and maintenance logs can be used as evidence of their competence. These records show whether the technician is following proper procedures, adhering to schedules, and ensuring equipment is functioning correctly.
- **Audit and Quality Control Data:** Objective evidence can also include audit reports, internal inspections, or quality control results that reflect the staff member's performance. If, for example, the staff consistently meets quality standards or resolves issues identified during audits, it provides concrete evidence of their capability.

- **Performance Metrics:** Quantifiable performance metrics, such as turnaround time for test results, error rates, or customer feedback, can also serve as objective evidence of competency. For example, consistently low error rates or meeting deadlines for report generation demonstrate proficiency.
- **Documentation of Training and Certifications:** Evidence of completed training programs, certifications, and continuing education courses also serves as objective proof of competency. This ensures that staff members are up to date with current techniques, standards, and regulations.

By using objective evidence, the laboratory ensures that competency evaluations are based on verifiable and reproducible data, leading to fair and consistent assessments of staff performance.

If a staff member does not meet the acceptable competency limit of 90%, they will undergo retraining to address any gaps in knowledge or skills. Following retraining, their performance will be closely monitored on a regular basis to ensure improvement. This process includes:

- **Retraining:** The staff member will receive targeted training to address the areas where they fell short. This may involve additional hands-on practice, theoretical learning, or revisiting specific laboratory procedures or safety protocols.
- **Regular Monitoring:** After retraining, the staff member's performance will be monitored regularly to track their progress. This may involve ongoing observation, periodic assessments, or review of their work outputs to ensure that improvements are being made and maintained.
- **Feedback and Support:** Constructive feedback will be provided to help the staff member understand their strengths and areas for improvement. Continuous support will be given to ensure that they can apply what they've learned and enhance their competency.
- **Re-evaluation:** Once the monitoring period is complete, the staff member’s competency will be reassessed using the same objective evidence methods to confirm that they now meet or exceed the 90% competency threshold.

The Molecular Laboratory encourages staff participation in continuing education programs and professional development activities.

This process ensures that staff members who do not initially meet the required standards have the opportunity to improve, while also maintaining the overall quality and performance of the laboratory.

6.2.5 Personnel Records

- Each employee's personnel file includes:
  - Educational and professional qualifications
  - Copies of certifications or licenses (if applicable)
  - Previous work experience

Resource Requirements

- Job description and competency requirements
- Orientation and introduction to the laboratory environment
- Training records for current job tasks
- Retraining records
- Monitoring competence of personnel
- Continuing education and professional development records
- Performance evaluation reports
- Occupational hazard exposure and accident reports
- Immunization records (if relevant to job duties)
- Confidentiality and Responsibility Agreement
- Reference letters from previous employers (if available)
- Authorization of personnel

References: Clause 6.1, 6.2 of ISO 15189:2022

Annexures

Record no.	**Record name**	**Record Type**	**Responsibility**	**Location**	**Retention Period**
ML/FL/19a	Staff training evaluation	File	Administrative manager	HR / Establishment Department	5 Years
ML/REG/6	Staff Training Register	Register	Laboratory Director	Laboratory office	Continuous
ML/F/13	Job Application	Form	Administrative manager	HR / Establishment Department	5 Years
ML/F/14	Staff Performance Evaluation Form	Form	Section-In-Charge	Laboratory office	5 Years
ML/F/15	Staff Technical Competency / Skills Evaluation	Form	Section-In-Charge	Laboratory office	5 Years

Resource Requirements

ML/FL/19b	Personnel Records	File	Administrative Manager	Laboratory office	Continuous
ML/F/16	Immunization form	Form	Section-In-Charge	Laboratory office	Continuous
ML/F/24	Induction training form	Form	Section-In-Charge	Laboratory office	Continuous

6.3 Facilities and environmental conditions (ML/QSP-11/FACENVCON)

1. Purpose:

The facilities and environmental conditions will be appropriate for laboratory activities, ensuring they do not negatively impact result validity or compromise the safety of patients, visitors, laboratory users, and personnel. This will encompass pre-examination-related facilities, off-site locations where examinations are conducted, and POCT.

Facilities and environmental conditions will be required to meet certain requirements, which will be defined, monitored, and documented. Factors that may adversely affect result validity will be controlled, including, but not limited to, adventitious amplified nucleic acid, microbial contamination, dust, electromagnetic disturbances, radiation, lighting (illumination), humidity, electrical supply, temperature, sound, and vibration.

2. Responsibility:

- Laboratory Director
- Section-In-Charge
- Bio-Medical Engineer
- Laboratory staff

3. Scope:

- Facility control
- Storage facilities
- Personnel facilities
- Sample collection facilities

Procedure

6.3.2 Facility control

i. **Air Conditioning & Environmental Control**
Air conditioning systems are provided wherever necessary to maintain an efficient operational environment. The laboratory maintains a room temperature between 18°C to 28°C and humidity levels between 30% to 70%, as most automated equipment operates within this range. These conditions are recorded daily in the Room Temperature Monitoring Record.

ii. **Power Supply & Backup**
The laboratory ensures a continuous power supply with **backup systems**, including **online UPS** for all auto analyzers and **generator backup**. **Electricians are available 24/7** to ensure uninterrupted operation.

iii. **Equipment Maintenance & Safety Measures**
All laboratory equipment is maintained in optimal working condition under the supervision of an

Instrument Technician. Safety facilities and devices are regularly inspected to ensure the well-being of laboratory staff. These include:

- **First aid kits** and **personal protective equipment (PPE)**
- **Emergency exits** that are accessible and functional
- **Handwashing stations** that are available and easily accessible
- **Fire extinguishers** for fire safety
- **Spillage kits** for handling hazardous spills
- **Biosafety cabinets** are used to prevent contamination and ensure a sterile environment while handling biological samples

iv. **Controlled access to medical information and patient samples** to maintain confidentiality and prevent unauthorized handling

The laboratory enforces strict **access control measures** to ensure the confidentiality, integrity, and security of **medical information and patient samples**. These measures are in place to protect patient privacy, prevent unauthorized handling, and maintain compliance with regulatory and ethical standards.

1. **Access Restrictions**
   - **Authorized Personnel Only**: Access to **patient records, test results, and samples** is restricted to authorized laboratory personnel, consultants, and other designated staff.
   - **Secure Laboratory Areas**: Sample storage rooms, testing areas, and data processing sections are secured CCTV surveillance.

2. **Data Security & Confidentiality**
   - Patient data is stored in **secured, password-protected** digital systems with **role-based access control** to limit information to only those who require it.
   - **Regular Audits & Monitoring**: Access logs and system usage are **monitored and audited** to prevent data breaches or unauthorized access.

3. **Sample Handling & Storage**
   - **Labeling & Tracking**: Each patient sample is **labelled** to ensure accurate tracking and prevent mix-ups.
   - **Temperature-Controlled Storage**: Biological samples are stored in temperature-controlled **refrigerators, freezers, or biosafety cabinets**, accessible only to trained personnel.
   - **Chain of Custody Documentation**: A clear record of sample handling, from collection to disposal, is maintained to ensure **traceability and accountability**.

4. **Compliance with Legal and Ethical Standards**
   - The laboratory follows national and international **data protection regulations** to safeguard patient information.
   - **Consent-Based Information Sharing**: Patient test results are shared **only with authorized individuals** (e.g., treating physicians) and **only after patient consent**, where required.
   - **Training & Awareness**: All laboratory staff undergo **regular training** on **data privacy, security protocols, and ethical handling of patient information and samples**.

By implementing these **strict security measures**, the laboratory ensures that **patient data remains confidential, medical samples are handled responsibly, and overall integrity in laboratory operations is maintained**.

v. Internal Communication

The laboratory has established **effective communication channels** to facilitate smooth coordination within departments and with laboratory users. Communication methods include:

- Departmental meetings once in two months
- Emails
- Telephone communication
- Printed copies for official communication
- Telephone intercom facilities within the laboratory and hospital for seamless communication

vi. Accommodation & Infrastructure

- The laboratory has **sufficient space** and appropriate arrangements for **primary sample collection** and **examinations at designated sites**.
- Proper separation of different **work areas and workflows** in a **molecular laboratory** is essential for preventing **cross-contamination, ensuring biosafety, and maintaining accurate test results**. A lack of **physical and procedural separation** can lead to several **critical risks** affecting laboratory operations, personnel safety, and compliance with standards like **ISO 15189:2022, NABL 112, and WHO biosafety guidelines**. The laboratory has a separate area for specimen processing, extraction, master preparation, positive template addition, and PCR rooms
- All instruments are **regularly serviced and calibrated** to ensure compliance with **ISO 15189:2022 and NABL 112** standards, covering all parameters that certify their **fitness for use, including acceptable noise levels**. Additionally, the laboratory is **strategically located in a low-noise environment**, minimizing external disturbances and ensuring optimal working conditions.
- There are **separate waiting areas** and **report collection areas** for patient convenience.
- **Dedicated restroom facilities** are provided separately for **staff and patient visitors**.
- The **laboratory layout** is designed to enhance operational efficiency, ensure staff and patient comfort, prevent injuries, and protect staff from occupational hazards.
- **Adequate lighting** is installed throughout the lab to support all work processes.
- **Housekeeping activities** are regularly conducted across all areas of the **Molecular Laboratory**.
- The **Molecular Laboratory** follows proper **biomedical and general waste disposal protocols** to prevent environmental contamination.

6.3.3 Storage facilities:

1. Adequate storage space and conditions are maintained to safeguard the integrity of samples, documents, files, manuals, equipment, reagents, laboratory supplies, records, and reports.
2. Primary patient samples and extracts are stored in a refrigerator to prevent deterioration. After testing is completed as per the TAT, samples are preserved at -80°C in accordance with the laboratory's retention policy.
3. Reagents, consumables, and chemicals are stored at room temperature or in a refrigerator, following company specifications.
4. CCTV surveillance is in place to prevent unauthorized access, ensuring the security of data, sample storage, and other critical materials.
5. A dedicated storage room is available for equipment, reagents, consumables, and housekeeping materials.
6. The laboratory provides sufficient storage for documents, records, and results.

6.3.4 Biomedical waste disposal

Waste Segregation and Disposal in the Molecular Laboratory

1. **Waste Segregation**

All waste generated in the laboratory is segregated into General Waste and Biomedical Waste (BMW) in accordance with local regulations and BMW 2016 guidelines (amended in 2022).

- General Waste: Waste not contaminated with human body fluids is classified as general waste. It is collected in black bins and handed over to the city corporation for disposal.
- Biomedical Waste: Biomedical waste includes materials contaminated or soiled with human tissues, body fluids, swabs, disposable syringes, and blood-stained cotton.

2. **Waste Management & Compliance**

- All laboratory waste is properly segregated and disposed of per local regulations and recommendations.
- The Section in charge is responsible for supervising waste management activities, maintaining records, and ensuring compliance.
- Adequate bins and color-coded bags are provided at all laboratory locations for proper waste segregation.
- All staff are trained on waste segregation protocols at all levels and sources.
- Segregated waste is collected at the BMW collection point, with proper documentation in the waste register.
- Periodic spot and surprise checks are conducted by the Laboratory Director.

3. Disposal of Viral Transport Medium (VTM), PPE, and Consumables

- VTM and consumables used for detecting respiratory viral pathogens are considered potentially hazardous and are autoclaved before disposal.
- An Autoclave Register is maintained and monitored to ensure proper decontamination.
- PPE worn in the laboratory is disposed of in yellow bags and handed over to authorized BMW handlers, with records maintained in the BMW register.

4. Disposal of Expired Reagents, Chemicals, and Body Fluids

- The molecular lab has a system in place to ensure the safe disposal of expired reagents, chemicals, and body fluids.
- Expired kits and reagents are disposed of as per the manufacturer's instructions and BMW guidelines.
- Chemical waste is handled according to hazardous waste disposal protocols to prevent environmental contamination.
- Proper documentation is maintained for the disposal of expired or unwanted kits, reagents, and body fluids.

Resource Requirements

Yellow *Yellow colored non-chlorinated plastic bags*	• Human Anatomical Waste. • Soiled waste items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and bags containing residual or discarded blood and blood components. • Expired or Discarded medicines. • Chemical wastes • Chemical liquid wastes. • Discarded linen, mattresses, beddings contaminated with blood fluid, routine mask and gown. • Microbiology, Biotechnology and other clinical laboratory waste.	• ಮಾನವ ಅಂಗಾಂಗಗಳ ತ್ಯಾಜ್ಯ • ರಕ್ತಸೋಂಕಿತಹತ್ತಿಬಟ್ಟೆ, ಪ್ಲಾಸ್ಟರ್ಕಾಸ್ಟ್, ತಿರಸ್ಕರಿಸಿದ ರಕ್ತ ಮತ್ತು ರಕ್ತದ ಸಾಮಗ್ರಿಗಳು • ಅವಧಿ ಮುಗಿದ ಮತ್ತು ತಿರಸ್ಕರಿಸಿದ ಔಷಧಗಳು • ರಾಸಾಯನಿಕ ತ್ಯಾಜ್ಯಗಳು • ರಾಸಾಯನಿಕ ದ್ರವತ್ಯಾಜ್ಯಗಳು • ತಿರಸ್ಕರಿಸಿದ ಲಿನಿನ್, ಹಾಸಿಗೆಗಳು, ರಕ್ತಅಥವಾದೇಹದ್ರವದ ಜೊತೆ ಕಲುಷಿತಗೊಂಡ ಬೆಡ್ಶೀಟ್ಗಳು, ದಿನನಿತ್ಯದ ಮಾಸ್ಕ್ಗಳು ಮತ್ತು ಗೌನ್ಗಳು • ಸೂಕ್ಷ್ಮಜೀವವಿಜ್ಞಾನ, ಜೈವಿಕತಂತ್ರಜ್ಞಾನ ಮತ್ತು ಇತರ ವೈದ್ಯಕೀಯ ಪ್ರಯೋಗಾಲಯ ತ್ಯಾಜ್ಯ
Red *Red colored non-chlorinated plastic bags or containers*	• Contaminated waste(Recyclable): Tubings, bottles, IV tubes and sets, catheters, urine bags, syringes (without needle and fixed needle syringes) and vaccutainers with their needle cut and gloves.	ಕಲುಷಿತತ್ಯಾಜ್ಯ (ಮರುಬಳಕೆಮಾಡಬಹುದಾದ): ಟ್ಯೂಬ್ಗಳು, ಬಾಟಲಿಗಳು, IV ಟ್ಯೂಬ್ಗಳು ಮತ್ತು ಸೆಟ್ಗಳು, ಕ್ಯಾತಿಟರ್ಗಳು, ಮೂತ್ರಚೀಲಗಳು, ಸಿರಿಂಜಿನಗಳು (ಸೂಜಿಮತ್ತು ಸ್ಥಿರಸೂಜಿ ಸಿರಿಂಜಿಲ್ಲದ) ಮತ್ತು ಸೂಜಿ ಕಟ್ಆದ ವ್ಯಾಕ್ಯೂಟೇನೇ ರ್ಸ್ಮತ್ತು ಕೈಗವಸುಗಳು.
White *White puncture proof, leak proof, tamper proof containers.*	• Waste sharps including Metals: Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps.	• ಬೇಡವಾದ ಚೂಪಾದ ಲೋಹದ ವಸ್ತುಗಳಾದ ಸೂಜಿಗಳು, ಸೂಜಿಯೊಂದಿಗಿನಸಿರಿಂಜ್ಗಳು, ಕಟ್ಟರ್ಅಥವಾ ಬರ್ನರ್ಗಳಿಂದ ಕತ್ತರಿಸಲ್ಪಟ್ಟ ಸೂಜಿಗಳು, ಸ್ಕಾಲ್ಪೆಲ್, ಬ್ಲೇಡ್ಗಳು ಅಥವಾ ಇತರೆ ಗಾಯಗೊಳಿಸಬಹುದಾದ ಹರಿತವಾದ ಕಲುಷಿತ ವಸ್ತುಗಳು.
Blue *Puncture proof, leak proof, boxes or containers with blue colored marking*	• Glassware: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes	• ಗಾಜಿನವಸ್ತುಗಳು: ಮುರಿದ ಹಾಗು ತಿರಸ್ಕರಿಸಿದ ಔಷಧೀಯ ಬಾಟಲ್ಗಳು ಮತ್ತು ಗಾಜಿನ ವಸ್ತುಗಳು, ಆಂಪ್ಯೂಲ್. ಸೈಟೊಟಾಕ್ಸಿನ್ತ್ಯಾಜ್ಯಗಳೊಂದಿಗೆ ಕಲುಷಿತಗೊಂಡ ವಸ್ತುಗಳನ್ನು ಹೊರತು ಪಡಿಸಿ

Instructions	Responsibility
Wastes are segregated into two major categories: Bio-medical waste (Infected waste) General waste (Non-infected waste)	Section Staff
All general waste, generated at the Donning area and office of the Molecular Laboratory is collected in black plastic bags and handed over to the waste collecting agency	House Keeping staff
Solid wastes contaminated with Respiratory specimens at the Molecular Laboratory are collected in yellow non-chlorinated bags, and sterilized by autoclaving, and pre-treated solid wastes are transferred to red bag and handed over to the Biomedical waste collecting agency	Technician and House keeping Staff

1. **Autoclaving**:
    a. Place bag to be autoclaved into a shallow pan or tub.
    b. Affix a small piece of chemical indicator tape or test strip to the outside of the bag.
    c. Place the pan and bag inside the autoclave. Do not overload the autoclave. There should be at least 2 inches of space around each waste bag on all sides to allow access to surfaces by steam. No other materials should be autoclaved together with waste in the same load.
    d. Run the autoclave at a chamber temperature of 121°c for 60 minutes, 121°c is a standard temperature for autoclave operation, and generally achieved under15 lbs pressure is 15-16 psi.
    e. Operation at higher temperatures will allow the time to be decreased, and operation at lower temperatures will require longer times. The 60 minute time specified in the directions is recommended as a starting point.
    f. When the cycle has been completed, verify that the autoclave chamber and ambient pressure are the same. The chamber may now be opened and the waste bag removed.
    g. Wear heat resistant gloves when handling hot items. Take caution when opening the autoclave door, as a small amount of hot steam may be released when opening the chamber.
    h. Verify that the cycle ran appropriately by visualizing the chemical indicator tape.

i. Once the bag has cooled, place the treated waste bag inside a plastic bag and close the bag either by knotting or with a twist tie and label it as covid-19 waste and hand over it further biomedical waste management.

2. **Validating autoclave performance**:
   a. Each autoclave must have a functional monitoring or measuring device (electronic or dial) to ensure that the recommended temperature is achieved for the proper length of time on each load.
   b. Each waste bag or container decontaminated by autoclaving should have a heat sensitive indicator such as autoclave tape or strip attached to the outside of the bag. These should be visualized before disposal of each bag and should remain with the bag.
   c. At least once a week, autoclaves that are used to decontaminate waste or to render materials biologically inactive should be tested by using a biological indicator, such as endospores from the bacterium *Geobacillus stearothermophilus*.
3. **Testing procedure:**
   a. Secure a biological indicator test containing endospores of *Geobacillus stearothermophilus*.
   b. Tie a piece of string to the testing vial containing spores to facilitate retrieval of the vial after the autoclave run.
   c. Leave the other end of the string attached to the vial trailing out of the opening of the waste bag.
   d. Secure the waste bag and start the autoclave run.
   e. Post autoclaving and once the bag has cooled, retrieve the vial.
   f. Read the results of the indicator according to manufacturer instructions.

Recording and documentation: records of repairs, service calls, and calibrations of autoclaves will be maintained by the user, Section-in-charge . Users maintains records of any validation testing they perform on the autoclaves. These records will be also kept for the lifetime of the autoclave, or as long as feasible.

6.3.4 Personnel facilities

Water Supply & Quality Control

- A continuous water supply is ensured for all laboratory activities.

- The lab is equipped with a **Reverse Osmosis (RO) water system**, ensuring water is free from microbial and chemical contamination.
- The RO water meets permissible limits for chemical and physical parameters required for laboratory testing.
- **Water quality is monitored every three months**, with microbiological parameters tested.
- Records of water quality tests are maintained in the **Water Analysis file** for reference and compliance.

Sanitation & Hygiene

- **Washroom facilities** are provided for laboratory staff to maintain hygiene and convenience.
- An **adequate supply of clean drinking water (RO)** is available to ensure staff well-being.

Safety & Personal Protection

- All staff members are **supplied with personal protective equipment (PPE)** and encouraged to use it for safety and compliance with laboratory protocols.
- A **safety locker** is available within the department for staff to securely store personal belongings.

Work Environment & Comfort

- The laboratory provides a **dedicated space for meetings**, facilitating discussions and team collaboration.
- A **quiet study area** is available for research, documentation, and focused work.
- A **rest area** is designated within the lab to allow staff to take breaks and recharge during work hours.

6.3.5 Sample collection facilities

1. **Designated Sample Collection Area**
   - A dedicated and well-ventilated sample collection room ensures a controlled and safe environment.
   - The area is designed to minimize cross-contamination and ensure patient privacy.
   - Proper biohazard labeling and signage are displayed to indicate restricted access.
2. **Separate Patient Reception & Collection Areas**
   - A separate reception area is provided to manage patient flow efficiently and reduce congestion.

- The sample collection area is distinct from the reception to maintain infection control protocols.
- Adequate spacing is ensured in waiting areas, with social distancing markers for patient safety.
- Patients are provided with clear pre-collection instructions at the reception before sample collection.

3. **Personal Protective Equipment (PPE) & Biosafety Measures**

- Trained healthcare professionals wear appropriate PPE, including N95 masks, gloves, gowns, and face shields.
- Hand hygiene stations with alcohol-based hand sanitizers are available at entry and exit points.
- Aerosol containment measures are implemented to reduce exposure risks during sample collection.

4. **First Aid Facilities**

- First aid kits are available in both the reception and sample collection areas.
- Kits contain basic medical supplies, including antiseptics, bandages, sterile gauze, pain relievers, gloves, and emergency medications.
- Staff members are trained in basic first aid procedures to assist patients and personnel in case of an emergency.
- An emergency response protocol is in place for handling any adverse reactions or medical incidents.

5. **Sample Collection Procedure**

- Sterile swabs (e.g., nasopharyngeal or oropharyngeal) are used for respiratory specimen collection following standard guidelines.
- Samples are collected in viral transport media (VTM) and immediately labeled with patient details.
- A strict protocol ensures proper chain of custody and prevents sample mix-ups.

6. **Storage & Transport**

- Collected specimens are stored in a temperature-controlled environment (2-8°C) before processing.
- For long-term storage, samples are preserved at -80°C per laboratory retention policies.
- Triple-layered leak-proof packaging is used for safe transportation to the testing facility.
- Transport follows biosafety and IATA guidelines for infectious materials.

7. Waste Disposal & Decontamination

- Used swabs, PPE, and other biohazardous waste are disposed of in color-coded biomedical waste bins as per regulatory guidelines.
- Regular disinfection of collection areas is carried out using hospital-grade disinfectants.

8. **Spill Management**

- A spill management protocol is in place to handle accidental spills of biological samples, reagents, or chemicals.
- Spill kits containing absorbent materials, disinfectants, gloves, and biohazard bags are readily available in collection and storage areas.
- Staff members are trained in spill response procedures, including immediate containment, decontamination, and proper waste disposal.
- Any spill incidents are documented and reviewed to improve safety measures and prevent recurrence.

9. Patient & Staff Safety

- Social distancing measures and appointment-based scheduling prevent overcrowding.
- Patients receive clear instructions before, during, and after sample collection.
- Staff undergo regular training on infection control practices, sample handling protocols, and emergency response.

Annexure

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/F/17	Laboratory Cleaning & Fumigation Checklist	Form	Section-In-Charge	Laboratory Office	1 year
ML/FL/20a	Environmental monitors	File	Section-In-Charge	Laboratory Office	1 year
ML/FL/20b	Communication file	File	Section-In-Charge	Laboratory Office	5 Years
ML/FL/20c	Minutes of meeting	File	Section-In-Charge	Laboratory Office	5 Years

Resource Requirements

ML/F/22	Daily restroom cleaning checklist	Form	Section-In-Charge	Laboratory Office	1 year
ML/REG/15	Biomedical Waste register	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/16	Autoclave log	Register	Section-In-Charge	Laboratory office	Continuous

6.4 Equipment (ML/QSP-13/EQUIP)

1. Purpose: The laboratory will have processes for the selection, procurement, installation, acceptance testing (including acceptability criteria), handling, transport, storage, use, maintenance, and decommissioning of equipment, in order to ensure proper functioning and to prevent contamination or deterioration. Laboratory equipment includes hardware and software of instruments, measuring systems, and laboratory information systems, or any equipment that influences the results of laboratory activities, including sample transportation systems.

2. Responsibility:

- Principal/ Medical Director
- Laboratory Director
- Section-In-Charge
- Bio-Medical Engineer
- Administrative manager
- Store In-charge

3. **Scope:**

- Equipment requirements
- Equipment acceptance procedure
- Equipment instructions for use
- Equipment maintenance and repair
- Equipment adverse incident reporting
- Equipment records

6.4.2 Equipment requirements

- The Laboratory Director submits the equipment requirements, along with a justification, to the Principal/Medical Director for review.
- Upon assessing the necessity, the Principal/Medical Director approves the request and forwards it to the Administrative Manager for order processing.
- The Administrative Manager evaluates potential suppliers, verifies the equipment specifications recommended by the Laboratory Director, and reviews the cost. The findings are then submitted to the Principal/Medical Director for final approval.
- Once final approval is granted, the Administrative Manager proceeds with placing the order under the agreed-upon conditions.

- The order is confirmed upon acceptance of the terms and conditions by the supplier.
- The Molecular Laboratory ensures that all necessary electrical wiring and equipment support arrangements are completed as per supplier and company protocols.
- Equipment procurement is based on the following criteria:
  - Introduction of new technology
  - Frequent failures of existing equipment
  - Compatibility with open/closed reagent systems
  - Cost-effectiveness
  - Use of approved methodologies
  - Availability of after-sales and maintenance services
  - Reputation of the supplier
  - Feedback from other laboratories
- Labeling and Documentation:
  - Upon receipt, each piece of equipment is labeled with a unique identification number for tracking and maintenance purposes.
  - A dedicated equipment register is maintained to record details such as purchase date, supplier information, specifications, maintenance schedules, and calibration records.

6.4.3 Equipment Acceptance Procedure

Delivery & Installation

- Once the equipment is delivered, it is installed by a **qualified service engineer from the supplier company**, following manufacturer guidelines and laboratory protocols.
- The **Laboratory Director grants approval** for accepting the equipment only after ensuring proper installation.
- The installed equipment undergoes **Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ)** to verify its functionality, accuracy, and compliance with laboratory requirements.
- The equipment is **not used** until it successfully passes all qualification tests.

Non-Conformance & Supplier Rectification

- If the equipment fails to meet the required specifications or does not function as expected, it is categorized as **non-conforming equipment**.

- The **supplier is informed immediately** and is responsible for identifying and resolving the issue.
- After necessary corrections or replacements, the equipment is **retested, validated, and requalified** before acceptance and use.

Performance Monitoring & Quality Assurance

- Once operational, the **user department continuously monitors the equipment's performance** to ensure consistent and reliable functionality.
- Routine **maintenance, calibration, and servicing** schedules are followed as per manufacturer guidelines and laboratory protocols.
- Any deviation or malfunction is **documented and reported**, and corrective actions are taken promptly.
- Preventive maintenance and performance checks are conducted **at regular intervals** to avoid unexpected breakdowns and ensure optimal efficiency.

Labelling & Documentation

- Each piece of equipment is assigned a **unique identification number**, which is clearly **labeled** on the equipment.
- An **equipment register** is maintained, recording details such as:
  - Purchase date and supplier details
  - Installation, validation, and calibration records
  - Maintenance and servicing history
  - User department observations and performance reports
- Proper documentation ensures **traceability, compliance, and audit readiness** for internal and external quality assessments.

Measurement Uncertainty & Measurement Accuracy

- **Measurement Uncertainty**: Every measurement has an associated level of uncertainty due to various influencing factors such as equipment precision, environmental conditions, and operator handling. The laboratory **assesses and documents measurement uncertainty** to ensure confidence in test results and compliance with regulatory standards.
- **Measurement Accuracy**: The accuracy of the equipment is verified through **routine calibration and performance checks** using standard reference materials or control samples. If any deviations are detected, corrective actions such as recalibration, equipment servicing, or method adjustments are implemented to maintain accuracy.

- Both measurement uncertainty and accuracy assessments are **documented and reviewed** periodically to enhance reliability and reproducibility in laboratory testing.

6.4.4 Equipment instructions for use

- **Training and Technical Support:** The supplier's technical team conducts comprehensive training sessions for Molecular Lab technicians and the Instrument Technician. This training covers essential aspects such as equipment operation, routine and preventive maintenance, troubleshooting common issues, and proper calibration procedures to ensure optimal performance and accuracy.
- **Authorized Personnel:** Only technicians who have successfully completed the training and received authorization from the department are permitted to operate the equipment. This ensures that all users have the necessary expertise to handle the instrument safely and effectively. Unauthorized personnel are strictly prohibited from using the equipment to prevent mishandling and potential damage.
- **Reference to Instrument Manual:** Technicians are encouraged to refer to the official instrument manual, which is readily available within the lab. The manual provides detailed guidance on proper handling, operation procedures, troubleshooting steps, and maintenance schedules. Consulting the manual ensures consistent adherence to best practices and helps prevent operational errors.
- **Safe Handling, Transport, and Storage:** The laboratory has established standardized procedures for the safe handling, transport, storage, and usage of equipment. These protocols are designed to prevent contamination, mechanical damage, or deterioration of the instrument. Proper storage conditions, careful transportation methods, and adherence to operational guidelines contribute to extending the lifespan of the equipment and maintaining its accuracy and reliability.
- **Unintended Adjustments:** Any unauthorized or unintended adjustments to the equipment settings, calibration, or internal components are strictly prohibited. Alterations made without proper guidance may compromise the accuracy, performance, and safety of the instrument. In case of any necessary adjustments, technicians must consult the instrument manual and seek approval from the designated authority or the supplier's technical team to ensure compliance with standard operating procedures.

6.4.5. Equipment Maintenance and Repair Procedures

Proper maintenance and timely repair of laboratory equipment are essential to ensure operational efficiency, accuracy, and safety. The following procedures outline the maintenance and repair processes for all equipment used in the laboratory.

1. Routine Maintenance

- Routine maintenance of equipment is carried out by trained laboratory technicians to ensure consistent functionality and prevent unexpected failures.

- Technicians adhere to the **Equipment Daily Maintenance Checklist**, manufacturer's instruction manuals, and any other guidelines provided by the supplier to ensure proper handling and maintenance.
- Daily maintenance may include tasks such as cleaning, lubrication, functional checks, and minor adjustments to maintain optimal performance.

2. Preventive Maintenance (PPM)

- The **Bio-Medical Engineer** is responsible for maintaining a **Periodic Preventive Maintenance (PPM) Schedule** for each piece of equipment.
- Preventive maintenance is conducted at scheduled intervals based on manufacturer recommendations, equipment usage, and environmental conditions.
- During PPM, all listed equipment is inspected, calibrated, and serviced as needed. Any defects or malfunctions discovered during the process are documented in the **Equipment Breakdown Register** for corrective action.
- If the equipment is still under a **warranty period**, the preventive maintenance schedule is aligned with the terms of the warranty agreement to ensure compliance and avoid voiding the warranty.

3. Maintenance Documentation and Procedures

- **Standardized maintenance procedures** are developed and documented for each piece of equipment where necessary, ensuring consistency in maintenance practices.
- Maintenance activities are carried out strictly as per the documented procedures to maintain equipment performance and safety.
- After each preventive maintenance session, the equipment is **tested and validated** to confirm that it is functioning correctly before being placed back into use.
- All preventive maintenance activities, including service details and any corrective actions taken, are **properly documented and filed** in the respective equipment records for future reference and audits.

4. Equipment Breakdown and Repair

- If an equipment failure or malfunction is identified, it is **immediately removed from service**, and a label stating **"NOT IN USE"** is affixed to prevent unintended operation.
- The breakdown details, including the nature of the failure and suspected causes, are recorded in the **Equipment Breakdown Register** by the **Bio-Medical Engineer**.
- The **company's service engineer** is notified about the issue, and follow-ups are conducted to ensure prompt repair.

- A **service report** is obtained from the engineer after the repair is completed, detailing the work done, parts replaced (if any), and any additional recommendations for future maintenance. This report is then **filed in the equipment records** for tracking purposes.
- If any components or spare parts are replaced during the repair process, the **replacement details are logged** in the Equipment File to maintain a complete service history.

5. Post-Service Testing and Validation

- Once the servicing or repair is completed, the equipment undergoes **thorough testing and validation** to verify its performance, accuracy, and safety before being recommissioned for use.
- Only after successful validation and approval from the designated authority is the equipment cleared for regular operation.
- The details of **equipment failures, repairs, and service interventions** are meticulously recorded in both the **Equipment Breakdown Register** and the **Equipment Record**, ensuring a comprehensive maintenance history.

6. Decontamination of Equipment Before Service, Repair, or Decommissioning

- Before any equipment undergoes servicing, repair, or decommissioning, it must be **properly decontaminated** to remove any hazardous substances, biological agents, or chemical residues.
- **Trained personnel** perform decontamination following standard laboratory protocols and manufacturer guidelines to ensure the safety of maintenance staff and service engineers.
- A **decontamination certificate or record** is completed and attached to the equipment before it is handed over for servicing or disposal.
- If the equipment is being **decommissioned**, final decontamination is carried out, and disposal is conducted in compliance with environmental and regulatory requirements.

7. Provision of Space for Equipment Repair

- A **dedicated space** is allocated within the laboratory or facility for conducting equipment repairs and servicing.
- The repair area is **clean, well-lit, ventilated, and equipped** with the necessary tools and utilities to facilitate safe and efficient maintenance.
- Equipment under repair will be **isolated** from operational areas to prevent contamination or interference with ongoing laboratory activities.
- Proper **workbenches, storage cabinets, and waste disposal systems** is available in the repair space to support technicians and service engineers.

- If repairs require extensive servicing beyond in-house capabilities, arrangements will be made to **transport equipment to an external service center**, ensuring compliance with handling and safety protocols.

7. Equipment Downtime and Impact on Operations

- **Tracking Downtime:** The time during which equipment remains non-functional due to an adverse incident, repair, or maintenance is recorded as **equipment downtime** in the **Equipment Downtime Log**.
- **Assessing Impact:** The Lab Director and Bio-Medical Engineer assess the impact of downtime on laboratory operations, particularly in critical testing areas.
- **Alternative Measures:** If downtime affects essential laboratory processes, alternative solutions such as:
  - Using backup equipment. All molecular equipment's has backup instruments, mainly, RTPCR, BIORAD is backup for ROTORGENE, Two cold centrifuge, two deep freezers, two minispin, three refrigerators (Ref Equipment list).
  - Outsourcing testing to an external facility.
  - Adjusting workflows to minimize disruptions.
- **Minimizing Downtime:** Efforts will be made to restore equipment functionality as soon as possible by ensuring timely repairs, availability of spare parts, and efficient coordination with service engineers.
- **Documenting Downtime:** The total downtime, reasons for delay, and actions taken to mitigate impact will be recorded in the **Equipment Maintenance Records** to help optimize future response strategies.

The laboratory has set an acceptable downtime of 24 hours for all equipment

By implementing these maintenance and repair procedures, the laboratory ensures:

- **Prolonged Equipment Lifespan** – Regular maintenance reduces wear and tear, extending the service life of equipment.
- **Operational Efficiency** – Well-maintained equipment functions optimally, minimizing downtime and disruptions.
- **Accuracy and Reliability** – Proper maintenance and validation prevent errors in laboratory testing and analysis.
- **Regulatory Compliance** – Proper documentation ensures compliance with industry standards, audits, and accreditation requirements.
- **Safety Assurance** – Decontamination measures protect technicians, engineers, and the environment from hazardous exposure.

- **Efficient Repairs** – A designated repair space ensures timely and organized servicing without affecting routine laboratory operations.

6.4.6 Equipment adverse incident reporting

Equipment Adverse Incident Reporting

Adverse incidents involving laboratory equipment will be reported and documented to ensure safety, compliance, and timely corrective action. The following procedure outlines the steps for reporting, investigating, and addressing adverse incidents related to equipment failure or malfunction.

1. Definition of an Adverse Incident

An adverse incident related to equipment is any unexpected event that results in or has the potential to result in:

- Injury to personnel.
- Contamination or exposure to hazardous substances.
- Damage to equipment or laboratory infrastructure.
- Incorrect or unreliable test results.
- Violation of safety or regulatory guidelines.

2. Immediate Actions

- **Stop Equipment Use:** As soon as an adverse incident is detected, the equipment will be **immediately removed from use**, and a **"NOT IN USE"** label affixed.
- **Ensure Safety:** Any personnel exposed to hazards (chemical, biological, electrical, or mechanical) will seek **immediate medical attention** if required.
- **Isolate the Equipment:** Secure the affected equipment in a designated area to prevent further incidents or contamination.
- **Notify the Relevant Personnel:** The Section in-charge, **Bio-Medical Engineer, Lab Director, manufacturer and distributor will** be informed of the incident without delay.

3. Incident Reporting Procedure

- Complete an Equipment Incident Report Form: The senior technician or Section-in-charge will fill out an Equipment Adverse Incident Report detailing:
  - Date, time, and location of the incident.
  - Description of the event and suspected cause.
  - Personnel involved or affected.
  - Actions taken immediately after the incident.

- Equipment identification details (model, serial number, manufacturer).

- **Submit the Report:** The completed report will be submitted to the **Lab Director and Bio-Medical Engineer** for review.
- **Log the Incident:** The incident is recorded in the **Equipment Incident Register**, ensuring a permanent record for reference and auditing.

4. Investigation and Root Cause Analysis

- **Assign Investigation Team:** The Laboratory director, Bio-Medical Engineer, and Section-In-Charge will conduct an investigation to determine the root cause of the incident.
- **Collect Evidence:** The team will inspect the equipment, review maintenance records, interview involved personnel, and check environmental factors.
- **Identify the Cause:** Possible causes include:
  - Operator error.
  - Equipment malfunction or wear and tear.
  - Electrical, mechanical, or environmental factors.
  - Manufacturer defect.
  - Lack of proper maintenance or calibration.

5. Corrective and Preventive Actions (CAPA)

- **Corrective Actions:**
  - Repair, recalibrate, or replace the faulty equipment as needed.
  - If the equipment is under warranty, notify the supplier or manufacturer for corrective action.
  - Implement temporary or alternative solutions to continue laboratory operations safely.
- **Preventive Actions:**
  - Update standard operating procedures (SOPs) to prevent similar incidents.
  - Provide additional training for staff on proper equipment use and maintenance.
  - Increase frequency of preventive maintenance for high-risk equipment.
  - Conduct regular safety audits and risk assessments.
- **Document Actions Taken:** All corrective and preventive actions must be recorded in the Incident Report File and Equipment Maintenance Records.

6. Equipment Recommissioning

- Once corrective actions have been implemented, the equipment will undergo **testing, validation, and quality assurance checks** before being returned to service.
- The equipment should only be cleared for use **after final approval from the Lab Director**.

7. Record Keeping and Review

- All equipment adverse incident reports, investigations, and corrective actions will be **documented and stored** for future reference.
- The lab management team will conduct **periodic reviews** of incident reports to identify trends and improve overall equipment safety and reliability.

6.4.7. Equipment records

Equipment File Contents

Each laboratory equipment has a dedicated **Equipment File** that serves as a comprehensive record of its history, maintenance, and operational status. This file is essential for **traceability, compliance, and quality assurance** and must be **updated regularly** to reflect the most recent changes. The following details are included:

1. Equipment Identification

Each piece of equipment is assigned a **unique identification number** or asset tag, which helps track its usage, maintenance, and movement within the facility.

2. Manufacturer's Information

The name of the manufacturer is recorded to ensure proper reference for troubleshooting, servicing, and procurement of spare parts.

3. Model and Serial Number

- The **model number** specifies the version of the equipment.
- The **serial number** provides a unique identifier assigned by the manufacturer, allowing easy reference for warranties and technical support.

4. Contact Person/Service Engineer and Contact Information

- The **name and contact details** of the designated service engineer or supplier representative are documented.
- This ensures prompt communication in case of breakdowns, preventive maintenance, or technical support needs.

5. Date of Receipt

- The exact date the equipment was received at the laboratory is recorded for inventory tracking and warranty verification.

6. Date of Installation

- The date when the equipment was installed and became operational is documented for future maintenance and audit purposes.

7. Current Location

- The specific location of the equipment within the facility (e.g., laboratory section, department, or room number) is recorded to facilitate easy tracking and accessibility.

8. Condition at the Time of Receipt

- The equipment's condition upon arrival is documented, specifying whether it was **new, used, or reconditioned.**
- This helps in assessing expected performance and determining the need for additional quality checks.

9. Warranty/Guarantee Period

- If applicable, the **warranty period and coverage details** (e.g., parts, labor, service) are recorded.
- Warranty terms dictate maintenance responsibilities and determine whether repairs should be covered by the manufacturer.

10. Instruction Manual

- A copy of the **manufacturer's instruction manual** is included in the equipment file for reference.
- This manual provides essential information on **operation, maintenance, troubleshooting, and calibration**.

11. Installation Qualification (IQ) Documentation

- Installation Qualification (IQ) confirms that the equipment is installed according to the manufacturer's specifications and laboratory standards.
- This includes checking power requirements, environmental conditions, and proper placement.

12. Operational Qualification (OQ) and Performance Qualification (PQ) Records

- **Operational Qualification (OQ)** verifies that the equipment functions correctly within its intended **operating range** after installation.

- **Performance Qualification (PQ)** ensures that the equipment consistently produces **accurate and reliable results** under real laboratory conditions.

13. Periodic Preventive Maintenance (PPM) Reports and Schedule

- The **PPM schedule** is maintained to ensure regular servicing and minimize the risk of equipment failure.
- Each **preventive maintenance session** is recorded, detailing:
  - Date of service
  - Tasks performed
  - Parts replaced (if any)
  - Next scheduled maintenance date

14. Records of Equipment Damage, Malfunction, Modifications, or Repairs

- Any **damage, breakdowns, repairs, or modifications** are documented to maintain a complete service history.
- This helps in **identifying recurring issues, evaluating maintenance effectiveness, and ensuring compliance with safety regulations**.

15. Calibration Date and Next Due Date for Recalibration

- Calibration ensures the equipment provides accurate measurements.
- The **last calibration date** and the **next scheduled recalibration** are recorded.
- If external calibration services are used, certificates from the calibration provider are attached.

16. List of Authorized Personnel Permitted to Operate the Equipment

- Only trained and authorized personnel should handle the equipment.
- A list of **approved operators**, along with their training records, is maintained to ensure competency in equipment handling.

17. Traceability Certificate

- If required, a **traceability certificate** is included, which provides evidence that the equipment complies with national or international **standards for measurement accuracy**.

Resource Requirements

Annexures

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/FL/21a	Purchase order /In-voice, comparative statement	File	Administrative manager	HR/ Establishmen t	5 Year
ML/FL/21b	Master Equipment file	File	Section-In-Charge	Laboratory office	Continuous
ML/FL/21c	Material Inspection /Acceptance checklist	File	Section-In-Charge	Laboratory office	5 Year
ML/F/6	Material Inspection /Acceptance checklist	Form	Section-In-Charge	Laboratory office	5 Year
ML/F/2	Vendor evaluation	Form	Section-In-Charge	Store	5 Year
ML/FL/3a	Vendor evaluation	File	Administrative officer	Administrativ e office	5 Year
ML/F/19	Temperature log	Form	Section-In-Charge	Laboratory office	1 Year
ML/F/20	Autoclave temperature log	Form	Section-In-Charge	Laboratory office	1 Year
ML/F/21	Biosafety user log	Form	Section-In-Charge	Laboratory office	1 Year
ML/F/26	Laminar air flow user log	Form	Section-In-Charge	Laboratory office	1 Year
ML/Reg/1	Equipment breakdown	Regist er	Section-In-Charge	Laboratory office	Continuous

6.5 Equipment calibration and metrological traceability (ML/QSP-14/EQIPCMT)

1. Purpose:

Proper calibration and validation of laboratory equipment are essential to ensure **accuracy, reliability, and metrological traceability** in testing and analysis. The Molecular Laboratory follows a structured approach to calibration, monitoring, and corrective actions when calibration results fall out of acceptable limits.

2. Responsibility:

- Principal/ Medical Director
- Laboratory Director
- Section-In-Charge
- Bio-Medical Engineer
- Administrative manager
- Store In-charge

3. Scope:

- Equipment calibration
- Metrological Traceability of measurements results

1. Equipment Calibration and Metrological Traceability

- The **Bio-Medical Engineer** ensures that all equipment undergoes proper **calibration** and that **metrological traceability** is established before being placed into regular service.
- Calibration details, including **date, parameters, reference standards, and results**, are systematically recorded in the **Equipment Record** at regular intervals.
- All calibration activities comply with **national and international measurement standards** to ensure the **traceability of results** to recognized reference standards.
- The **Molecular Laboratory ensures metrological traceability** by maintaining a documented link between equipment calibration results and **standardized reference materials or certified measuring systems**.

2. Approval and Validation of Equipment Before Use

- Equipment is **approved for use** only after:
  - **Proper functionality checks** are performed.
  - Performance is validated using **standard reference materials** with known characteristics.

- Calibration results fall within the acceptable range of tolerance.

- Equipment can be **commissioned for use** only after receiving formal approval from the in-house **Bio-Medical Engineer** and lab management.

3. Regular Monitoring and Recalibration

- The laboratory management has established a **monitoring program** to:
  - Regularly assess and verify the **calibration and performance** of instruments, reagents, and analytical systems.
  - Conduct periodic recalibration of equipment as per manufacturer recommendations and regulatory requirements.
- **Calibration services** are only assigned to **ISO-recognized and approved vendors**, ensuring compliance with international quality and metrological standards. A formal **work order** is issued to the selected vendor for performing calibration services.

4. Handling Out-of-Control Calibration Results

Despite regular maintenance and calibration, situations may arise where calibration results **fall outside the acceptable control limits**. The following steps outline how the laboratory handles such cases:

Step 1: Immediate Actions

- If an equipment's calibration result is found to be **out of acceptable control limits**, the equipment is **immediately removed from service**, and a **"NOT IN USE"** label is affixed to prevent further use.
- Laboratory Director and the **Bio-Medical Engineer** are notified to initiate an investigation.

Step 2: Root Cause Analysis (RCA)

- A **detailed investigation** is conducted to determine the reason for the deviation. Potential causes may include:
  - **Instrument drift** due to prolonged use or aging components.
  - **Environmental factors** such as temperature, humidity, or power fluctuations.
  - **Human errors** in calibration procedures or incorrect handling.
  - **Wear and tear** or mechanical issues affecting instrument accuracy.
  - **Defective calibration standards** or incorrect reference materials.
- The Bio-Medical Engineer, along with the laboratory Director, assesses the impact of the deviation on previously generated test results.

Step 3: Corrective Actions

- Depending on the root cause, appropriate corrective actions are taken, such as:
  - **Recalibration** using certified reference materials or an alternative standard.
  - **Servicing or repair** of the instrument by an authorized engineer.
  - **Replacement** of defective components affecting calibration accuracy.
  - **Re-evaluation of affected test results** and reprocessing samples if necessary.
- If recalibration or repairs fail to bring the equipment back within acceptable limits, the equipment is either:
  - **Permanently decommissioned** and removed from service.
  - **Replaced with a new, fully calibrated instrument**.

Step 4: Documentation and Compliance

- **All findings, actions taken, and recalibration details** are recorded in the **Equipment Calibration Record** for traceability and future audits.
- If the issue had an impact on previously conducted tests, **corrective measures** are taken to address potential inaccuracies in reported results.
- The laboratory management ensures compliance with **quality assurance programs, regulatory requirements, and ISO standards**.

5. Preventive Measures to Minimize Calibration Issues

To reduce the likelihood of out-of-control calibration results, the Molecular Laboratory implements the following preventive measures:

- **Routine preventive maintenance and servicing** of all equipment.
- **Use of certified reference materials and traceable calibration standards.**
- **Strict adherence to calibration schedules** based on manufacturer guidelines. **Comprehensive training for technicians** on proper equipment handling and calibration procedures.
- **Environmental control measures** to prevent external factors from affecting equipment performance.
- **Regular quality control checks** to identify deviations before they become critical.

By following these procedures, the Molecular Laboratory ensures:

- **Accurate and reliable test results** through proper calibration and validation.
- **Immediate identification and correction** of out-of-control calibration situations.

- **Compliance with ISO and regulatory standards** for metrological traceability.
- **Minimized downtime and optimized equipment performance** through proactive maintenance.
- **Continuous quality improvement and risk mitigation** to maintain laboratory integrity.

With a well-structured calibration and validation system, the laboratory maintains **high-quality testing standards**, ensuring accurate, reproducible, and **traceable measurement results** that meet global regulatory and accreditation requirements.

Annexures

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/FL/21b	Master Equipment file	File	Section-In-Charge	Laboratory office	Continuous
ML/FL/21c	Material Inspection /Acceptance checklist	File	Section-In-Charge	Laboratory office	5 Year
ML/F/6	Material Inspection /Acceptance checklist	Form	Section-In-Charge	Laboratory office	5 Year
ML/FL/3a	Vendor evaluation	File	Administrative officer	Administrative office	5 Year
ML/F/19	Temperature log	Form	Section-In-Charge	Laboratory office	1 Year
ML/F/20	Autoclave temperature log	Form	Section-In-Charge	Laboratory office	1 Year
ML/F/21	Biosafety user log	Form	Section-In-Charge	Laboratory office	1 Year
ML/F/26	Laminar air flow user log	Form	Section-In-Charge	Laboratory office	1 Year
ML/Reg/1	Equipment breakdown	Register	Section-In-Charge	Laboratory office	Continuous

6.6 Reagents and Consumables (ML/QSP-15/REACON)

1. Purpose:

The laboratory will have processes for the selection, procurement, reception, storage, acceptance testing, and inventory management of reagents and consumables.

2.Responsibility:

- Principal/ Medical Director
- Laboratory Director
- Section-In-Charge
- Administrative manager
- Store In-charge

3. Scope:

- Reagents and consumables: Receipt and storage
- Reagents and consumables: Acceptance testing
- Reagents and consumables: Inventory management
- Reagents and consumables: Instructions for use
- Reagents and consumables: Adverse incident reporting
- Reagents and consumables: Records

6.6.2 Receipt and storage

Inspection of Received Materials

- Upon delivery, the Store In-charge conducts a visual inspection of the materials and verifies them against the purchase order. Acceptance and rejection criteria are outlined in the Material Acceptance Checklist.
- Any non-conforming, damaged, or broken items are rejected and returned to the respective suppliers.
- Details of non-conforming items are recorded in the rejection register.
- Replacement items received are inspected before being stored.
- In cases of emergency purchases from unapproved suppliers, approval must be obtained from the Administrative Manager. The materials are monitored, and the supplier's performance is evaluated for future procurement.

Monitoring of Environmental Conditions

- Storage conditions, including temperature, humidity, and light exposure, are regularly monitored to ensure compliance with manufacturer specifications.
- For all items requiring a strict cold chain, the temperature is checked upon receipt using an IR thermometer to ensure compliance with the required storage conditions.
- Environmental parameters are recorded and reviewed periodically to prevent material degradation.
- Any deviations from the required conditions are promptly addressed, and corrective actions are taken as necessary.

6.6.3 Reagents and consumables-Acceptance testing

The following criteria are adhered to for the acceptance and rejection of reagents and kits used in the laboratory:

Acceptance Criteria:

- Must be within the expiry date.
- No signs of leakage or damage.
- Proper transportation under recommended temperature conditions.
- Free from contamination.

Rejection Criteria:

- Expired reagents or kits.
- Evidence of leakage or physical damage.
- Contamination detected.
- Non-compliance with the purchase order specifications.
- Manufacturer differs from the one listed in the Approved Vendor List.
- Transportation conditions do not comply with the manufacturer’s instructions.
- Improper transport conditions that could compromise reagent integrity.

Acceptance Testing

- Consumables that may impact examination quality are checked for expiry dates. Any reagent kit beyond its expiry date is not used for testing.
- It is the policy of the laboratory that any new reagent kit with modifications in reagents, procedures, or a new lot undergoes performance verification before being used in testing.

- Any procedural or reagent changes are communicated to technicians and implemented by the section in charge.
- Lot-to-lot verification is conducted by testing internal quality control samples, known patient samples, or PT samples before implementing new kits for patient testing.
- For lot-to-lot verification, testing is performed on **two samples**, while for a **new kit**, testing is conducted on **three samples** to ensure accuracy and reliability before use in patient examinations.
- Documentation of these verifications is maintained.

6.6.4 Reagents and consumables-Inventory management

The laboratory ensures the availability of necessary reagents and consumables to meet daily operational needs.

- For items procured from vendors within the state, a **minimum stock sufficient for 30 days** is maintained.
- For items sourced from vendors outside the state, a **minimum stock sufficient for 60 days** is maintained.
- Each item has a predefined minimum stock level, and when inventory falls below this threshold, the **Section-In-charge raises a request**.
- The **Administrative Manager reviews and approves the purchase order** before forwarding it to the respective supplier.

Once delivered, the supplied items are stored in the laboratory under appropriate conditions. Distribution to the laboratory is managed by the Store In-charge upon submission of an **Indent and Issue Form**.

Storage and Issuance

- Before issuing, reagents and consumables are checked for **acceptability** to ensure they meet quality standards.
- For efficient usage, **short-expiry reagents are placed at the front** and labeled with a **yellow sticker**, while **long-expiry reagents are stored at the back** with a **green sticker**.
- **Accepted reagents and consumables are stored separately from those that have not yet been inspected or approved for use**, ensuring clear segregation.

All materials, including reagents and consumables, are **procured from the standard and approved vendors** to maintain quality and reliability.

6.6.5 Reagents and consumables — Instructions for use

- Detailed instructions for the proper use of reagents and consumables are documented and maintained within the laboratory in the form of SOP, ensuring they are easily accessible to all lab staff. These instructions include handling guidelines, storage conditions, preparation procedures, and safety precautions to ensure optimal usage and compliance with quality standards.
- Additionally, the **manufacturer's instructions and package inserts** are systematically organized and stored in the **departmental package insert files**. These documents serve as a reference for laboratory technicians, providing essential details such as reagent composition, intended use, stability, expiration, and any special precautions required during handling and testing.
- This structured documentation ensures that all laboratory personnel have access to accurate and up-to-date information, promoting consistency, efficiency, and adherence to best practices in reagent and consumable usage.

6.6.6 Reagents and consumables: Adverse incident reporting

- Adverse incidents refer to situations where reagents are deemed unsuitable for use due to factors such as contamination, leakage, physical damage, expiration, or exposure to improper storage conditions, including uncontrolled temperatures. These issues can compromise the accuracy and reliability of laboratory testing, posing potential risks to patient safety and laboratory operations.
- To ensure quality control and compliance, any such adverse incidents or accidents are **promptly identified, documented, and thoroughly investigated** to determine the root cause. Appropriate corrective and preventive actions are taken to prevent recurrence. Additionally, these incidents are **reported to the reagent manufacturers** for further evaluation to ensure adherence to safety and quality standards.
- By implementing a structured incident reporting and investigation process, the laboratory maintains accountability, minimizes risks, and upholds high standards of operational integrity and patient care.

6.6.7 Reagents and consumables: Records

To ensure the reliability, traceability, and quality control of laboratory processes, detailed records are maintained for each reagent and consumable that contributes to the performance of examinations. These records are systematically organized and stored in designated files to facilitate efficient tracking and compliance with regulatory requirements.

Components of Reagent and Consumable Records

- **Identity of the Reagent or Consumable** –

- Each reagent or consumable used in the laboratory is clearly identified and documented in the **Invoice File**.
- This ensures easy reference and traceability in case of audits, quality control checks, or investigations related to testing performance.

- **Manufacturer's Name, Batch Code, or Lot Number** –
  - The name of the manufacturer and the specific batch code or lot number are recorded in the **Invoice File**.
  - This allows for batch tracking, facilitating recalls or performance reviews if quality issues arise.
- **Supplier or Manufacturer Contact Information** –
  - Details such as the name, address, phone number, and email of the supplier or manufacturer are documented in the **Invoice File**.
  - This information is essential for communication in cases of complaints, quality concerns, or reordering.
- **Key Dates Related to Reagent or Consumable Usage** –
  - **Date of receipt**, **expiry date**, **date of entering into service**, and, if applicable, **date of removal from service** are recorded in the **Invoice File**.
  - Tracking these dates helps in inventory management, ensuring that expired reagents or consumables are not used and allowing proactive stock replenishment.
- **Condition at the Time of Receipt** –
  - Upon delivery, reagents and consumables are inspected for quality, and their condition (e.g., acceptable or damaged) is documented in the **Material Acceptance Checklist**.
  - This step helps in identifying any non-conformities and ensures that only acceptable materials are used in laboratory operations.
- **Manufacturer's Instructions and Kit Inserts** –
  - The manufacturer's guidelines, including storage requirements, preparation steps, and handling instructions, are stored in the **Kit Insert File**.
  - These documents are readily accessible to laboratory staff to ensure proper usage in accordance with manufacturer recommendations.
- **Performance Records and Ongoing Suitability for Use** –
  - Regular performance evaluations, including lot-to-lot verifications and internal quality control tests, are conducted to confirm the continued acceptability of reagents and consumables.

- These records are reviewed periodically to ensure that only high-quality materials are used for laboratory testing.

These records ensure traceability, quality control, and compliance with laboratory standards.

Annexures

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/FL/21a	Purchase order /Invoice, comparative statement	File	Administrative manager	HR/ Establishment	5 Year
ML/FL/21c	Material Inspection /Acceptance checklist	File	Section-In-Charge	Laboratory office	5 Year
ML/F/6	Material Inspection /Acceptance checklist	Form	Section-In-Charge	Laboratory office	5 Year
ML/F/2	Vendor evaluation	Form	Section-In-Charge	Store	5 Year
ML/FL/3a	Vendor evaluation	File	Administrative officer	Administrative office	5 Year
ML/REG/8	Stock register (RTPCR & Extraction)	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/9	Stock register (Other Consumables)	Register	Section-In-Charge	Laboratory office	Continuous

6.7 Service agreements (ML/QSP-16/SERAG)

Purpose

This procedure explains the activities relating to establishing and reviewing agreement for providing Laboratory services.

Responsibility

- Principal/ Medical Director
- Laboratory Director
- Administrative manager
- Section in charge

Scope

- Agreements with laboratory users
- Agreements with POCT operators

Procedure

6.7.1 Agreements with laboratory users

- The Molecular Laboratory establishes service agreements with patients at the time of receiving examination requests.
- Upon accepting patient samples or receiving examination requisitions, the Molecular Laboratory is contractually obligated to provide accurate reports.
- The laboratory employs only skilled and qualified technical personnel by NABL 112 standards.
- Internal processes are carefully and diligently applied to ensure accurate examination results and timely report delivery.
- In case of any delay in examination or report delivery, the Molecular Laboratory promptly informs the patient.
- Adequate resources—including equipment, manpower, and environment—are provided for conducting tests listed in the Directory of Services.
- The Laboratory Director is responsible for ensuring the proper provision of resources, and oversees the implementation of the quality management system. The Section in charge ensures adherence to correct test methods and technical requirements.
- The laboratory follows a policy of referring any work outsourced to another laboratory or consultant.

- Customers and users of laboratory services include clinicians, healthcare organizations, and patients.
- When the customer is the patient, the referring doctor is recorded as "SELF" in the laboratory report.
- The laboratory does not engage in financial arrangements with referring practitioners or funding agencies that could serve as an inducement for referrals or interfere with the practitioner's independent medical judgment.
- The service agreement is reviewed annually to ensure comprehensive coverage of all relevant aspects.
- The review process includes testing methodologies, turnaround time (TAT), test requisition forms (TRFs), and the suitability of tests.
- Any amendments to the service agreement during the contract period are communicated to all affected parties.
- Records of all reviews and changes to the service agreement will be maintained for future reference and compliance.

6.7.2 Agreements with POCT operators

The Molecular Laboratory currently does not provide Point-of-Care Testing (POCT) as part of its scope. However, if POCT is incorporated in the future, the laboratory will implement a structured framework to ensure compliance with quality standards and regulatory requirements. The following guidelines will be followed:

- **Formal Agreements with POCT Operators**: The laboratory will establish agreements with POCT operators to define roles, responsibilities, and compliance requirements. These agreements will ensure that all POCT activities align with laboratory policies, regulatory standards, and best practices.
- **Adherence to Established Procedures**: POCT operators will be required to strictly follow standardized procedures set by the laboratory to maintain accuracy, reliability, and consistency in test results.
- **Competency Assessments**: To ensure that POCT operators are qualified and proficient, the laboratory will conduct periodic competency assessments. These assessments will include both theoretical knowledge and practical skills to verify operators' ability to perform tests accurately.
- **Quality Assurance Programs**: POCT operators will be required to participate in ongoing quality assurance programs, including internal quality control (IQC) and external quality assessment (EQA) schemes. This will help monitor and improve testing performance.
- **Training and Certification**: The laboratory will provide training programs to POCT operators to keep them updated on advancements in testing methodologies, regulatory

changes, and quality management practices. Certification may be mandated to ensure continued compliance.

- **Monitoring and Audits**: Regular audits and performance reviews will be conducted to ensure that POCT operations meet laboratory and regulatory standards. Any deviations or non-compliance will be addressed with corrective and preventive actions.

By implementing these measures, the Molecular Laboratory will ensure that if POCT is added to its scope, it will be conducted with the highest level of quality, accuracy, and reliability.

References: Clause 6.7 of ISO 15189:2022

Annexure

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/QMS/DOS & PSCM	Directory of Services and Primary sample collection manual (DOS)	Document	Laboratory Director	Laboratory office	Continuous
ML/FL/5	Review of Service agreement Records	File	Section-In-Charge	Laboratory office	5 Year

6.8 Externally provided products and services (ML/QSP-17/EXTERPS)

1. Purpose:

The laboratory will ensure that externally provided products and services that affect laboratory activities are suitable when such products and services are: intended for incorporation into the laboratory's own activities, provided, in part or in full, directly to the user by the laboratory, as received from the externally provided, used to support the operation of the laboratory, It can be necessary to collaborate with other organizational departments or functions to fulfill this requirement.

2. Responsibility:

- Principal
- Medical Director
- Laboratory Director
- Administrative Manager
- Section-In-Charge

3. Scope:

- Referral laboratories and consultants
- Review and approval of externally provided products and services

6.8.2 Referral laboratories and consultants

- The Molecular Laboratory utilizes referral laboratories and their NABL-authorized consultants for tests that are not performed in-house and for inter-laboratory comparison.
- Based on feedback from laboratory users and relevant departments, the Molecular Laboratory identifies suitable referral laboratories.
- A Memorandum of Understanding (MoU) is established and signed by representatives of both parties to facilitate the outsourcing process.
- The Molecular Laboratory selects only NABL-accredited laboratories or reputable government organizations for tests that fall within the NABL accreditation scope.
- Discussions and reviews regarding referral laboratory processes and procedures are documented and maintained.
- Referral laboratories are evaluated once every 12 months as per the criteria outlined in the Referral Lab Evaluation Form.

Sending Samples

- Customers will be informed about the referral laboratory where their samples are being sent for testing.
- Tests that fall within the scope of accreditation will only be outsourced to NABL-accredited laboratories when they cannot be performed in-house.
- Samples are properly labeled and transported by trained technicians with approval from the Laboratory Director and Section In-Charge ensuring compliance with sample transportation requirements.
- Details of sent samples and their corresponding test results are recorded in the Outsourcing Sample Register, maintained in the Primary Sample Collection section.
- The Section In charge follows up with the referral laboratory in case of delays.
- Turnaround Time (TAT) is established considering factors such as the type of test, sample transportation conditions, testing frequency, and any necessary advisory services. For test requests sent to referral laboratories, a TAT of up to 48 hours is deemed acceptable.

Receiving and Delivering Reports

- Referral laboratory reports are reviewed by the Section In-Charge and appropriately filed.
- If a report is not accepted, the reason for rejection is identified. Corrective actions (such as addressing demographic details or reporting content issues) and preventive measures (such as communicating with the referral lab to prevent future errors) are planned and implemented.
- The Molecular Laboratory ensures that the original examination results from the referral laboratory are provided to the requesting individual, with a copy retained in the Referral Lab Report File.

Evaluation of Referral Laboratories

- The Laboratory Director periodically evaluates referral laboratories using the Referral Lab Evaluation Form.
- The laboratory ensures that referral test reports meet accuracy, turnaround time, transcription reliability, and interpretive requirements.
- Evaluations are conducted annually.
- Records of all periodic reviews are maintained for reference and compliance.
- Referral laboratories must notify the Molecular Laboratory of any changes in their accreditation status, testing methodology, authorized signatories, location, or premises.

Non-availability of referral laboratory

The unavailability of a referral laboratory poses a risk to timely confirmatory testing and continuity of specialized diagnostic services. But, the laboratory maintains calibrated backup instruments, eliminating the immediate need for a referral laboratory. However, as there are no NABL-accredited laboratories available for H1N1 testing, in the event such testing becomes necessary, samples will be sent to NIV Pune with the patient's informed consent.

Management of Critical result reports

The molecular laboratory is dedicated to the detection and reporting of **COVID-19** and **H1N1** infections (both are Critical tests). These tests are critical due to the potential for rapid disease transmission and the need for timely intervention. As such, the laboratory is committed to providing accurate and reliable results within a clearly defined turnaround time (TAT). This requirement will be incorporated into the Memorandum of Understanding (MoU) with referral laboratories, ensuring that test reports are prioritized. Additionally, referral laboratories are encouraged to provide soft copies of test reports via email to minimize delays. To ensure effective communication, the following measures are implemented.

6.8.3 Review and approval of externally provided products and services

- **Supplier Selection and Approval:** The laboratory management follows a structured process for selecting and approving suppliers to ensure the quality, reliability, and compliance of external services, equipment, reagents, and consumables. Suppliers are assessed based on their ability to meet regulatory standards, past performance, certifications, and adherence to quality requirements. Only vendors that meet the laboratory's stringent criteria are approved to prevent any compromise in the accuracy, precision, and efficiency of laboratory operations.
- **Procurement Coordination:** The Administrative Manager plays a key role in coordinating procurement activities in collaboration with the Laboratory Director and Section In-Charge. This includes identifying laboratory requirements, sourcing suppliers, obtaining quotations, negotiating terms, and ensuring timely delivery of goods and services. The procurement process is carried out in a transparent manner, aligning with budget constraints and quality expectations while minimizing supply chain disruptions.
- **Approved Supplier List and Purchase Indents:** The laboratory maintains an updated list of pre-approved suppliers who have been evaluated and approved based on their quality standards, reliability, and compliance with laboratory requirements. Any purchase request (indent) from the laboratory clearly specifies product or service requirements, including technical specifications, quantity, and delivery timelines. This ensures that procurement is aligned with laboratory needs and that only compliant products and services are acquired.
- **Annual Supplier Evaluation:** To maintain high standards of service and supply, the Molecular Laboratory conducts an annual evaluation of all suppliers. This evaluation is based on predefined criteria outlined in the vendor evaluation form, which may include

factors such as product quality, service reliability, compliance with regulatory standards, adherence to delivery timelines, and customer feedback. Vendors failing to meet these standards may be re-evaluated, placed on probation, or removed from the approved supplier list.

Calibration Service Providers

The laboratory ensures the accuracy and reliability of its equipment by engaging accredited calibration service providers. These providers are selected based on their competency, accreditation status (national or international), and adherence to recognized calibration standards. All calibration activities are documented, and the following measures are taken to ensure compliance:

- **Regular Calibration:** All laboratory equipment is calibrated at scheduled intervals as per regulatory requirements and manufacturer guidelines.
- **Accreditation Verification:** Calibration service providers must hold accreditation from recognized bodies and follow international standards to ensure the validity of results.
- **Documentation and Compliance:** Calibration certificates, records of adjustments, and compliance reports are maintained and reviewed periodically. Any discrepancies or deviations identified during calibration are addressed immediately through corrective action.

Facilities and Equipment Maintenance Services

The laboratory engages qualified and accredited service providers to manage routine maintenance, servicing, and repairs of laboratory infrastructure and equipment. Proper maintenance ensures uninterrupted operations, enhances equipment longevity, and prevents breakdowns. The following practices are implemented:

- **Scheduled Maintenance:** A preventive maintenance schedule is maintained for all critical equipment, ensuring regular servicing by authorized personnel**.**
- **Service Contracts:** Maintenance agreements with vendors specify the scope of services, response times, and compliance with safety and quality standards.
- **Repair and Troubleshooting:** In case of equipment failure, service providers are promptly notified to minimize downtime. All repairs and maintenance activities are documented for future reference.
- **Compliance Audits:** Regular audits are conducted to verify that maintenance practices align with laboratory quality management systems and accreditation requirements.

Proficiency Testing (PT) Providers

To ensure the accuracy, reliability, and consistency of test results, the laboratory actively participates in Proficiency Testing (PT) programs. These programs serve as an external quality

assurance measure, helping the laboratory assess its testing capabilities. The selection and management of PT providers involve:

- **Accredited PT Providers:** The laboratory engages PT providers that comply with international standards such as ISO/IEC 17043 to ensure the validity and reliability of PT results.
- **Periodic Participation:** The laboratory takes part in PT programs at scheduled intervals to assess the performance of its testing procedures and personnel.
- **Performance Review and Corrective Actions:** PT results are analyzed to identify any deviations or inaccuracies. If discrepancies are detected, corrective and preventive actions are implemented to enhance testing accuracy.
- **Documentation and Compliance:** PT reports, corrective action plans, and follow-up measures are documented and reviewed periodically to maintain compliance with quality assurance protocols.

Biomedical Waste (BMW) Service Provider

The Molecular Laboratory is committed to the safe and responsible disposal of biomedical waste (BMW) in compliance with regulatory guidelines. To achieve this, the laboratory partners with authorized BMW service providers who meet all legal and environmental standards. The following protocols are followed:

- **Selection of Authorized BMW Providers**: The laboratory engages only government-authorized and certified biomedical waste disposal agencies to ensure adherence to environmental and health regulations.
- **Proper Waste Segregation and Disposal**: The laboratory follows strict waste segregation guidelines, categorizing waste into appropriate bins (e.g., sharps, infectious waste, non-infectious waste) before collection by the service provider.
- **Regular Collection and Transport**: The BMW service provider collects waste at scheduled intervals to prevent accumulation and ensure proper disposal. Collection records, transport manifests, and disposal certificates are maintained.
- **Compliance with Regulatory Standards**: The laboratory ensures that BMW disposal adheres to the Biomedical Waste Management Rules set by regulatory authorities. Any non-compliance by the BMW service provider is addressed immediately.
- **Annual Review and Documentation**: The laboratory evaluates the performance of the BMW service provider annually, reviewing documentation, disposal practices, and regulatory compliance. In case of any non-compliance, corrective measures are implemented, and alternative providers may be considered.

Non-Compliance by Service Providers

In cases where external service providers, including suppliers, calibration service providers, maintenance vendors, or proficiency testing (PT) providers, fail to meet the agreed-upon quality, regulatory, or contractual requirements, the following steps will be taken:

- **Incident Reporting:** Any instance of non-compliance will be documented, detailing the nature of the issue, the impact on laboratory operations, and any associated risks.
- **Corrective and Preventive Actions (CAPA):** The laboratory will communicate identified issues to the concerned service provider and request corrective action within a specified timeframe. Preventive measures will be implemented to avoid recurrence.
- **Re-Evaluation and Probation:** Non-compliant service providers may undergo re-evaluation and be placed on probation, during which their performance will be closely monitored.
- **Contract Termination and Replacement:** If a service provider consistently fails to meet quality standards despite corrective actions, the contract may be terminated, and an alternative provider will be engaged to ensure uninterrupted laboratory operations.
- **Regulatory Reporting (if applicable):** If non-compliance affects regulatory standards, the laboratory may report the issue to relevant authorities and accreditation bodies.

By maintaining strict compliance measures and quality controls, the Molecular Laboratory ensures that all external services and supplies align with its operational and regulatory standards, safeguarding the integrity of laboratory testing and results.

Annexure

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/F/2	Vendor evaluation Form	Form	Administrative Manager	Laboratory office	5 Year
ML/F/5	Indent and issue form	Form	Section-In-Charge	Laboratory office	5 Year
ML/FL/7	External services and agreements	File	Section-In-Charge	Laboratory office	5 Year

7.0 Process requirements

7.1 General (ML/QSP-18/GEN)

The laboratory will identify potential risks to patient care in the pre-examination, examination and post-examination processes. These risks will be assessed and mitigated to the extent possible. The residual risk will be communicated to users as appropriate. The identified risks and effectiveness of the mitigation processes will be monitored and evaluated according to the potential harm to the patient.

The laboratory will also identify opportunities to improve patient care and develop a framework to manage these opportunities.

7.2 Pre-examination processes (ML/QSP-19/PREX)

1. Purpose:

The purpose of this procedure is to explain the method of sample collection, handling and transporting.

2. Responsibility:

- Laboratory Director
- Section-In-Charge
- Sample collection Nurse / Technicians / Duty Doctor

3.Scope:

- Specimen collection, handling, and storage
- Scope of services offered to the customers

Procedure – The molecular lab has a set procedure for the pre-examination process. It also has a Sample Collection Manual to ensure the quality of reports.

7.2.2 Laboratory information for patients and users

The Molecular Laboratory ensures that patients and users are informed about the services it offers and the laboratory's location, including:

- **Location:**
- **Operating Hours:**
  - Monday to Saturday: 9:00 AM to 5:00 PM
  - Sundays and Holidays: 9:00 AM to 1:00 PM

- **Contact Information:**
  - Phone:
  - Contact Person:
  - Email:
- **Scope of the molecular laboratory:**
  - Qualitative H1N1 RTPCR,
  - Qualitative SARS-CoV-2 RTPCR
- **Place of sample collection**: OPD samples are collected at the Molecular Laboratory, while all emergency and IP samples are collected at the hospital. The Molecular Laboratory operates from 9:00 AM to 5:00 PM, Monday to Saturday. All samples collected within these hours will be transported to the laboratory by 5:00 PM. Samples collected after 5:00 PM or on Sundays/ holidays after 1:00 PM will be stored in a designated refrigerator in the Microbiology section of the Central Laboratory.
- **Reports availability:** Sample collected before 10:00 AM, Reports will be available at 1:00 PM, samples collected between 10:00 AM to 1:00 PM, reports will be available at 5:00 PM, samples collected
- **Sample processing** is done in the sample processing area as per the SOP. The requisition forms are checked for demographic data and completeness. Urgent samples should be separated and to be sent for immediate processing. Retention period of samples as per the ICMR guidelines.
  - Information about samples related to the examinations, as appropriate.
  - Required primary sample volumes, special precautions, turnaround times, biological reference intervals, and clinical decision values.
  - Instructions for completing the request form.
  - Guidelines for patient-collected samples.
  - Instructions for sample transportation, including special handling requirements.
  - Patient consent is required, such as consent to disclose clinical information and family history to relevant healthcare professionals when referral is needed.
  - Criteria for accepting and rejecting samples.
  - Availability of clinical advice on ordering examinations and interpreting examination results.
  - Policy on the protection of personal information.
  - Complaint procedure/ feedback for patients and users.

These details are outlined in the Directory of Services, with copies available in the Molecular Laboratory section, all wards, and OPDs.

7.2.3 Requests for providing laboratory examination

Requisition forms are submitted along with the respective specimens. The following details are included in the SRF/TRF:

- Patient identification, including gender, age, and contact details.
- Name of the referring doctor.
- IP/OP number and ward number.
- Type of primary sample
- Examinations requested.
- Clinically relevant information about the patient.
- Date, time, and ward, of sample collection.
- Name of the sample collector
- Date and time of sample receipt and name of the person receiving the specimen at the molecular laboratory.

7.2.3.2 Oral requests

The laboratory strictly requires that all examination requests be submitted in written form. Oral requests are not accepted to ensure accuracy, proper documentation, and compliance with standard operating procedures. This policy helps maintain clear communication, reduces the risk of errors, and ensures that all requests are appropriately recorded and processed.

7.2.4 Primary Sample Collection and Handling.

The Molecular Laboratory adheres to a detailed **Primary Sample Collection Manual**, which outlines the proper procedures for the collection and handling of primary samples. Nurses are trained extensively in these procedures to ensure accuracy and compliance.

7.2.4.2 Information for Pre-Collection Activities

The pre-collection instructions are as follows:

- Completion of SRF/TRF forms.
- Preparation of the patient.
- Specification of the type and amount of the primary sample to be collected, including descriptions of the containers and any necessary additives.
- Timing of the sample collection.

- Documentation of clinically relevant information that may affect sample collection, examination performance, or result interpretation.
- Sample rejection criteria
  - Specimen inadequacy,
  - Illegible information on specimen container,
  - Color change in the VTM
  - Specimen container information error (Patient information not matching with the SRF details)
  - Missing test request form/specimen
  - Improper packing

These details are fully documented in the **Primary Sample Collection Manual**.

7.2.4.3 Patient Consent

Obtaining patient consent is an essential component of the sample collection process to ensure both ethical and legal compliance. In the Molecular Laboratory, separate consent forms for sample collection are not required. Instead, the completion and submission of the Sample Requisition Form (SRF) or Test Requisition Form (TRF) serve as an implicit acknowledgment of the patient's consent for the collection and testing of their samples.

- **Implicit Consent via SRF/TRF**: The SRF/TRF includes detailed information about the patient, the type of test requested, and the purpose of the sample collection. By completing and submitting this form, patients and healthcare providers confirm their understanding and agreement to the testing process, which serves as the necessary consent.
- **Information Included**: The SRF/TRF typically contains:
  - Patient identification details.
  - A description of the tests to be performed.
  - Relevant clinical information.
  - The name and signature of the referring healthcare provider.
- **Patient Awareness**: It is the responsibility of the healthcare provider to inform the patient about the nature of the tests, the purpose of the sample collection, and any associated risks or implications. This ensures that patients are making an informed decision when their SRF/TRF is submitted.
- **Streamlined Process**: This approach streamlines the consent process, reducing the need for additional paperwork while ensuring that the patient's agreement is recorded and

traceable. It simplifies logistics, especially in high-volume or urgent scenarios, without compromising on ethical standards.

- **Legal and Ethical Compliance**: By using the SRF/TRF as a consent mechanism, the laboratory ensures compliance with regulatory and ethical requirements for patient consent. This method aligns with best practices, ensuring that patient's rights are respected and that they are adequately informed about the procedures being undertaken.
- **Documentation and Record Keeping**: All SRF/TRF forms are carefully documented and maintained as part of the patient's medical records. This ensures that there is a clear audit trail of the consent process, which can be referenced if necessary.

7.2.4.4 Sample collection activities

The following instructions for sample collection are outlined in the **Primary Sample Collection Manual**:

- Verification of the patient's identity from whom the primary sample is being collected.
- Confirmation that the patient meets all pre-examination requirements.
- Documentation of the **identity of the person collecting the sample**, along with the date and, if necessary, the time of collection.
- Guidelines for the proper storage of collected samples before they are delivered to the laboratory.
- Labelling of samples (VTM) with patient identification details and **transportation to the laboratory in three-layer packaging, as per ICMR guidelines**.
- Safe disposal of materials used during the collection process.

7.2.5 Sample Transportation

The laboratory has established protocols for the transportation of samples to ensure:

- Timely delivery appropriate to the nature of the requested examinations.
- Maintenance of specified temperature conditions and the use of designated preservatives to preserve sample integrity.
- Transportation methods that safeguard the sample's integrity and ensure the safety of the carrier, the public, and the receiving laboratory, in compliance with established regulations.
- The sample is transported to the laboratory in **three-layer packaging, as per ICMR guidelines.**

7.2.6 Sample Receipt

7.2.6.1 Sample Receipt Procedure and Acceptance Exceptions

The Molecular Laboratory ensures the following conditions are met for sample reception:

- Samples are clearly traceable to an identified patient or site through proper request and labeling.
- Adherence to criteria for the acceptance or rejection of samples, as established by the laboratory. Sample rejection criteria
    - Specimen inadequacy,
    - Illegible information on specimen container,
    - Color change in the VTM
    - Specimen container information error (Patient information not matching with the SRF details)
    - Missing test request form/specimen
    - Improper packing
- Trained personnel evaluate received samples to ensure they meet acceptance criteria for the requested examinations.
- Documentation of any issues with sample stability due to transport delays, inappropriate containers, or insufficient sample volume. If a clinically critical condition or irreplaceable sample is processed despite rejection criteria, the final report will note the problem.
- All samples received are recorded in the LIS (ICMR portal), including the date and time of receipt and registration. If the ICMR LIS is non-functional, patient details for SARS-CoV-2 testing will be entered in the SARS-CoV-2 sample register, and for H1N1, patient details will be entered in the H1N1 sample register. The date and time of receipt and the name of the person receiving the sample will be recorded.
- All samples are processed based on priority, and requests for urgent processing will not be entertained.

7.2.7 pre-examination handling, preparation, and Storage

The Molecular Laboratory is equipped with sufficient space and specialized storage facilities, including dedicated deep freezers and refrigerators. These are designed to maintain optimal temperature conditions for the preservation of patient samples. This ensures the integrity and stability of the samples are upheld, minimizing the risk of degradation or contamination. The laboratory's storage systems comply with regulatory standards and are regularly monitored to maintain consistent temperature control, essential for accurate and reliable diagnostic results.

7.2.7.1 Sample protection

The technicians are thoroughly trained in standardized procedures for sample collection, ensuring that each sample is properly labeled with all necessary patient and test information. Once collected, samples are immediately placed in designated storage areas that are specifically designed to prevent contamination, loss, or damage. The storage locations are carefully monitored to maintain optimal conditions (e.g., temperature control for blood or tissue samples) and to ensure the samples are easily accessible when needed for testing.

Additionally, a detailed movement register is maintained to track the sample's journey throughout the laboratory. This register logs each step, from sample collection to processing, including times, locations, and any changes in status or personnel handling the sample. This helps maintain a clear chain of custody and allows for quick identification of any potential issues should a sample be misplaced or delayed. The tracking system is regularly audited to ensure compliance with laboratory protocols and regulatory standards.

7.2.7.2 Criteria for additional examination requests

The laboratory will accommodate additional examinations or repeat tests on the original sample if requested by the physician. These additional requests must be submitted within 48 hours from the time of the initial sample collection. This policy ensures timely and accurate diagnostic services, allowing for further analysis or alternative tests without the need for a new sample, provided the sample remains viable. Physicians are encouraged to communicate any additional testing needs promptly to ensure optimal patient care.

7.2.7.3 Sample stability

Outpatient Department (OPD) samples are collected directly at the Molecular Laboratory, while all emergency and inpatient (IP) samples are gathered within the hospital. The Molecular Laboratory operates from 9:00 AM to 5:00 PM, Monday to Saturday, ensuring that all samples collected during these hours are transported to the laboratory by 5:00 PM for processing. For samples collected after 5:00 PM or on Sundays and holidays after 1:00 PM, they are carefully stored in a designated refrigerator located in the Microbiology section of the Central Laboratory. This refrigeration maintains the stability of the primary samples, preserving their integrity and preventing degradation until they can be processed. The proposed turnaround time (TAT) for tests is 24 hours, with this timeframe being documented and closely monitored through records kept in a register. Regarding report availability, samples collected before 10:00 AM will have their reports ready by 1:00 PM, while those collected between 10:00 AM and 1:00 PM will have reports available by 5:00 PM, ensuring timely communication of results.

References: Clause 7.2.1, 7.2.2, 7.2.3, 7.2.4, 7.2.5, 7.2.6, 7.2.7 of ISO 15189:2022

Annexure

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/QMS/ DOS & PSCM	Directory of Services	Document	Laboratory Director	Laboratory office	Continuous
ML/REG/10	Errors at registration	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/11	Sample Rejection Register	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/13	COVID Register	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/14	H1N1 Register	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/13	Movement of specimen and Report for COVID	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/14	Movement of specimen and Report for H1N1	Register	Section-In-Charge	Laboratory office	Continuous
ML/F/27	H1N1 test request form	Form	Section-In-Charge	Laboratory office	10 Year
ML/F/28	COVID-SRF	Form	Section-In-Charge	Laboratory office	10 Year

7.3 Examination Process (ML/QSP-20/EXP)

1. Purpose:

This procedure explains the procedure for identifying and reviewing examination processes.

2. Responsibility:

- Lab Director
- Section In charge
- Consultants
- All Technicians

3. Scope:

- Verification of examination procedures
- Validation of examination procedures
- Evaluation of examination of uncertainity
- Biological reference intervals and clinical decision limits
- Documentation of examination procedurals
- Ensuring the validity of examination results

Procedure:

The Molecular Laboratory strictly adheres to using only validated examination procedures to ensure the accuracy, reliability, and consistency of test results. These procedures are conducted by trained personnel who are proficient in the specific methodologies used.

Key Processes and Policies:

- **Adoption of Examination Procedures**:
  - The laboratory adopts examination procedures only after thorough verification of their contents. This ensures that the procedures meet the necessary standards and are suitable for the intended tests.
- **Procedure Review and Change Management**:
  - The laboratory conducts regular reviews of examination procedures, particularly when there is a need to change test methods. These reviews are discussed in departmental meetings and Management Review Meetings (MRM).
  - Proposed changes are carefully evaluated, discussed, and require formal approval before implementation.

3. **Reasons for Procedural Changes**:

Changes to examination procedures may be initiated for several reasons, including:

- **Change in Kits**: Introduction of new kits with updated features or improved performance.
- **Change in Equipment**: Upgrades or replacements of laboratory equipment that necessitate procedural adjustments.
- **Change in Methodology**: Adoption of more advanced or efficient methodologies.
- **Cost Implications**: Adjustments made to optimize costs without compromising quality.
- **Improvement in the Test Process**: Enhancements aimed at improving test accuracy, speed, or reliability.
- **Increased Sample Volume**: Adaptations to handle higher volumes of samples efficiently.
- **Approval of New Testing Technology**: Integration of new technologies that offer superior diagnostic capabilities.

4. **Implementation and Outcome Evaluation**:

- Once changes are approved, they are implemented, and the outcomes are rigorously compared with the results obtained from existing methods.
- If the new method demonstrates superior performance, a detailed evaluation, including cost analysis, is conducted before final approval.

5. Development and Documentation of New Procedures:

- Upon approval, new procedures are developed by the section In-Charge in collaboration with the Laboratory Director.
- These procedures undergo strict document control practices to ensure accuracy, traceability, and compliance with quality standards.

6. **Training and Implementation**:

- The section In-Charge is responsible for ensuring that all technicians are adequately trained in the new test methodologies.
- Training records are meticulously maintained in the personnel files of each employee.
- All necessary requirements for the implementation of new methodologies are met in accordance with the SOP.

7.3.2 Verification of Examination Procedures:

- The Molecular Laboratory ensures that only validated procedures are used, without modification, unless independently verified.
- Verification involves running controls according to both manufacturer instructions and the laboratory's SOPs.
- This verification process provides objective evidence that the performance characteristics of the examination procedures meet the required claims.
- The performance claims evaluated during verification are directly related to the intended use of the examination results.
- Detailed documentation of the verification process and results is maintained. These are reviewed and recorded by the section In-Charge and consultants.

7.3.3 Validation of Examination Processes/Test Procedures:

- The laboratory's policy mandates that examination procedures are performed strictly as described in the kit inserts, without modifications.
- The laboratory does not validate procedures derived from:
  - **Nonstandard Methods**: Procedures not conforming to recognized standards.
  - **Laboratory Designed or Developed Methods**: Custom methods developed internally.
  - **Standard Methods Used Outside Their Intended Scope**: Standard procedures applied beyond their originally intended purpose.
  - **Validated Methods Subsequently Modified**: Methods that have been altered after initial validation.

By adhering to these comprehensive processes, the Molecular Laboratory ensures that all examination procedures are accurate, reliable, and meet the highest standards of quality and compliance. This meticulous approach supports the delivery of consistent and trustworthy diagnostic results.

7.3.4 Evaluation of measurement uncertainty (MU)

Measurement Uncertainty (MU) refers to the range within which the true value of a measured quantity is expected to lie, considering all possible sources of error and variability in the measurement process. It provides an estimate of the potential deviation from the true value, offering a quantitative expression of the confidence in the accuracy of the measurement.

Key Components of Measurement Uncertainty:

- **Sources of Uncertainty**:
  - **Instrumental**: Variations due to the precision and calibration of measuring instruments.

  - **Environmental**: Factors such as temperature, humidity, and vibration that can affect measurements.
  - **Methodological**: Variability introduced by the measurement method or procedure.
  - **Human Factors**: Errors or variations caused by the operator or analyst.
- **Quantifying Uncertainty**:
  - **Type A Evaluation**: Based on statistical analysis of repeated measurements (e.g., calculating the standard deviation of a series of measurements).
  - **Type B Evaluation**: Based on scientific judgment, using all available information other than statistical data (e.g., manufacturer's specifications, previous measurements, or experience).
- **Expression of Uncertainty**:
  - **Standard Uncertainty (u)**: Represents the uncertainty of a single measurement, typically expressed as the standard deviation.
  - **Combined Standard Uncertainty (uc)**: The combination of multiple standard uncertainties from various sources.
  - **Expanded Uncertainty (U)**: Provides a wider range of uncertainty by applying a coverage factor (k), usually providing a 95% confidence level (U = k * uc).
- **Importance of Measurement Uncertainty**:
  - **Quality Assurance**: Helps in verifying the reliability and accuracy of measurement results.
  - **Compliance**: Ensures that measurements meet regulatory and standard requirements.
  - **Decision-Making**: Provides critical information for making informed decisions based on measurement results.

By understanding and applying measurement uncertainty, laboratories can enhance the reliability of their test results, maintain compliance with standards, and improve overall quality control processes.

Procedure

a. Mean:

The procedure describes how to calculate the average value of a set of measurements, which provides a central value around which individual test results are distributed.

The mean is defined as the arithmetic average of a set of data points. It is expressed as:

Mean = $\sum x_i / n$

Where,

x_i = Individual observations / data / result in the set

n = the total number of data /observations / results in the set

∑ = Summation Symbol

Standard deviation:

It outlines the steps to determine the standard deviation, a measure of the dispersion or spread of the test results around the mean. This helps understand the variability in the test outcomes.

The standard deviation (SD) is a measure of the dispersion of observations / data / data points above and below the mean and is used to set acceptable limits for values obtained with internal QC samples.

$$s = \sqrt{\frac{\sum(x_i - \bar{x})^2}{(n - 1)}}$$

Where,

$\sum (x^2)$ = the sum of the squares of each value of x

$(\sum x)^2$ = the sum of all data points squared

n = the total number of data points in the set.

b. Coefficient of variation:

The method for calculating the coefficient of variation, which is the ratio of the standard deviation to the mean expressed as a percentage, is also detailed. This parameter allows for comparison of the relative variability across different tests regardless of the unit of measurement.

The coefficient of variation (CV) is a measure of the variability of an assay and is expressed as a percentage.

CV = (SD/ mean) □ (100)

D. Measurement Uncertainty:

MU = CV% X 1.96

MU information will be made available to laboratory users on request.

When the qualitative result of an examination depends on a test that produces quantitative output data, which is categorized as positive or negative based on a defined threshold, it is essential to estimate the measurement uncertainty (MU) in the quantitative output to ensure accurate interpretation of results. The estimation process involves using representative samples that are clearly positive and negative relative to the threshold value.

Steps for Estimating MU in Quantitative Output:

- **Identify the Threshold Value**:
  - The threshold is the specific quantitative value that distinguishes between a positive and a negative result. This value is often determined based on clinical relevance, regulatory guidelines, or historical data.
- **Selection of Representative Samples**:
  - **Positive Samples**: These are samples with quantitative results that are clearly above the threshold, indicating a positive outcome.
  - **Negative Samples**: These are samples with quantitative results that are clearly below the threshold, indicating a negative outcome.
  - It is crucial to select samples that are representative of the population being tested, ensuring variability in the measurements is adequately captured.
- **Performing Repeated Measurements**:
  - Conduct multiple measurements on the selected positive and negative samples to gather sufficient data on the variability of the test results.
  - This helps in capturing the inherent variability in the measurement process, including any instrumental, methodological, and operator-induced variations.
- **Statistical Analysis**:
  - Calculate the Mean, Standard Deviation, and Coefficient of Variation for both positive and negative sample groups.
  - Use these statistical parameters to assess the consistency and reliability of the test results around the threshold value.
- **Estimating Measurement Uncertainty**:
  - For each sample group, calculate the standard uncertainty based on the standard deviation of repeated measurements.
  - Combine the uncertainties from positive and negative sample groups to estimate the overall measurement uncertainty around the threshold.
  - Consider any additional sources of uncertainty, such as calibration of equipment, environmental conditions, and sample handling.
- **Impact on Qualitative Results**:
  - The estimated MU is used to assess the confidence in the test's ability to correctly classify samples as positive or negative.

- For results near the threshold, the MU may influence the interpretation, potentially leading to the need for confirmatory testing or re-evaluation of the threshold criteria.

- **Documentation and Reporting**:
  - Clearly document the process of MU estimation, including the selection of representative samples, measurement procedures, and statistical analysis.
  - Report the estimated MU alongside the qualitative results, providing transparency and confidence in the interpretation of test outcomes.

By systematically estimating and reporting MU in quantitative output data, laboratories can enhance the reliability of qualitative test results, particularly in cases where the results are close to the threshold. This ensures better decision-making and supports the overall quality assurance process.

7.3.5 Biological reference intervals and clinical decision limits

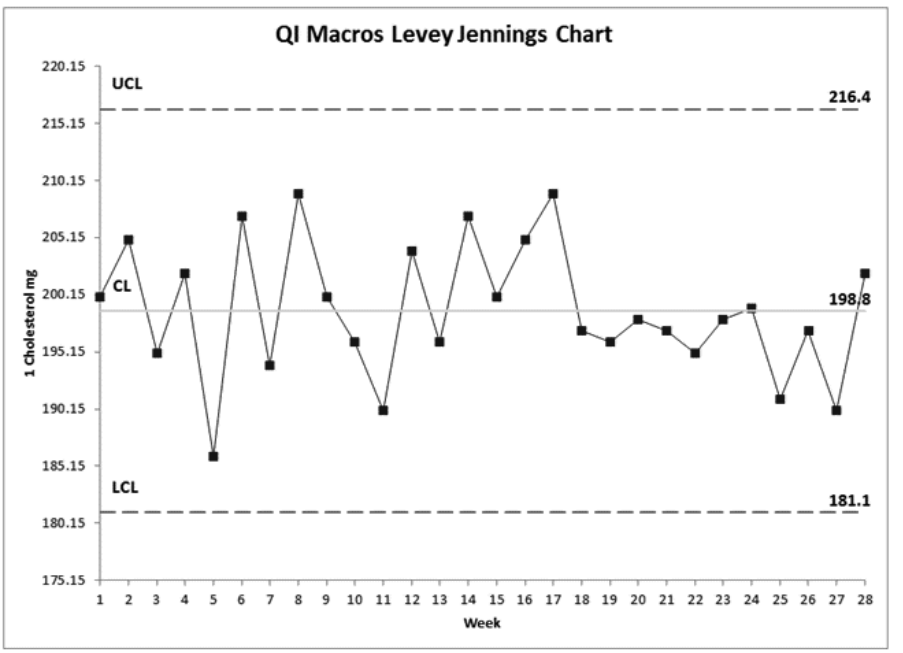
The lab has defined the biological reference intervals or clinical decision values, has documented the basis for the reference intervals or decision values and the same is communicated to end users. Usually the reference value reported from the lab is as given in the relevant reagent kit insert or the standard textbooks. (Departmental SOP file) When a particular biological reference interval or decision value is no longer relevant, appropriate changes will be made and communicated to the end-users. When the lab changes an exam procedure or pre-examination procedure, the lab will review associated reference intervals and clinical decision values, as applicable.

For all the tests/ analytes done in the lab these reference values are communicated along with reported test results.

Biological reference intervals are periodically reviewed. If the intervals are found to be no longer appropriate, the section in charges will review the biological reference interval and follow corrective action. A review of the biological reference interval is also done when the examination procedure is changed.

Procedure for L.J Chart

Unity web 2.0 online software is used to calculate the CV% and make Levey-Jennings (LJ) chart.



Reference of source document on which the procedure is based: NABL 141 Guidelines for Estimation & Expression of Uncertainty in Measurement

References: Clause 7.3.5 of ISO 15189:2022

7.3.6 Documentation of Examination Procedures

The Molecular Laboratory ensures that each examination procedure is governed by a detailed Standard Operating Procedure (SOP), which is essential for maintaining consistency, accuracy, and quality in all laboratory processes. The SOPs serve as comprehensive guides for laboratory personnel, detailing every aspect of the examination procedures and ensuring that all staff members are fully aware and trained in their application. These SOPs are readily accessible in each relevant section of the laboratory for immediate reference and use during routine operations.

- **Language Appropriateness**
  - **Clear and Simple Language**: Procedures will be written in clear, straightforward language, avoiding complex jargon or technical terms that may not be widely understood by all personnel. If technical terms are necessary, they will be defined within the document.
  - **Use of Common Terminology**: Where possible, commonly used terminology within the laboratory will be employed to facilitate comprehension and ensure consistency in understanding.
  - **Translation, if Necessary**: For laboratories with multilingual staff, key procedures may be translated into other relevant languages to ensure that all personnel can access and understand the instructions.
- **Purpose of the Examination:**
  - Each SOP begins by clearly stating the objective of the examination, explaining why the test is performed and its significance in the diagnostic process.
- **Principle and Method:**
  - This section describes the scientific principles underlying the examination, along with the specific methods used. It helps ensure that personnel understand the rationale behind the procedure and can correctly execute it.
- **Performance Characteristics:**
  - Details the expected performance metrics of the procedure, such as sensitivity, specificity, accuracy, and precision. This helps in evaluating the reliability of the test results.
- **Type of Sample:**
  - Specifies the types of samples suitable for the test (e.g., respiratory specimens, blood, tissue) and any particular requirements for sample collection and handling.

- **Patient Preparation:**
  - Outlines necessary steps for patient preparation before sample collection to ensure the integrity of the test results. This might include fasting, avoiding certain medications, or specific postures during collection.
- **Type of Container and Additives:**
  - Identifies the appropriate sample containers and any required additives (e.g., anticoagulants, preservatives) to maintain sample stability and prevent degradation.
- **Required Equipment and Reagents:**
  - Lists all equipment, instruments, and reagents necessary for the procedure, ensuring that laboratory personnel can verify their availability and functionality before starting the test.
- **Environmental and Safety Controls:**
  - Describes the environmental conditions (e.g., temperature, humidity) and safety measures (e.g., biosafety protocols, personal protective equipment) required to safely and effectively conduct the examination.
- **Calibration Procedures:**
  - Details the calibration steps to ensure metrological traceability, maintaining the accuracy of measurements. This includes routine calibration of instruments and verification of reagent performance.
- **Procedural Steps:**
  - Provides a detailed, step-by-step guide on how to conduct the examination, ensuring consistency in the execution of the procedure across different personnel and shifts.
- **Quality Control Procedures:**
  - Specifies the internal quality control measures to be implemented during the procedure, such as running control samples to monitor the performance of the test and identify any deviations.
- **Calculation of Results:**
  - Explains how to calculate the results, including the principles of result interpretation and, where relevant, the estimation of measurement uncertainty to provide a confidence range for the reported values.
- **Reportable Interval:**
  - Defines the range of result values that can be reliably reported, helping to standardize reporting practices and ensure accurate communication of test outcomes.

- **Instructions for Out-of-Range Results:**
  - Provides guidance on how to handle and interpret results that fall outside the predefined measurement interval, including steps for retesting or additional verification.
- **Alert/Critical Tests:**
  - Highlights tests that have critical thresholds requiring immediate attention and action, ensuring timely communication of potentially life-threatening results to clinicians.
- **Laboratory Clinical Interpretation:**
  - Offers guidance on the clinical interpretation of test results, helping laboratory personnel understand the implications of the findings in the context of patient care.
- **Potential Sources of Variation:**
  - Identifies potential factors that could cause variability in test results, such as sample quality, environmental conditions, or instrument performance, and how to mitigate these risks.

References:

- Provides a list of relevant literature, guidelines, and manuals that support the SOP, ensuring that the procedure is based on established scientific and regulatory standards.

Accessibility of Documents

- **Strategic Placement**: SOPs will be made readily available in all sections of the laboratory where the procedures are performed. This includes placing hard copies in accessible locations and ensuring that digital copies are available on the laboratory's internal network or document management system.
- **Immediate Reference**: SOPs will be positioned in locations where they can be quickly referenced during routine operations, such as near workstations, equipment, or sample collection areas.
- **Digital Access**: Digital versions of SOPs will be stored in a centralized document management system, accessible to all authorized personnel through laboratory computers or tablets. This ensures that the latest version is always available and reduces the risk of using outdated procedures.
- **Physical Copies for Critical Areas**: In critical areas where immediate digital access may not be possible or practical, physical copies of SOPs will be maintained. These copies will be regularly updated to reflect the latest revisions.

Training and Familiarization

- **Introduction During Training**: New personnel will be introduced to the relevant SOPs during their initial training, ensuring they are familiar with the procedures before beginning their duties.
- **Periodic Refresher Sessions**: Regular training sessions will be conducted to refresh the knowledge of existing staff and update them on any changes to the procedures.
- **Acknowledgment of SOP Review**: Personnel will be required to sign an acknowledgment form confirming they have read and understood the SOPs, ensuring accountability and awareness.

Visual Aids and Supporting Materials

- **Diagrams and Flowcharts**: Where applicable, procedures will include diagrams, flowcharts, and other visual aids to help personnel quickly grasp complex steps or processes.
- **Checklists**: For procedures involving multiple steps, checklists will be provided to help personnel ensure that all steps are completed correctly and in the proper sequence.

Continuous Feedback and Improvement

- **Feedback Mechanism**: A system will be in place for personnel to provide feedback on the clarity and usability of the SOPs. Suggestions for improvement can be submitted to the section In-Charge or quality assurance team.
- **Regular Reviews**: SOPs will be reviewed regularly to incorporate feedback from personnel, ensuring that the language remains clear and the procedures continue to meet the needs of the laboratory.

Implementation and Use:

- These SOPs are living documents, regularly reviewed and updated to incorporate new scientific findings, technological advancements, and regulatory changes.
- All laboratory personnel are trained in the relevant SOPs, ensuring they are proficient in executing the procedures accurately.
- Training records are maintained for all staff, documenting their familiarity and competence with the procedures outlined in the SOPs.

7.3.7 Ensuring the validity of examination results

Procedure:

- Standard glassware, analytical grade chemicals, approved kits, reagents are used for testing.

- The chemicals, reagents and kits are stored at the temperature and humidity conditions specified in the product insert or as specified by the manufacturer.
- The expiry date of the reagents and kits are verified before use.
- The Section-in-charge ensures that all technicians of the department are knowledgeable about the contents of standard operating procedures & procedures including changes relevant to the scope of their testing activities.
- Equipment's, Micropipettes and Temperature measuring devices are calibrated through external agency once in a year as specified by the agencies.

7.3.7.2 Internal quality control

Internal Daily Quality Control Schedules. Each test is run by using the positive, negative controls and internal controls as per the guidelines by ICMR-NIV.

Quality Control Implementation

a. Pre-analytical Phase

- **Sample Collection and Handling:**
  - Using appropriate collection kits and following standardized protocols for sample collection, transport, and storage.
  - Training personnel on proper techniques to avoid contamination and degradation of RNA.
- **Reagent Quality:**
  - Using high-quality reagents and kits, ensuring they are stored and handled per manufacturer guidelines.
  - Regularly checking expiration dates and batch-specific quality control (QC) data.

b. Analytical Phase

- **Instrument Calibration and Maintenance:**
  - Regularly calibrating RT-PCR machines and ensuring they are serviced according to the manufacturer's schedule.
  - Running diagnostic tests to confirm instrument performance.
- **Internal Controls:**
  - Including internal controls (e.g., positive and negative controls) in each run to monitor the assay's performance.
  - Using housekeeping genes as endogenous controls to assess the quality and quantity of RNA in each sample.

- **Assay Validation:**
  - Validating new assays and modifications through rigorous testing, including sensitivity, specificity, and reproducibility.

c. Post-analytical Phase

- **Data Analysis and Interpretation:**
  - Using standardized software for data analysis to minimize human error.
  - Ensuring that interpretation criteria are consistently applied across all samples.
- **Documentation and Record Keeping:**
  - Maintaining comprehensive records of all QC measures, including sample handling, reagent lot numbers, control results, and instrument maintenance logs.

2. Selection of IQC

- **Positive Control (PC):**
  - Selecting a positive control that contains a known quantity of target nucleic acid to verify the entire assay process from extraction through amplification.
  - Ensuring the PC is specific to the target sequence and represents typical clinical samples.
- **Negative Control (NC):**
  - Choosing a negative control containing no target nucleic acid (e.g., water or RNA-free buffer) to detect contamination or non-specific amplification.
- **No Template Control (NTC):**
  - Using a no template control that consists of the PCR reagents without any RNA/DNA template to ensure no contamination in the reaction mix.
- **Endogenous Control (Housekeeping Gene):**
  - Selecting a stable housekeeping gene that is consistently expressed in the sample type being tested (e.g., GAPDH, ACTB) to monitor RNA quality and ensure successful extraction and amplification.
- **External Quality Control Materials:**
  - Considering using third-party external control materials for proficiency testing and to validate the consistency and accuracy of the assay.

3. Acceptability Criteria for IQC

- **Positive Control (PC):**
  - The PC is consistently producing a positive result, confirming that the assay reagents and process are functioning correctly.
  - Ct (Cycle threshold) values are falling within an established range based on assay validation, typically ±2 Ct from the mean of historical values.
- **Negative Control (NC):**
  - The NC is yielding no amplification (or a Ct value indicating no significant signal), ensuring no contamination in the reagents or process.
- **No Template Control (NTC):**
  - The NTC is showing no amplification, confirming that there is no contamination in the reaction mix.
- **Endogenous Control (Housekeeping Gene):**
  - Ct values for the housekeeping gene are falling within a predefined range, ensuring consistent sample quality and RNA integrity.
  - Deviations from the expected range may indicate issues with sample handling or extraction.
- **Inter-run and Intra-run Variability:**
  - Acceptable variation in Ct values between runs (inter-run) and within the same run (intra-run) is minimal, typically within ±2 Ct.

4. Frequency of IQC Testing

- **Daily Runs:**
  - Performing IQC testing at the beginning of each day's batch of tests.
  - Including positive and negative controls, and no template controls in each batch run.
- **Every Run:**
  - Including internal controls (positive and negative controls) with every RT-PCR run to ensure consistent performance.
  - Including endogenous controls in every sample run to monitor RNA integrity and sample quality.
- **New Reagent Lots:**

- Conducting IQC testing whenever a new batch of reagents or consumables is introduced to ensure batch-to-batch consistency.

- **Instrument Maintenance:**
  - Performing IQC tests following any maintenance, servicing, or recalibration of RT-PCR instruments.

5. Release of Patient Results When IQC Fails

- **Immediate Action:**
  - If IQC fails (e.g., positive control does not amplify as expected or negative control shows amplification), stopping the release of patient results for that batch.
  - Investigating the cause of the failure, including potential contamination, reagent issues, or instrument malfunction.
- **Review and Repeat:**
  - Reviewing the data and documentation for any errors or deviations from standard procedures.
  - Repeating the assay for the affected batch with new IQC controls to confirm the integrity of the test.
- **Patient Result Validity:**
  - Not releasing patient results until all IQC parameters are within acceptable criteria.
  - If repeat testing confirms consistent IQC failure, invalidating the affected batch and reprocessing patient samples using fresh reagents and controls.
- **Documentation:**
  - Documenting all IQC failures, investigations, and corrective actions taken.
  - Maintaining records of the decision-making process regarding the release or withholding of patient results.
- **Communication:**
  - Communicating with relevant clinical teams about delays in results due to QC issues, providing estimated timelines for resolution and re-testing.

6. If IQC Material is Not Available

- **Alternative Measures:**
  - In the absence of commercial IQC materials, considering using previously validated in-house controls, such as archived positive samples that have been characterized and verified.

- Implementing additional checks like using known low-positive samples or replicates to ensure assay consistency.

- **Verification of Reagents and Instruments:**
  - Performing additional verification of reagent quality and instrument functionality to compensate for the lack of commercial IQC materials.
  - Using historical data to establish temporary QC benchmarks until commercial materials become available.

- **Documentation and Justification:**
  - Thoroughly documenting the unavailability of IQC materials and the alternative measures implemented.
  - Providing a justification for using alternative controls and ensuring that all steps are in compliance with regulatory guidelines.

- **Review by Quality Assurance:**
  - Having the alternative IQC strategy reviewed and approved by the laboratory's quality assurance team to ensure it meets internal and external quality standards.

- **Communication:**
  - Informing relevant stakeholders, including clinical teams and regulatory bodies if necessary, about the temporary use of alternative IQC measures.

7. Mitigation Strategies

a. Contamination Control

- Implementing strict laboratory practices to prevent cross-contamination, such as using separate areas for pre- and post-PCR processes.
- Regularly decontaminating work surfaces and equipment with appropriate solutions like bleach or ethanol.

b. Training and Competency

- Providing ongoing training for laboratory personnel on proper RT-PCR techniques and QC protocols.
- Conducting regular competency assessments to ensure staff adhere to quality standards.

c. Proficiency Testing

- Participating in external proficiency testing programs to benchmark performance against other laboratories.

- Using feedback from proficiency testing to identify and address areas for improvement.

d. Continuous Improvement

- Establishing a system for regularly reviewing QC data to identify trends and anomalies.
- Implementing corrective and preventive actions (CAPA) when QC failures or deviations occur.

e. Standard Operating Procedures (SOPs)

- Developing and maintaining detailed SOPs for all aspects of the RT-PCR process, ensuring they are accessible and updated regularly.
- Ensuring that deviations from SOPs are documented and investigated.

f. Incident Reporting and Investigation

- Encouraging a culture of transparency where staff report any QC issues or deviations.
- Investigating incidents thoroughly to determine root causes and prevent recurrence.

By ensuring a robust plan for when IQC materials are unavailable, laboratories are maintaining the reliability and accuracy of RT-PCR testing, minimizing disruptions to patient result reporting.

7.3.7.3 External quality assessment EQA / PT

Selection of EQAS Provider

The Molecular Laboratory selects an EQAS provider based on their accreditation status, relevance to the parameters tested, and reliability of their evaluation processes. Preference is given to providers recognized by national or international regulatory bodies to ensure high-quality assessment and benchmarking.

Participation in EQA/PT

The Molecular Laboratory shall participate in External Quality Assessment (EQA) or Proficiency Testing (PT) for each parameter based on its availability. EQA/PT samples are integrated into the routine laboratory workload to ensure realistic performance assessment. These samples are analyzed in rotation by personnel who routinely test patient samples to maintain consistent and accurate evaluations of the laboratory's capabilities.

When EQA samples are received, they are reported by designated staff at the appropriate levels within the department, ensuring the confidentiality of data. Analysis of External Quality Assurance Scheme (EQAS)

- **Sample Processing**: EQAS samples are treated as patient samples and are tested alongside other patient samples to simulate routine laboratory conditions. Laboratory Technicians are responsible for processing EQAS samples, ensuring adherence to standard operating procedures.
- **Submission of Results**: The values obtained from EQAS testing are submitted to the respective EQA provider for evaluation.
- **Restriction on Referrals**: The Molecular Laboratory ensures that EQAS samples are not referred to external agencies for testing, maintaining the integrity of internal evaluations.
- **Evaluation of Laboratory Performance**: The laboratory compares the reports received from the EQA provider with the values obtained during internal testing.
- Acceptability criteria: Molecular laboratory has set a benchmark of 20% noncompliance with the EQAS result.
- In cases where the obtained results fall outside the acceptable range, immediate corrective actions are undertaken based on the EQA evaluation report. Additionally, the Molecular Laboratory monitors the percentage of unacceptable EQAS reports as part of its Quality Indicators. These indicators are reviewed annually and presented during the Management Review Meeting (MRM) to identify trends and implement improvements.

Inter-Laboratory Comparison

In situations where a formal national PT program is unavailable for specific analytes of interest, the Molecular Laboratory ensures quality assurance by sending tests for inter-laboratory comparison to an accredited reference laboratory. This process helps to maintain the accuracy and reliability of test results despite the lack of a formal PT program.

Alternative Approaches

If participation in a PT program is not feasible, the Molecular Laboratory employs alternative approaches to validate performance. Feasibility issues may arise due to the following reasons:

- Non-availability of a formal national PT program for the analytes of interest.
- Limited number of laboratories performing the specific test.
- Unavailability of control material with a matching matrix.
- Complete consumption of the PT sample during the testing process.

To address these challenges, the Molecular Laboratory adopts one or more of the following alternative approaches:

- **Replicate Testing**: Conducting repeated tests on the same sample to confirm reliability and consistency.
- **Examination of Split Samples**: Analyzing divided portions of the same sample within the laboratory to validate results.

- **Use of Reference Methods and Materials**: Applying standardized reference methods and certified reference materials, when available, to ensure accuracy.
- **Exchange of Samples with Other Accredited Laboratories**: Collaborating with other laboratories to compare results and validate performance.

When exchanging samples with other laboratories, an NABL-accredited laboratory will serve as the "reference laboratory," providing a benchmark against which the Molecular Laboratory's values will be evaluated.

7.3.7.4 Comparability of examination results:

- In the Molecular Laboratory, quality is ensured by running controls provided with the kits and periodic EQAS samples. These processes help verify procedures and methods, and all comparison data are systematically maintained.
- The laboratory will notify end users of any discrepancies in result comparability and, whenever possible, discuss the clinical implications. This is particularly important when measurement systems provide different intervals for the same parameter or when examination methods are changed.
- The Molecular Laboratory will document, record, and promptly address any results from the comparisons performed. Identified problems or deficiencies will be acted upon, with all actions thoroughly documented and retained. Any deviations observed in QC results are typically resolved by calibrating reagent kits, replacing reagent kits, or using a different calibrator.

Acceptance Criteria

- **Acceptance Criteria for Rerun of the Same Sample**

  The quantitative (CT value) and qualitative (positive/negative) results of the previous run are compared with the rerun data. For positive results, concordance is assessed based on CT values. The assay is considered acceptable if any deviation in CT values is within 1.5-fold.

- **Acceptance Criteria for Lot-to-Lot Verification**

  The quantitative (CT value) and qualitative (positive/negative) results from the old kit are compared with those obtained using the new kit on the same samples. For positive results, concordance is assessed based on CT values. The assay is considered acceptable if any deviation in CT values is within 1.5-fold.

- **Acceptance Criteria for Comparability of Examination Processes Between Two PCR Amplification Equipment**

  The quantitative (CT value) and qualitative (positive/negative) results obtained from the same samples are compared between the two PCR amplification systems. For positive

results, concordance is assessed based on CT values. The assay is considered acceptable if any deviation in CT values is within 1.5-fold.

Non-Conformities (NC) with Comparability Results for Examination Processes in a Molecular Laboratory

When non-conformities (NC) are identified in the comparability results of examination processes, immediate corrective and preventive actions are necessary to maintain test reliability, regulatory compliance, and patient safety. Below are key actions to resolve such NCs effectively:

1. Immediate Actions (Containment & Assessment)

- **Cease Reporting of Affected Test Results (If Critical)**
  - If the NC significantly impacts patient safety, temporarily suspend the affected test method until the issue is resolved.
  - Notify relevant stakeholders (clinicians, laboratory management, and regulatory bodies if required).
- **Review Comparability Data & Identify Root Cause**
  - Analyze the test performance across different instruments, methodologies, or locations.
  - Identify discrepancies in accuracy, precision, or bias in results.
  - Check for systematic errors, reagent issues, calibration differences, or operator variations.
- **Verify Sample Integrity & Pre-Analytical Factors**
  - Ensure that sample handling, storage conditions, and processing protocols were consistent across platforms.
  - Investigate if sample degradation or contamination contributed to the NC.
- **Re-Evaluate Equipment & Reagents**
  - Check if calibration, maintenance, or reagent batch changes have affected the results.
  - Perform instrument-to-instrument comparison testing to confirm variability sources.

2. Corrective Actions (Resolve the Issue)

- **Standardize Testing Protocols**
  - Implement uniform testing procedures across all examination methods to ensure consistency.
  - Adjust protocols as per manufacturer guidelines and international standards.

- **Recalibrate Instruments & Verify Assay Performance**
  - Conduct recalibration and maintenance of affected equipment.
  - Perform method validation and verification, if needed, before resuming routine testing.
- **Replace or Revalidate Reagents & Consumables**
  - If reagent lot-to-lot variability is suspected, replace with a validated batch and re-run comparability tests.
- **Train Laboratory Staff**
  - Conduct refresher training for personnel on proper testing protocols, result interpretation, and method standardization.
  - Reinforce the importance of comparability studies in maintaining quality assurance.
- **Perform Repeat Comparability Testing**
  - After implementing corrective measures, conduct a repeat comparability study to confirm resolution.
  - Use quality control (QC) and proficiency testing (PT) samples to verify consistency.

3. Preventive Actions (Long-Term Solutions)

- **Develop a Standard Operating Procedure (SOP) for Comparability Testing**
  - Implement a structured approach for routine comparability checks across different methods and platforms.
  - Define acceptance criteria for variations and establish protocols for addressing deviations.
- **Schedule Regular Method Verification & Internal Audits**
  - Conduct periodic internal audits to ensure comparability across all examination processes.
  - Use trending analysis to monitor test performance over time.
- **Engage in External Quality Assessment (EQA) Programs**
  - Participate in proficiency testing (PT) and inter-laboratory comparison programs to validate performance.
  - Benchmark laboratory results against national and international standards.
- **Document All Actions Taken**
  - Maintain detailed records of NC identification, corrective actions, and verification results.

- Ensure compliance with accreditation and regulatory requirements (e.g., CAP, CLIA, ISO 15189).

- **Monitor and Evaluate Continuous Improvement**
  - Set up a quality monitoring committee to review and improve comparability processes regularly.
  - Encourage proactive identification and resolution of potential NCs before they impact patient results.

References: Clause 7.3.7, ISO 15189:2022

Annexures:

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/FL/26a	Kit Inserts	File	Section-In-Charge	Laboratory office	5 year
ML/FL/26b	EQAS and ILQA Records	File	Section-In-Charge	Laboratory office	5 year
ML/REG/17	Lot to lot Verification records and validation Records	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/4	Internal Quality Control Records-COVID	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/5	Internal Quality Control Records-H1N1	Register	Section-In-Charge	Laboratory office	Continuous
ML/QMS/SOP	SOP file	File	Section-In-Charge	Laboratory office	Continuous

7.4. Post-Examination processes (ML/QSP-21/POSTEX)

1. Purpose:

This procedure specifies the manner in which results of the completed tests are verified authorized and released; and it also covers the sample storage / sample disposal for which testing is completed.

2. Responsibility:

- Laboratory Director
- Section In-Charge
- Consultants
- Lab Technicians

3. Scope:

- Reporting of results
- Result review and release
- Critical result release
- Special consideration for results
- Additional information for reports
- Amendments to reported results
- Post-examination handling of samples

7.4.1 Reporting of Results

- **Standardized Format for Reporting:**
  - The molecular laboratory follows a standardized format for result reporting.
- **Timely Communication:**
  - Laboratory staff ensures that reports are delivered to the appropriate individuals within the agreed time frame.
- **Accuracy and Authorization:**
  - Reports are verified to be legible, free from transcription errors, and shared only with individuals authorized to access and utilize medical information.
- **Mandatory Report Details:**
  - Each report includes the following information:

- Clear and unambiguous identification of the examination, including the measurement procedure (if applicable).
- Identification of the issuing laboratory.
- Unique patient identification and location.
- Requester's name.
- Date and time the sample was received by the laboratory.
- Date and time the report was released.
- Type of primary sample.
- Examination results, reported in SI units or units traceable to SI units, as applicable.
- Biological reference intervals, where applicable.
- Interpretation of results, if required.
- Additional comments, as necessary.
- Identification of the individual authorizing the report release.
- Original and corrected results, if relevant.
- Signature or authorization of the person verifying or releasing the report (digitally signed where possible).
- NABL logo usage is restricted to parameters accredited by NABL.
- Page numbering in the format "Page X of Y".
- Report will be issued in hardcopy and the soft copy of the issued report will be maintained in the system for two years

- **Report Preparation and Validation:**
  - The final report is prepared by a laboratory technician. It is then reviewed, verified, and digitally signed by consultants before being released.
- **Quality Evaluation:**
  - Results are thoroughly evaluated against internal quality control measures and, where applicable, compared to clinical information and previous examination results.

Procedure for Notifying Delayed Reports

If reporting is delayed beyond the defined TAT, the following measures will be initiated

- Identify and document the cause of the delay.
- Notify stakeholders, including the requester, patient (if authorized), and relevant management, via phone or email.

- Communicate a revised timeline for report release.
- Escalate critical delays to management for prioritization.
- Provide regular updates until the report is finalized.
- Conduct a quality review to determine the root cause and implement corrective actions.
- Maintain detailed records of the delay and related communications.
- Implement preventive measures, such as workflow improvements or resource enhancements, to minimize future delays.

7.4.1.2 Result review and release

- **Verification:**
  - NABL authorized/approved consultant (s) reviews results for accuracy, ensuring compliance with internal quality control standards and standard operating procedures (SOPs).
  - Results are evaluated for consistency with clinical information and previous examination findings.
- **Approval:**
  - Consultants verify and sign the final report after a thorough review.
- **Report Release:**
  - Verified reports are released to test requesting individuals with acknowledgment (signing with date and time in the test register.
  - It is the policy of the Molecular laboratory not to deliver oral/verbal reports
  - Reports are released within the defined TAT.
- **Documentation:**
  - All steps, including verification and release, are documented for traceability and audit purposes.
- **Continuous Monitoring:**
  - Periodic audits are conducted to ensure the accuracy and reliability of the process.

7.4.1.3 Critical result reports

The molecular laboratory is dedicated to the detection and reporting of **COVID-19** and **H1N1** infections (Critical tests). These tests are critical due to the potential for rapid disease transmission and the need for timely intervention. As such, the laboratory is committed to providing accurate and reliable results within a clearly defined turnaround time (TAT).

To ensure effective communication, the following measures are implemented:

- **Prioritization of Tests**: Both COVID-19 and H1N1 tests are treated as high-priority due to their clinical significance and potential public health impact.
- **Timely Communication**: Results are processed and verified promptly to adhere to the agreed-upon TAT, minimizing delays in clinical decision-making.
- **Hardcopy Report Delivery**: Finalized reports are delivered to the physician in hardcopy format to ensure secure and reliable communication of results.

7.4.1.4 Special considerations for results

Special Considerations for Reporting COVID-19 and H1N1 Results

Given the critical nature of COVID-19 and H1N1 testing, the molecular laboratory adheres to strict reporting protocols to ensure accuracy and reliability.

- **No Interim or Preliminary Reports:**
  - The laboratory does not issue interim or preliminary reports for COVID-19 and H1N1 to prevent the dissemination of incomplete or unverified information.
- **No Oral Reporting:**
  - Results are not communicated orally to maintain accuracy and avoid miscommunication. Only finalized reports are issued in hardcopy format to authorized individuals.
- **No Counselling:**
  - The molecular laboratory does not provide patient counselling. This responsibility lies with the treating physician or healthcare provider who uses the results for diagnosis and treatment planning.

To support public health efforts and research, the molecular laboratory may provide test data for **epidemiological studies**, **demographic analyses**, or other statistical purposes. However, strict measures are implemented to protect patient confidentiality and comply with ethical and legal standards:

- **De-Identification of Patient Data:**
  - All patient-identifiable information, such as name, age, address, and unique identifiers, is removed from the dataset before sharing it for analysis.
  - Only anonymized data, such as test results, sample collection dates, and other relevant non-identifiable information, is included.
- **Compliance with Regulations:**
  - Data handling follows established guidelines for patient privacy, such as those outlined in local laws, institutional policies, and international standards (e.g., GDPR, HIPAA).

- **Secure Data Sharing:**
  - Anonymized data is shared only with authorized agencies or researchers via secure channels to prevent unauthorized access.
- **Purpose Limitation:**
  - Shared data is strictly used for epidemiological, demographic, or statistical purposes and cannot be repurposed for commercial or non-research activities.
- **Ethical Oversight:**
  - Data sharing agreements and ethical clearances are obtained when required to ensure compliance with research ethics.
- **Traceability and Documentation:**
  - A record of all data shared, including the purpose and recipients, is maintained for transparency and accountability. These measures allow the laboratory to contribute to public health research while safeguarding patient privacy and upholding confidentiality.

7.4.1.5 Automated selection, review, release and reporting of results

The molecular laboratory does not employ automation for the release of reports. Instead, it follows a **manual method** for the review, release, and reporting of results to ensure accuracy and compliance

If automation is adapted in future, following procedure will be implemented:

Procedure for Automation of Review, Release, and Reporting of Results in the Molecular Laboratory

- **Integration of Laboratory Information Management System (LIMS):**
  - Implement an automated LIMS to manage and streamline the review, release, and reporting process.
  - Configure the system to ensure compatibility with molecular testing instruments for seamless data transfer.
- **Automated Data Review:**
  - Test results are automatically reviewed by the LIMS for compliance with pre-set quality control parameters and flagged for abnormalities or inconsistencies.
  - Results outside the acceptable range are automatically withheld for manual review by laboratory staff or consultants.
- **Consultant Authorization:**
  - Configure the system to route results flagged for consultant review.

- Consultants can review and authorize results electronically using secure login credentials.

- **Report Generation:**
  - The system generates standardized reports with pre-filled patient and test information, minimizing transcription errors.
  - The reports include all required details such as test identifiers, results, and interpretation.
- **Digital Signatures:**
  - Consultants or authorized personnel electronically sign the reports for final approval.
- **Automated Report Release:**
  - After authorization, reports are automatically distributed to designated recipients via secure email, web portals, or printed hardcopies as required.
- **Audit Trail and Traceability:**
  - The system maintains a detailed log of all actions, including reviews, authorizations, and report releases, ensuring full traceability and accountability.
- **Notifications and Alerts:**
  - Automated notifications alert physicians or authorized personnel when reports are ready for review or retrieval.
- **Regulatory Compliance:**
  - The automation system is configured to comply with data protection and accreditation standards (e.g., NABL, HIPAA).
- **Continuous Monitoring and Maintenance:**
  - Regular updates and maintenance of the automated system ensure optimal performance and adherence to evolving laboratory requirements.

By adopting automation, the molecular laboratory can significantly reduce turnaround time, enhance accuracy, and improve overall operational efficiency while maintaining compliance with regulatory standards.

7.4.1.6 Requirements for reports

Details Included in Each Report Issued by the Molecular Laboratory

The molecular laboratory ensures that every report is comprehensive, accurate, and standardized. Each report includes the following essential elements to maintain clarity, reliability, and regulatory compliance:

- **Examination Identification:**
  - The report clearly specifies the type of test performed (e.g., COVID-19 RT-PCR, H1N1 RT-PCR), along with any relevant measurement procedures or methods used.
- **Laboratory Identification:**
  - The name and details of the issuing laboratory are included to ensure traceability and accountability.
- **Patient Identification and Location:**
  - Each report contains unique patient identifiers, such as name, IP/OP number, Bill number or Govt ID such as Aadhar, PAN, Voters ID, driving licence, ensuring that the results are linked to the correct individual.
- **Requester's Details:**
  - The report includes the name of the physician or clinician who requested the test.
- **Date and Time Stamps:**
  - The date and time of sample receipt by the laboratory and the date and time of report release are included to provide a complete timeline of the process.
- **Primary Sample Type:**
  - The type of biological sample tested (e.g., nasal swab, throat swab, sputum) is documented.
- **Examination Results:**
  - Results are presented clearly and reported in SI units or units traceable to SI units, ensuring consistency and adherence to international standards if requested by the physician.
- **Biological Reference Intervals:**
  - Where applicable, reference ranges are provided to help the physician interpret the results in the clinical context.
- **Interpretation of Results:**
  - If necessary, the report includes an interpretation of the findings, such as viral load or clinical significance.
- **Additional Comments:**
  - Any other relevant information, such as testing limitations or observations, is included in this section.

- **Authorization Details:**
  - The report identifies the individual (consultant or authorized staff) who has reviewed and authorized the release of the report.
- **Original and Corrected Results:**
  - If applicable, the report contains both the original and corrected results, ensuring full transparency.
- **Verification and Authorization:**
  - The report includes the signature or digital authorization of the individual who verified or released the report.
- **NABL Logo:**
  - The NABL logo is used only for parameters accredited by NABL, maintaining compliance with accreditation guidelines.
- **Page Numbering:**

  Reports are numbered in the format "Page X of Y" for clarity and completeness.
  - Since the tests are inherently **critical**, it is not necessary to explicitly label this test as critical.

7.4.1.7 Additional information for reports

- The report will include the time of primary sample collection and details of transportation conditions.
- The time of report release will be clearly specified within the report.
- When applicable, the report will provide result interpretation and comments on sample quality and suitability that could impact the clinical value of results.
- All examinations or components conducted by referral laboratories, with unaltered information from consultants and the name of the performing laboratory, are clearly identified.

7.4.1.8 Amendments to Reported Results

The molecular laboratory ensures that when an original report is revised, clear procedures are followed to maintain transparency and accountability:

- If an issued report is amended, the Laboratory Director or an Authorized Signatory informs the referring doctor, patient, or relevant party. The amended report is then issued with a footnote clearly stating that it has been amended.
- The original report is retained alongside a copy of the amended report, and the reasons for the amendment are documented in an Incident Report form. The Section In-charge

conducts a root cause analysis and implements necessary corrective and preventive actions.

- When a new test report is issued, references to the original report are included.
- The revised report includes the time and date of the change, the name of the person responsible for the change, and the reason for the amendment.

Note: In cases if the laboratory uses automated reporting system and if the reporting system cannot / fails to capture revisions, manual processes must be implemented to ensure proper documentation and communication of amendments to all concerned parties.

References: Clause 7.4.1.8 ISO 15189:2022

7.4.2 Post-examination handling of samples

- The Molecular laboratory has a documented procedure for identification, collection, retention, indexing access, storage, maintenance and safe disposal of clinical information and previous examination results.
- The Molecular laboratory has defined the length of time clinical samples are to be retained. Retention time is defined by the nature of sample, the examination and any applicable requirements.
- Retention period of samples will be as specified by ICMR and samples will be stored at -80^0C
- The laboratory maintains appropriate records to provide identification and traceability of samples, test results after processing, wherever required.
- The details of sample storage and disposal are recorded in the Sample storage and Discard register. Clinical samples are stored at ultra-low temperatures (-80°C) to ensure long-term preservation and to prevent the degradation of biological materials. These retention periods are strictly adhered to in compliance with the Indian Council of Medical Research (ICMR) guidelines or other applicable standards. Once the retention period has elapsed, samples are safely discarded.
- The laboratory maintains comprehensive records to ensure the identification and traceability of samples throughout their lifecycle. These records include:
    - Unique sample identification codes linked to patient or study information.
    - Test results and supplementary data obtained during processing.
    - Documentation of storage conditions and any movements of samples.
    - Access logs to track handling and prevent unauthorized interactions

Details regarding the storage and disposal of samples are meticulously documented in the "Sample Storage and Discard Register." This register includes:

- The type, source, and date of receipt for each sample.
- The specific storage location (e.g., rack or box number) for quick retrieval.
- The assigned retention period and expiration date.
- The date, method, and personnel responsible for disposal, ensuring compliance with biohazard and environmental safety regulations.

Duration of Retention of Samples

1. **Retention of Positive and Negative Samples:**

  - **10% of positive samples** and **2% of negative samples** are stored for a period of **1 year** to ensure quality assurance and retrospective analysis.

- **Retention of Remaining Samples:**
  - All other samples and their extracts (excluding those mentioned in point 1) are retained for a period of **2 months**, after which they are disposed of following standard protocols.

- **Samples for Research Purposes:**
  - If samples are required for research purposes, their retention period will be determined based on the specific **research protocol** and institutional review board (IRB) approvals.

- **Retention of Extracts from Point 1:**
  - Extracts obtained from the **10% of positive samples** and **2% of negative samples** mentioned in point 1 are stored for a period of **5 years** to support long-term research, quality control, and reference needs.

This retention framework ensures compliance with regulatory guidelines while balancing operational efficiency and scientific utility.

- **Sample Disposal Protocols:**
  - After the retention period, samples are reviewed for further use in research or quality control. If no further use is warranted, they are discarded.
  - **Method of Disposal:** Samples are autoclaved or incinerated, depending on the nature of the material, in alignment with biohazard waste management protocols.
  - All disposals are conducted under the supervision of authorized personnel to ensure safety and compliance.

Annexures

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/REG/18	Sample retention register-COVID	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/24	Sample retention register-H1N1	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/19	Sample Discard Register-COVID	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/25	Sample Discard Register-H1N1	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/13	TAT Records-COVID	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/14	TAT Records-H1N1	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/20	Duplicate reports	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/21	Revised reports	Register	Section-In-Charge	Laboratory office	Continuous
ML/FL/30	Revised reports	File	Section-In-Charge	Laboratory office	10 Years

7.5 Nonconforming work (ML/QSP-22/NCONW)

1. Purpose:

The purpose of this procedure is to define the method of identifying, reporting and handling all non – conforming activities related to QMS, Pre examination and post examination processes as per requirements of the users of the Laboratory office.

2.Responsibility:

- All Laboratory Staffs.

3.Scope:

- Identification & control of nonconformities in QMS including pre-examination, examination, and post examination

Procedure:

Non-Conformity Management Procedure

a. Identification of Non-Conformity

- Non-conformities may be identified by laboratory staff, patients, or physicians. These are reported to the Section-In charge or Laboratory Director for further evaluation.
- The Section In-Charge assesses the criticality of the non-conformity observed during the testing process or within the Quality Management System.
- Risk analysis will be done based on the criticality of the non-conformity observed.
- If a non-conformance is identified, the Section In-Charge initiates necessary actions.
- Immediate actions may include:
    - Withholding or stopping the testing process.
    - Withholding or recalling released reports if required.

b. Areas of Non-Conformity Identification

Non-conformities in the Molecular Laboratory are identified in the following areas of the Quality System and technical operations:

- Quality Control
- Instrument Calibration
- Customer Complaints
- Checking of Consumable Materials

- Staff Observation or Supervision
- Test Report Checking
- Customer requirement.
- **Performance in External Quality Assurance Scheme (EQAS):**
  - Any deviation or unsatisfactory performance identified during EQAS is considered a non-conformance.
  - Such findings are thoroughly evaluated, and corrective actions are implemented to address the root cause.
- **Discrepancies Between Internal Audit and External NABL Audit:**
  - Any non-conformity or discrepancy identified between the findings of internal audits and those of external NABL audits is recorded and addressed.
  - A detailed review is conducted to determine the root cause of discrepancies, and corrective actions are implemented to align processes with NABL standards and internal protocols.

c. Evaluation and Corrective Action

- The extent of non-conformity and its clinical implications are evaluated.
- Root Cause Analysis (RCA) is performed to determine the actual cause of the non-conformity.
- Suitable corrective and preventive actions are initiated based on the RCA findings, and all details are documented.

d. Deviation from Standard Operating Procedures (SOPs)

In cases of deviation from SOPs, the Section In-Charge and Consultant take necessary corrective actions based on the identified non-conformity.

e. Non-Conformities Identified After Test Result Release

- If non-conformities are identified after a test result has been released:
  - The issue is communicated to the user.
  - The laboratory may recall the report if necessary.
- A fresh sample is sought, if required, and re-testing is conducted. A revised report is then issued and filed in the "Revised Reports File."

f. Authorization of Resumption of Work

The Laboratory Director is responsible for authorizing the resumption of normal work after corrective actions have been taken and satisfactory results have been achieved.

g. Documentation of Non-Conformities

- Non-conformities observed during testing (including internal quality controls) and related areas are recorded in the **NC Register-IQC**.
- Non-conformities related to EQAS and audits (internal and NABL) are documented for tracking and resolution.
- Each episode of non-conformity is documented, and the root cause is analyzed. Corrective and preventive actions are taken accordingly.
- These records are reviewed during Management Review Meetings to identify trends and initiate additional corrective actions if required.

h. Follow-Up of Closed Non-Conformities

- The follow-up of closed non-conformities is conducted every 3 months to ensure effective resolution and prevent recurrence.
- If there is a possibility of recurrence, compliance with operating procedures is reassessed, and documented, and necessary corrective actions are determined and implemented.

i. Prevention of Recurrence

When doubt arises or there is a possibility of recurrence of non-conformities, steps are taken to eliminate the root cause. Compliance with operating procedures is ensured, documented, and reviewed for effectiveness.

Annexures

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
L/REG/3	Non Conformance records-IQC	Register	Section-In-Charge	Laboratory office	Continuous

7.6 Control of data and information management (ML/QSP-23/CDIM)

1. Purpose:

To ensure that all data and information generated, received, or managed by the laboratory are accurate, secure, accessible, and appropriately maintained throughout their lifecycle, thereby supporting the reliability, confidentiality, and integrity of laboratory operations and decision-making processes.

2. Responsibility:

- All Laboratory Staffs.

3. Scope:

- Authority and responsibility
- Access control
- Test report generation process
- Data storage
- Information system management
- System maintenance and documentation
- Downtime plan
- Off-site management

Procedure:

Molecular Laboratory Computer Usage

- A **dedicated computer** is installed in the molecular laboratory office to manage and enter test reports.
- This computer serves as a critical component of the laboratory's information management system, ensuring accurate and timely recording of test results.
- The computer is strategically placed in a secure environment to ensure only authorized personnel can access it.

7.6.2 Authorities and Responsibilities

- The Laboratory Director has overall responsibility for the secure operation of the computer and the integrity of the data.
- The Section-in charge is tasked with **setting or changing the computer password** whenever necessary, ensuring access is restricted to authorized personnel only. The Director also validates and approves any **hardware or software changes** proposed by the EDP Technician before they are implemented to maintain the reliability of the system.

- **Data Entry Operator and Designated Senior Technician** are **authorized to enter the registration of patient and test reports** into the system, ensuring accurate data input as part of routine laboratory operations. They are responsible for adhering to the laboratory's established protocols and confidentiality standards while handling sensitive data.
- **Authorize the release of examination results and reports**: This is by lab consultants after the results/reports are marked complete in the computer.
- The EDP Technician oversees the **maintenance and troubleshooting** of the computer's hardware and software. Any updates, upgrades, or repairs to the system require **validation and approval from the Laboratory Director** before being implemented. This ensures that all changes comply with laboratory standards and do not compromise the integrity of the data.

Access Control

To maintain the security and confidentiality of the molecular laboratory's data, the following access control measures are implemented:

- **Password Protection**:
  - The computer is secured with a strong password to prevent unauthorized access.
  - The password is updated periodically by the Section in charge to enhance security.
- **Confidentiality**:
  - The password is treated as **strictly confidential** and is only shared with authorized personnel.
- **Network Isolation**:
  - The computer is deliberately **not connected to any external or local network** to minimize the risk of unauthorized remote access, hacking, or data breaches.
- **Authorized Access**:
  - The following individuals are granted access to the computer using the password:
    - Laboratory Director
    - Section In charge
    - Consultant
    - Data Entry Operator
    - Designated Senior Technician

- **Modification of Printed Reports**:
  - Any changes to a printed test report can only be made by the Section In charge. This ensures accountability and prevents unauthorized alterations to official documents.

Additional Safeguards

- The laboratory implements **routine audits** to ensure compliance with access control policies and detect any potential security breaches.
- Personnel accessing the computer are trained in the importance of data security, and any violations are subject to disciplinary action.
- A **logbook or electronic record** is maintained to track all data entries and modifications, ensuring a clear audit trail for accountability.

Test Report generation process

The test report is entered in a pre-existing Microsoft word format saved on the desktop.

After entry, the test report is converted into the PDF format

The PDF format of the test report is printed on a pre-printed paper containing the laboratory name and address along with the NABL logo.

Data storage

- The PDF format of the test report is saved in a protected folder in the computer on a daily basis.
- No Microsoft Word formats are saved.
- At the end of a month the reports are transferred to an external hard disk and stored in the laboratory office under the supervision of the Section-In-Charge.

7.6.3 Information Systems Management

Future Implementation of Automated Information Systems Management

The Molecular Laboratory currently employs a **manual method** of information systems management. However, with the adoption of an **automated information management system**,

the following protocols will be implemented to ensure secure, efficient, and accurate handling of data:

Information Management System

- **User Access and Authentication**:
  - Each user is assigned a **unique username and password** to log in to the system.
  - **Password Encryption**:
  - User passwords are securely encrypted to protect against unauthorized access.
  - The database itself is protected by a **separate password**, ensuring an additional layer of security.
- **Menu Accessibility**:
  - **Role-Based Access Control**:
    - Access to specific menus and functions within the system is granted or revoked by the **Administrative Manager**, based on the user's role and responsibilities.
  - This ensures that users can only access the information and tools relevant to their job functions.
- **Transaction Monitoring**:
  - For every transaction or update in the system, the following details are **automatically recorded**:
    - Username of the individual making the entry
    - Date and time of login
    - **IP address** of the device used for the entry
  - These logs provide a comprehensive audit trail for monitoring system activity and ensuring accountability.

2. **Database Backup**:
   - A **daily automatic backup** of the database is created to safeguard data against loss or corruption.
   - The backup is securely copied to a **separate computer system**, ensuring data redundancy and disaster recovery preparedness.

System Maintenance and Documentation

1. **Downtime plans (Breakdown Calls and Maintenance)**:
   - Any technical issues or breakdowns are handled by the **EDP Technician**, who is responsible for diagnosing and resolving hardware or software-related problems.

- A **record of breakdown calls** is maintained to document and track issues, ensuring timely resolution.
- Downtime period of 24 hours is accepted, during this time if patient requires an urgent report, the manual report will be provided and the same will be communicated to the stakeholders

2. **Software Enhancements**:
   - Updates and enhancements to the system's existing software are performed by **I-Platina Systems** in collaboration with the Molecular Laboratory.
   - A **call-sheet** is maintained for every software update or enhancement, detailing the changes made and the work completed.
3. **Documentation**:
   - All records and technical details are maintained in the **LIS (Laboratory Information System) file**, ensuring comprehensive documentation of system operations and updates.

The transition to an automated information system will significantly enhance the efficiency, accuracy, and security of the Molecular Laboratory's operations. These protocols ensure that data is managed systematically, access is controlled, and all activities are logged and documented for transparency and accountability.

7.6.4 Downtime plans

- Any technical issues or breakdowns are handled by the **EDP Technician**, who is responsible for diagnosing and resolving hardware or software-related problems.
- A **record of breakdown calls** is maintained to document and track issues, ensuring timely resolution.
- A downtime period of 24 hours is accepted, during this time if the patient requires an urgent report, the handwritten report will be provided and the same will be communicated to the stakeholders

4. **Software Enhancements**:
   - EDP performs updates and enhancements to the system's existing software in collaboration with the Molecular Laboratory.
   - A **call sheet** is maintained for every software update or enhancement detailing the changes and work completed.
5. **Documentation**:
   - All records and technical details are maintained in the **LIS (Laboratory Information System) file**, ensuring comprehensive system operations and updated documentation.

7.6.5 Off-site management

The molecular laboratory information systems are entirely managed and maintained by a dedicated team of in-house Electronic Data Processing (EDP) technicians. This internal team is responsible for all aspects of system upkeep, including software updates, hardware maintenance,

troubleshooting, and ensuring system security. The laboratory has not engaged any off-site or external providers for information systems management, relying solely on the expertise of its in-house team. This approach allows for greater control over system operations, immediate response to technical issues, and the ability to tailor solutions to the laboratory's specific needs without the dependency on third-party vendors.

Annexure:

Record no.	**Record name**	**Record Type**	**Responsibility**	**Location**	**Retention Period**
ML/FL/31	LIS Records	File	EDP Technician	Laboratory office	10 Year
ML/REG/22	ICMR portal - Fetched reports	Register	Section-In-Charge	Laboratory office	Continuous

7.7 Complaints (ML/QSP-24/COMPL)

1. Purpose

This procedure explains the activities associated with the receipt, handling and resolution of complaints / suggestions and feedback received from the customers, clinicians, patients, laboratory staff & other parties, who use the services of the Molecular laboratory.

2.Responsibility

- Laboratory Director,
- Section-In Charge
- Administrative manager

3. Scope

- Receipt of complaint
- Resolution of complaint

Procedure

- **Informal Resolution of Complaints:** Complainants are encouraged to seek an informal resolution for their grievances or concerns. This process promotes direct communication between the involved parties or through an intermediary to develop a mutual understanding of differing perspectives. If the informal process does not resolve the issue to the complainant's satisfaction, they may proceed with the formal complaint procedure. All issues are discussed and documented by the Section In-Charge.
- **Patient Suggestions/Complaints:** A Suggestion/Complaint Box is available at the Laboratory reception for patients to submit their feedback. Additionally, Patient Feedback Forms are provided in the same location for ease of access. For patients unable to visit the laboratory reception area, the form can be provided to them personally upon request.
- **Physician Feedback:** The quality of test results and other laboratory services is reviewed annually through a Physician Feedback Form, collected by the Section In-Charge.
- **Complaint Review Process:** All complaints, suggestions, and feedback are reviewed and critically analyzed by the Section In-Charge, who then informs the Laboratory Director.
- **Addressing Specific Complaints:** Complaints regarding specific nonconforming services or test results from physicians are promptly brought to the attention of the Laboratory Director.
- **Analysis and Improvement:** The Section In-Charge, in consultation with the Laboratory Director, analyzes reported issues and determines whether improvements are required for nonconforming services or test results.

- **Corrective and Preventive Actions:** Complaints are prioritized based on criticality, the root cause is identified, and appropriate corrective and preventive actions are taken.
- **Communication with Staff:** Relevant personnel and technicians are informed of the complaint and the planned corrective and preventive actions, as necessary.
- **Training and Accountability:** Technicians or personnel responsible for nonconforming services or test results are identified by the Section In-Charge, and necessary training is planned and provided.
- **Implementation and Documentation:** Corrective and preventive actions are undertaken only after verifying the availability of sufficient resources and ensuring their effectiveness in addressing the identified issues. All details related to these actions are thoroughly documented in the Complaint/Suggestion File to maintain proper records and allow for future reference.

To uphold transparency and foster trust, a curated selection of feedback, including both complaints and suggestions, will be displayed publicly at a designated area in front of the molecular laboratory. This approach ensures that patients and stakeholders are aware of the laboratory's commitment to addressing concerns, implementing improvements, and maintaining high standards of service quality.

- **Reporting in Review Meetings:** Feedback, complaints, and details of corrective and preventive actions are presented and discussed during the Laboratory Management Review Meeting.
- **Effectiveness Evaluation:** The effectiveness of corrective actions is reviewed in subsequent internal audits and Management Review Meetings.
- **Staff Feedback:** Laboratory staff are encouraged to provide feedback on services using Lab Staff Feedback Forms, which are freely available at the Laboratory office reception.
- **Feedback Integration:** Staff and user feedback are discussed and evaluated during Management Review Meetings. Suggestions are implemented only after assessing their potential impact on quality and confirming their suitability within the system.

Annexures

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/F/8	Customer Suggestion/Complaint form	Form	Section-In-Charge	Laboratory office	5 Years
ML/F/9	Clinicians Feedback Form	Form	Section-In-Charge	Laboratory office	5 Years
ML/F/10	Staff Suggestion Form	Form	Section-In-Charge	Laboratory office	5 Years
ML/FL/9	Suggestion/ Complaint record	File	Section-In-Charge	Laboratory office	5 Year

7.8 Continuity and Emergency Preparedness Planning (ML/QSP-25/CONEPP)

Purpose

The purpose of this procedure is to formulate a plan in case of emergencies such as power failure, instrument breakdown, increase in work load, short supply of kits/reagents, and break down of computer / LIS.

Responsibility

- Laboratory Director
- Section In-charge
- Administrative manager
- Lab Technicians

Scope:

General and specific preparedness of laboratory system so as to deal with emergency viz., power failure, instrument breakdown, increase in work load, short supply of kits/reagents, and break down of computer / LIS.

Procedure:

The contingency plan is designed to ensure the uninterrupted operation of the laboratory office, even in challenging situations such as power failures, equipment breakdowns, increased workload, shortages of kits/reagents, or manpower issues or natural calamities. The Lab Director, Section-in-charge , and Administrative Manager will initiate appropriate measures to address such scenarios effectively. The detailed plan is as follows:

- **Power Failure:** All major equipment is equipped with UPS backup to prevent sudden shutdowns, ensuring that testing processes are not disrupted and turnaround times are maintained. Additionally, a generator backup is available to provide power support in case of extended outages.
- **Equipment Breakdown:** To manage equipment breakdowns, backup equipment is kept on standby. A trained instrument technician will address the issue promptly. If the technician is unable to resolve the problem, the matter will be escalated to the concerned instrument engineer for immediate action. Furthermore, the laboratory has agreements with other NABL-accredited labs to outsource tests, if necessary, to ensure continuity of diagnostic services. For example, molecular laboratory tests under the scope will only be outsourced to NABL-accredited laboratories if they cannot be performed in-house.
- **Increased Workload:** In the event of an increased workload, both the primary and backup instruments will be operated simultaneously to meet demand and maintain efficiency.

- **Shortage of Kits/Reagents:** The molecular laboratory maintains daily inventory monitoring. In the event of a shortage, kits/reagents will be procured from alternate suppliers listed in the approved suppliers' database. If the required items are not available from these suppliers, they will be sourced from other reputed manufacturers or suppliers. In cases where kits/reagents remain unavailable, the affected tests will be outsourced to referral laboratories to avoid service disruption.
- **Computer/LIS Breakdown:** In case of a computer or Laboratory Information System (LIS) failure, manual reports will be issued without undue delay to avoid impacting patient care. Once the LIS is restored, the same report—unaltered in terms of examination values—will be uploaded to the system to maintain data integrity for future reference.
- The laboratory has a partnership with backup laboratories for sample processing.
- **Manpower Issues:** The molecular laboratory prioritizes maintaining adequate staffing levels to ensure uninterrupted and efficient diagnostic services at all times. To address unexpected manpower shortages, particularly when a technician is absent due to emergencies without prior notice, the following measures are implemented:
    - **Shift Adjustment:** The on-duty technician will initially be requested to cover the additional workload or extend their shift to ensure immediate continuity of laboratory operations.
    - **Reserve Staff Activation:** If the on-duty technician is unable or unwilling to take on the extra shift, technicians from the reserve pool will be called upon to step in. These reserve technicians are trained and experienced, enabling them to quickly adapt to the situation.
    - **Workflow Briefing:** Before the reserve technician begins handling specimens, they will be thoroughly briefed on the current workflow, pending tasks, and priority cases to ensure seamless integration into the ongoing operations.
    - **Proactive Planning:** To minimize such disruptions, the laboratory maintains a policy of hiring and training an adequate number of skilled staff members, ensuring there is always a buffer of reserve personnel available to handle emergencies. Regular cross-training of staff also ensures that all team members are versatile and capable of performing critical tasks when needed.
    - The molecular laboratory is affiliated with the medical college, ensuring access to a sufficient number of trained consultants for its operations. As a result, the likelihood of a consultant shortage in the laboratory is minimal. However, in the rare event of a consultant shortage, the molecular laboratory will address the situation by appointing either a full-time or part-time consultant, depending on availability, to maintain seamless operations.

Reference: Clause 7.8 of ISO 15189: 2022

Annexures:

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/RG/1	Equipment break down register	Register	Section-In-Charge, Biomedical Engineer	Laboratory office	Continuous
ML/F/2	Vendor evaluation Form	Form	Section-In-Charge	Laboratory office	5 Years
ML/F/3	Electrical Safety Checklist	Form	Electrician	Laboratory office	5 Years
ML/FL/3a	Vendor Evaluation records	File	Administrative Manager	Administrative Office	5 Years
ML/FL/3b	Referral lab MOU's	File	Section-In-Charge	Laboratory office	Continuous

8.0 Management System Requirements

8.1 General (ML/QSP-26/GENREQ)

The laboratory will establish, document, implement and maintain a management system to support and demonstrate the consistent fulfilment of the requirements of this document. As a minimum, the management system of the laboratory will include the following: responsibilities, objectives and policies, documented information, actions to address risks and opportunities for improvement, continual improvement, corrective actions, evaluations and internal audits, management reviews

1.Purpose:

This procedure outlines the management system requirements for the (Name of the Laboratory), in compliance with ISO 15189:2022.

2. Responsibility:

It applies to all laboratory personnel, processes, and activities involved in the provision of molecular diagnostic services.

- Principal
- Laboratory Director
- Administrative Manager
- Section-In-Charge
- Consultants
- Clerk
- Technical staff

3. Scope:

- Fulfilment of management system requirements
- Management system awareness

Quality Policy

- The laboratory's quality policy emphasizes commitment to accurate, timely, and reliable diagnostic services.
- The policy is communicated to all employees and is available in the laboratory's quality manual.

Quality Objectives

- Establish measurable quality objectives such as:
  - Reducing turnaround time for test results by 10% annually.

- Achieving 98% accuracy in molecular diagnostic tests.
- Enhancing patient satisfaction scores by 15%.

- Regular review and update of objectives during management review meetings.

Organizational Structure and Responsibilities

- **Organizational Chart:** Documented in the quality manual, showing hierarchy and reporting relationships.
- **Roles and Responsibilities:**
  - **Laboratory Director:** Overall responsibility for laboratory operations and compliance and
  - **Section-In-charge**: Monitor & ensure QMS implementation and maintenance.
  - **Consultants**: Ensures lab meets and maintains accreditation standards and daily reporting.
  - **Technical Staff:** Conduct diagnostic tests and adhere to SOPs.
  - **Support Staff:** Maintain laboratory environment and equipment.

8.1.2 Fulfilment of management system requirements

1. Quality Management System (QMS) Implementation

- **Quality Manual**: Develop a comprehensive quality manual outlining the scope, policies, and procedures of the QMS.
- **Document Control**: Establish a system for controlling documents and records to ensure they are current, accessible, and properly maintained.

2. Management Responsibility

- **Leadership Commitment**: Top management must demonstrate commitment to the implementation and continuous improvement of the QMS.
- **Quality Policy and Objectives**: Define and communicate the quality policy and measurable quality objectives aligned with the laboratory's mission.

3. Risk Management

- **Risk Identification**: Identify potential risks to the quality of laboratory services and patient safety.
- **Risk Mitigation**: Implement measures to mitigate identified risks and regularly review their effectiveness.

4. Resource Management

- **Personnel Competence**: Ensure all staff are appropriately trained, qualified, and competent for their roles. Maintain records of training and competence assessments.
- **Facilities and Equipment**: Provide and maintain appropriate laboratory facilities, equipment, and environmental conditions necessary for molecular testing.
- **Supplies and Services**: Ensure reliable procurement and quality control of reagents, consumables, and outsourced services.

5. Process Requirements

- **Pre-Examination Processes**: Define procedures for patient identification, sample collection, handling, transport, and storage to ensure sample integrity.
- **Examination Processes**: Validate and verify molecular testing methods (e.g., PCR, qPCR, NGS) and ensure accurate, reliable, and timely testing.
- **Post-Examination Processes**: Establish procedures for reviewing, validating, and reporting test results, including handling critical results and ensuring confidentiality.

6. Continual Improvement

- **Internal Audits**: Regularly conduct internal audits to assess compliance with ISO 15189:2022 requirements and identify areas for improvement.
- **Management Review**: Periodically review the QMS to evaluate its effectiveness, consider audit findings, customer feedback, and performance metrics.

7. Corrective and Preventive Actions (CAPA)

- **Non-Conformity Management**: Establish a system to identify, document, and address non-conformities, ensuring timely corrective actions.
- **Preventive Actions**: Implement preventive measures to reduce the likelihood of potential non-conformities.

8. Customer Focus

- **Patient and User Satisfaction**: Regularly collect and analyze feedback from patients, clinicians, and other stakeholders to improve services.
- **Communication**: Ensure effective communication channels for handling inquiries, complaints, and providing information about laboratory services.

9. Information Management

- **Laboratory Information System (LIS)**: Use an LIS to manage patient data, test orders, results, and reports securely and efficiently.

- **Data Integrity and Confidentiality**: Implement measures to protect the integrity, confidentiality, and availability of laboratory data.

10. Safety and Ethics

- **Biosafety and Biosecurity**: Adhere to biosafety and biosecurity protocols to protect laboratory personnel and the environment.
- **Ethical Practices**: Ensure ethical conduct in all laboratory operations, including informed consent, patient rights, and data privacy.

8.1.3 Management system awareness

Management system awareness as per ISO 15189:2022 in a molecular laboratory is crucial to ensure that all staff understand the quality management system (QMS) and their roles within it. Here's how to promote awareness:

1. Understanding of ISO 15189:2022

- **Core Principles**: Educate staff on the key principles of ISO 15189:2022, focusing on patient safety, quality of results, and continual improvement.
- **Importance of Accreditation**: Explain the significance of accreditation and how it enhances the laboratory's credibility and reliability.

2. Quality Policy and Objectives

- **Communication**: Ensure that the quality policy and objectives are clearly communicated to all staff members.
- **Alignment**: Encourage staff to align their daily activities with the laboratory's quality objectives.

3. Roles and Responsibilities

- **Defined Roles**: Clearly define and communicate individual roles and responsibilities concerning the QMS.
- **Accountability**: Emphasize the importance of each role in maintaining quality and compliance with ISO 15189:2022.

4. Training and Competence

- **Regular Training**: Conduct regular training sessions on ISO 15189:2022 requirements, QMS processes, and any updates or changes.
- **Competence Assessment**: Periodically assess staff competence and provide additional training if needed.

5. Risk Awareness

- **Risk Identification**: Train staff to identify potential risks in their workflow that could impact the quality of results or patient safety.
- **Risk Mitigation**: Promote a culture of proactive risk management, encouraging staff to report and address risks promptly.

6. Document Control

- **Access to Documentation**: Ensure all staff have access to current versions of relevant documents, including SOPs, guidelines, and policies.
- **Understanding Documentation**: Train staff on the importance of following documented procedures and keeping accurate records.

7. Internal Audits and Non-Conformities

- **Audit Participation**: Involve staff in internal audits to increase their understanding of compliance requirements and QMS effectiveness.
- **Non-Conformity Reporting**: Encourage staff to report non-conformities and participate in developing corrective actions.

8. Customer Focus

- **Patient-Centered Approach**: Emphasize the importance of a patient-centered approach and how their roles contribute to patient care.
- **Feedback and Complaints**: Make staff aware of the procedures for handling feedback and complaints and their role in improving service quality.

9. Safety and Ethical Practices

- **Biosafety Protocols**: Regularly train staff on biosafety and biosecurity protocols to ensure a safe working environment.
- **Ethical Conduct**: Reinforce ethical practices, including patient confidentiality, informed consent, and data protection.

10. Continuous Improvement

- **Encourage Improvement**: Foster a culture of continuous improvement, encouraging staff to suggest changes and improvements to processes.
- **Monitoring and Review**: Involve staff in monitoring QMS performance and participating in management reviews to understand the impact of their work on the laboratory's objectives.

By fostering comprehensive awareness of the management system as per ISO 15189:2022, molecular laboratory staff can contribute effectively to maintaining high standards of quality, safety, and efficiency.

8.2 Management system documentation (ML/QSP-27/MGMTSD)

1.Purpose:

Management system documentation as per ISO 15189:2022 includes a quality policy and quality objectives, quality manual, SOPs for all processes, and procedures for risk management, internal audits, and CAPA. Molecular laboratory will maintain records of patient data, equipment maintenance, personnel training, and management reviews. Documentation also covers pre-examination, examination, and post-examination processes, customer feedback, safety protocols, ethical practices, and communication procedures. Proper documentation ensures compliance, enhances quality and supports continual improvement in the molecular laboratory's operations.

2.Responsibility:

It applies to all laboratory personnel, processes, and activities involved in the provision of molecular diagnostic services.

- Principal
- Laboratory Director
- Administrative Manager
- Section-In-Charge
- Consultants
- Clerk
- Technical staff

3.Scope:

- Competence and quality
- Evidence of commitment
- Documentation
- Personnel access

8.2.3 Competence and Quality

The policies and objectives are focused on ensuring the laboratory's competence, quality, and consistent operations through rigorous staff training, robust quality management practices, regular performance evaluations, and continual process improvements to ensure compliance with the standard and excellence in laboratory services.

8.2.3 Evidence of commitment

Laboratory management will ensure the commitment by;

- Active participation in developing and reviewing the Quality Management System (QMS) and setting quality objectives.
- Regular involvement in quality meetings and management reviews.
- Ensuring adequate resources by providing sufficient staff, , equipment, and facilities, to maintain laboratory operations and quality standards.
- Clearly communicating the quality policy and objectives to all staff and stakeholders.
- Conducting periodic management reviews to assess QMS effectiveness and make necessary improvements.
- Providing ongoing training, support, and development opportunities for laboratory personnel to maintain competence.
- Personnel should demonstrate their ability to perform specific tasks and adhere to documented procedures.
- Regular assessments of personnel competence through proficiency testing, internal assessments, or other evaluations.
- Documentation of competence assessments and actions taken to address any deficiencies.
- Driving initiatives for continuous improvement by attending conference, workshop, participating in EQAS, internal audits, addressing non-conformities, and implementing corrective and preventive actions (CAPA).
- Prioritizing patient care and satisfaction by ensuring timely, accurate, and reliable laboratory results.
- And adequate documentation

8.2.4 Documentation

1. Quality Manual

- **Purpose:** Describes the scope of the management system, quality policies, objectives, and commitments to quality.
- **Contents:**
  - Laboratory scope and services.
  - Quality policy and objectives.
  - Organizational structure and responsibilities.
  - Summary of processes and their interactions.

- References to detailed procedures and SOPs.

2. Quality Policy

- **Purpose:** States the laboratory's commitment to quality and compliance with ISO 15189:2022.
- **Contents:**
  - Commitment to meeting customer and regulatory requirements.
  - Goals for continuous improvement.
  - Assurance of impartiality, confidentiality, and integrity.

3. Standard Operating Procedures (SOPs)

- **Purpose:** Provide detailed instructions on how specific tasks and processes are performed.
- **Contents:**
  - Sample collection, handling, and processing.
  - Equipment operation, maintenance, and calibration.
  - Molecular testing methods and validation procedures.
  - Quality control and assurance activities.
  - Reporting of results and handling of non-conformities.

4. Document Control Procedure

- **Purpose:** Describes how documents are created, reviewed, approved, distributed, and controlled.
- **Contents:**
  - Document identification and numbering.
  - Roles and responsibilities for document control.
  - Procedures for document revision, approval, and distribution.
  - Handling of obsolete documents.

5. Record Control Procedure

- **Purpose:** Outlines how records are managed to ensure they are identifiable, retrievable, and protected.
- **Contents:**
  - Types of records maintained (e.g., test results, equipment logs, training records).
  - Record retention periods.

- Storage, protection, and disposal of records.
- Access control and confidentiality measures.

6. Internal Audit Procedure

- **Purpose:** Defines the process for conducting internal audits to verify compliance with the management system.
- **Contents:**
  - Audit planning and scheduling.
  - Selection and qualification of auditors.
  - Audit execution, reporting, and follow-up on findings.
  - Corrective and preventive action tracking.

7. Management Review Procedure

- **Purpose:** Describes how management reviews are conducted to assess the effectiveness of the management system.
- **Contents:**
  - Inputs to the management review (e.g., audit results, customer feedback, non-conformities).
  - Frequency and participants of the review.
  - Outputs and actions from the review (e.g., improvement plans, resource needs).

8. Corrective and Preventive Action Procedure

- **Purpose:** Details how the laboratory identifies, investigates, and addresses non-conformities and potential issues.
- **Contents:**
  - Reporting and recording non-conformities.
  - Root cause analysis methods.
  - Implementation and monitoring of corrective and preventive actions.
  - Effectiveness evaluation.

9. Training and Competency Records

- **Purpose:** Document staff qualifications, training, and competency assessments.
- **Contents:**
  - Training programs and schedules.

- Records of completed training and assessments.
- Competency evaluation criteria and results.

10. Equipment and Maintenance Records

- **Purpose:** Maintain records of equipment calibration, maintenance, and performance verification.
- **Contents:**
  - Equipment identification and calibration schedules.
  - Maintenance logs and service records.
  - Performance verification results.

11. Customer Feedback and Complaints Procedure

- **Purpose:** Describes how customer feedback and complaints are handled and used for improvement.
- **Contents:**
  - Process for receiving and recording feedback.
  - Investigation and resolution of complaints.
  - Communication with customers and follow-up actions.

12. Continual Improvement Procedure

- **Purpose:** Outlines how the laboratory identifies and implements opportunities for improvement.
- **Contents:**
  - Sources of improvement opportunities (e.g., audits, feedback, reviews).
  - Methods for evaluating and prioritizing improvements.
  - Implementation and monitoring of improvement actions.

Final Steps

- **Review and Approval:** Ensure all documents are reviewed and approved by authorized personnel.
- **Distribution and Accessibility:** Make documents available to relevant personnel and ensure they are easily accessible.
- **Training:** Train staff on the documented procedures and ensure they understand their roles in the management system.

By thoroughly documenting these components, a molecular laboratory can establish a robust management system that meets the requirements of ISO 15189:2022 and ensures the quality and reliability of its services.

8.2.5 Personnel access

Controlling personnel access to management system documentation is crucial to ensure the integrity, confidentiality, and proper use of the documents. Here's how to manage personnel access for a molecular laboratory's management system documentation in compliance with ISO 15189:2022:

1. Access Levels

- **Full Access:** Granted to personnel responsible for creating, reviewing, approving, and maintaining documentation (e.g.,, Laboratory Director).
- **Read-Only Access:** Provided to staff who need to reference documents to perform their tasks but do not have authority to edit (e.g., laboratory technicians, administrative staff).
- **Restricted Access:** Limited to specific documents or sections for personnel who only require access to certain information (e.g., external auditors, temporary staff).

2. Secure Document Storage and Access

- **Electronic Documents:** Use a secure document management system (DMS) with user authentication (e.g., login credentials) to control access.
    - Implement features like role-based permissions, audit trails, and document version control.
- **Physical Documents:** Store hard copies in secure locations (e.g., locked cabinets) with controlled access.
    - Keep a log of personnel who access physical documents.

3. Training and Awareness

- **Access Policies:** Train staff on the laboratory's document access policies, emphasizing the importance of protecting sensitive information.
- **Confidentiality Agreements:** Have personnel sign confidentiality agreements, especially those with access to sensitive or proprietary information.

5. Monitoring and Auditing Access

- **Access Logs:** Maintain logs of who accessed documents, what actions were taken, and when.
- **Regular Audits:** Conduct regular audits of access logs to ensure compliance with access control policies and identify any unauthorized access.

6. Managing External Access

- **Controlled Access for External Parties:** Provide limited and controlled access to external auditors, regulators, or consultants, as necessary.
- **Temporary Access:** Grant temporary access for specific purposes with defined start and end dates.

7. Handling Obsolete and Archived Documents

- **Restrict Access:** Limit access to obsolete and archived documents to authorized personnel.
- **Proper Labelling:** Clearly label and segregate obsolete documents to prevent accidental use.

8. Incident Response

- **Reporting:** Establish a process for reporting and responding to unauthorized access or security breaches.
- **Corrective Actions:** Implement corrective actions to address and prevent future incidents.

By implementing these access control measures, a molecular laboratory can ensure that only authorized personnel can access management system documentation, maintaining the integrity and confidentiality of its processes and data.9. EQAS Participation Records:

- **EQAS Enrollment**: Documentation of laboratory enrollment in external quality assessment programs, including the specific schemes or organizations involved.
- **EQAS Reports**: Records of results and performance feedback received from EQAS providers, including any corrective actions taken.
- **Action Plans**: Documented corrective or preventive actions taken in response to EQAS findings to address any identified deficiencies or areas for improvement.

10. Internal Audit Documentation:

- **Audit Schedule**: A documented internal audit schedule outlining the frequency and scope of audits, ensuring all processes and areas are reviewed as required by ISO 15189:2022.
- **Audit Reports**: Detailed reports from each internal audit, including findings, non-conformities identified, and recommendations for improvement.
- **Corrective and Preventive Actions (CAPA)**: Documentation of actions taken in response to internal audit findings, including timelines for implementation and verification of effectiveness.

- **Audit Records**: Evidence of staff involvement in audits, including qualifications, training records, and any audit findings discussed during management review meetings.

11. Document Control

- **Procedure:**
  - Documents are created, reviewed, approved, and distributed as per the document control SOP.
  - All documents are uniquely identified, version-controlled, and reviewed annually.
- **Storage and Accessibility:**
  - Documents are stored electronically and physically, ensuring easy access for authorized personnel.

12. Risk Management

- **Risk Identification:**
  - Conduct regular risk assessments for processes, equipment, and personnel.
- **Risk Mitigation:**
  - Implement control measures and monitor their effectiveness.
  - Document risk management activities and outcomes.

13. Competence and Training

- **Competence Requirements:**
  - Define required competencies for each role.
  - Maintain personnel files with qualifications, training records, and competency assessments.
- **Training Program:**
  - Conduct initial and ongoing training for all staff.
  - Assess effectiveness of training through periodic competency evaluations.

14. Process Control

- **Standard Operating Procedures (SOPs):**
  - Develop and maintain SOPs for all critical laboratory processes.
  - Ensure adherence through regular audits and staff training.
- **Monitoring and Measurement:**

- Use quality control samples and proficiency testing to monitor process performance.

15. Customer Feedback and Complaints

- **Feedback Mechanism:**
  - Implement a system for collecting and analyzing customer feedback.
  - Address complaints promptly and document corrective actions.

16. Internal Audits

- **Audit Schedule:**
  - Conduct internal audits at least twice a year.
- **Audit Process:**
  - Plan, execute, and document audits following the internal audit SOP.
  - Report findings and track corrective actions.

17. Management Review

- Management reviews are conducted at planned intervals to evaluate the performance of the QMS.
- Inputs include audit results, customer feedback, non-conformities, and improvement opportunities.
- Outputs include decisions on resource needs, improvements, and updates to the quality policy and objectives.

18. Non-Conformance and Corrective Actions

- **Identification:**
  - Document all non-conformances using a non-conformance report form.
- **Corrective Actions:**
  - Investigate root causes, implement corrective actions, and verify their effectiveness.

19. Continuous Improvement

- **Improvement Initiatives:**
  - Encourage staff to suggest improvements.
  - Document and track improvement projects.

20. Confidentiality and Data Protection

- **Confidentiality Measures:**
  - Implement policies to ensure the confidentiality of patient information.
- **Data Security:**
  - Secure data storage, access controls, and regular data backup.

21. Documentation

- **Quality Manual:**
  - Includes quality policy, objectives, organizational structure, and procedures.
- **Records:**
  - Maintain records of training, audits, non-conformances, and management reviews.
  - Ensure records are complete, accurate, and securely stored.

22. Review and Update of Procedures

- **Review Cycle:**
  - Review all procedures annually or as needed.
- **Change Control:**
  - Document changes and communicate updates to all relevant staff.

Annexure

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/QMS/QM	Quality Manual	Document	Laboratory Director	Laboratory office	Continuous
ML/QMS/QSP	Quality system procedures	Document	Laboratory Director	Laboratory office	Continuous
ML/QMS/DOS & PSCM	Directory of services & Primary Sample Collection Manual	Document	Laboratory Director	Laboratory office	Continuous
ML/QMS/LSM	Laboratory Safety Manual	Document	Laboratory Director	Laboratory office	Continuous
ML/QMS/SOP	SOPs	Document	Laboratory Director	Laboratory office	Continuous

8.3 Control of management system documents (ML/QSP-28/CTRLMSD)

1. Purpose

The purpose of this procedure is to provide a uniform and consistent method for the control and handling of essential documents and data affecting test quality and quality management system. To control management system documents per ISO 15189:2022, ensure proper document creation, approval, version control, and secure distribution. Implement role-based access, regularly review and update documents, archive obsolete versions, monitor access, and conduct audits. This maintains document integrity, ensuring only current, approved documents are used and accessible to authorized personnel.

2. Responsibility:

It applies to all laboratory personnel, processes, and activities involved in the provision of molecular diagnostic services.

- Principal
- Laboratory Director
- Administrative Manager
- Section-In-Charge
- Consultants
- Clerk
- Technical staff

3. Scope:

Method for indexing, revision and control of documents so as to facilitate the easy and safe maintenance of laboratory documents.

1.Document Creation and Identification

- **Standardized Format:** Use a consistent format for all documents, including titles, headers, footers, and version control.
- **Unique Identification:** Assign a unique identifier to each document (e.g., document number, title, version number, issue date).
- **Version Control:** Clearly indicate the current version of each document to avoid confusion with outdated versions.

2. Approval and Review

- **Authorized Personnel:** Ensure that only authorized personnel (Laboratory Director) review and approve documents before they are released.

- **Document Approval:** Include signatures or electronic approvals to confirm that documents have been reviewed and approved.
- **Regular Review Schedule:** Documents will be reviewed once a year. If an amendment is requested, the documents will be reviewed and amended to ensure they remain current and relevant.
- **Change in Version:** If more than 10 amendments are done for a document, the version number will be changed for easier identification

3. Document Distribution

- **Controlled Distribution:** Distribute documents in a controlled manner, ensuring that all users have access to the latest versions.
- **Electronic Access:** Use a document management system (DMS) to provide electronic access to documents, with role-based permissions to control who can view or edit documents.
- **Physical Copies:** If physical copies are used, ensure they are distributed only to authorized locations and personnel, with clear markings indicating the version and approval status.

4. Access Control

- **Role-Based Access:** Define who can access, modify, and approve documents based on their roles and responsibilities.
- **Secure Storage:** Store documents securely, whether electronically (with password protection and access logs) or physically (in locked cabinets).
- **Confidentiality:** Ensure that access to sensitive or proprietary information is restricted to authorized personnel only.

5. Obsolete Documents

- **Obsolete Marking:** Clearly mark obsolete documents to prevent their accidental use (e.g., “Superseded” or “Obsolete”).
- **Segregation and Archiving:** Remove obsolete documents from active use and store them separately, either physically or electronically, for reference or audit purposes as needed.
- **Retention Policy:** A single hardcopy of obsolete documents is retained and extra hardcopies will be shredded by the authorised shredder (Bio-Medical Engineer) & softcopies will be deleted from hard disk, drives, cloud by the IT department of the institute. Retained hardcopy of obsolete documents will be stored separately in a large sealed envelope in the laboratory office for 2 years or until the next cycle.

6. Document Change Control

- **Change Requests:** Implement a formal process for requesting, reviewing, and approving changes to documents.
- **Version Updates:** Update version numbers and revision histories to reflect changes made, including the date of revision and reasons for the change.
- **Communication of Changes:** document changes will be communicate to all relevant personnel to ensure they are aware of and understand the updates.

7. Monitoring and Auditing

- **Access Logs:** Maintain logs of who accessed or modified documents, including time and actions taken.
- **Internal Audits:** Conduct regular internal audits to verify that document control processes are being followed and that only current, approved documents are in use.
- **Non-Conformity Handling:** Address any non-conformities identified during audits by implementing corrective actions.

8. Document Retention and Disposal

- **Retention Periods:** Define how long documents need to be retained, based on regulatory requirements and laboratory policies as per NABL 112 which is documented in the control of records (master log of documents).
- **Secure Disposal:** Dispose of documents securely (e.g., shredding, secure deletion from the computer, drives, and clouds) when they are no longer required, ensuring sensitive information is not compromised at the end of retention period.

9. Integration with Quality Management System (QMS)

- **Consistent Practices:** Laboratory ensure document control practices are consistent across all aspects of the QMS.
- **Continuous Improvement:** Laboratory uses feedback from audits, reviews, and staff to continuously improve document control processes.

8.4 Controls of Records (ML/QSP-29/CONREC)

1.Purpose

The purpose of this procedure is to provide a uniform and consistent method for the identification, collection, indexing, filing, access, storage, maintenance, amendment, retention and safe disposal of quality and technical records.

2 Responsibility

It applies to all laboratory personnel, processes, and activities involved in the provision of molecular diagnostic services.

- Principal
- Laboratory Director
- Administrative Manager
- Section-In-Charge
- Consultants
- Clerk
- Technical staff

3.Scope

1. Creation of records
2. Amendment of records
3. Retention of records
4. disposal of records.

Procedure

Establishing Record

- The records are established in discussion with the Laboratory Director, Section In-Chair, Consultants, Technical staff, Administrative Manager and Section in charge.
- The established records are identified in the following manner.
    - Forms – ML/F/Number
    - Registers – ML/REG/QSP Number/sub number
    - Files – ML/FL/QSP number/sub number
    - Standard Operating Procedures – ML/QMS/SOP
    - Quality System Procedures - ML/QSP-number/name in abbreviation.

- Manuals – ML/QMS/Name of the Document

- The records will be reviewed annually if changes required as per the monitoring body or as per national policy
- The records will be created during day to day lab activities.

Maintenance of records

The records will be maintained as mentioned in the list (Master log of document). The list will contain Name of the record, unique identifier number, type of record, responsibility, location and retention period. Records will be stored in designated room (Laboratory office)

Electronic records are protected by using

- password and kept on 'read only' mode
- access control
- Backup-responsibility

Storage

- Storage of records is done in a manner to prevent loss, damage or deterioration of any kind and also for easy retrieval.
- All records are stored in secured predetermined locations as per Document Log for easy access.
- The TRF/ SRF will be bundled daily and kept in a safe box, a separate box is kept for each month and stored in the Record Storage Room.
- All records are stored for a period of one year in the respective location mentioned in Document log.
- Records stored for more than 6 months are inspected for deterioration by the concerned user and suitable action is taken whenever required.

Access

- Access to records is given only after the approval of the Laboratory Director.
- Copies of records are made only with the approval of the Laboratory Director.
- Departmental SOPs and concerned QSPs will be made available in hard copy in respective sections for immediate reference.
- Quality Manual and QSPs are kept safely with Laboratory Director and Section In-Charge.
- DOS and Primary Sample collection manual will be distributed to the hospital OPDs /Wards/ sample collection centre.

- Copies of all empty forms will be easily available at the laboratory office for immediate use.

Retention

- All records are retained till the end of the retention period specified in Master log.
- The retention period and location of each record is indicated in the document manual.
- The reported results are retained as long as they are medically relevant or as required by the regulations.
- The soft copies of all the records will be maintained in the hard disk drive in a secure offsite location with Lab Director. This will take care of damage to such records by natural disasters / Fire Outbreak.
- A single hardcopy of obsolete documents is retained and extra hardcopies will be shredded by the authorised shredder (Bio-Medical Engineer) & softcopies will be deleted from hard disk, drives, cloud by the IT department of the institute.
- Retained hardcopy of obsolete documents are stored separately in a large sealed envelope in the laboratory office for 2 years or until the next cycle.

Disposal

At the end of the retention period, records will be shredded followed by the authorized shredder (Bio-Medical Engineer) and soft copies will deleted hard disk, drives, cloud by the IT department of the institute.

References: Clause No: 4.13 of ISO 15189:2022

Annexures

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/QMS/ DOS & PSCM	Directory of Services	Document	Laboratory Director	Laboratory office	Continuous
ML/REG/10	Errors at registration	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/11	Sample Rejection Register	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/13	COVID Register	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/14	H1N1 Register	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/13	Movement of specimen and Report for COVID	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/14	Movement of specimen and Report for H1N1	Register	Section-In-Charge	Laboratory office	Continuous
ML/F/27	H1N1 test request form	Form	Section-In-Charge	Laboratory office	10 Year
ML/F/28	COVID-SRF	Form	Section-In-Charge	Laboratory office	10 Year
ML/FL/26a	Kit Inserts	File	Section-In-Charge	Laboratory office	5 year
ML/FL/26b	EQAS and ILQA Records	File	Section-In-Charge	Laboratory office	5 year
ML/REG/17	Lot to lot Verification records and validation Records	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/4	Internal Quality Control Records-COVID	Register	Section-In-Charge	Laboratory office	Continuous

ML/REG/5	Internal Quality Control Records-H1N1	Register	Section-In-Charge	Laboratory office	Continuous
ML/QMS/SOP	SOP file	File	Section-In-Charge	Laboratory office	Continuous
ML/REG/18	Sample retention register-COVID	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/24	Sample retention register-H1N1	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/19	Sample Discard Register-COVID	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/25	Sample Discard Register-H1N1	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/13	TAT Records-COVID	Register	Section-In-Charge	Laboratory office	Continuous
ML/REG/14	TAT Records-H1N1	Register	Section-In-Charge	Laboratory office	Continuous

8.5 Action to address risk and opportunities for improvement (ML/QSP-30/ACTROI))

1.Purpose:

The laboratory will identify risks and opportunities for improvement associated with the laboratory activities to: prevent or reduce undesired impacts and potential failures in the laboratory activities; achieve improvement, by acting on opportunities; assure that the management system achieves its intended results; mitigate risks to patient care; help achieve the purpose and objectives of the laboratory.

The laboratory will prioritize and act on identified risks. Actions taken to address risks will be proportional to the potential impact on laboratory examination results, as well as patient and personnel safety. The laboratory will record decisions made and actions taken on risks and opportunities. The laboratory will integrate and implement actions on identified risks and improvement opportunities into its management system and evaluate their effectiveness.

Options to address risks will include identifying and avoiding threats, eliminating a risk source, reducing the likelihood or consequences of a risk, transferring a risk, taking a risk in order to pursue an opportunity for improvement, or accepting risk by informed decision.

2.Responsibility:

- Laboratory Director
- Section-In-Charge
- Consultants
- Technicians

3. Scope

- Identification of risks and opportunities for improvement
- Acting on risks and opportunities for improvement

Procedure:

The risk and opportunities is detailed in annexure 1

Annexures

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/REG/3	Non Conformance Records-IQC	Register	Laboratory Director	Laboratory office	Continuous
ML/F/11	Incident Report Form	Form	Laboratory Director	Laboratory office	5 Year
ML/FL/11	Incident / Accident Records	File	Laboratory Director	Laboratory office	5 Year
ML/FL/16	Risk Management Records	File	Laboratory Director	Laboratory office	Continuous
ML/F/23	Risk Management form	Form	Laboratory Director	Laboratory office	5 Year

8.6 Improvement (ML/QSP-31/IMPV)

1. Purpose

This is to achieve continuous improvement of customer satisfaction through on going Quality surveillance, in order to improve the services and reduce errors.

This procedure explains the activities associated with the receipt, handling, and resolution of suggestions and feedback received from the customers, clinicians, patients, laboratory staff & other parties, who use the services of the Molecular laboratory.

2.Responsibility

It applies to all laboratory personnel, processes, and activities involved in the provision of molecular diagnostic services.

- Principal
- Laboratory Director
- Administrative Manager
- Section-In-Charge
- Consultants
- Clerk
- Technical staff

3.Scope

- Improve the services of the laboratory, Decreasing the errors by active future planning
- Handling suggestions and feedback by clinicians.
- Handling suggestions and feedback by patients.
- Handling suggestions and feedback to laboratory personnel

Procedures

- This procedure outlines a systematic approach to monitoring and improving key operational processes, prioritizing actions based on risk assessments and identified opportunities.
- Any current problem in the organizational processes performances are identified from the existing/ available data and records and will be resolved as part of corrective action and preventive action.
- Laboratory management reviews and compares the actual performance of laboratory activities, and corrective and preventive actions with its intentions as stated in quality policy and quality objectives.

- Improvement activities are directed at areas of highest priority based on risk assessment.

Selecting an improvement processes:

- A major decision in implementing an on-going quality surveillance program starts with selecting an appropriate improvement process.
- Laboratory management ensures the laboratory has a continual improvement plan covering outcomes of patient care.
- The following quality indicators have been developed by the Molecular Laboratory to monitor the continual quality improvement (CQI)

Pre-analytical indicators

- Specimen inadequacy,
- Illegible information on specimen container,
- Color change in the VTM
- Duplicate SRF generated in ICMR portal
- Specimen container information error (Patient information not matching with the SRF details)
- Missing test request form / specimen
- Improper packing

Analytical indicators

- Proficiency testing performance
- Non-conformity with Quality control
- Suggestions given in MRM and departmental meeting
- Regular training and retraining of personnel.

Post-analytical indicators

- Turnaround time
- Revised reports due to transcription error
- Duplicate reports generated as a result of reports not reaching the clinicians.

To implement any of these processes the laboratory:

- Collects appropriate data for prioritized objectives and indicators.
- Evaluates the data.
- Determines appropriate action.

- The laboratory staff will be communicated plans and goals required for quality improvement purposes. The effectiveness of the actions taken will be reviewed in the MRM and recorded.

Reference: Clause No 8.6.1 of ISO 15189:2022

8.6.2 Laboratory patients, users, and personnel feedback

Procedure

- Complainants are encouraged to seek informal resolution of their grievances or concerns. This informal procedure is intended to encourage communication between the parties involved, either directly or through an intermediary, in order to facilitate a mutual understanding of what may be different perspectives regarding the complaint. If the informal process does not result in the resolution of the complaint to the satisfaction of the complainant, the complainant may utilize the formal complaint procedure. However, all issues are discussed and documented by the Section In-charge.
- In case of Patients reporting to the Laboratory reception a Suggestion/Complaint Box is kept in which they can write their suggestion/complaint. In addition to that, the Patient Feedback form is also available at the same place.
- Feedback on the quality of test results and other services offered by the laboratory is also obtained from the Physicians through the Physicians Feedback Form once a year.
- All Complaints, Suggestions, and feedback received are reviewed, and critically analyzed by the Section In charge and will be informed to the Laboratory Director.
- Where complaints regarding any specific nonconforming service/test results are received from Physicians, the same is brought to the notice of the Section In charge.
- The Section In charge in consultation with the laboratory director analyses and decides whether any improvements are needed on the reported nonconforming service /test result.
- Based on the criticality, the complaints are prioritized and root cause is identified and suitable corrective & preventive action is taken.
- Personnel and technicians are informed of the customer's complaint and the proposed / planned corrective & preventive action whenever necessary.
- The concerned technician(s) / other personnel who are responsible for the nonconforming service / test result are identified by Section In charge and necessary training is planned and provided if necessary.
- The Corrective and Preventive action decided is implemented after providing adequate resources if needed and after ensuring the effective implementation of the improvement activities. Section in charge updates the details in the Complaint/Suggestion File (ML/FL/9).

- The Complaints / Suggestions received from the patients, attendants/hospitals, and feedback received from physicians, and the details of corrective and preventive actions taken for complaints/suggestions are submitted in the laboratory Management Review Meeting and discussed.
- Also the effectiveness of the corrective action taken against complaints is reviewed in the next internal audit/ Management Review Meeting.
- The lab Staff are encouraged to give feedback on the Laboratory office. Lab Staff feedback forms are freely available at the reception area of the laboratory office.
- Feedback given by the user/staff will be discussed and evaluated in the MRM. The possible usefulness and its impact on quality will be considered and the suggestions will be implemented only after finding it to fit in the system.

Reference: Clause No 8.6.2 of ISO 15189:2022

Annexure

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/FL/13	Continual improvement Record	File	Section-In-Charge	Laboratory office	5 Year
ML/REG/6	Staff training	Register	Section-In-Charge	Laboratory office	Continuous
ML/F/14	Staff Performance Evaluation Form	Form	Laboratory Director	Laboratory office	5 Year
ML/F/15	Competency Evaluation of Technical staff	Form	Laboratory Director	Laboratory office	5 Year
ML/FL/19b	Personnel Records	File	Administrative Manager	Laboratory office	Continuous
ML/F/24	Induction training form	Form	Laboratory Director	Laboratory office	Continuous

8.7 Nonconformities and Corrective Actions (ML/QSP-32/NCCA)

Purpose:

The purpose of this procedure is to define the method of identifying, reporting and handling all non – conforming activities related to QMS, Pre examination and post examination processes as per requirements of the users of the molecular Laboratory.

Responsibility:

It applies to all laboratory personnel, processes, and activities involved in the provision of molecular diagnostic services.

- Principal
- Laboratory Director
- Administrative Manager
- Section-In-Charge
- Consultants
- Clerk
- Technical staff

Scope:

- Identification & control of nonconformities in QMS including pre-examination, examination, and post examination.
- Corrective action effectiveness
- Records of non conformities and corrective action

Procedure:

- The identification of non-conformity may be by any laboratory staff/ Patient/ Physician, who brings it to the notice of theLaboratory Director by the Section-in-charge .
- The Section-in-charge evaluates the criticality of the nonconformance observed in the laboratory during the testing process as well as Quality Management Systems in the laboratory.
- If non-conformances are found, necessary action is initiated by the section in charge
- Immediate actions are initiated which may include not performing/ or withholding the test, or withholding/ recalling of released reports if necessary.
- In the Molecular laboratory, the Non-conformances are identified in the following areas of both the Quality system and technical operations:

- Quality Control
- Instrument Calibration
- Customer Complaints
- Checking of Consumable materials
- Staff Observation / Supervision
- Test report checking
- Meeting Customer requirements

Extent of non-conformity and its implication to clinical settling is evaluated. Root cause analysis is done to find out the actual cause of the non-conformance, and suitable corrective and preventive actions are initiated and the details are recorded.

- In case of deviation from SOP the section in-charge and consultant takes necessary corrective action according to the NC.
- When non-conformance is detected after release of the test result, the physician is informed and a fresh sample is requested if necessary. A new report is issued after re-testing. These reports are filed in revised reports file (ML/FL/30)
- The Laboratory director is responsible for authorizing the resumption of normal work after initiating appropriate corrective action and finding satisfactory results.
- The non-conformances observed in the process of testing (Internal quality controls) and their related areas are entered in the NC register-IQC (ML/REG/10). Non-conformances observed in quality control are analyzed for root cause and Corrective action is taken. Each episode of nonconformity is documented and recorded, with these records being reviewed in the management review meeting to detect trends and initiate corrective action.
- The raised NCs, Corrective Action, and Preventive actions initiated will be reviewed once in a month for the trends.
- When there is doubt or possibility of recurrence of nonconformities, compliance with operating procedures is identified, documented and the cause is eliminated. Corrective action is determined and documented.

Reference: Clause No 8.7.1 of ISO 15189:2022.

8.7.2 Corrective action effectiveness

Procedure

Non-conformities will be reviewed by the section in charge or lab director. Root cause analysis will be done to determine the cause/s of non-conformities.

1. Sample Collection and Handling

- **Potential Non-Conformities:**
  - Improper sample collection.
  - Inadequate labeling or documentation.
  - Contamination or degradation of samples.
- **Mitigation Strategies:**
  - **Standardized Protocols**: Implement and strictly adhere to standard operating procedures (SOPs) for sample collection and handling.
  - **Training**: Provide comprehensive training for staff on proper sample collection, labeling, and handling.
  - **Quality Control**: Use quality control measures like barcoding and electronic tracking systems to ensure accurate sample identification and handling.

2. Reagent Preparation and Storage

- **Potential Non-Conformities:**
  - Use of expired or contaminated reagents.
  - Incorrect storage conditions affecting reagent integrity.
- **Mitigation Strategies:**
  - **Inventory Management**: Maintain a robust inventory system with regular checks to prevent the use of expired reagents.
  - **Storage Protocols**: Ensure that all reagents are stored under appropriate conditions (e.g., temperature-controlled environments).
  - **Quality Assurance**: Perform routine checks and validations of reagent quality before use.

3. Equipment and Instrumentation

- **Potential Non-Conformities:**
  - Equipment malfunction or calibration errors.
  - Inadequate maintenance or incorrect use of instruments.
- **Mitigation Strategies:**
  - **Regular Maintenance**: Implement a scheduled maintenance and calibration program for all equipment.

- **User Training**: Provide detailed training and certification for staff on the correct use of laboratory instruments.
- **Performance Monitoring**: Use control samples and routine equipment performance checks to detect issues early.

4. Contamination Control

- **Potential Non-Conformities:**
  - Cross-contamination between samples.
  - Environmental contamination affecting test results.
- **Mitigation Strategies:**
  - **Dedicated Workspaces**: Designate separate areas for sample preparation, amplification, and analysis to prevent cross-contamination.
  - **Cleanroom Practices**: Implement strict cleanroom protocols, including the use of personal protective equipment (PPE) and regular cleaning schedules.
  - **Environmental Monitoring**: Conduct routine environmental monitoring for contamination and maintain logs for corrective actions.

5. Testing and Analysis Procedures

- **Potential Non-Conformities:**
  - Deviations from SOPs during testing.
  - Incorrect interpretation or reporting of results.
- **Mitigation Strategies:**
  - **Standardized Testing Protocols**: Develop and enforce detailed SOPs for all testing procedures.
  - **Proficiency Testing**: Participate in external proficiency testing programs to ensure consistency and accuracy.
  - **Result Verification**: Implement a double-check system where another qualified staff member verifies critical results before reporting.

6. Data Management

- **Potential Non-Conformities:**
  - Data entry errors or loss of critical data.
  - Inadequate data security or breaches.

- **Mitigation Strategies:**
  - **Electronic Data Management Systems**: Use secure, validated laboratory information management systems (LIMS) for data entry and storage.
  - **Regular Audits**: Conduct regular data audits to ensure accuracy and integrity.
  - **Data Security Measures**: Implement strict data security protocols, including access controls and regular backups.

7. Quality Control and Assurance

- **Potential Non-Conformities:**
  - Failure to detect errors through quality control checks.
  - Inadequate response to quality control failures.
- **Mitigation Strategies:**
  - **Routine QC Checks**: Regularly perform quality control checks using known controls to validate test accuracy.
  - **Documented Response Plans**: Develop and document response plans for handling QC failures, including root cause analysis and corrective actions.
  - **Continuous Improvement**: Use QC data to identify trends and areas for improvement, updating procedures as needed.

8. Personnel Competence

- **Potential Non-Conformities:**
  - Insufficient training or lack of proficiency in new techniques.
  - Non-adherence to laboratory protocols.
- **Mitigation Strategies:**
  - **Training Programs**: Implement ongoing training and competency assessments for all staff.
  - **Competency Testing**: Regularly test staff proficiency in critical procedures and provide feedback.
  - **Clear Communication**: Foster a culture of clear communication and continuous learning to encourage adherence to protocols.

9. Faulty Reporting:

- **Data Entry Errors**: Typographical mistakes during manual data entry.
- **Misinterpretation of Results**: Incorrect interpretation of molecular assay results.

- **Inaccurate Data Transfer**: Errors in transferring results from instruments to reports.
- **Lack of Verification**: Insufficient review or verification of reports before release.
- **Software/System Errors**: Faults in laboratory information management systems (LIMS) leading to incorrect reporting.
- **Communication Breakdowns**: Miscommunication between laboratory personnel and reporting staff.

Mitigation Strategies:

1. Data Entry and Reporting Protocols

- **Standardized Templates**: Use standardized reporting templates to minimize manual data entry errors.
- **Electronic Data Transfer**: Implement automated data transfer from instruments to LIMS to reduce manual transcription errors.
- **Pre-defined Reporting Rules**: Establish clear rules for interpreting and reporting results to ensure consistency.

By proactively addressing these areas with effective mitigation strategies, molecular laboratories can reduce the occurrence of non-conformities and ensure the reliability and accuracy of their testing processes.

8.7.3 Records of nonconformities and corrective actions

Components of Non-Conformity Records:

- **Identification of Non-Conformity**
  - **Unique Identifier**: Assign a unique identification number or code to each non-conformity for tracking.
  - **Date and Time**: Record the date and time when the non-conformity was identified.
  - **Source**: Document how the non-conformity was discovered (e.g., internal audit, external audit, staff observation, customer complaint).
- **Description of Non-Conformity**
  - **Detailed Description**: Provide a clear and detailed description of the non-conformity, including the specific process, equipment, or area affected.
  - **Impact Assessment**: Describe the potential or actual impact of the non-conformity on test results, patient care, or laboratory operations.

- **Root Cause Analysis**
  - **Investigation Process**: Record the steps taken to investigate the root cause of the non-conformity.
  - **Findings**: Document the findings of the root cause analysis, including contributing factors.
- **Corrective Action Plan**
  - **Actions to be Taken**: Outline the specific corrective actions planned to address the root cause.
  - **Responsibilities**: Assign responsibility for each corrective action to specific individuals or teams.
  - **Timeline**: Set deadlines for the implementation of each corrective action.
- **Implementation of Corrective Actions**
  - **Action Taken**: Document the actual actions taken to correct the non-conformity.
  - **Completion Date**: Record the date when each corrective action was completed.
- **Effectiveness Review**
  - **Monitoring and Evaluation**: Document the process of monitoring the effectiveness of the corrective actions.
  - **Outcomes**: Record the outcomes of the effectiveness review, including any evidence that the non-conformity has been resolved and prevented from recurring.
- **Follow-Up and Continuous Improvement**
  - **Further Actions**: Note any additional actions required if the corrective actions were found to be ineffective.
  - **Lessons Learned**: Record any lessons learned from the incident and how they will be applied to prevent similar issues in the future.

Best Practices for Record Management:

- **Centralized Record Keeping**
  - Use a centralized system, such as a Laboratory Information Management System (LIMS), to store and manage all non-conformity and corrective action records.
  - Ensure that the system allows for easy retrieval, updating, and reporting of records.
- **Regular Review and Updates**
  - Regularly review records to ensure they are up-to-date and complete.

- Update records promptly as new information becomes available or as corrective actions progress.

- **Confidentiality and Security**
  - Ensure that records are kept confidential and secure, with access limited to authorized personnel.
  - Implement data protection measures to prevent unauthorized access or loss of records.
- **Audit and Compliance**
  - Ensure that records are available for internal and external audits.
  - Maintain records in compliance with regulatory and accreditation requirements, such as ISO 15189:2022.
- **Retention Period**
  - Establish and adhere to a retention policy for non-conformity and corrective action records, as required by regulatory standards and laboratory policies.

By systematically recording and managing non-conformities and corrective actions, molecular laboratories can enhance their quality management systems, improve operational efficiency, and ensure compliance with international standards.

Reference: Clause: 8.7.3 of ISO 15189:2022

Annexures

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/REG/3	Non Conformance Records-IQC	Register	Laboratory Director	Laboratory office	Continuous
ML/F/11	Incident Report Form	Form	Laboratory Director	Laboratory office	5 Year
ML/FL/11	Incident / Accident Records	File	Laboratory Director	Laboratory office	5 Year

8.8 Evaluations (ML/QSP-33/EVAL)

1.Purpose

The laboratory will conduct evaluations at planned intervals to demonstrate that the management, support, and pre-examination, examination, and post-examination processes meet the needs and requirements of patients and laboratory users, and to ensure conformity to the requirements of this document.

2.Responsibility

It applies to all laboratory personnel, processes, and activities involved in the provision of molecular diagnostic services.

- Principal
- Laboratory Director
- Administrative Manager
- Section-In-Charge
- Consultants
- Clerk
- Technical staff

3.Scope

- Quality indicators
- Internal audit

Best Practices for Evaluations

- **Regular Reviews**: Schedule regular evaluations of non-conformities, corrective actions, and preventive measures to ensure ongoing effectiveness.
- **Data-Driven Approach**: Use data and evidence to support evaluations, ensuring decisions are based on measurable outcomes.
- **Stakeholder Involvement**: Involve relevant stakeholders, including laboratory staff and management, in the evaluation process for broader insights.
- **Transparent Reporting**: Document and report evaluation findings transparently to foster accountability and continuous improvement.

By conducting thorough evaluations, molecular laboratories can ensure that corrective and preventive actions are effective, maintain high standards of quality, and comply with ISO 15189:2022.

8.8.2 Quality Indicators

Pre-analytical indicators

Unacceptable specimen

- Specimen inadequacy,
- Illegible information on specimen container,
- Color change in the VTM
- Specimen container information error (Patient information not matching with the SRF details)
- Missing test request form / specimen
- Improper packing

Registration error

- Duplicate SRF generated in ICMR portal

Analytical indicators

- Proficiency testing performance
- Non-conformity with Quality control

Post-analytical indicators

- Turnaround time
- Revised reports due to transcription error

Quality Indicators calculation with formula

Sl No	Quality Indicator	Formula for calculation	Benchmark
1	Number of unacceptable samples	Total Number of Unacceptable Samples X100 Total Number of Samples Received	<2%
2	Registration error	Number of errors at registration X 100 Total Number of registration	<2%
3	EQAS/PT performance	Number of Unacceptable performances in EQAS X 100 Number of performances in EQAS	<20%
4	Turnaround time (TAT)	Number of reports delivered outside the TAT X 100 Total Number of reports	<2%
6	Revised reports	Number of Revised reports X 100 Total Number of reports	<2%
7	Non conformity with Quality control	Number of NC with QC X 100 Total Number of Tests	<2%

1. Procedure:

The quality indicators are monitored on day to day activity and trend is analysed monthly and if necessary corrective and preventive actions will be initiated.

2. References: Clause No. 8.8.2 of ISO 15189:2022

8.8.3 Internal Audit

- **Evaluation and audit:**
  - Demonstrate that the pre-examination, examination, and post-examination and supporting process are conducted so that it meets the requirements of users.
- **Internal Audit:**
  - The internal audit addresses the requirements of the ISO 15189:2022 quality management system. Both managerial and technical operations are audited **once in a year**. Internal audit emphasizes areas critically important to quality & patient care.
  - Audits are planned, organized and facilitated by Section In-charge. The procedures for internal audits are defined, documented and methodology for documentation are defined. When deficiencies or opportunities for improvement are noted, the laboratory undertakes appropriate corrective or preventive actions, which are documented and carried out within an agreed-upon time.
- **Appointment of Auditors:**
  - Laboratory Director identifies the Internal Auditors and the list of the same is maintained by the Section-In-Charge.
  - Internal auditors are trained internally or externally by trained auditors as per ISO 15189:2022, for auditing skills before being appointed as internal auditors.
  - The Auditor will be unrelated to the area being audited.
  - The Auditor submits the audit report to the Laboratory Director.
- **Audit Plan:**
  - The Section in charge along with the Laboratory Director decides and prepares the audit plan and schedule as per the clauses of ISO 15189:2022
  - The internal audit is conducted once a year.
  - The audit plan is circulated among the auditor and auditee staff one week before schedule.
  - The audit scope, frequency, and method of audit are defined.
  - The audit considers technical and management areas to be audited and the results of previous audits.
- **Audit:**
  - During the Audit, the Auditor seeks the following:
  - Determine whether documented procedures and instructions meet the requirements of the Standard.

- Verify whether procedures and instructions are being implemented.
- Examine the data and quality records to ensure compliance with specified procedures.
- Observe the task being carried out to see whether these confirm to specified norms and procedures.
- The Auditor assesses whether the service is meeting the customers' quality requirements wherever appropriate.
- All the instances of compliance and noncompliance are submitted in the Internal Audit report.

The Internal Quality Audit Report contains a summary of findings & observations recorded in the internal audit checklist and an overall conclusion on the effectiveness of the quality system.

- On completion of the audit, the findings are reviewed and clarifications are obtained.
- The audit report is signed by the auditor and auditee.
- A copy of the Audit Report is given to the Lab Director.
- The Lab Director will conduct a meeting to discuss the audit report. The Lab Director appraises the audit report highlighting Non-conformances and rectification measures to the responsible person within a time frame.
- Corrective actions are reviewed by the Section-In-charge. The Section-In-charge will ensure its implementation.
- After 15 days, the follow-up audit, to verify and record the implementation and effectiveness of agreed corrective actions, is conducted by the section in charge along with the auditor.
- Upon review, if the corrective action is found to be effectively implemented, the non-conformances are closed by the section in charge in consultation with the auditor.
- Any deviation from the Quality System procedures for performing tests is identified through the internal audit by the auditor or by the Section-In-charge and suitable actions are taken according to the seriousness of the deviation.
- The results of the internal audits are submitted to laboratory management for review and it forms part of the Management Review meeting.

Reference: Clause 8.8 of ISO 15189:2022

Annexure

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/FL/17	Quality Indicators	File	Section-In-Charge	Laboratory office	1 Year
ML/F/25	Quality Indicators-Monthly analysis	Form	Section-In-Charge	Laboratory office	1 Year
ML/FL/15a	Internal Audit Records	File	Section-In-Charge	Laboratory office	5 Year
ML/FL/15b	External Audit Records	File	Section-In-Charge	Laboratory office	5 Year
ML/F/12	Internal Audit Checklist	Form	Section-In-Charge	Laboratory office	5 year

8.9 Management reviews (ML/QSP-34/MRM)

1.Purpose:

The purpose of this procedure explain the conduct of a Management Review Meeting (MRM) to ensure the continuing suitability and effectiveness of the Quality Management System.

2.Responsibility

It applies to all laboratory personnel, processes, and activities involved in the provision of molecular diagnostic services.

- Principal
- Laboratory Director
- Administrative Manager
- Section-In-Charge
- Consultants
- Clerk
- Technical staff

3.Scope

- Over all functioning of the lab
- Purchase of equipment
- Lab staff management and policy
- Quality assurance
- Performance of suppliers
- Internal audit and accreditation

Procedure:

- Management reviews are carried out to ensure continuing suitability and effectiveness of the Quality Management System in meeting the quality policy and achieving the quality objectives
- The Management Reviews are conducted once in a year, if necessary could be held at shorter intervals.
- The Lab Director is responsible for planning and conducting Management Review Meetings at regular intervals to ensure suitability, adequacy and effectiveness and responsible to inform the venue, time and date of the agenda to all participants.

- The management review meeting is conducted under the chairmanship of the laboratory Director and is attended by the following:
    - Principal
    - Medical Director
    - Lab Director
    - Administrative Manager
    - Head of the Department
    - Biomedical engineer
    - EDP
    - Central supply department (Store)
    - If required invitees from other departments

The agenda for the Management Review Meeting is prepared by the Section In charge, after approval by the Laboratory Director, the agenda will be communicated.

The agenda will be prepared on the following aspects and will include evaluation of the following aspects:

8.9.2 Review Input

- status of actions from previous management reviews, internal and external changes to the management system, changes in the volume and type of laboratory activities and adequacy of resources;
- fulfilment of objectives and suitability of policies and procedures;
- outcomes of recent evaluations, process monitoring using quality indicators, internal audits, analysis of non-conformities, corrective actions, assessments by external bodies;
- patient, user and personnel feedback and complaints;
- quality assurance of result validity;
- effectiveness of any implemented improvements and actions taken to address risks and opportunities for improvement;
- performance of external providers;
- results of participation in inter-laboratory comparison programmes;
- evaluation of POCT activities;
- other relevant factors, such as monitoring activities and training.

8.9.3 Review output

The output from the management review will be a record of decisions and actions related to at least:

- the effectiveness of the management system and its processes;
- improvement of the laboratory activities related to the fulfilment of the requirements of this document;
- provision of required resources;
- improvement of services to patients and users;
- In the Management Review meeting the Management assesses opportunities for improvement and needs for reviewing Quality Policy and Quality Objectives.
- MRM analyses the input information for causes of nonconformities, trends and patterns that indicate process problems. MRM assesses opportunities for improvement and the need for change to the QMS, Quality policy, and Quality objectives.
- The Laboratory Director reviews the testing activities to ensure their continuing suitability with the customer requirements and to the changes and developments that take place in the industry.
- The output from the management review includes any decisions and actions related to
    - Improvement of the effectiveness of the Quality management system and its processes
    - Improvement of services related to users.
    - Resources needed
- The minutes of the MRM conducted are prepared and circulated to lab staff.
- The minutes of the meeting include the date of the meeting, attendance, points discussed, decisions taken, action plans drawn up, responsibility and implementation dates of the action plans, goals & objectives fixing, etc.
- The Section-In Charge coordinates and ensures that decisions taken in the meeting are implemented by the persons responsible within the agreed-upon time.
- The action taken and the conclusion of the MRM will be communicated to all the stakeholders.
- In case the implementation is not satisfactory, the Section-in-charge brings it to the attention of the Laboratory Director and acts accordingly.
- Resources needed, if any, for improvement are identified and necessary actions are taken to incorporate them.

Reference: Clause No. 8.9 of ISO 15189:2022

Annexures

Record no.	Record name	Record Type	Responsibility	Location	Retention Period
ML/FL/18	Management Review meeting records	File	Laboratory Director	Laboratory office	5 Years

DECLARATION FORM

I have read and understood the contents mentioned in the document. I agree to follow the instructions/procedures mentioned in the document. I also understand that it is a controlled document and will not make a copy/ share the document with anyone else.

Sl. No	Name	Signature

Risk management as per ISO 15189:2022

RISK MANAGEMENT AS PER ISO 15189:2022

Table of Contents

17	Examination	Non-availability of SOPs, standard manuals, and reference data at the place of workflow	240
18	Examination	Changes in validated examination methods	241
19	Examination	Measurement of uncertainty evaluation for qualitative data	242
20	Examination	IQC failure	243
21	Examination	Non-compliance of EQAS	244
22	Examination	Non-availability of IQC material	245
23	Examination	Non-availability of PT provider	246
24	Examination	Non-compliance with the results of comparability of examination processes	248
25	Post-examination	Delayed results	249
26	Post-examination	Insufficient review of results	250
27	Post-examination	Unauthorized release of reports	251
28	Post-examination	Missing information in the report	252
29a	Post-examination	Non availability of consultants	254
29b	Post-examination	Non availability of technicians	255
30	Post-examination	LIS break down	256
31	Post-examination	Inappropriate storage of processed samples	257
32	Post-examination	Data Privacy	258
33	Post-examination	Unauthorized access to LIS (Information management system)	259
34	Continuity and emergency preparedness planning	Natural Calamities	260
35	Continuity and emergency preparedness planning	Retention, retrieval, disposal, and archiving of records	261
36	Continuity and emergency preparedness planning	Civic Unrest	262

RISK MANAGEMENT AS PER ISO 15189:2022

Sr. No.	Process/Activity	Type of Errors / Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
1	**Impartiality**	**Being partial**	**1. Ethical Risks** • **Bias in Sample Handling & Testing** – Favoritism or preferential treatment may lead to errors in sample prioritization, potentially affecting patient outcomes. • **Unfair Resource Allocation** – Certain staff or departments may receive better resources, training, or funding, leading to inefficiencies. • **Workplace Inequality** – Favoritism in promotions, task assignments, or recognition can create a toxic work environment **2. Quality & Accuracy Risks** • **Inconsistent Test Results** – If certain samples or cases are prioritized unfairly, it can compromise the reliability and reproducibility of results. • **Manipulation of Data** – Bias in reporting results (e.g., altering findings to favor certain individuals or research) can undermine scientific integrity. • **Compromised Accreditation & Compliance** – Regulatory bodies (e.g., ISO 15189, CAP, CLIA) require strict adherence to standard operating procedures (SOPs). Any bias can lead to failed audits or penalties.	a) Maintain impartiality and integrity when handling patient samples, data, and related activities. Employees are expected to perform their duties without bias or favoritism. b) Laboratory management has a strict policy to protect employees from any commercial, financial, or external pressures that could affect the quality, accuracy, or reliability of laboratory work. Employees must report any undue influences to management immediately. c) A Quality Policy has been established to monitor and oversee employee conduct, ensuring strict adherence to laboratory guidelines, ethical responsibilities,	Wrong diagnoses and improper treatment, which can have serious consequences.	High	1. **Implement Transparent Policies** – Ensure clear SOPs for sample processing, hiring, and promotions. 2. **Promote Ethical Leadership** – Train staff on impartiality and ethical decision-making. 3. **Conduct Regular Audits** – Internal and external audits can detect favoritism in operations. 4. **Encourage Anonymous Feedback** – Provide a safe platform for employees to report bias or

			3. Legal & Regulatory Risks • **Violation of Laboratory Standards** – Partiality in decision-making can lead to non-compliance with regulations, resulting in fines, loss of certification, or even lab shutdown. • **Discrimination Claims** – If employees feel they are being unfairly treated, they may file workplace discrimination lawsuits. • **Patient Harm & Liability** – If biased management leads to errors in genetic testing, misdiagnosis, or delayed results, the lab could face medical malpractice claims. **4. Operational Risks** • **Low Staff Morale & Productivity** – If employees perceive management as unfair, motivation and performance may decline, affecting overall efficiency. • **Inconsistent Workflow** – Unequal task assignments may burden some employees while others receive preferential treatment, leading to delays in test processing.	and professional standards. d) All employees participate in an induction program. e) Employees receive ongoing professional training. f) Section In-Charges conduct regular interactions, reviews, and performance assessments to ensure employees uphold ethical standards and maintain a high level of integrity in their professional conduct.			unfair practices. **5. Ensure Fair Work Distribution** – Use standardized protocols to assign tasks and manage resources equally.

Sr. No.	Process/Activity	Type of Errors / Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
2	**Confidentiality**	**Leak of patient data**	**Privacy & Confidentiality Risks** a) Unauthorized disclosure of patient data can violate regulations b) Patients may lose trust in the healthcare system, making them reluctant to molecular testing **Ethical Risks** a) Genetic Discrimination b) **Psychological Impact:** Patients may experience stress or anxiety if sensitive information is disclosed without proper counseling **Legal & Financial Risks** Molecular labs could face lawsuits, fines, or loss of accreditation due to data breaches. **Cybersecurity Risks** Internal breaches, where unauthorized staff access patient records, can also lead to identity exposure. **Research & Ethical Misuse** a) Patient genetic data could be used in research without proper consent. b) Incorrect interpretations due to errors or miscommunication may lead to unnecessary medical procedures or stigmatization.	1. Respect for Patient Confidentiality a) Protection of Patient Information b) Controlled Access and Restrictions on Information Disclosure a) Confidentiality Agreement for Staff b) Secure Handling and Storage of Patient Records 2. Employee Training and Awareness 3. Compliance with Legal and Regulatory Standards	None	High	1. Implement strict **data anonymization and encryption** techniques. 2. Enforce **access control policies** for patient records. 3. Train staff on **ethical and legal responsibilities** related to patient data. 4. Use **secure databases and cybersecurity protocols** to protect genetic information. 5. Ensure proper **informed consent** before using patient data for research.

RISK MANAGEMENT AS PER ISO 15189:2022

Sr. No.	Process/Activity	Type of Errors / Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
3	**Requirements regarding patients**	Insufficient information provided to the patient/user	1. Misinterpretation of Test Results a) False Sense of Security b) Overreaction to Positive Results c) Confusion About Test Accuracy. Psychological & Emotional Distress a) Anxiety & Depression b) Family Strain Inappropriate Medical Decisions a) Unnecessary Medical Interventions b) Delayed or Missed Treatment Legal & Ethical Risks a) Violation of Informed Consent b) Non-Compliance with Regulatory Standards 2. Loss of Trust in Laboratory & Healthcare Providers a) Patient Distrust b) Reputation Damage 3. Financial burden and cost transparency issues	a. Facilitating Patient and User Input b. Transparent Communication About Testing c. Periodic Review of Laboratory Examinations d. Incident Reporting and Patient Disclosure e. Ethical Handling of Patients, Samples, and Human Remains	Impact on diagnosis and treatment	High	**Provide Clear & Comprehensive Reports** – Test results should include interpretation guidelines, limitations, and next steps. a) Ensure Counseling Availability – Offer pre- and post-test counseling to help patients understand the implications. b) Use Layman's Terms – Avoid excessive scientific jargon when communicating results to patients. **c) Obtain Fully Informed Consent**

			a) Unclear Cost Breakdown: Patients may b) be unaware of the full cost of molecular testing, including potential additional charges for confirmatory testing, genetic counseling, or insurance coverage limitations. c) Unexpected Expenses: If a patient is not informed about out-of-pocket costs, they may be unprepared for financial burdens. 4. Turnaround Time (TAT) Expectations a) Frustration Over Delays: If the lab does not clearly communicate the expected TAT (e.g., 24-48 hours for RT-PCR, 2-4 weeks for whole-genome sequencing), patients may become anxious about delays. b) Misaligned Medical Decisions: If a doctor or patient expects results sooner than the actual TAT, it may lead to delayed treatment plans or missed medical interventions.	f. Obtaining Informed Consent g. Safeguarding Patient Records and Samples h. Providing Patient Information to Healthcare Providers i. Ensuring Non-Discriminatory Patient Care			– Ensure patients understand what the test measures, possible outcomes, costs, and implications. a) **Train Healthcare Providers** – Educate physicians and lab personnel on how to effectively communicate test results. b) Be Transparent About Cost, Method, Specimen Collection & TAT – Provide detailed pre-test information to help patients and providers make informed decisions.

RISK MANAGEMENT AS PER ISO 15189:2022

Sr. No.	Process/Activity	Type of Errors / Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
4	Facility controls	Insufficient energy source	1. Sample Degradation & Loss of Integrity a) Unstable Freezer & Refrigerator Temperatures: Molecular labs require -80°C or -20°C freezers for proper storage of DNA, RNA, and reagents. Power failures can lead to sample degradation, making them unusable. b) Enzyme & Reagent Instability: Essential reagents like Taq polymerase, primers, and probes must be kept at specific temperatures. Any temperature fluctuations can affect reaction efficiency, leading to invalid results. 2. Equipment Malfunction & Damage a) PCR Errors: Instruments such as real-time PCR machines, thermal cyclers, require constant power. An energy disruption during a run can result in failed reactions or incomplete sequencing data. b) Increased Maintenance Costs c) Inaccurate or Incomplete Test Results 3. Compromised Biosafety & Hazardous Situations a) Failure of Biosafety Cabinets & Fume Hoods: Power loss can lead to loss of containment, increasing	The laboratory ensures a continuous power supply with backup systems, including online UPS for RT-PCR and generator backup for all other equipment. Electricians are available 24/7 to ensure uninterrupted operation.	Impacts on workflow and the outcome of the test	High	1. Install Backup Power Systems – Use uninterruptible power supplies (UPS), generators, or solar power to maintain continuous energy supply. 2. Use Temperature Monitoring Systems – Automated alarms for freezers, refrigerators, and incubators can prevent sample loss. 3. Stagger Equipment Use to Reduce Power Load – Overloading circuits can cause failures, so ensure power distribution is balanced. 4. Maintain Emergency Power Protocols – Have clear SOPs for power outages, including sample relocation plans and equipment shutdown procedures. 5. Invest in Energy-Efficient Equipment

			the risk of biological contamination or exposure to hazardous chemicals. b) Airflow Disruptions in Clean Rooms: Molecular labs require constant airflow control in clean areas. Power failures can increase contamination risk. 4. Delays in Patient Diagnosis & Treatment a) Prolonged Turnaround Times (TAT): Power failures can halt testing, leading to delays in releasing critical results for patients awaiting diagnosis. b) Impact on Emergency Testing: In cases of infectious disease outbreaks (e.g., COVID-19, TB, HIV), power loss can disrupt mass testing efforts, affecting public health responses.				– Newer lab instruments may have built-in power failure protections, reducing risks during outages.

RISK MANAGEMENT AS PER ISO 15189:2022

Sr. No.	Process/Activity	Type of Errors / Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
5	Facility controls	Short Circuit	Fire Hazard & Workplace Safety Risks a) Increased Fire Risk b) Electrocution & Injuries c) Toxic Fumes from Burning Equipment: Equipment Failure & Financial Losses Damage to Sensitive Instruments a) Frequent Downtime & Disruptions: b) Loss of Calibration & Reproducibility Sample & Data Loss a) Irrecoverable Sample Degradation b) Data Corruption & Loss c) Unrepeatable Experiments Non-Compliance with Safety Regulations a) Violation of Electrical Safety Standards Legal & Liability Issues: If a short circuit causes injuries, sample loss, or result errors, the lab could face legal consequences and reputational damage.	1. UPS is installed for RTPCR machines 2. The electrical engineer does regular electrical safety inspection	Impacts on workflow, health, property, and the outcome of the test	High	1. Use Surge Protectors & Uninterruptible Power Supplies (UPS): 2. Conduct Regular Electrical Safety Inspections: 3. Ensure Proper Lab Wiring & Load Management: . 4. Keep Flammable Chemicals Away from Electrical Sources: 5. Train Staff on Electrical Safety Protocols.

RISK MANAGEMENT AS PER ISO 15189:2022

Sr. No.	Process/Activity	Type of Errors / Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
6a	Facility controls	Improper ventilation	1. Increased Risk of Contamination a) Aerosol & Cross-Contamination: Poor ventilation can cause aerosolized nucleic acids (from pipetting, centrifugation, or PCR reactions) to linger in the air, leading to false-positive results. b) Uncontrolled Airflow in PCR Areas: Inappropriate air movement may allow pre-PCR and post-PCR areas to mix, increasing contamination risks in sensitive amplification reactions. 2. Temperature & Humidity Fluctuations a) Degradation of DNA, RNA & Reagents: Molecular assays require strict temperature control, especially for reagents like enzymes, primers, and fluorescent probes, which degrade if exposed to excessive heat or humidity. b) PCR & qPCR Reaction Failures: Molecular techniques like PCR, qPCR,	Air conditioning systems are provided wherever necessary to maintain an efficient operational environment. The laboratory maintains a room temperature between 18°C to 28°C	Impacts on workflow and the outcome of the test	High	a) Use HEPA & ULPA Filtration Systems: Ensure high-efficiency particulate air (HEPA) filters are installed in biosafety cabinets and cleanrooms to trap airborne contaminants. b) Maintain Separate Airflow for Pre-PCR & Post-PCR Areas: Prevent carryover contamination by having negative-pressure pre-PCR areas and positive-pressure post-PCR areas. Monitor Temperature & Humidity Regularly: Use digital sensors and automated alarms to keep environmental conditions stable. a) Ensure Proper AC Functionality: Keep lab AC

			and NGS require controlled environmental conditions. Fluctuations in temperature or humidity can cause poor amplification, inconsistent fluorescence signals, and invalid results. 3. Equipment Malfunction & Shortened Lifespan a) Overheating of Instruments b) Condensation & Corrosion Damage 4. Biosafety & Health Risks a) Spread of Infectious Agents b) Chemical & Fume Exposure Mold & Fungal Growth				calibrated and serviced to maintain cool, dry conditions (recommended: 18-25°C, 30-50% humidity). b) Install Chemical Fume Hoods & Biosafety Cabinets: Ensure volatile chemicals and biological agents are handled in areas with dedicated exhaust systems.

RISK MANAGEMENT AS PER ISO 15189:2022

Sr. No.	Process/Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
6b	Facility controls	Improper lighting	Errors in Sample Handling & Interpretation Poor Visibility During Pipetting & Sample Preparation: Inadequate lighting can lead to incorrect sample volumes, cross-contamination, or missed well-loading in PCR plates. Workplace Safety & Health Hazard a) Eye Strain & Fatigue: Inadequate lighting can cause visual discomfort, affecting precision in pipetting and reading fine instruments like PCR plates. b) Increased Accident Risk: Poor lighting in storage areas, corridors, or workbenches may lead to spills, misplacement of reagents, or accidents involving hazardous materials.	**1.** Adequate lighting is installed throughout the lab to support all work processes 2. Laboratory has generator backup 24/7	Impacts on workflow and the outcome of the test	High	a) Use Task-Specific Lighting: Ensure bright, shadow-free lighting for precision tasks like pipetting and microscopy. b) Implement Light-Sensitive Storage Protocols: Store light-sensitive reagents and nucleic acids in amber vials or dark conditions to prevent degradation.

RISK MANAGEMENT AS PER ISO 15189:2022

Sr. No.	Process/Activity	Type of Errors / Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
7	Facility controls	Risk associated with contaminated drinking water	Health Risks to Laboratory Personnel, Waterborne Diseases Laboratory Safety & Regulatory Compliance 1. Occupational Health & Safety Violations 2. Failure to Meet Biosafety & ISO Standards	1. A continuous water supply is ensured for all laboratory activities. 2. The lab is equipped with a Reverse Osmosis (RO) water system, ensuring water is free from microbial and chemical contamination. 3. The RO water meets permissible limits for chemical and physical parameters required for laboratory testing. 4. Water quality is monitored every three months, with microbiological parameters tested. 5. Records of water quality tests are maintained in the Water Analysis file for reference and compliance. 6. Drinking water is not used in the examination process.	Impacts on workflow and the outcome of the test	High	1. Provide Purified & Filtered Drinking Water: Install RO (reverse osmosis), UV filtration, or distilled water dispensers for safe drinking water. 2. Regularly Test Water Quality: Conduct routine microbial, chemical, and physical testing to ensure water meets health and safety standards. 3. Ensure Proper Water Source & Storage: Use clean water supply systems, regularly sanitize storage tanks, and avoid standing water contamination.

RISK MANAGEMENT AS PER ISO 15189:2022

Sr. No.	Process/Activity	Type of Errors / Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
8a	Facility controls	Cross-contamination due to lack of separation / separate section	Risk of Cross-Contamination False-Positive & False-Negative Results Reagent & Sample Contamination Microbial Contamination Biosafety & Occupational Health Hazards Exposure to Pathogens & Chemicals Poor Airflow Control & Aerosol Spread Ineffective Decontamination Equipment Damage & Malfunction 1. DNA/RNA Carryover into Clean Instruments 2. Increased Maintenance Costs Non-Compliance & Accreditation Risks Inefficient Workflow & Increased Turnaround Time (TAT) 1. Bottlenecks in Sample Processing Increased Sample Handling Errors	The laboratory has sufficient space and appropriate arrangements for primary sample collection and examinations at designated sites. Proper separation of different work areas and workflows in a molecular laboratory is essential for preventing cross-contamination, ensuring biosafety, and maintaining accurate test results. The laboratory has a separate area for specimen processing, extraction, master preparation, positive template addition, and PCR rooms	Impacts on workflow, health, result and environment	high	Access Control & Restricted Entry: Limit personnel movement between clean and contaminated zones to prevent contamination spread.

RISK MANAGEMENT AS PER ISO 15189:2022

Sr. No.	Process/Activity	Type of Errors / Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
8b	Facility controls	Inappropriate disposal of Biomedical waste	Health Hazards to Laboratory Staff & Public 1. Infectious Disease Transmission 2. Sharp Injuries & Infections 3. Toxic Exposure Environmental Contamination 1. Soil & Water Pollution 2. Airborne Hazards Cross-Contamination Risks in the Laboratory 1. Spread of Residual DNA/RNA Contaminants 2. Increased Risk of Laboratory Accidents due to Piling up biomedical waste Legal & Regulatory Violations 1. Non-Compliance with Waste Management Guidelines Liability for Public Health Risks	1. Segregation of waste done as per BMW regulation 2022 2. Segregated waste is handed over to the BMW management service provider 3. We have an MOU with the BMW management service provider 4. PPE is provided to all personnel handling BMW 5. Periodic training is provided to all staff 6. Documentation is done as per the regulator compliance.	Impacts on workflow, health, and environment	High	1. Implement Proper Waste Segregation 2. Treat biohazardous waste before disposal. 3. Train Staff on Waste Management Protocols periodically 4. Collaborate with Certified Waste Disposal Services 5. Monitor & Audit Waste Disposal Practices

RISK MANAGEMENT AS PER ISO 15189:2022

Sr. No.	Process/Activity	Type of Errors / Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
9a	Equipment	Equipment failure, Malfunctioning, Parameter, Deviations, and breakdown	Inaccurate test results and Diagnostic Errors 1. PCR Machine Malfunction 2. Centrifuge Failure Loss of Samples and Reagents 1. Cold Storage Unit Failure (Freezers & Refrigerators) 2. Microplate Reader or Sequencer Malfunction 3. Autoclave or Biosafety Cabinet Issues Safety Hazards & Workplace Risks 1. Fire or Electrical Hazards 2. Mechanical Failures & Injuries 3. Chemical & Biohazard Exposures Workflow Disruptions & Increased Turnaround Time (TAT) 1. Delayed Patient Diagnoses 2. Increased Retesting & Reagent Wastage 3. Extended Downtime & Repair Delays Non-Compliance with Regulatory & Accreditation Standards 1. Failure to meet QC & Validation Requirements	The laboratory has backup instruments that are calibrated for all parameters as per NABL 112A If an equipment failure or malfunction is identified, it is immediately removed from service, and a label stating "NOT IN USE" is affixed to prevent unintended operation. The breakdown details, including the nature of the failure and suspected causes, are recorded in the Equipment Breakdown Register by the Biomedical Engineer. The Company's service engineer is notified about the issue, and follow-ups are conducted to ensure prompt repair. The laboratory has set an acceptable downtime of 24 hours for all equipment.	Impact on results accuracy may lead to wrong treatment and impact on equipment users	High	Real-Time Monitoring & Alarms: Install temperature, pressure, and performance monitoring sensors with alarm notifications for freezers, incubators, and biosafety cabinets.

RISK MANAGEMENT AS PER ISO 15189:2022

Sr. No.	Process/Activity	Type of Errors / Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
9b	Equipment	Equipment not calibrated or inaccurately calibrated	Inaccurate test results and Diagnostic Errors 1. Incorrect qPCR & PCR results 2. Inconsistent Pipetting Volumes 3. Erroneous Spectrophotometer Readings 4. Poor Centrifuge Speed & Balance Failed Quality Control (QC) & Unreliable Reproducibility 1. Non-Reproducible Results 2. Inconsistent Data Errors 3. Frequent Retesting & Sample Wastage Equipment Malfunction & Increased Maintenance Costs 1. Premature Equipment Failure	1. The Bio-Medical Engineer ensures that all equipment undergoes proper calibration and that metrological traceability is established before being placed into regular services. 2. Calibration details, including date, parameters, reference standards, and results, are systematically recorded in the Equipment Record at regular intervals 3. All calibration activities comply with national and international measurement standards to ensure the traceability of results to recognized references standards. 4. The Molecular Laboratory ensures metrological traceability by maintaining a documented link between equipment calibration results and standardized reference materials or certified measuring systems.	Impact on results accuracy may lead to wrong treatment and impact on equipment users	High	Monitor Equipment Performance: conduct routine quality control checks to detect early deviation in equipment accuracy. Train Staff on Calibration Procedures: Educate personnel on the importance of calibration, how to verify instrument performance, and when to report deviations.

RISK MANAGEMENT AS PER ISO 15189:2022

Sr. No.	Process/Activity	Type of Errors / Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
9c	Equipment	Unintended adjustment of equipment, untrained personnel, and unauthorized access to the equipment	Inaccurate Test Results & Diagnostic Errors 1. Incorrect Temperature or Time Settings in PCR Machines 2. Misaligned Centrifuge Speed & Time Settings Equipment Malfunction & Damage 1. Overloaded or Unbalanced Centrifuges 2. Incorrect Laminar Flow & BSC Settings: Non-Compliance with Regulatory Standards 1. Failure to Meet ISO 15189 & NABL 112 Standards 2. Compromised Traceability & Documentation Safety Risks for Lab Personnel 1. Increased Risk of Accidents 2. Electrical & Mechanical Hazards	1. The supplier's technical team trains Molecular Lab and Instrument Technicians on equipment operation, maintenance, and troubleshooting. 2. Only trained and authorized technicians may operate equipment. Unauthorized adjustments to settings, calibration, or components are prohibited. 3. SOPs are provided, and any necessary changes must follow the instrument manual and be approved by the designated authority or the supplier's team.	Impacts on workflow, health, result and environment	High	Use Lockout Features & Password Protections: Enable password-protected settings on sensitive instruments to prevent accidental changes.

RISK MANAGEMENT AS PER ISO 15189:2022

Sr No	Process/ Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
10	Reagents and consumables	Change of Vendor	Changing vendors for reagents, consumables, or equipment in a molecular laboratory can introduce variability, operational disruptions, regulatory challenges. A new supplier may provide materials with different specifications, quality standards, performance characteristics, potentially affecting laboratory efficiency & test accuracy. **Workflow Disruptions & Increased Turnaround Time (TAT):** 1. **Delayed deliveries & supply chain issues:** transitioning vendors may lead to stock shortages, backorders, or longer lead times, affecting sample processing schedules. 2. **Incompatibility with existing equipment:** some reagents or consumables may not be compatible with existing instruments, requiring additional adapters, consumable modifications, or software updates. 3. **Rewriting standard operating procedures (SOPs):** Changing vendors necessitates updating procedural documents, quality manuals, and staff training protocols, causing temporary workflow inefficiencies	1. The laboratory ensures availability of necessary reagents and consumables to meet daily operational needs. 2. For items procured from vendors within the state, a minimum stock sufficient for 30 days is maintained. 3. For items sourced from vendors outside the state, a minimum stock sufficient for 60 days is maintained. 4. Each item has a predefined minimum stock level, and when inventory falls below this threshold, the Section-In-charge raises a request. 5. The Administrative Manager reviews and approves the purchase order before forwarding it to the respective supplier.	Impact on workflow and the diagnosis	High	1. Conduct Comparative Validation Studies: Perform side-by-side testing of new and old vendor products before full implementation. 2. Negotiate Trial Periods & Quality Guarantees: Request sample batches and performance assurances before committing to a vendor switch. 3. Implement a Phased Transition Plan: Gradually introduce new vendor supplies to avoid workflow disruptions and reagent incompatibilities. 4. Ensure Proper Documentation & Compliance: Update SOPs, validation reports, regulatory documents, and procurement policies to meet accreditation standards. 5. Establish Vendor Performance Metrics: Regularly evaluate supplier reliability,

			Extended Validation & Re-Optimization Time: 1. **Need for additional validation studies:** Before adopting new reagents or consumables, the lab must perform method validation, comparison studies, and quality control assessments, delaying routine testing. 2. **Re-establishing QC thresholds:** A new vendor may require adjusting Ct values (qPCR), RNA/DNA extraction yields, or background fluorescence levels, requiring extensive recalibration and SOP modifications.				reagent quality, and customer support to ensure long-term stability.

RISK MANAGEMENT AS PER ISO 15189:2022

Sr No	Process/ Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
11	Reagents and consumables	Improper Storage of Reagents and Consumables	**Reagent degradation & loss of test accuracy:** 1. Temperature-sensitive reagents affected 2. Contaminated/ degraded nucleic acids 3. pH & chemical stability alteration **Increased risk of cross-contamination:** 1. Unsealed or improperly stored reagents 2. Non-Segregated storage of pre-PCR & post-PCR reagents 3. Biohazardous waste mismanagement **Reduced Shelf Life:** 1. Early expiration of reagents 2. Freeze-thaw cycles shorten enzyme activity 3. Consumable damage **Laboratory workflow disruptions & increased (TAT):** 1. Delayed testing due to reagent instability 2. Repeated experiments due to inconsistent results 3. Instrument contamination & malfunction **Biosafety & health hazards:** 1. Toxic chemical exposure 2. Microbial growth in improperly stored culture media 3. Fire & explosion risks	1. Once delivered, supplied items are stored in the laboratory under appropriate conditions. Distribution to the laboratory is managed by the Store In-charge upon submission of an Indent and Issue Form. 2. Before issuing, reagents and consumables are checked for acceptability to ensure they meet quality standards. 3. For efficient usage, short-expiry reagents are placed at the front and labeled with a yellow sticker, while long-expiry reagents are stored at the back with a green sticker. 4. Accepted reagents and consumables are stored separately from those that have not yet been inspected or approved for use, ensuring clear segregation. 5. All materials, including reagents and consumables, are procured from the standard and approved vendors to maintain quality and reliability.	Impact on workflow and the diagnosis	High	1. Follow manufacturer-recommended storage conditions: Store reagents at appropriate temperatures (-80°C, -20°C, 4°C, or RT) and humidity levels. 2. Use clearly labeled & segregated storage areas: Maintain separate storage areas for pre-PCR and post-PCR reagents to prevent cross-contamination. 3. Implement inventory & expiry tracking systems: Regularly monitor expiration dates, FIFO (First In, First Out) usage, and reagent integrity. 4. Aliquot enzymes & sensitive reagents to avoid freeze-thaw cycles: Store in small, single-use aliquots to prevent degradation.

RISK MANAGEMENT AS PER ISO 15189:2022

Sr No	Process/ Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
12	Reagents and consumables	Inadequate acceptance testing of reagents and consumables	Acceptance testing of reagents and consumables is crucial to ensure that all materials meet quality standards, manufacturer specifications, and regulatory requirements before use. Failing to perform adequate acceptance testing can lead to compromised test accuracy, reagent inconsistencies, financial losses, non-compliance issues. **Inaccurate test results, diagnostic errors:** 1. **Use of substandard reagents:** Without proper quality checks, molecular assays may use reagents with incorrect concentrations, contaminants, degraded components, altering results. 2. **Lot-to-Lot variability impacting consistency**: Different batches may have variations in enzyme activity, buffer composition, or purity, affecting assay reproducibility. 3. **Contaminated or degraded consumables:** Non-sterile pipette tips, reaction tubes, can introduce contamination altering results **Risk of experimental failures, retesting:** 1. Unstable probes and primers 2. **Delayed identification of faulty kits:** Without initial acceptance testing, labs may discover reagent defects only after patient testing has begun, causing sample wastage and repeat testing. 3. **Inconsistent nucleic acid extraction efficiency:** Poor-quality extraction kits may fail to recover high-purity DNA/RNA affecting amplification **Workflow disruptions & increased turnaround time (TAT):** **1. Delays in Sample Processing:** If defective reagents are only identified during testing,	1. Consumables that may impact examination quality are checked for expiry dates. Any reagent kit beyond its expiry date is not used. 2. It is the policy of the laboratory that any new reagent kit with modifications in reagents, procedures, or a new lot undergoes performance verification before being used in testing. 3. Any procedural or reagent changes are communicated to technicians and implemented by the section in charge. 4. Lot-to-lot verification is conducted by testing internal quality control samples, known patient samples, or PT samples before implementing new kits for patient testing. 5. For Lot-to-Lot verification, testing is performed on two samples, while for a new kit, testing is conducted on three samples to ensure accuracy and	Impact on workflow and the diagnosis	High	1. **Implement Mandatory Acceptance Testing:** Establish lot-to-lot validation protocols for all incoming reagents and consumables before use in patient testing. 2. **Compare New vs. Previously Validated Lots:** Use side-by-side testing of new and existing reagent batches to ensure performance consistency. 3. **Verify Reagent Performance Using QC Samples:** Conduct tests with positive and negative controls to check reagent reliability before clinical application. 4. **Maintain Proper Documentation:** Record batch numbers, supplier certificates, validation results, and performance logs for regulatory compliance. **Train Staff on Acceptance Testing Protocols:** Ensure personnel understand testing criteria, documentation procedures, and reporting mechanisms for defective materials

			patient reports may be delayed, impacting clinical decisions. 2. **Frequent Assay Modifications:** Labs may need to adjust protocols to compensate for reagent inconsistencies, leading to workflow inefficiencies **Financial losses due to wasted resources:** 1. **Increased Costs from Failed Experiments:** Using low-quality reagents can lead to failed reactions, requiring repeat testing and additional reagent consumption. 2. **Reagent Expiry & Mismanagement:** If reagents are not tested on arrival, defective batches may go unnoticed until expiration or stock depletion, leading to financial losses. 3. **Unnecessary Instrument Downtime:** Poor-quality consumables (e.g., clogged pipette tips, misaligned PCR plates) may damage instruments, requiring maintenance and repair costs	reliability before use in patient examinations. 6. Documentation of these verifications is maintained			

RISK MANAGEMENT AS PER ISO 15189:2022

Sr No	Process/ Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
13	Service agreement with the laboratory users	Change in the agreements with the laboratory users	A patient test request form in a molecular laboratory is a critical document that captures essential details such as patient demographics, test type, clinical history, sample type, physician details. Any changes can introduce risks affecting test accuracy, patient safety, regulatory compliance. **Risk of data entry errors & misinterpretation:** 1. Omission of essential patient information 2. Unclear test ordering options 3. Confusion in sample type selection **Workflow Disruptions & Increased TAT:** 1. Delays due to staff relearning & misuse: Lab personnel/ clinicians may take time to adapt to the new form layout, increasing processing errors. 2. Increased query resolution time: Unclear or missing form fields require additional communication between the lab, physicians, and sample collection staff, delaying results. 3. Inconsistencies in laboratory information system (LIS) data entry: If test request form changes but LIS is not updated accordingly, discrepancies in electronic records may cause sample mismatches or reporting errors. **Patient safety risks & incorrect test reporting:** 1. Misidentification of patient samples: 2. Missed critical clinical information 3. Failure to Capture Consent 4. Rejected samples due to form errors 5. Increased Rework, Administrative Burden:	1. The service agreement is reviewed annually to ensure comprehensive coverage of all relevant aspects. 2. The review process includes testing methodologies, turnaround time (TAT), and suitability of tests. 3. Any amendments to the service agreement during contract period are communicated to all affected parties. 4. Records of all reviews and changes to the service agreement will be maintained for future reference and compliance.	Impact on workflow and the diagnosis	High	1. Ensure stakeholder review before changes: Involve clinicians, lab technicians, and quality control teams before modifying forms. 2. Maintain mandatory regulatory fields: Ensure the revised form retains all ISO, NABL, and legal compliance requirements. 3. Synchronize with LIS & digital records: Update Laboratory Information Systems (LIS) to match the new form structure. 4. Implement a transition plan: Keep both old and new formats available for a transition period to prevent workflow disruption. 5. Monitor & collect feedback: Regularly review error rates, complaints, processing times to ensure successful adaptation.

RISK MANAGEMENT AS PER ISO 15189:2022

Sr No	Process/ Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
14a	Agreement with the external service providers	Risks Associated with Changes in the Service Agreements-EQAS	A service agreement in a molecular laboratory covers External Quality Assurance Schemes (EQAS), referral laboratories, biomedical waste (BMW) management, pest control, and contractual staff (consultants/ technicians). Any changes to these agreements can lead to operational, compliance, and quality risks, affecting laboratory performance and accreditation. **Risks Related to Changes in EQAS:** 1. **Failure in Proficiency Testing (PT):** If the new EQAS provider has different testing protocols, the lab may fail PT evaluations, affecting accreditation. 2. **Loss of Benchmarking with Previous Data:** Switching EQAS providers may cause inconsistencies in trend analysis, making it difficult to compare past and current lab performance. 3. **Delayed Quality Control Reports:** If the new provider has a longer turnaround time, labs may experience delayed corrective actions on QC issues	1. The Molecular Laboratory selects only NABL-accredited laboratories or reputable government organizations for tests that fall within the NABL accreditation scope. 2. A Memorandum of Understanding (MoU) is established and signed by representatives of both parties to facilitate outsourcing process. 3. Accredited PT Providers: The laboratory engages PT providers that comply with international standards such as ISO/IEC 17043 to ensure the validity and reliability of PT results. **4.** Contract Termination and Replacement: If a service provider consistently fails to meet quality standards despite corrective actions, the contract may be terminated, and an alternative provider will be engaged to ensure uninterrupted laboratory operations.	Impact on workflow and the diagnosis	High	1. **Review New Service Provider Agreements** Carefully to comply with ISO 15189, NABL, and regulatory guidelines. 2. **Pilot-Run Services Before Full Implementation:** with existing workflows to detect inconsistencies. 3. **Monitor Quality Metrics Post-Change:** Track error rates, TAT, compliance status, customer feedback for any deviations. 4. **Maintain Clear Communication with All Stakeholders:** Inform lab personnel, referring physicians, regulatory bodies of any changes affecting lab operations. 5. Align TAT with previous benchmarks to avoid report delays. 6. Verify the reliability, accreditation status, and turnaround time of the new EQAS provider before transitioning.

RISK MANAGEMENT AS PER ISO 15189:2022

Sr No	Process/ Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
14b	Agreement with the external service providers	Risks Associated with Changes in the Service Agreements- **Referral Laboratory**	1. **Turnaround Time (TAT) Delays:** A new referral lab may have a longer processing time, delaying critical patient reports. **2. Differences in Methodologies** 3. **Data Integrity & Traceability Issues:** Incompatibility between LIS (Laboratory Information Systems) of both labs may lead to misreported or lost patient results. **4. Accreditation Mismatch:** If the new referral lab does not have ISO 15189/NABL accreditation, results may be non-compliant with regulatory requirements.	1.The Molecular Laboratory selects only NABL-accredited laboratories or reputable government organizations for tests that fall within the NABL accreditation scope. 2.A Memorandum of Understanding (MoU) is established and signed by representatives of both parties to facilitate outsourcing process. 3. Contract Termination and Replacement: If a service provider consistently fails to meet quality standards despite corrective actions, the contract may be terminated, and an alternative provider will be engaged to ensure uninterrupted laboratory operations.	Impact on workflow and the diagnosis	High	1. **Review New Service Provider Agreements** Carefully to comply with ISO 15189, NABL, and regulatory guidelines. 2. **Pilot-Run Services Before Full Implementation:** with existing workflows to detect inconsistencies. 3. **Monitor Quality Metrics Post-Change:** Track error rates, TAT, compliance status, customer feedback for any deviations. 4. **Maintain Clear Communication with All Stakeholders:** Inform lab personnel, referring physicians, regulatory bodies of any changes affecting lab operations. 5. Validate the new referral lab's accreditation, methodology, and compliance with regulatory standards before contract finalization. 6. Align turnaround times with previous benchmarks to avoid report delays.

RISK MANAGEMENT AS PER ISO 15189:2022

Sr No	Process/ Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
14c	Agreement with the external service providers	Risks Associated with Changes in the Service Agreements- **Pest Control Service:**	1. **Increased Risk of Contamination:** If the new pest control provider does not follow biosafety-approved fumigation and rodent control protocols, contamination of reagents, consumables, and instruments may occur. 2. **Health Hazards from Inappropriate Chemicals:** Use of non-laboratory-safe pesticides may lead to toxic exposure risks for lab personnel. 3. **Disruptions in Laboratory Operations:** Inefficient pest control may cause **insect or** rodent infestations, damaging stored reagents, nucleic acid samples, and electrical wiring. 4. **Improper Disposal & Environmental Hazards:** If the new vendor does not follow proper segregation, autoclaving, or incineration protocols, biomedical waste may cause public health risks. 5. **Inconsistent Waste Collection Schedule:** Any delays in BMW collection may lead to accumulation of infectious waste, increasing cross-contamination risks.	1. The Molecular Laboratory selects only NABL-accredited laboratories or reputable government organizations for tests that fall within the NABL accreditation scope. 2. A Memorandum of Understanding (MoU) is established and signed by representatives of both parties to facilitate outsourcing process. 3. The laboratory engages only government-authorized and certified biomedical waste disposal agencies to ensure adherence to environmental and health regulations. 4. Contract Termination and Replacement: If a service provider consistently fails to meet quality standards despite corrective actions, the contract may be terminated, and an alternative provider will be engaged to ensure uninterrupted laboratory operations.	Impact on workflow and the diagnosis	High	1. **Review New Service Provider Agreements** Carefully to comply with ISO 15189, NABL, and regulatory guidelines. 2. **Pilot-Run Services Before Full Implementation:** with existing workflows to detect inconsistencies. 3. **Monitor Quality Metrics Post-Change:** Track error rates, TAT, compliance status, customer feedback for any deviations. 4. **Maintain Clear Communication with All Stakeholders:** Inform lab personnel, referring physicians, regulatory bodies of any changes affecting lab operations. 5. Schedule **regular pest control without disrupting molecular testing**. 6. Ensure the new BMW vendor is **authorized, licensed, and compliant** with regulatory guidelines.

RISK MANAGEMENT AS PER ISO 15189:2022

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14d	Agreement with the external service providers	Risks Associated with Changes in the Service Agreements- **Consultants & Technicians**	1. **Loss of Skilled Personnel & Expertise:** Changing consultants or technicians may lead to reduced efficiency in molecular techniques like qPCR, sequencing, and extraction protocols. 2. **Errors Due to Lack of Training on Lab-Specific SOPs:** New staff may take time to **adapt to** existing workflows, increasing the risk of sample mishandling, cross-contamination, and misreporting. **3. Delays in Accreditation & Audits:** Frequent changes in consultants may lead to gaps in documentation and preparedness	1. A Memorandum of Understanding (MoU) is established and signed by representatives of both parties to facilitate outsourcing process. 2. Contract Termination and Replacement: If a service provider consistently fails to meet quality standards despite corrective actions, the contract may be terminated, and an alternative provider will be engaged to ensure uninterrupted laboratory operations. 3. The molecular laboratory is affiliated to medical college, ensuring access to sufficient number of trained consultants for its operations. As a result, the likelihood of a consultant shortage in the laboratory is minimal. However, in the rare event of a consultant shortage, the molecular laboratory will address the situation by appointing a full-time/ part-time consultant, depending on availability, to maintain seamless operations.	Impact on workflow and the diagnosis	High	1. **Review New Service Provider Agreements** Carefully to comply with ISO 15189, NABL, and regulatory guidelines. 2. **Pilot-Run Services Before Full Implementation:** with existing workflows to detect inconsistencies. 3. **Monitor Quality Metrics Post-Change:** Track error rates, TAT, compliance status, customer feedback for any deviations. 4. **Maintain Clear Communication with All Stakeholders:** Inform lab personnel, referring physicians, regulatory bodies of any changes affecting lab operations. 5. Maintain **continuity by staggering staff transitions** instead of making immediate workforce changes. 6. Conduct **proper onboarding, training, and competency assessments** for new consultants/technicians.

RISK MANAGEMENT AS PER ISO 15189:2022

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15	Pre-Examination Process	Wrong name	The report may have the wrong name/spelling of the name	Technologist verifies TRF and customers identify before sample collection	Impact on workflow and the diagnosis	High	Technologist cross checks the test with TRF /SRF before sample collection
		Wrong identification	Mix up with other number making the report total erroneous	Technician writes the customer ID on containers	Error in reporting	High	Always verify the name and other relevant information from customer. If discrepancy is observed then reject the sample and ask for re-sample
		Sample transport - Inappropriate temperature conditions	Inappropriate temperature conditions during transport may cause deterioration in sample	Samples are transported at required storage condition to prevent any deterioration	Deteriorated sample may give erroneous results.	High	Check for temperature conditions while receipt and indicate on TRF if inappropriate. See the time lag between sample collection and receipt at laboratory & temperature conditions in which it is received and, if inappropriate, repeat sample
		Sample storage: Inappropriate sample storage conditions	Inappropriate temperature conditions during storage may cause deterioration in sample	Samples are stored at required storage condition to prevent any deterioration	Samples may deteriorate	High	If storage temperature deviates, isolate and assess samples, test integrity, discard or recollect if compromised, document actions, and improve monitoring.
		Insufficient patient volume	**Analytical & Technical Risks:** 1. Inconclusive Results 2. Insufficient DNA/RNA may lead to weak signals, or inconclusive results. **3.** Poor sample quality can result in inefficient amplification **Diagnostic & Clinical Risks:** **1.** False-Negative Results **2.** Need for Repeat Sampling: **3.** Delayed Patient Management	Trained personnel evaluate received samples to ensure the sample is adequate and meets acceptance criteria for the requested examinations.	Impact on workflow and the diagnosis	High	**Establish Minimum Volume Requirements:** Clearly define required sample volumes for each test and communicate with clinicians. **Optimize Sample Collection Protocols:** Train healthcare providers on proper sample collection techniques.

RISK MANAGEMENT AS PER ISO 15189:2022

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15	Pre-Examination Process	Samples collected in the wrong container	**Sample Contamination:** **1.** Some containers contain preservatives or stabilizers that interfere with nucleic acid extraction and amplification **2.** Cross-contamination **3.** Degradation of DNA/RNA **4.** Incorrect Sample Processing	Trained personnel evaluate received samples to ensure the sample is collected in an appropriate container and meets acceptance criteria for the requested examinations	Impact on workflow, diagnosis, and TAT	High	**Standardized Collection Protocols:** Provide detailed guidelines for sample collection **Pre-Analytical Checkpoints:** Implement a verification step to ensure proper sample collection before processing. **Establish Sample Rejection Criteria:** Define strict policies for rejecting and recollecting samples collected in the wrong container
		Samples misplaced or lost	In molecular diagnostics, misplaced or lost samples pose serious risks, affecting patient care, laboratory efficiency, and regulatory compliance. **Patient Care & Clinical Risks:** Delayed or missed diagnosis, need for repeat sample collection, risk of incorrect clinical decisions	The technicians are trained in proper sample collection, labeling, and placement in designated areas to prevent loss or damage. A movement register is also maintained to track the sample throughout the process.	Impact on workflow, diagnosis, and TAT	High	**Implement a Laboratory Information Management System (LIMS):** To digitally track samples **Use Barcode & RFID Tracking:** Automate sample identification and location tracking. **Standardized Sample Handling Protocols:** Clearly define chain-of-custody procedures **Regular Staff Training:** Educate personnel on the importance of proper sample tracking **Designated Sample Storage Areas:** Ensure proper organization, labelling in refrigerators and freezers

RISK MANAGEMENT AS PER ISO 15189:2022

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15	Pre-Examination Process	Oral request for testing	1. **Miscommunication, Errors:** Misinterpretation, spelling error, language barriers 2. **Lack of Documentation:** No paper trail, liability issues 3. **Sample and Test Mismatch:** Incorrect test selection, sample misidentification 4. **Delays in Testing:** Follow-up clarifications, repeat testing	1. The laboratory strictly requires that all examination requests be submitted in written form. 2. Oral requests are not accepted to ensure accuracy, proper documentation, and compliance with standard operating procedures. 3. This policy helps maintain clear communication, reduces the risk of errors, and ensures that all requests are appropriately recorded and processed.	Impact on workflow, diagnosis, and TAT	High	**Require Written Requests**: Use electronic or paper-based test request forms. **Standardized Order Entry Systems**: Implement electronic laboratory information systems (LIS) for request tracking. **Verbal Confirmation Protocol**: If oral requests are unavoidable, require immediate written follow-up.

RISK MANAGEMENT AS PER ISO 15189:2022

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16	Examination	Improper sample verification during sample preparation / processing	**Analytical & Technical Risks:** **1.** Sample mislabelling & mix-ups **2.** Contamination & cross-contamination **Diagnostic & Clinical Risks:** **1.** False-positive or false-negative results **2.** Need for repeat testing **3.** Delayed diagnosis & treatment	1. The Molecular Laboratory strictly adheres to using only validated examination procedures to ensure the accuracy, reliability, and consistency of test results. 2. These procedures are conducted by trained personnel who are proficient in the specific methodologies used.	Impact on workflow, diagnosis, and TAT	High	**1. Implement a Double-Check System:** Require two independent verifications for patient identity and sample integrity before processing. **2. Use Barcode & RFID Tracking:** Automate sample verification using electronic systems to reduce human errors. **3. Standardize Pre-Analytical Workflows:** Establish strict protocols for sample labelling, handling, and verification. **4. Regular Staff Training:** Conduct frequent competency assessments on sample verification procedures. **5. Monitor & Audit Sample Processing:** Perform routine quality control (QC) checks to detect discrepancies early.

RISK MANAGEMENT AS PER ISO 15189:2022

Sr No	Process/ Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
17	Examination	Non-availability of SOPs, standard manuals, and reference data at the place of workflow	Standard Operating Procedures (SOPs), reference manuals, and validated data are essential for maintaining accuracy, compliance, and efficiency in a molecular laboratory. Their absence at the point of workflow can lead to significant risks affecting test reliability, laboratory operations, and regulatory compliance. **Analytical & Technical Risks:** 1. Inconsistent testing procedures 2. Increased risk of errors 3. Incorrect interpretation of results **Diagnostic & Clinical Risks:** 1. False-positive or false-negative results 2. Delayed diagnosis & treatment 3. Need for repeat testing **Operational Risks:** 1. Reduced laboratory efficiency 2. Increased costs due to waste & rework 3. Non-compliance with regulatory standards	1. The Molecular Laboratory ensures that only validated procedures are used, without modification, unless independently verified. 2. Verification involves running controls according to both manufacturer instructions and laboratory's SOPs. 3. This verification process provides objective evidence that the performance characteristics of the examination procedures meet the required claims. 4. The performance claims evaluated during verification are directly related to the intended use of the examination results. 5. Detailed documentation of the verification process and results is maintained. These are reviewed and recorded by the section In-Charge and consultants.	Impact on workflow, diagnosis, and TAT	High	1. **Ensure SOPs & Manuals Are Easily Accessible:** Maintain printed and electronic copies of all relevant documents at the place of workflow. 2. **Implement a Digital Laboratory Information Management System (LIMS):** Use electronic SOPs and reference databases integrated into lab software. 3. **Regularly Update & Review SOPs:** Ensure all protocols reflect the latest best practices, assay updates, and regulatory changes. 4. **Train & Educate Staff:** Conduct routine training sessions to ensure all lab personnel are familiar with SOPs and reference materials. **5. Perform Internal Audits:** Regularly verify that all essential documents are available and being followed correctly.

RISK MANAGEMENT AS PER ISO 15189:2022

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18	Examination	Changes in validated examination methods	In Molecular Laboratory, changes to validated examination methods can introduce significant risks if not properly managed. Validated methods ensure accuracy, reliability, compliance with regulatory standards. Modifications without proper verification and validation can compromise test quality and patient safety. **Analytical & Technical Risks:** 1. Loss of test accuracy, precision 2. Increased risk of false-positive or false-negative results 3. Incompatibility with existing equipment & software **Diagnostic & Clinical Risks:** 1. Delayed or incorrect diagnosis 2. Loss of established reference ranges & quality control metrics 3. Increased need for repeat testing **Operational Risks:** 1. Increased cost & resource utilization **Regulatory Non-Compliance & Accreditation Risks:** 1. Staff Training & Competency Issues 2. Unauthorized modifications may lead to audit failures, regulatory penalties, or loss of laboratory accreditation.	1. The Section in charge is responsible for ensuring that all technicians are adequately trained in the new test methodologies 2. These procedures undergo strict document control practices to ensure accuracy, traceability, and compliance with quality standards.	Impact on workflow, diagnosis, and TAT	High	1. **Perform Full Validation Studies:** Before implementing a new method, conduct analytical and clinical validation to assess accuracy, sensitivity, specificity, and reproducibility. 2. **Follow Regulatory Guidelines:** Ensure all changes comply with CAP, CLIA, ISO 15189, or other applicable standards. 3. **Conduct Parallel Testing:** Run the new method alongside the validated method for a defined period to compare performance and detect discrepancies. 4. **Update SOPs & Train Staff:** Ensure all laboratory personnel are trained on the new method, with updated Standard Operating Procedures (SOPs) and quality control measures in place. **5. Monitor Post-Implementation Performance:** Implement a quality assurance program to track the new method's performance and troubleshoot issues.

RISK MANAGEMENT AS PER ISO 15189:2022

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19	Examination	Measurement of Uncertainty evaluation for Qualitative data	In Molecular Laboratory, qualitative tests (e.g. presence/ absence of pathogens) rely on binary or categorical results rather than numerical values. Unlike quantitative assays, measuring uncertainty in qualitative data is challenging, yet crucial for ensuring diagnostic accuracy and reliability. **Analytical & Technical Risks:** 1. False-positive or false-negative results 2. Lack of repeatability & reproducibility 3. Failure to detect low-level targets **Diagnostic & Clinical Risks:** 1. Incorrect patient diagnosis 2. Delayed or inappropriate treatment 3. Challenges in Reporting Indeterminate or Borderline Results **Operational Risks:** 1. Increased need for repeat testing 2. Regulatory, compliance risks **3.** Reputation & liability issues	1. When the qualitative result of an examination depends on a test that produces quantitative output data, which is categorized as positive or negative based on a defined threshold, it is essential to estimate the measurement uncertainty (MU) in the quantitative output to ensure accurate interpretation of results. 2. The estimation process involves using representative samples that are clearly positive and negative relative to the threshold value. 3. The MU of measured quantity values will be evaluated and maintained for its intended use, where relevant. 4. The MU will be compared against performance specifications and documented.	Diagnosis, treatment, workflow	High	1. **Define & Document Uncertainty Factors:** Identify sources of variability, such as reagent batch effects, instrument variability, operator influence. 2. **Use Quality Controls, Reference Materials:** Implement positive/ negative controls, blank samples, proficiency testing to assess test consistency. 3. **Perform Repeatability, Reproducibility Studies:** Evaluate how often qualitative test results remain consistent across different runs and conditions. 4. **Implement Equivocal Result Handling Guidelines:** Establish clear protocols for managing borderline or inconclusive results. **5. Regularly Monitor Performance Metrics:** Track false-positive and false-negative rates, assay sensitivity, and limit of detection (LoD) to refine uncertainty estimates.

RISK MANAGEMENT AS PER ISO 15189:2022

Sl. No.	Process/ Activity	Type of Errors / Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
20	Examination	IQC failure	Internal Quality Control (IQC) is essential in a molecular laboratory to ensure accuracy, reliability, and consistency of test results. IQC failures indicate potential errors in the testing process and, if not addressed, can lead to incorrect diagnoses, operational inefficiencies, and regulatory non-compliance. Below are the key risks associated with IQC failure **Analytical & Technical Risks** 1. Inaccurate Test Results (False Positives & False Negatives) 2. Unreliable Assay Performance 3. Loss of Test Validity 4. Increased Contamination Risks: IQC failure may indicate cross-contamination, reagent contamination, or environmental contamination, leading to erroneous test interpretations. **Diagnostic & Clinical Risks** 1. Delayed or Incorrect Diagnosis 2. Compromised Patient Safety 3. Uncertainty in Reporting & Decision-Making **Operational & Financial Risks** 1. Laboratory Downtime & Workflow Disruptions	1. Each test is run by using the positive, negative controls and internal controls 2. If IQC fails (e.g., positive control does not amplify as expected or negative control shows amplification), the release of patient results for that batch are stopped. 3. Investigating the cause of the failure, including potential contamination, reagent issues, or instrument malfunction. 4. Reviewing the data and documentation for any errors or deviations from standard procedures. 5. Repeating the assay for the affected batch with new IQC controls to confirm the integrity of the test.	Diagnosis, treatment, workflow	High	1. **Implement a Robust IQC Program:** Regularly test positive/negative controls and ensure proper documentation of IQC performance. 2. **Investigate and Address Failures Immediately:** Identify root causes (e.g., reagent integrity, instrument issues, human errors) and apply corrective actions. 3. **Use Automated QC Monitoring Systems:** Digital tracking of IQC trends can help detect performance drifts before full failure occurs. 4. **Ensure Proper Staff Training:** Train personnel on recognizing and troubleshooting IQC failures to minimize errors. 5. **Maintain Backup Controls & Alternative Testing Strategies:** Always have contingency plans in case of repeated IQC failures to avoid workflow disruption.

RISK MANAGEMENT AS PER ISO 15189:2022

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21	Examination	Non-compliance of EQAS	External Quality Assessment Scheme (EQAS) is a critical component of quality assurance in a molecular laboratory. It ensures that laboratory test results are accurate, reproducible, and comparable across different laboratories. Non-compliance with EQAS requirements can lead to serious consequences affecting test reliability, patient safety, regulatory status, and overall laboratory performance. Below are the key risks associated with EQAS non-compliance. **Analytical & Technical Risks** 1. Inaccuracy & lack of standardization 2. Increased risk of systematic errors 3. Loss of method reliability & reproducibility 4. Failure to detect performance issues in instruments & reagents **Diagnostic & Clinical Risks** 1. False-positive & false-negative results 2. Compromised patient safety 3. Loss of confidence from clinicians & patients **Operational Risks** 1. Regulatory & accreditation non-compliance 2. Increased cost of retesting & investigations	1. Molecular laboratory has set a benchmark of 20% non-compliance with EQAS result. 2. In cases where the obtained results fall outside the acceptable range, immediate corrective actions are undertaken based on the EQA evaluation report. 3. Additionally, the Molecular Laboratory monitors the percentage of unacceptable EQAS reports as part of its Quality Indicators. 4. These indicators are reviewed annually and presented during the Management Review Meeting (MRM) to identify trends and implement improvements.	Diagnosis, treatment, workflow	High	1. **Ensure Regular EQAS Participation:** Enroll in an accredited EQAS program and comply with submission schedules. 2. **Analyze EQAS Reports & Implement Corrective Actions:** Address any performance deviations identified through EQAS evaluations. 3. **Train Staff on EQAS Compliance:** Educate laboratory personnel on importance of EQAS & how to interpret proficiency testing results. 4. **Integrate EQAS into the Quality Management System:** Use EQAS feedback to improve laboratory workflows, SOPs, and training programs. 5. **Perform Internal Quality Control (IQC) Alongside EQAS:** Use IQC to monitor test performance daily while relying on EQAS for external validation.

RISK MANAGEMENT AS PER ISO 15189:2022

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22	Examination	Non-availability of IQC material	Quality Control (QC) materials are essential in Molecular laboratory to ensure test accuracy, precision, and reproducibility. These materials help detect errors in reagents, instruments, and workflows before they affect patient results. The absence of QC materials can lead to serious analytical, clinical, operational, and regulatory risks. **Analytical & Technical Risks** 1. Unreliable Test Performance 2. Inability to Detect Assay Failures 3. Compromised Calibration & Standardization 4. Increased False-Positive & False-Negative Rates: Lack of QC checks result in incorrect test classifications. **Diagnostic & Clinical Risks** 1. Inaccurate Patient Diagnoses 2. Delayed or Inappropriate Treatment Decisions: Uncontrolled test variability may result in incorrect clinical decisions **Operational & Financial Risks** 1. High Rate of Test Failures & Retesting: Lack of QC materials increases the risk of undetected assay failures 2. Laboratory Downtime & Workflow Disruptions: Running assays without QC checks lead to undetected errors, requiring large-scale corrective actions.	1. In the absence of commercial IQC / PT provider, previously validated in-house controls, such as archived positive samples that have been characterized and verified are used. 2. Implementing additional checks like using known low-positive samples or replicates to ensure assay consistency.	Diagnosis, treatment, workflow	High	1. **Ensure Continuous Supply of QC Materials:** Maintain an adequate inventory of QC materials and implement a stock monitoring system. 2. **Use Alternative QC Strategies:** If QC materials are temporarily unavailable, validate test performance using patient-derived QC samples/ historical data trends. 3. **Implement a Risk-Based QC Plan:** Establish contingency plans to manage QC shortages, including supplier diversification and backup validation protocols. 4. **Regularly Train Staff on QC Importance & Management:** Educate personnel on alternative QC approaches and proper QC tracking. 5. **Monitor & Document QC Performance Trends:** Maintain records of QC trends to detect performance shifts even in the absence of fresh QC materials.

RISK MANAGEMENT AS PER ISO 15189:2022

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23	Examination	Non-availability of PT provider	Proficiency Testing (PT) is a critical component of External Quality Assessment (EQA) that evaluates a laboratory's ability to produce accurate and reliable test results. It involves analyzing blinded samples provided by an external agency and comparing results with other laboratories. Non-availability of PT provider poses risks to laboratory operations, compliance, patient care. **Analytical & Technical Risks** 1. Inability to Validate Assay Accuracy & Reliability: Without PT samples, the laboratory cannot assess the accuracy of its test methods against external benchmark 2. Loss of Standardization & Inter-Laboratory Comparability: PT ensures that different laboratories generate comparable results for the same tests. 3. Delayed Detection of Testing Errors: PT helps identify biases, drifts in assay performance, and operator errors. Without regular PT evaluations, errors may go unnoticed, compromising test validity over time	1. **Replicate Testing**: Conducting repeated tests on the same sample to confirm reliability and consistency. 2. **Examination of Split Samples**: Analyzing divided portions of same sample within laboratory to validate results. 3. **Use of Reference Methods and Materials**: Applying standardized reference methods and certified reference materials, when available, to ensure accuracy. 4. **Exchange of Samples with Other Accredited Laboratories**: To compare results and validate performance.	Diagnosis, treatment, workflow	High	1. **Identify Alternative PT Providers:** Maintain a list of accredited PT providers and be prepared to switch providers if necessary. 2. **Use Inter-Laboratory Comparison Programs:** Partner with other laboratories to exchange blinded samples for performance evaluation. 3. **Implement Internal Proficiency Testing (IPT):** Simulate PT using internally prepared or patient-derived QC samples. 4. **Seek Regulatory Guidance for PT Waivers:** If no PT provider is available, document efforts to find alternatives and seek approval for alternative validation methods.

			Diagnostic & Clinical Risks 1. Increased False-Positive & False-Negative Rates: Lack of PT oversight means the laboratory may unknowingly report incorrect results. 2. Lack of External Validation in Critical Disease Testing: PT is particularly important for high-risk testing. Without PT participation, the lab cannot assure clinicians and patients of test accuracy in life-threatening conditions. **Operational & Financial Risks** 1. Regulatory & Accreditation Non-Compliance				5. **Monitor Performance Using Historical Data:** Track and compare laboratory results over time to detect inconsistencies in test performance.

RISK MANAGEMENT AS PER ISO 15189:2022

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24	Examination	Non-compliance with the results of comparability of examination processes	Comparability of examination processes ensures that different instruments, methods, or locations within a molecular laboratory produce consistent and reliable results. Non-compliance with comparability results can lead to significant risks across analytical, clinical, operational, and regulatory domains **Analytical & Technical Risks** 1. Inconsistent test results across platforms & locations: If comparability studies are ignored, different instruments/ testing sites may produce conflicting results. 2. Undetected bias & systematic errors: Comparability studies identify biases between new and existing test methods. 3. Inaccurate method validation & verification: Non-compliance may result in the use of non-validated methods that do not meet required performance standards. **Diagnostic & Clinical Risks** 1. Incorrect patient diagnoses & treatment decisions 2. Compromised patient safety	1. If the NC significantly impacts patient safety, temporarily suspend the affected test method until the issue is resolved. 2. Notify relevant stakeholders (clinicians, laboratory management, and regulatory bodies if required). 3. Analyze the test performance across different instruments, methodologies, or locations. 4. Identify discrepancies in accuracy, precision, or bias in results. 5. Check for systematic errors, reagent issues, calibration differences, or operator variations. 6. Verify sample integrity & pre-analytical factors 7. Re-evaluate equipment & reagents	Diagnosis, treatment, workflow	High	1. **Strictly implement comparability study recommendations:** Regularly assess, align different test methods to ensure consistency. 2. **Monitor, document test performance over time:** Establish trending analysis to detect deviations in test comparability. 3. **Regularly train staff on method comparability & compliance:** Educate laboratory personnel on importance of comparability studies, adherence to protocols. 4. **Standardize testing protocols across platforms, sites:** Ensure uniform sample processing, analytical techniques to maintain comparability. 5. **Perform routine inter-laboratory comparisons:** Engage in external proficiency testing (PT) and peer comparisons to validate test consistency. 6. **Develop a corrective action plan** for non-comparable results

RISK MANAGEMENT AS PER ISO 15189:2022

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25	Post-examination	Delayed results	**Clinical & Patient Safety Risks** 1. Delayed Diagnosis & Treatment Initiation **Operational, Laboratory Workflow Risks** 1. Increased Sample Backlog & Workflow Disruptions 2. Compromised Sample Integrity & Rejection Rates 3. Increased Turnaround Time (TAT) Variability 4. Increased Manual Errors & Data Mismanagement	1. Identify, document cause of delay. 2. Notify stakeholders, including the requester, patient (if authorized), and relevant management, via phone or email. 3. Communicate a revised timeline for report release. 4. Escalate critical delays to management for prioritization. 5. Provide regular updates until the report is finalized. 6. Conduct a quality review to determine the root cause and implement corrective actions. 7. Maintain detailed records of the delay and related communications. 8. Implement preventive measures, such as workflow improvements or resource enhancements, to minimize future delays.	Diagnosis, treatment, workflow	High	1. Optimize laboratory workflow & sample prioritization 2. Regularly maintain & calibrate equipment 3. Ensure adequate staffing & training 4. Implement real-time tracking & notification systems 5. Establish contingency plans for supply chain disruptions

RISK MANAGEMENT AS PER ISO 15189:2022

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26	Post examination	Insufficient review of results	The review of results is a critical step in the molecular laboratory workflow to ensure accuracy, reliability, and compliance with quality standards. Insufficient or inadequate review of results can lead to serious clinical, operational, and regulatory risks, ultimately impacting patient safety and laboratory credibility. **Clinical & Patient Safety Risks** 1. False-Negative & False-Positive Results 2. Failure to Identify Laboratory Errors: Insufficient review may overlook analytical issues such as PCR amplification failures, sequencing errors, or contamination in molecular assays. 3. Without proper verification, incorrect results may be released to clinicians, increasing diagnostic uncertainty.	Consultants verify and sign the final report after a thorough review.	Diagnosis, treatment, workflow	High	Implement a Multi-Level Result Review System • Establish a 3-tier review process: 1. Primary Review (Technician/Analyst): Checks raw data for inconsistencies and potential errors. 2. Secondary Review (Senior Scientist/Supervisor): Verify result accuracy, cross-checks QC data. 3. Final Authorization (Pathologist/Clinical Director): Ensures clinical relevance and approves report release. • Automate data verification, interpretation • Ensure proper training & competency assessment of staff

RISK MANAGEMENT AS PER ISO 15189:2022

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27	Post examination	Unauthorized release of reports	The release of molecular test reports must strictly follow established protocols to ensure result accuracy, data integrity, and patient confidentiality. Unauthorized release—whether intentional or accidental—can lead to serious clinical, operational, financial, and legal consequences. **Clinical & Patient Safety Risks** 1. Release of incorrect or unverified results: Unauthorized personnel may release preliminary, incorrect, or unvalidated results, leading to misdiagnosis and inappropriate treatment decisions. 2. Errors in results 3. Compromised patient safety & treatment decisions **Data Integrity & Confidentiality Risks** 1. Violation of patient privacy & breach of confidentiality: Unauthorized release of reports violates HIPAA, GDPR, ISO 15189, CAP, and CLIA regulations regarding patient data protection. 2. Patient information may be leaked to unauthorized third parties, leading to ethical and legal violations. 3. Tampering or misuse of laboratory data **Operational & Workflow Risks** 1. Bypassing standard result review & approval processes 2. Unclear accountability & lack of documentation 3. Legal liability & risk of lawsuits	1. NABL authorized/approved consultant (s) reviews results for accuracy, ensuring compliance with internal quality control standards and standard operating procedures (SOPs). 2. Results are evaluated for consistency with clinical information and previous examination findings.	Diagnosis, treatment, workflow	High	1. Implement a secure report authorization system 2. Enforce strict access control measures 3. Standardize report review & release protocols 4. Establish a strong audit & monitoring system 5. Implement an incident response plan 6. Regularly review & update security policies

RISK MANAGEMENT AS PER ISO 15189:2022

Sr No	Process/ Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
28	Post examination	Missing information in the report	A molecular test report must be **comprehensive, accurate, and complete** to ensure proper clinical interpretation and decision-making. Missing critical information in the report can lead to **misdiagnosis, improper treatment, regulatory violations, and loss of credibility** for the laboratory. **Clinical & Patient Safety Risks** 1. Misinterpretation of results due to missing key details such as reference range, CT value, and viral load in case of quantitative report and clinical interpretations may lead to incorrect diagnosis 2. Failure to identify high-risk or critical conditions 3. Loss of diagnostic value due to missing sample details **Operational & Workflow Risks** 1. Breakdown in communication between lab & clinicians 2. Inconsistent report standardization across the laboratory 3. Increased risk of manual errors in report corrections **Key Report Sections Prone to Missing Information** 1. Patient & sample details 2. Test details & methodology 3. Reference ranges & interpretation guidelines 4. Result units & measurement standards 5. Critical Alerts & Comments 6. Review & authorization signatures	The molecular laboratory ensures that every report is comprehensive, accurate, and standardized. Each report includes the following essential elements to maintain clarity, reliability, and regulatory compliance: 1. **Examination Identification:** The report clearly specifies the type of test performed (e.g., COVID-19 RT-PCR, H1N1 RT-PCR), with any relevant measurement procedures/ methods used. 2. **Laboratory Identification**: Name and details of issuing laboratory are included to ensure traceability and accountability. 3. **Patient Identification and Location:** Each report contains unique patient identifiers, such as name or ID number, and location, ensuring that the results are linked to the correct individual. 4. **Requester's Details:** The report includes the name of the physician or clinician who requested the test. 5. **Date and Time Stamps: D**ate and time of sample receipt by laboratory and the date, time of report release are included to provide complete timeline of the process. 6. **Primary Sample Type:** The type of biological sample tested (e.g., nasal swab, throat swab, sputum) is documented. 7. **Examination Results:** Results are presented clearly and reported in SI units or units traceable to SI units, ensuring consistency and adherence to international standards if requested by the physician. 8. **Biological Reference Intervals:** Where applicable, reference ranges are provided to help the physician interpret the results in the clinical context.	Diagnosis, treatment, workflow	High	1. Implement a standardized report format 2. Automate data validation & entry checks 3. Enforce a multi-level report review system 4. Use electronic report tracking & audit logs 5. Train staff on reporting requirements & compliance 6. Perform routine internal audits & quality control checks 7. Establish a clear protocol for report corrections

			4. NABL logo	9. **Interpretation of Results**: If necessary, the report includes an interpretation of the findings, such as viral load or clinical 10. significance. 11. **Additional Comments:** Any other relevant information, such as testing limitations or observations, is included in this section. 12. **Authorization Details:** The report identifies the individual (consultant or authorized staff) who has reviewed and authorized the release of the report. 13. **Original and Corrected Results**: If applicable, the report contains both the original and corrected results, ensuring full transparency. 14. **Verification and Authorization:** The report includes the signature or digital authorization of the individual who verified or released the report. 15. **NABL Logo:** The NABL logo is used only for parameters accredited by NABL, maintaining compliance with accreditation guidelines. 16. **Page Numbering:** Reports are numbered in the format "Page X of Y" for clarity and completeness. 17. Since the tests are inherently critical, it is not necessary to explicitly label this test as critical.			

Sr No	Process/ Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
29a	Post examination	Non availability of consultants	Consultants in a molecular laboratory play a critical role in result interpretation, troubleshooting, quality assurance, regulatory compliance. Their absence leads to diagnostic errors, operational inefficiencies, compromised patient safety. **Clinical & Patient Safety Risks** 1. Incorrect interpretation of test results: Without consultants, technical staff may misinterpret data, leading to misdiagnosis or inappropriate treatment. 2. Failure to identify critical or high-risk cases and report **Operational & Workflow Risks** 1. Delays in report authorization & release 2. Disruption in laboratory troubleshooting & decision-making	The molecular laboratory is dedicated to the detection and reporting of COVID-19 and H1N1 infections (Critical tests). These tests are critical due to the potential for rapid disease transmission and the need for timely intervention. As such, the laboratory is committed to providing accurate and reliable results within a defined turnaround time. To ensure effective communication, the following measures are implemented: 1. Prioritization of tests: Both COVID-19 and H1N1 tests are treated as high-priority due to clinical significance and public health impact. 2. Timely Communication: Results are processed and verified promptly to adhere to agreed-upon TAT, minimizing delays in decision-making. 3. Hardcopy Report Delivery: Finalized reports are delivered to the physician in hardcopy format to ensure secure and reliable communication of results. 4. The molecular laboratory is affiliated to medical college, ensuring access to sufficient number of trained consultants for its operations. As a result, the likelihood of a consultant shortage in the laboratory is minimal. However, in the rare event of a consultant shortage, the molecular laboratory will address the situation by appointing a full-time/ part-time consultant, depending on availability, to maintain seamless operations.	Diagnosis, treatment, workflow	High	1. Ensure a minimum number of consultants per shift 2. Develop SOPs & guidelines for junior staff in consultant absence 3. Train senior laboratory scientists to handle consultant duties 4. Establish partnerships with external consultant networks 5. Implement AI-assisted data interpretation & decision support 6. Regularly audit, assess laboratory staffing needs

RISK MANAGEMENT AS PER ISO 15189:2022

Sr No	Process/ Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
29b	Post examination	Non availability of technicians	**Diagnostic Errors and Delays** • Delayed reporting of time-sensitive tests. • Increased risk of false negatives/positives due to improper sample handling or protocol deviations. • Reduced ability to meet turnaround times (TAT), affecting clinical decision-making. Compromised Quality Control and Assurance • Inadequate execution of **IQC, EQA** procedures. • Failure to detect and troubleshoot technical problems. • Violation of **ISO 15189 / NABL standards**, threatening accreditation.	• **Shift Adjustment:** The on-duty technician will initially be requested to cover the additional workload or extend their shift to ensure immediate continuity of laboratory operations. • **Reserve Staff Activation:** If the on-duty technician is unable or unwilling to take on the extra shift, technicians from the reserve pool will be called upon to step in. These reserve technicians are trained and experienced, enabling them to quickly adapt to the situation. • **Workflow Briefing:** Before the reserve technician begins handling specimens, they will be thoroughly briefed on the current workflow, pending tasks, and priority cases to ensure seamless integration into the ongoing operations. • **Proactive Planning:** To minimize such disruptions, the laboratory maintains a policy of hiring and training an adequate number of skilled staff members, ensuring there is always a buffer of reserve personnel available to handle emergencies. Regular cross-training of staff also ensures that all team members are versatile and capable of performing critical tasks when needed. The molecular laboratory is affiliated with the medical college, ensuring access to a sufficient number of trained consultants for its operations. As a result, the likelihood of a consultant shortage in the laboratory is minimal. However, in the rare event of a consultant shortage, the molecular laboratory will address the situation by appointing either a full-time or part-time consultant, depending on availability, to maintain seamless operations.	Diagnosis, treatment, workflow	High	1. Maintain an updated SOP repository and training manual. 2. Establish collaborative agreements with nearby institutions or agencies for temporary staffing support.

RISK MANAGEMENT AS PER ISO 15189:2022

Sr No	Process/ Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
30	Post examination	LIS breakdown	A Laboratory Information System (LIS) is essential for managing sample tracking, test workflows, result analysis, and report generation in a molecular laboratory. A breakdown in LIS can severely disrupt laboratory operations, leading to data loss, reporting errors, compliance issues, and patient safety risks. **Clinical & Patient Safety Risks** 1. Delayed test results & treatment decisions 2. Increased risk of sample misidentification 3. Loss of patient data & incomplete reports 4. Failure to flag critical or abnormal results **Operational & Workflow Risks** 1. Disruptions in Sample Processing & Tracking 2. Increased Manual Workload & Human Errors 3. Inability to Integrate with Other Laboratory Systems 4. Disruptions in Quality Control (QC) & Workflow Monitoring	The molecular laboratory does not employ automation for the release of reports. Instead, it follows a manual method for the review, release, and reporting of results to ensure accuracy and compliance.	Diagnosis, treatment, workflow	High	1. Implement a backup LIS & disaster recovery plan 2. Use cloud-based LIS with remote access 3. Ensure LIS integration with ups & power backup systems 4. Set up real-time system monitoring & it support 5. Regularly test data backup & recovery procedures 6. Establish contracts with LIS vendors for emergency support

RISK MANAGEMENT AS PER ISO 15189:2022

Sr No	Process/ Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
31a	Post examination	Inappropriate storage of processed samples	Proper storage of processed samples is critical in a molecular laboratory to maintain sample integrity, prevent contamination, and ensure reliable test results. Inappropriate storage such as incorrect temperature, exposure to contaminants, or improper labeling can lead to data inaccuracies, sample degradation, compliance issues, and patient safety risks. **Clinical & Patient Safety Risks** 1. Sample degradation leading to inaccurate results: Molecular samples are highly sensitive to temperature fluctuations. 2. Improper storage can lead to: • RNA degradation, affecting gene expression studies/ viral load tests. • DNA fragmentation, leading to failed sequencing/ PCR amplification. • Protein denaturation, impacting biomarker detection assays • Loss of sample viability for retesting or confirmation • False negatives/ positives due to contamination during retest • Bacterial/ fungal growth affecting sample integrity **Operational & Workflow Risks** 1. Inability to retrieve samples for further analysis 2. Overcrowding & suboptimal storage conditions	1. The Molecular laboratory has a documented procedure for identification, collection, retention, indexing access, storage, maintenance and safe disposal of clinical information and previous examination results. 2. The Molecular laboratory has defined the length of time clinical samples are to be retained. Retention time is defined by the nature of sample, the examination and any applicable requirements. 3. Retention period of samples will be as specified by ICMR and samples will be stored at -80^0C 4. The laboratory maintains appropriate records to provide identification and traceability of samples, test results after processing, wherever required. 5. The details of sample storage and disposal are recorded in the Sample storage and Discard register.	Diagnosis, treatment, workflow	High	Use barcode-based sample tracking systems

RISK MANAGEMENT AS PER ISO 15189:2022

Sr No	Process/ Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
32	Post examination	Data Privacy	In a molecular laboratory, patient data and test results must be handled with strict confidentiality, even when reports are issued for non-diagnostic purposes such as research, academic studies, legal cases, or third-party requests. Failure to protect patient privacy can lead to legal, ethical, reputational risks **Legal & Regulatory Risks** 1. Violation of data protection laws 2. Improper consent & data sharing violations 3. Ethical concerns 4. Legal issues **Data Security** 1. Unauthorized access to patient data 2. Data leakage & third-party misuse 3. Loss of data integrity & modification risks 4. Insecure data transmission & storage **Operational & Reputation Risks** 1. Misuse of patient data in research & commercialization 2. Reputation damage due to privacy breaches 3. Errors in report issuance & distribution	**De-Identification of Patient Data**: 1. All patient-identifiable information, such as name, age, address, and unique identifiers, is removed from the dataset before sharing it for analysis. 2. Only anonymized data, such as test results, sample collection dates, and other relevant non-identifiable information, is included.	Impact on confidentiality and legal issue	High	1. Ensure compliance with data protection laws & ethical guidelines 2. Obtain explicit patient consent for non-diagnostic report usage 3. Anonymize & de-identify patient data when possible 4. Implement strong cybersecurity & data access controls 5. Ensure secure data storage & transmission 6. Limit third-party data sharing & establish data use agreements (DUAs) 7. Regularly audit & monitor data access logs

RISK MANAGEMENT AS PER ISO 15189:2022

Sr No	Process/ Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
33	Post examination	Unauthorized access to LIS (Information management system)	A Laboratory Information System (LIS) is crucial for managing patient data, test results, sample tracking, and workflow automation in a molecular laboratory. Unauthorized access to LIS poses serious risks, including data breaches, result manipulation, regulatory violations, and cybersecurity threats. **Data security & privacy risks** 1. Patient confidentiality breach 2. Data theft, cybercrime risks 3. Unauthorized alteration of test results 4. If unauthorized parties access this information, they could use it for unethical genetic profiling. **Operational & Workflow Risks** 1. Disruption of laboratory operations 2. Unauthorized sample modifications, tracking issues 3. Unauthorized LIS downtime & system lockout	1. The laboratory uses manual method for information management which is password protected 2. A dedicated computer is installed in the molecular laboratory office to manage and enter test reports. 3. This computer serves as a critical component of the laboratory's information management system, ensuring accurate and timely recording of test results. 4. The computer is strategically placed in a secure environment to ensure only authorized personnel can access it. 5. The laboratory implements routine audits to ensure compliance with access control policies and detect any potential security breaches. 6. Personnel accessing the computer are trained in the importance of data security, and any violations are subject to disciplinary action. 7. A logbook or electronic record is maintained to track all data entries and modifications, ensuring a clear audit trail for accountability.	Impact on confidentiality and legal issue	Medium	1. Implement strong access controls & user authentication 2. Restrict remote access & monitor login activity 3. Ensure LIS is encrypted & regularly backed up 4. Train laboratory staff on cybersecurity best practices 5. Secure LIS against cyber threats

RISK MANAGEMENT AS PER ISO 15189:2022

Sr No	Process/ Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
34	Continuity and emergency preparedness planning	Natural Calamities	Natural calamities such as earthquakes, floods, hurricanes, tornadoes, fires, and power outages due to storms can severely disrupt the operations of a molecular laboratory. These disasters cause loss of critical samples, damage to equipment, destruction of data, safety risks to personnel. Proper risk assessment and disaster preparedness plans are crucial to ensure continuity and minimize losses. **Risks to Laboratory Personnel & Safety** 1. Injury or fatalities due to structural collapse 2. Exposure to hazardous chemicals & infectious materials 3. Fire risks due to electrical short circuits: Storms, floods, or earthquakes can cause power fluctuations or short circuits **Risks to Laboratory Samples & Research Data** 1. Loss of patient samples & research specimens 2. Damage to laboratory information system (LIS) & data loss 3. Disruption of molecular testing due to instrument malfunctions **Risks to Operational Continuity & Compliance** 1. Extended power outages affecting lab operations 2. Disruptions in supply chain & logistics	1. The laboratory has a partnership with backup laboratories for sample processing. 2. Adequate fire safety measures are in place to take timely actions without causing a major area of concern 3. Staff are trained on evacuation and fire drill, and they are supposed to vacate the premises promptly 4. CAB has a technical backup to run the tests in case of the unavailability of regular technicians due to natural calamities, and the facilities to commute technicians & consultants to the laboratory	Diagnosis, treatment, workflow, safety	High	1. Implement a laboratory disaster preparedness plan 2. Ensure backup power & secure storage for critical samples 3. Use cloud-based LIS & offsite data backup 4. Implement fire & flood safety measures 5. Install fire-resistant storage cabinets for flammable reagents. 6. Use elevated storage for critical equipment & samples in flood-prone areas. 7. Secure insurance coverage for natural disasters

RISK MANAGEMENT AS PER ISO 15189:2022

Sr No	Process/ Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
35	Control of management system documents	Retention, Retrieval, Disposal, and Archiving of Records	**Risks associated with Retention of Records** 1. Loss or misplacement of critical records 2. Retention of expired or outdated records 3. Lack of clear guidelines on retention periods **Risks associated with Retrieval of Records** 1. Delayed access to critical information 2. Inaccurate or incomplete record retrieval **3.** Dependence on manual record retrieval **Risks associated with Disposal of Records** 1. Unauthorized disposal of active or critical records 2. Breach of patient confidentiality & data privacy 3. Environmental & biosafety risks from improper disposal methods **Risks Associated with Archiving of Records** 1. Storage limitations & data overload 2. Vulnerability to physical damage & cyber threats 3. Non-compliance with legal & regulatory requirements	1. All records are retained till the end of the retention period specified in Master log. 2. The retention period and location of each record is indicated in document manual. 3. The reported results are retained as long as they are medically relevant/ required by regulations. 4. Soft copies of all records will be maintained in the hard disk drive in a secure offsite location with Lab Director to take care of damage to such records by natural disasters / Fire Outbreak. 5. A single hardcopy of obsolete documents is retained and extra hardcopies will be shredded by the authorized shredder (Bio-Medical Engineer) & softcopies will be deleted from hard disk, drives, cloud by the IT department of the institute. 6. Retained hardcopy of obsolete documents - stored separately in a large sealed envelope in the laboratory office for 2 years/ until the next cycle. 7. At the end of retention period, records will be shredded by the authorized shredder (Bio-Medical Engineer) and soft copies will be deleted from hard disk, drives, cloud by the IT department of the institute.	Impact on confidentiality, legal issue, diagnosis, treatment, workflow	High	1. Develop a standardized record retention policy 2. Implement a secure & efficient record retrieval system 3. Ensure proper & secure disposal of records 4. Enhance security measures for archived records 5. Train staff on record management best practices

Sr No	Process/ Activity	Type of Errors/ Problem	Nature of Risks	Current Control	Impact of customer care	Priority	Recommended action(s)
36	Continuity and emergency preparedness planning	Civic unrest	Disruption of Laboratory Operations • **Staff shortages** due to inability to commute safely during curfews. • **Suspension of routine testing** and emergency diagnostics • **Delay in processing time-sensitive samples**, especially from ICU, transplant units, or cancer centres. Sample Integrity and Loss • **Degradation of biological samples** (blood, CSF, tissue) due to delayed processing or power outages. • **Breakdown of cold chain logistics** affect reagent sample transport. • **Spoilage of high-value reagents** requiring cold storage, especially enzymes and probes. Supply Chain Interruptions • Delay in procurement of **critical consumables** • **Logistics breakdown** for external quality control materials or test reports. • **Inaccessibility of maintenance personnel** for breakdowns of essential instruments (PCR, sequencers, biosafety cabinets). Physical Security Risks • **Risk of vandalism or break-ins** targeting research institutions or hospitals during riots. • **Theft, sabotage** of sensitive laboratory equipment, reagents, data. • **Threats to staff safety** if the lab is located in affected zones. Patient Care Impact • **Disruption in critical patient management** (e.g., delay in diagnosis of drug resistance in TB or genetic conditions). • **Delayed decision-making in infection control** and outbreak investigations. • Possible **mistrust among clinicians** due to unavailability of reliable lab services.	• Approximately 50% of the staff are currently available on campus. • Ambulance services will be utilized to transport essential staff during civic unrest, if necessary. • Physical security is being maintained by the institute's deployed security personnel. • Sufficient stock of reagents and consumables is available to ensure continuity of daily diagnostic operations.	Diagnosis, treatment, workflow, safety	High	• Maintain a business continuity and disaster recovery plan (BCP/DRP). • Digitize and secure critical patient and research data on cloud backups. • Engage institutional security and local administration for emergency support.

RISK MATRIX AS PER ISO 15189:2022

Risk Matrix as per ISO 15189:2022

Table of Contents

41	Resource requirements	Change of Vendor	284
42	Resource requirements	Improper Storage of Reagents and Consumables	285
43	Resource requirements	Change in the agreements with the laboratory users	285
44	Resource requirements	Inadequate acceptance testing of reagents and consumables	286
45	Process requirements	Risks Associated with Changes in the Service Agreements	287
46	Process requirements	Oral request for testing	287
47	Resource requirements	Improper ventilation	288
48	Resource requirements	Improper lighting	288
49	Resource requirements	Risk associated with contaminated drinking water	288
50	Resource requirements	Adverse effect of Noise	289
51	Resource requirements	Unintended adjustment of equipments, untrained personnel and unauthorized access of the equipments	290
52	Management system	NC with internal and external audit	290

RISK MATRIX AS PER ISO 15189:2022

RISK MATRIX

1. Definitions:

- **Risk:** The combination of the probability of occurrence of harm and the severity of that harm.
- **Residual Risk:** The risk remaining after control measures have been implemented.
- **RPN (Risk Priority Number):** A numerical assessment of risk, calculated by multiplying the scores of *Occurrence (O)* and *Severity (S)*.
- **FMEA (Failure Mode and Effects Analysis):** A structured approach used to identify and evaluate potential failure modes and their impact.

2. Risk Evaluation Procedure:

2.1 Identification of Risk:

Potential risks are identified through internal audits, incident reports, equipment validation, quality indicators, staff feedback, or during planning and implementation of new processes.

2.2 Risk Assessment Criteria:

a. Occurrence (O): Likelihood that a failure or error may occur:

Description	Frequency	Score
Frequent	Once per week	5
Probable	Once per month	4
Occasional	Once per year	3
Remote	Once every few years	2
Improbable	Unlikely (5–10 years)	1

RISK MATRIX AS PER ISO 15189:2022

b. Severity (S): Consequence of the failure on patient safety, personnel, or equipment:

Description	Impact	Score
Catastrophic	Patient death	5
Critical	Permanent impairment or life-threatening injury	4
Serious	Requires medical intervention	3
Minor	Temporary injury, no professional help needed	2
Negligible	Inconvenience or discomfort	1

c. Risk Priority Number (RPN):
RPN=Occurrence(O)×Severity(S)RPN = Occurrence (O) × Severity

(S)RPN=Occurrence(O)×Severity(S)

Risk Assessment Matrix –					
Probability of Harm	**Severity of Harm**				
	Negligible (1)	**Minor (2)**	**Serious (3)**	**Critical (4)**	**Catastrophic (5)**
Frequent (5)	5	10	15	20	25
Probable (4)	4	8	12	16	20
Occasional (3)	3	6	9	12	15
Remote (2)	2	4	6	8	10
Improbable (1)	1	2	3	4	5

5.3 Risk Acceptance Criteria:

RPN Score	Risk Level	Action Required
1–4	Acceptable	Risk is low; monitor periodically
5–25	Unacceptable	Immediate mitigation required; document actions

6. Risk Mitigation Procedure:

6.1 Acceptable Risk (RPN 1–4):

- These risks are considered low-priority.
- No immediate corrective action is needed.
- Risk shall be documented and reviewed periodically for any change in frequency or severity.

6.2 Unacceptable Risk (RPN >4):

- These risks require timely intervention.
- The laboratory shall implement **preventive and corrective actions** to reduce either the severity or occurrence (or both).
- Actions may include process revision, staff retraining, equipment maintenance, use of safer reagents, or administrative control.

6.3 Residual Risk Management:

- After initial mitigation, if residual risk remains unacceptable, **additional controls** (e.g., automation, redundancies, enhanced PPE, double-checking) shall be introduced.
- All such steps shall be **documented**, evaluated for effectiveness, and reviewed during the Management Review.

7. **Documentation and Records:**

All identified risks, their RPN calculations, mitigation actions, and follow-up reviews must be recorded in the **Risk Register** or **Corrective and Preventive Action (CAPA) log**. These records must be retained for at least 5 years and made available during internal and external audits.

8. **References:**

- ISO 15189:2022 – Medical Laboratories – Requirements for Quality and Competence
- NABL 112A: Specific Criteria for Accreditation of Medical Laboratories
- WHO Laboratory Quality Management System Handbook
- FMEA Guidelines – AIAG & JAMA

RISK MATRIX AS PER ISO 15189:2022

S. No	Process/ Clause	Activities/ Processes	Quality Concerns/ Risks	Initial Risk Assessment (without any controls in place)			Control Measures taken by the lab	Residual Risk Assessment			Further measures required
				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
1	Process Requirements	Patient identification	Wrong Patient identification/ Sample labelling	5	1	5	Trained nurse/ technician verifies the registration slip	5	1	5	Follow up
2	Process Requirements	Patient Privacy	Intrusion of patient privacy	3	1	3	Separate room for sample collection, Curtains	3	1	3	Follow up
3	Resource Requirements	Waste disposal In the specimen collection	Wastes discarded into the wrong container	3	1	3	Availability of colour-coded waste bins, BMW chart, Personnel training	3	1	3	Follow up
4	Process Requirements	Inappropriate temperature conditions	Inappropriate temperature conditions during transport may cause deterioration in the sample	4	1	4	Samples are transported at required storage conditions to prevent deterioration	4	1	4	Follow up
5	Resource Requirements	Storage of hazardous chemicals	Improper handling may cause harm	5	1	5	Stored in separate boxes, caution labels in place, Staff trained, informed regarding danger, chemicals placed in sand boxes	5	1	5	Follow up

RISK MATRIX AS PER ISO 15189:2022

S. No	Process / Clause	Activities/ Processes	Quality Concerns/ Risks	Initial Risk Assessment (without any controls in place)			Control Measures taken by the lab	Residual Risk Assessment			Further measures required
				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
6	Resource Requirements	Fire	Fire break out may harm staff, patients	5	1	5	Fire safety training, emergency exit map, fire extinguishers, smoke detectors	5	1	5	Follow up
7	Resource Requirements	Electrical hazards	Electrical shocks to staff, Patients	5	1	5	Proper electrical work, insulated wires used, regular safety checks, no open electrical boards, no loose wires	5	1	5	Follow up
8	Process Requirements	Handling chemicals	Spillage of chemicals	5	1	5	Spillage training, Spillage kits, SOP to spill handling	5	1	5	Follow up
9	Process Requirements	Handling clinical samples	Risk of infection	4	1	4	Training, Use of PPE, ssanitisers	4	1	4	Follow up
10	Process Requirements	Sample accepting	Wrong samples may be accepted leading to wrong results	5	1	5	Established sample rejection criteria, training staff, display of rejection criteria at registration/ sample reception area	3	1	3	Follow Up
11	Process Requirements	IQC failure	Non- acceptance of results	5	1	5	Training of technicians regarding the handling of QC material/ reagents, SOP, calibration of the instruments	5	1	5	Follow Up

RISK MATRIX AS PER ISO 15189:2022

S. No	Process / Clause	Activities/ Processes	Quality Concerns/ Risks	Initial Risk Assessment (without any controls in place)			Control Measures taken by the lab	Residual Risk Assessment			Further measures required
				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
12	Process Requirements	Results reporting	Transcription errors during result entry	4	1	4	Training of DEO to minimize transcription error	4	1	4	Follow up
13	Process Requirements	Use of expired kits	This leads to wrong results	5	1	5	Technician trained to check expiry dates before use	5	1	5	Follow up
14	Resources Requirements	Electrical failure	Power failure interruption will stop results, delay in reporting, equipment damage	5	1	5	UPS battery backup for all types of equipment	5	1	5	Follow up
15	Process Requirements	Wrong test method followed for testing	Erroneous results	5	1	5	SOP for tests are prepared, technicians are trained, SOPs are available in section, & with section-in-charge for consultation	5	1	5	Follow up
16	Process Requirements	Erroneous test results due to wrong equipment & reagents	Erroneous results	4	1	4	Technicians trained, IQC testing, EQAS participation and outlier correction on regular basis, equipment calibration maintenance	4	1	4	Follow up
17	Process Requirements	Specimen spillage	No result, need to take fresh sample	4	1	4	All samples are handled with care to avoid spill	4	1	4	Follow up

RISK MATRIX AS PER ISO 15189:2022

S. No	Process / Clause	Activities/ Processes	Quality Concerns/ Risks	Initial Risk Assessment (without any controls in place)			Control Measures taken by the lab	Residual Risk Assessment			Further measures required
				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
18	Process Requirements	Autoclaving BMW	Faulty autoclaving leading to inefficient BMW treatment	5	1	5	Autoclave calibration done, use of chemical and biological indicators during run in place	5	1	5	Follow Up
19	Process Requirements	Wrong data entry	Wrong result	5	1	3	The random results are validated from the machine printout at the time of validation by the consultants	5	1	5	Follow up
20	Process Requirements	Wrong data entry in the manual test in register / worksheet	Wrong result	5	1	5	At the time of verification of result by authorized signatory, gross variation can be documented.	5	1	5	Follow up
21	Resource Requirements	Non-availability of an authorized signatory	Delay in report	5	1	5	We have three signatories and during an emergency, the signatory will make alternate arrangements for reporting	5	1	5	Follow up
22	Resource Requirements	Natural calamities, earthquake, flood	Delay in report	5	1	5	Staff are trained on evacuation and fire drill, and they are supposed to vacate the premises promptly	5	1	5	Follow Up

RISK MATRIX AS PER ISO 15189:2022

S. No	Process / Clause	Activities/ Processes	Quality Concerns/ Risks	Initial Risk Assessment (without any controls in place)			Control Measures taken by the lab	Residual Risk Assessment			Further measures required
				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
23	General Requirements	Impartiality	Ethical / Quality and accuracy risk, legal and regulatory issues	5	1	5	Laboratory management has a quality policy to maintain impartiality and integrity	5	1	5	Follow Up
24	General Requirements	Confidentiality	Privacy, Ethical / Quality, and accuracy risk, legal and regulatory issues	5	1	5	Laboratory management has a quality policy to respect patient confidentiality, regular training, and awareness	5	1	5	Follow Up
25	Resource Requirements	Equipment malfunction/ damage/ breakdown	Inaccurate test results, increase TAT, and safety risk	5	1	5	The laboratory has calibrated backup instruments and an active MOU with accredited referral laboratory	5	1	5	Follow Up
26	Resource Requirements	Vendor change for equipment calibration	Erroneous results, risk for handlers	5	1	5	NABL-approved calibration service providers are selected, and all parameters relevant to the laboratory's scope are verified accordingly	5	1	5	Follow up

RISK MATRIX AS PER ISO 15189:2022

S. No	Process / Clause	Activities/ Processes	Quality Concerns/ Risks	Initial Risk Assessment (without any controls in place)			Control Measures taken by the lab	Residual Risk Assessment			Further measures required
				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
27	Resource requirement	Shortage of technical staff	Delay in report, increase in TAT	5	1	5	Adequate technical staff from other departments are trained to respond during emergencies. If regular technicians are on leave, resource technicians are reoriented prior to being assigned to emergency duties	5	1	5	Follow up
28	Process Requirements	• Insufficient volume of specimen • Collection of specimens in the wrong container • Contamination of VTM	Test failure, Inconclusive results	5	1	5	Technicians are trained to use the correct volume in the designated container and are skilled in identifying suitable VTM for specimen collection	5	1	5	Follow up

RISK MATRIX AS PER ISO 15189:2022

S. No	Process / Clause	Activities/ Processes	Quality Concerns/ Risks	Initial Risk Assessment (without any controls in place)			Control Measures taken by the lab	Residual Risk Assessment			Further measures required
				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
29	Process Requirements	Non-availability of SOP, manuals, kit inserts, and reference data at the place of workflow	Increase risk of errors, delayed TAT, increased cost per test due to repetition of tests	5	1	5	SOPs, manuals, and kit inserts are readily available at the workplace. Technicians are oriented to the established work patterns and workflows, and all documents are periodically reviewed and updated as required, with proper documentation.	5	1	5	Follow up
30	Process Requirements	NCs with EQAS	Lack of standardization, failure to detect performance in instruments and reagents, increases the risk of systematic errors	5	1	5	The molecular laboratory has established a benchmark of 20% NC in EQAS results. If results fall outside the acceptable range, immediate corrective actions are implemented.	5	1	5	Follow up

RISK MATRIX AS PER ISO 15189:2022

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				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
31	Process Requirements	Non-availability of PT provider	• Inability to validate assay accuracy & reliability • Delayed detection of testing errors • Increased false-positive & false-negative rates	5	1	5	1. Replicate testing. 2. Examination of split samples 3. Use of reference method & materials 4. Exchange of samples with other accredited laboratories	5	1	5	Follow up
32	Process Requirements	Non-availability of a referral laboratory	The unavailability of a referral laboratory poses a risk to timely confirmatory testing and continuity of specialized diagnostic services	5	1	5	CAB maintains calibrated backup instruments, eliminating the immediate need for a referral laboratory. However, as there are no NABL-accredited laboratories available for H1N1 testing, in the event such testing becomes necessary, samples will be sent to NIV Pune with the patient's informed consent.	5	1	5	Follow up

RISK MATRIX AS PER ISO 15189:2022

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				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
33	Process Requirements	Non-availability of IQC material	1. Unreliable test performance 2. Inability to detect assay failures 3. Compromised calibration & standardization 4. Increased false-positive & false-negative rates	5	1	5	Using previously validated in-house controls, such as archived positive samples that have been characterized and verified.	5	1	5	Follow up
34	Process Requirements	NC with the result of the comparability of the examination process	1. Inconsistent test results across platforms & locations 2. Undetected bias & systematic errors: comparability 3. Inaccurate method validation & verification	5	1	5	1. Analyze test performance across different instruments, methodologies 2. Identify discrepancies in accuracy, precision or bias in results. 3. Check for systematic errors, reagent issues, calibration differences or operator variations. 4. Verify sample integrity & pre-analytical factors	5	1	5	Follow up

RISK MATRIX AS PER ISO 15189:2022

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				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
35	Process Requirements	Insufficient review of results	1. False-Negative & False-Positive Results 2. Failure to Identify Laboratory Errors.	5	1	5	Consultants verify and sign the final report after a thorough review	5	1	5	Follow up
36	Process Requirements	Unauthorized release of reports	1. Release of incorrect or unverified results. 2. Compromised patient safety & treatment decisions	5	1	5	NABL authorized/ approved consultant (s) reviews results for accuracy, ensuring compliance with internal quality control standards and standard operating procedures (SOPs).	5	1	5	Follow up
37	Process Requirements	LIS breakdown	1. Delayed test results & treatment decisions 2. Increased risk of sample misidentification 3. Loss of patient data & incomplete reports 4. Failure to flag critical or abnormal results	5	1	5	The molecular laboratory follows a manual method for the review, release, and reporting of results to ensure accuracy and compliance.	5	1	5	Follow up

RISK MATRIX AS PER ISO 15189:2022

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				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
38	Process Requirements	Inappropriate storage of processed samples	Sample degradation leading to inaccurate results	5	1	5	1. The Molecular laboratory has defined the length of time clinical samples are to be retained. Retention time is defined by the nature of the sample, the examination, and any applicable requirements. 2. Retention period of samples will be as specified by ICMR, and samples will be stored at -80^{0}C	5	1	5	Follow up

RISK MATRIX AS PER ISO 15189:2022

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				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
39	Process Requirements	Unauthorized access to LIS (Information management system)	1. Patient confidentiality breach 2. Data theft & cybercrime risks 3. Unauthorized alteration of test results 4. Unauthorized sample modifications & tracking issues	3	1	3	1. The laboratory uses manual method for information management which is password protected 2. The computer is strategically placed in a secure environment to ensure only authorized personnel can access it. 3. Personnel accessing the computer are trained in the importance of data security, and any violations are subject to disciplinary action	3	1	3	Follow up

RISK MATRIX AS PER ISO 15189:2022

S. No	Process / Clause	Activities/ Processes	Quality Concerns/ Risks	Initial Risk Assessment (without any controls in place)			Control Measures taken by the lab	Residual Risk Assessment			Further measures required
				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
40	Control of management system documents	Retention, retrieval, disposal, and archiving of records	1. Loss or misplacement of critical records 2. Delayed access to critical information 3. Inaccurate or incomplete record retrieval 4. Breach of patient confidentiality & data privacy 5. Vulnerability to physical damage & cyber threats	5	1	5	1. Records are retained till end of retention period specified in Master log. 2. Reported results are retained as long as they are medically relevant/ as required by the regulations 3. At the end of the retention period, records will be shredded followed by the authorized shredder (Bio-Medical Engineer) and soft copies will deleted hard disk, drives, cloud by IT department of institute.	5	1	5	Follow up

RISK MATRIX AS PER ISO 15189:2022

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				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
41	Resource Requirements	Change of Vendor	1. Delayed deliveries & supply chain issues 2. Incompatibility with existing equipment 3. Need for additional validation studies 4. Re-establishing QC thresholds	5	1	5	1. Laboratory ensures the availability of necessary reagents and consumables to meet daily operational needs. 2. Each item has a predefined minimum stock level, and when inventory falls below this threshold, the Section-In-charge raises a request. 3. The Administrative Manager reviews and approves the purchase order before forwarding it to the respective supplier.	5	1	5	Follow up

RISK MATRIX AS PER ISO 15189:2022

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				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
42	Resource Requirements	Improper Storage of Reagents and Consumables	1. Reagent degradation & loss of test accuracy 2. Increased risk of cross-contamination 3. Reduced shelf life	5	1	5	1. Accepted reagents and consumables are stored separately from those that have not yet been inspected or approved for use, ensuring clear segregation. 2. All materials, including reagents and consumables, are procured from the standard and approved vendors to maintain quality.	5	1	5	Follow up
43	Resource Requirements	Change in the agreements with the laboratory users	Any changes to the form's content can introduce risks affecting test accuracy, patient safety, workflow efficiency, and regulatory compliance.	5	1	5	1. The service agreement is reviewed annually to ensure comprehensive coverage of all relevant aspects. 3. Any amendments to the service agreement during the contract period are communicated to affected parties.	5	1	5	Follow up

RISK MATRIX AS PER ISO 15189:2022

S. No	Process / Clause	Activities/ Processes	Quality Concerns/ Risks	Initial Risk Assessment (without any controls in place)			Control Measures taken by the lab	Residual Risk Assessment			Further measures required
				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
44	Resource Requirements	Inadequate acceptance testing of reagents and consumables	1. Use of substandard reagents 2. Lot-to-Lot variability impacting consistency 3. Contaminated or degraded consumables 4. Increased risk of experimental failures & retesting	5	1	5	1. It is the policy of the laboratory that any new reagent kit with modifications in reagents, procedures, or a new lot undergoes performance verification before being used in testing. 2. Lot-to-lot verification is conducted by testing internal quality control samples, known patient samples, or PT samples before implementing new kits for patient testing	5	1	5	Follow up

RISK MATRIX AS PER ISO 15189:2022

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				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
45	Resource Requirements	Risks Associated with Changes in the Service Agreements	1. Failure in proficiency testing (PT) 2. Loss of benchmarking with previous data 3. Delayed quality control report 4. Turnaround time (TAT) delays	5	1	5	The Molecular Laboratory selects only NABL-accredited laboratories or reputable government organizations for tests that fall within the NABL accreditation scope.	5	1	5	Follow up
46	Process Requirements	Oral request for testing	Miscommunication and errors Lack of documentation	3	1	3	The laboratory strictly requires that all examination requests be submitted in written form. Oral requests are not accepted to ensure accuracy, proper documentation, and compliance with standard operating procedures. This policy helps maintain clear communication, reduces the risk of errors, and ensures that all requests are appropriately.	3	1	3	Follow up

RISK MATRIX AS PER ISO 15189:2022

S. No	Process / Clause	Activities/ Processes	Quality Concerns/ Risks	Initial Risk Assessment (without any controls in place)			Control Measures taken by the lab	Residual Risk Assessment			Further measures required
				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
47	Resource requirements	Improper ventilation	1. Increased risk of contamination 2. Temperature & humidity fluctuations 3. Uncontrolled airflow 4. Overheating of instruments	5	1	5	Air conditioning systems are provided wherever necessary to maintain an efficient operational environment. The laboratory maintains a room temperature between 18°C -28°C	5	1	5	Follow up
48	Resource requirements	Improper lighting	1. Errors in Sample Handling & Interpretation **2.** Workplace Safety & Health Hazard	5	1	5	1. Adequate lighting is installed throughout the lab to support all work processes 2. Laboratory has generator backup 24/7	5	1	5	Follow up
49	Resource requirement	Risk associated with contaminated drinking water	1. Health Risks to Laboratory Personnel 2. Waterborne Diseases	5	1	5	1. Lab is equipped with a Reverse RO water system, ensuring water is free from microbial and chemical contamination. 2. Water quality is monitored every three months, with microbiological parameters tested regularly.	5	1	5	Follow up

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				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
50	Resource Requirements	Adverse effect of Noise	1. Communication barriers & increased errors 2. Workplace stress & health issues 3. Workplace accident	5	1	5	All instruments are regularly serviced and calibrated to ensure compliance with ISO 15189:2022 and NABL 112 standards, covering all parameters that certify their fitness for use, including acceptable noise levels. Additionally,laboratory is strategically located in a low-noise environment, minimizing external disturbances and ensuring optimal working conditions.	5	1	5	Follow up

RISK MATRIX AS PER ISO 15189:2022

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				Severity Rating	Probability	Risk Rating		Severity Rating	Probability	Risk Rating	
51	Resource Requirements	Unintended adjustment of equipment, untrained personnel and unauthorized access of the equipment	1. Inaccurate test results & diagnostic errors 2. Increased sample contamination & wastage 3. Non-compliance with regulatory standards 4. Safety risks for lab personnel	5	1	5	1. Supplier's technical team conducts comprehensive training sessions for Molecular Lab technicians and the Instrument technician 2. Any unauthorized or unintended adjustment to the equipment settings, calibration, or internal components are strictly prohibited 3. SOPs for operating instruments are provided to technicians	5	1	5	Follow up
50	Management system requirements	NC with internal and external audit	Compliance and Accreditation Risk	5	1	5	NC of external and internal audit will be compared regularly and CAPA will be initiated	5	1	5	Follow up

Name and address of the laboratory

Confidentiality and Ethical Conduct Agreement

1. I hereby agree to respect the confidentiality and Privacy of the patient.
2. I maintain entire patient related details and the patients' health condition as closely guarded information.
3. I take care, so that test results of the patients are sent directly to the doctor concerned.
4. I do not disclose patient's personal and medical information to others unless the patient concerned has given specific permission for such release.
5. I hereby agree to abide by the quality policy laid down by the management.
6. I hereby agree that I will avoid activities that would diminish confidence in its competence, impartiality, judgement, operational integrity.
7. I have been trained/educated/briefed/communicated about the lab quality policy, ethics and confidentiality matters and I agree to abide by them.

Date: Name and Signature of the employee

Form No:

Name and address of the laboratory

Vendor Information

Vendor Name		Vendor ID	
Business Title		Date	
Division			
Review Period			

Evaluation

S.No.	Evaluation Parameters	Maximum Marks
1	Is the vendor having certificate / accreditation / meet the requirements	
2	Are the product / product range given by vendor suitable to your requirements	
3	The price quoted is competitive	
4	Terms and conditions are acceptable	
5	Whether they have system to supply on credit basis	
6	Does the quality of the reagents / consumables meet the requirements of the user satisfaction and national guidelines	
7	Do the vendor supplies the materials in cold chain when it is required	
8	Do the chemicals and reagents supplied belong to the same grade / class as required by the user	
9	Does the vendor has good sales and service network (local & National)	
10	Do the vendor have a provision to provide service 24X7	
Overall rating		

Rating: 1: Poor, 2: Fair, 3: Satisfactory, 4: Good, 5: Excellent

Preferred supplier	>80%
Approved supplier	70-80 %
Short listed	60-70%
Remove from supplier list	<60%

Evaluation Comment

Next evaluation due on Approved by

Evaluated by

Form No:

Name and address of the laboratory

Referral Laboratory Evaluation form

Name of the referral laboratory: **Date:**

Sl. No.	Parameters	Satisfactory (Y/N)
1	Are they collecting the sample in time	
2	Preparation, packing, and labeling of the sample before shipping	
3	Are storage and transport conditions are appropriate	
4	Ease of communication	
5	Are consultants qualified to report	
6	Do they adhere to MOU	
7	Is lab Accredited(NABL)	
8	Do they have a policy for sample collection and rejection?	
9	Do they have a policy for the rejection of samples?	
10	Are reports clinically correlating	
11	Clinicians' feedback (Clinicians feedback form)	
12	Are they adhering to defined TAT	

Note: The laboratory (s) qualifying above all the parameters and nearest to the referring laboratory will be considered as the referral laboratory

Remarks:

Laboratory Director

Form No:

Name & address of the laboratory

INDENT FORM

Section: _____ **Date:** _____

Sl. No.	Particulars	Quantity	Issued Quantity	Pending Quantity

Indent By **Store In charge** **Received By**

Form No

Name and address of the laboratory

Staff Technical Evaluation

Name:

Sl. No.	Points for assessment	Level of competency
1	Daily checking of log sheet	
2	Knowledge of surface cleaning protocol	
3	Knowledge of donning and doffing	
4	Daily check of equipment performance	
5	Knowledge of hand hygiene	
6	Demonstration of hand hygiene	
7	Preparation & usage of sodium hypochlorite	
8	Knowledge of biomedical waste management	
9	Demonstration of pipetting technique	
10	Handling RTPCR machine	

Note: Grading of Competency

1: Novice, 2: Advanced beginner, 3: Competent, 4: Proficient, 5: Expert

Laboratory Director

Form No.

Name and address of the laboratory

Month/Year

Quality Indicators Monthly Analysis

Sl No	Quality Indicator	Formula for calculation	Data	Percentage	Benchmark	Remarks
1	Number of unacceptable samples	Total Number of Unacceptable Samples X100 / Total Number of Samples Received			2%	
2	Registration errors	Number of errors at registration X 100 / Total Number of registration			2%	
3	EQAS/PT performance	Number of Unacceptable performances in EQAS X 100 / Number of performances in EQAS			20%	
4	Turnaround time (TAT)	Number of reports delivered outside the TAT X 100 / Total Number of reports			2%	
5	Non Conformance for IQC	Number of NCT X 100 / Total Number of reports			2%	
6	Revised reports	Number of Revised reports X 100 / Total Number of reports			2%	

Form No

Name and address of the laboratory

Vendor Evaluation – EQAS Provider

Name of the EQAS Provider:

Sl No	Parameters	Score
1	Is the centre accredited by NABL?	
2	Does the vendor meet the required criteria/scope of the lab?	
3	PT program meets the laboratory needs	
5	Does the quality of the material supplied meet the requirements of and national and international guidelines?	
6	Does the vendor supply materials in cold chain when required?	
7	Are the samples received on time?	
8	Is the package received in good condition?	
9	Is the information sheet clear and easy to follow?	
10	Is the quantity of the sample sufficient for testing?	
11	Is the result entry form clear and easy to fill?	
12	Is feedback related to PT documents appropriate?	
13	Time taken to declare results of PT appropriate?	
14	Evaluation report of last cycle clear and appropriate?	
15	Is the PT program affordable?	
16	Ease of communication with the PT provider?	
	Total	

1= Poor, 2=Fair, 3= Satisfactory, 4=Good, 5=Excellent

Preferred EQAS Provider	> 80%
Approved EQAS Provider	70-80%
Shortlisted	60-70%
Rejected EQAS Provider	<60%

Evaluation Comment:

Next Evaluation due on:

Evaluated by:

Approved by
Laboratory Director

Form No

Name and address of the laboratory

Immunization Record

Name:	**Age/Gender:**
Staff ID:	**Department:**
Designation:	

Immunization Details

Vaccine and Dose	Batch No.	Date	Vaccination Given by
Hepatitis B			
Dose1			
Dose2			
Dose3			
Titre value			
Booster			
Titre Value			
Tetanus Toxoid			
Dose1			
Dose2			
Booster			
Booster			

Vaccine and Dose	Batch No.	Date	Vaccination given by
Typhoid			
Dose1			
Dose2			
Booster			
Booster			
Influenza			
Dose1			
Dose2			
Dose3			
Booster			
AnyOther			
COVID			
Dose1			
Dose2			

Note: 5years after the third dose of Hepatitis B, check for anti-HbSAg titre, if the titre value<10IU/mL go for booster dose.