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CILM
Center Infectiology Lao-Christophe Merieux

2023

QUALITY MANUAL

Center of Infectiology Lao-Christophe Merieux (CILM)

Version: 06

Last Reviewed Date: 20/05/2023

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History of modifications:

Version	Date	Comments
01	2017	Initial version.
02	15/12/2018	• Update template; • Summary reorganization to match with the ISO 15189:2012 requirement; • Update the responsible and rewriting all the sections with more details; • Add "CILM quality standard" section.
03	05/02/2019	• Add "CILM's organization chart" in the section "Organization and management responsibility"; • Add the quality indicator table in the section "evaluation and audit"; • Add the header information to each page; • Add section 4.5. Selection and evaluation of referral laboratories.
04	12/03/2019	• Policy statement are extended for ISO 15190:2003; • Redefinition of the responsibilities.
05	07/01/2020	• Update application date and revise contain information. • Update quality policy • Update the accreditation on 1.2.1.2. • Update mapping process on 1.2.1.1.
06	09/05/2023	• Update template. • Revised chapter o 1.3. Document Control o 1.4. Service Agreement o 2.6. Ensuring quality of examination results o 2.10. Laboratory Information System

Copy needed and location

Amount	Location of copies				
	Copy N°1	Copy N°2	Copy N°3	Copy N°4	Copy N°5
1	Reception Room	Na	Na	Na	Na

Contents

SCOPE:

The QM is applied to all staff and all quality activities at CILM including pre-analysis, analysis and post-analysis. It should be reviewed at least every 2 years.

OBJECTIVES:

The Quality Manual is the main document of the Quality Management System (QMS). According to the requirements of ISO 15189:2012 (4.2.2.2), the purpose of the quality manual is to describe the QMS of the laboratory which includes various related techniques.

ABBREVIATION AND DEFINITION

- CILM: Center of Infectiology Lao-Christophe Merieux
- QMS: Quality Management System
- ISO: International Standardization Organization;
- EQA: External Quality Assessment;
- QC: Quality Control;
- QM: Quality Manual;
- SOP: Standard Operating Procedure;
- WHO: World Health Organization.

REFERENCE

- ISO15189:2012 – Medical laboratories – Requirements for quality and competency;
- ISO15190:2003 and 2020 – Medical laboratories – Requirements for safety.

RELATED DOCUMENTS:

All procedures (SOPs), forms, templates and annexes including external related documents.

RESPONSIBILITIES

The Quality Officer and Assistant are responsible for the current use of the Quality Manual including reviewing, revision, and proper control including archiving and destroy.

Lab Director is ensuring the quality policy is established, implemented and communicated to all CILM staff.

1. MANAGEMENT

1.1. Organization and management responsibility

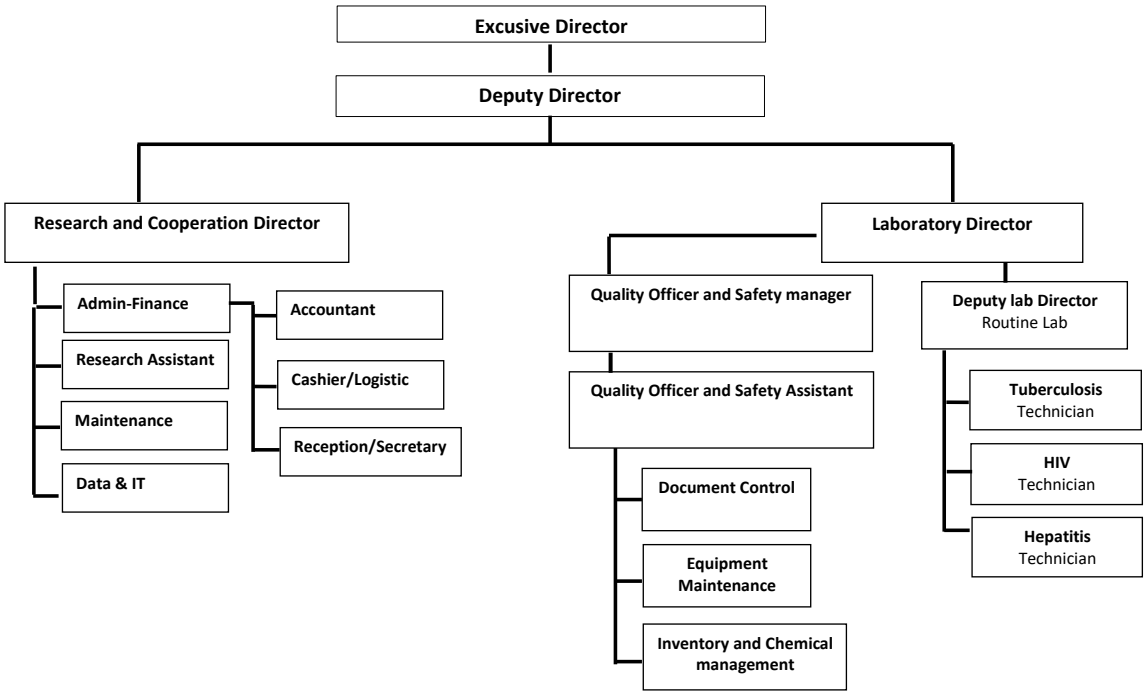
1.1.1. Organization

1.1.1.1. General

Following a visit of the Lao Ministry of Health in France in 2005, Dr Christophe Mérieux has been struck by the alarming needs of the country in terms of diagnosis.

Because the country didn't have at that time a facility dedicated to clinical biology and because making the right diagnosis is essential in the success of disease treatment, Dr Christophe Mérieux decided to help Laos in providing the tool for fighting against infectious diseases. As a result, the Center of Infectiology Lao-Christophe Merieux (CILM) was established in 2009 with a mission to serve public health. Today, the CILM is integrated into the Lao public health infrastructures and is under the guidance of the Lao Ministry of Health.

CILM Organization chart



1.1.1.2. ACTIVITIES:

Routine and specialized biology testing of plasma for viral load quantification; Hepatitis B and C viral load measurement and Mycobacterium Tuberculosis testing and identification of resistant strains.
Applied research project on infectious disease and respiratory pathogens.
Scientific conferences to share knowledge and strengthen capacity in the field of infectious diseases.
Provide training relating to Medical Laboratory Quality and Safety management, include technic requested.

1.1.1.3. Mission:

Provide patient with quality diagnostic for improvement care.

Conduct project that addresses public health issues in Lao PDR.

Contribute to educating student in clinical biology and infection disease and promote high quality training by implementing advanced conferences.

1.1.1.4. Legal entity

The CILM has been inaugurated in 2009 and belongs to the Ministry of Health of Lao PDR under the Communicable Diseases Control Department **(Refer to: document Authorization management - n°163/26th Jan 2009).**

1.1.1.5. Ethical conduct

CILM director ensuring the ethical conduct of CILM personnel and patient's welfare is of the highest priority.

1.1.1.6. Laboratory director / Deputy Director

a. Provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities;
b. Relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required;

c. Ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users;
d. Ensure the implementation of the quality policy;
e. Implement a safe laboratory environment in compliance with good practice and applicable requirements;
f. Serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate;
g. Ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results;
h. Select and monitor laboratory suppliers;
i. Select referral laboratories and monitor the quality of their service;
j. Provide professional development programs for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations;
k. Define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services;
NOTE This may be done within the context of the various quality improvement committees of the parent organization, as appropriate, where applicable.
l. Monitor all work performed in the laboratory to determine that clinically relevant information is being generated;
m. Address any complaint, request or suggestion from staff and/or users of laboratory services;
n. Design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable;
NOTE Contingency plans should be periodically tested.
o. Plan and direct research and development, where appropriate

1.1.2. Management responsibility

1.1.2.1. Management commitment

CILM management provides evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:

a. Communicating to laboratory personnel the importance of meeting the needs and requirements of users as well as regulatory and accreditation requirements.
b. Establishing the quality policy
c. Ensuring that quality objectives and planning are established.
d. Defining responsibilities, authorities and interrelationships of all personnel.
e. Establishing communication processes.
f. Appointing a quality manager, however named.
g. Conducting management reviews.
h. Ensuring that all personnel are competent to perform their assigned activities.

i. Ensuring availability of adequate resources to enable the proper conduct of pre-examination Procedure, examination and post-examination activities.

1.1.2.2. Needs of Users

Every test is developed with detailed requirements regarding procedure from sample collection to examination in the laboratory. To ensure that the laboratory has enough capability and resource needed and that the procedures selected meet the test requirements and clinical trial needs.

Customer satisfaction and requirements are identified, reviewed and promptly responded to ensure that the needs and requirements are fully understood and met. (Refer to: LRM-SERV-SOP001-Customer Management Procedure).

1.1.2.3. Quality Policies

Quality policy is communicated and understood with the organization trough the quality manual reading. This manual is located in the server can access by all CILM staff.

1. Regularly conducting customer satisfaction survey and continue improvement CILM service.
2. Continuing implementing IQC, EQA, equipment maintenance and calibration and also good professional practices.
3. Provide Quality and Safety training, support information and materials to provincial laboratories.

1.1.2.4. Quality objective and planning

Objectives:

1. Provide satisfaction service to clients.
2. Provide accuracy, precision results and complied to Turnaround Time (TAT).
3. To straightening the provincial laboratory Quality Management and Biosafety Management System.

Planning:

Quality year plan is implemented based on the corrective action requests from audit, assessments and daily nonconformity events. (Refer to: LRM-GQP-SOP002: Planning Management).

1.1.2.5. Responsibility, authority and interrelationships

All staff responsibilities are written on job description of each position in the personnel file. (Refer to: LRM-PER-SOP001: Personnel Management Procedure).

1.1.2.6. Communication

CILM management is ensuring that appropriate communication process is established between the laboratory and its stakeholders and that communication takes place regarding the effectiveness of the laboratory's pre-examination, examination and post-examination process and quality management.

CILM management is having an effective means for communicating with staff and records is being kept of items discussed in communications and meetings.

Internal communication:

Communication Type	Participants	Objective	Internal	External	Out put
Management Review Meeting	Management, QBO and QBA	To review the effectiveness of implementing QMS and plan the next strategy.	Y		MR Report.
Monthly meeting	CILM staff.	To review CILM previous month activities and plan for next upcoming month.	Y		Minute of meeting.
Weekly meeting	Lab Staff, Maintenance Manager, IT Manager QBO and QBA	To monitor all issue (problems, suggestion for improvement) discussed from the last week are implementing on time.	Y		Minute of meeting.
Computerized server	CILM staff.	To share information and safely storage.	Y		Share folders (\\192.168.1.3) (Z).
Email	CILM staff.	To communicate within CILM and between CILM and its partners/clients.	Y		Emails.
Telecommunications	CILM staff.	To communicate within CILM.	Y		N/A.
Results reports	Lab-staff.	To communicate the tests results to partners/clients.		Y	Request forms and Result report.
Results reports	Lab-staff.	To communicate the tests results to partners/clients.		Y	Request forms and Result report.
Seminars organization	CILM staff and its users.	To provide training and service information to partners/clients.		Y	Reports.

1.1.2.7. Quality Officer

A competent Quality Officer and Assistant with appropriate qualifications and experience in quality management, who have been formally designed by the CILM Director to assume to the responsibilities of running of QMS of the laboratory. QBO and QBA responsibilities are refer to their job descriptions.

1.2. Quality management system

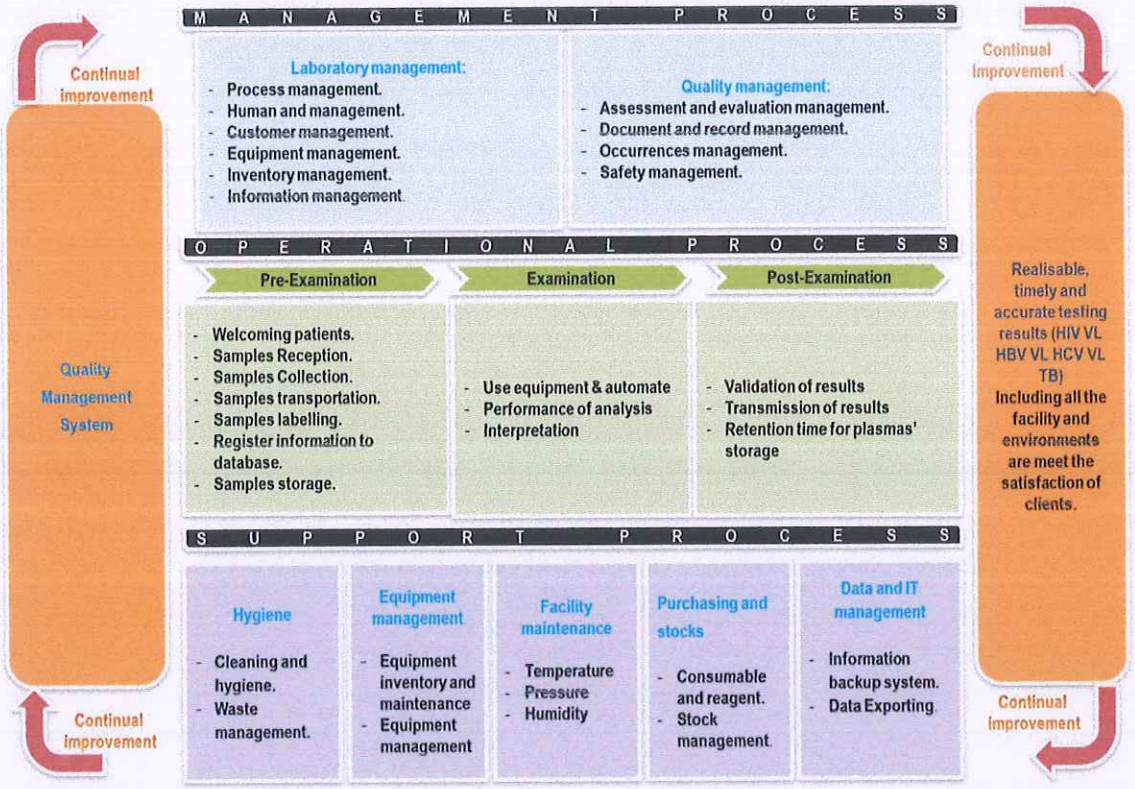
1.2.1. General requirements

CILM laboratory establish, documents, implements and maintain a QMS and improve its effectiveness comply with the requirements of ISO15189 standard.

1.2.1.1. Mapping process

QMS in the CILM is defined base on 3 objectives as:

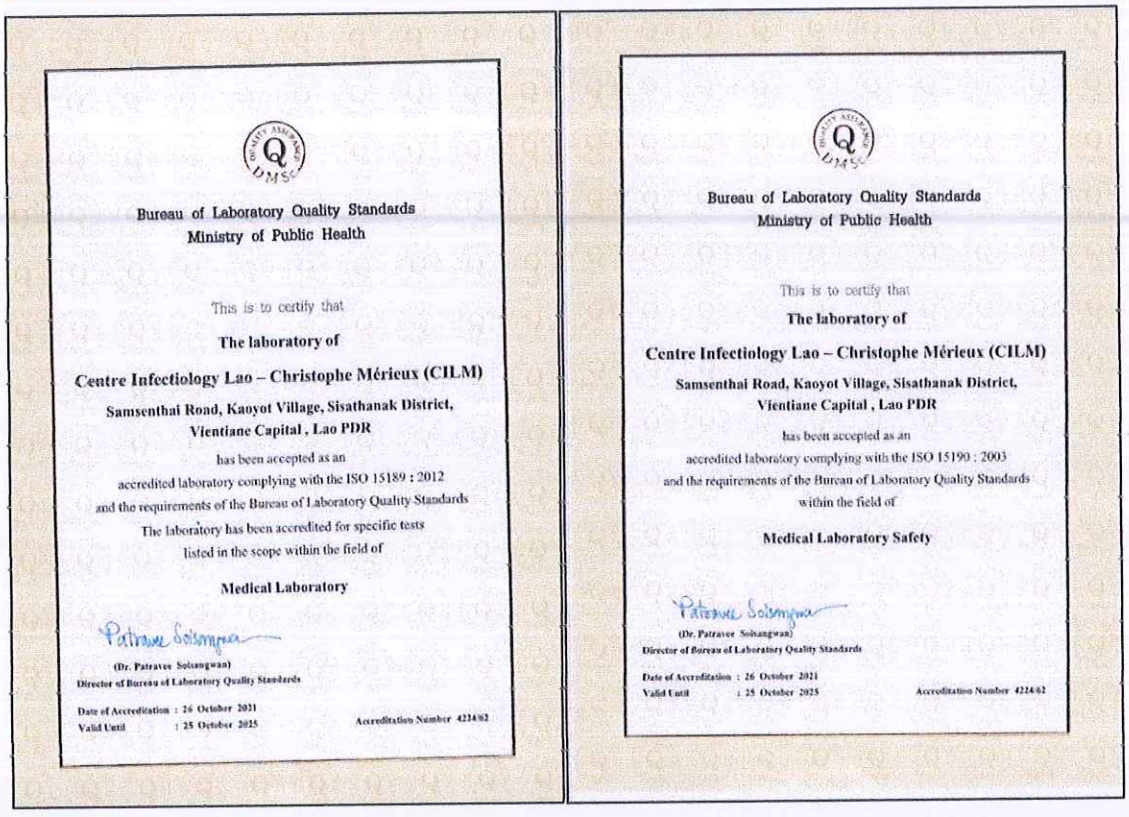
- **Management process:** all the general procedure, policy and means of CILM organization;
- **Operational process**: is the process of performing laboratory activities which cover pre-analytical, analytical and post-analytical process;
- **Support process:** is all the procedure that supports the main activities in the laboratory.



1.2.1.2. Accreditation

Roadmap to accreditation of CILM, is implementing ISO15189 and ISO15190 requirements for Hepatitis B & C viral load, and TB GeneXpert testing.

Accreditation surveillance is conducted in every 2 years, responsible by QBO and QBA. Implementing the accreditation will be based on the mention document (Refer to: R0715001TRev2020-Policies, requirements and condition for a medical and public health laboratory accreditation (DMSc_blqs_Thailand)).



Bureau of Laboratory Quality Standards
Ministry of Public Health

This is to certify that

The laboratory of

Centre Infectiology Lao – Christophe Mérieux (CILM)

Samsenthai Road, Kaoyot Village, Sisathanak District,
Vientiane Capital , Lao PDR

has been accepted as an
accredited laboratory complying with the ISO 15189 : 2012
and the requirements of the Bureau of Laboratory Quality Standards
The laboratory has been accredited for specific tests
listed in the scope within the field of

Medical Laboratory

(Dr. Patravee Soisangwan)
Director of Bureau of Laboratory Quality Standards

Date of Accreditation : 26 October 2021
Valid Until : 25 October 2025
Accreditation Number 4224/62

Bureau of Laboratory Quality Standards
Ministry of Public Health

This is to certify that

The laboratory of

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has been accepted as an
accredited laboratory complying with the ISO 15190 : 2003
and the requirements of the Bureau of Laboratory Quality Standards
within the field of

Medical Laboratory Safety

(Dr. Patravee Soisangwan)
Director of Bureau of Laboratory Quality Standards

Date of Accreditation : 26 October 2021
Valid Until : 25 October 2025
Accreditation Number 4224/62

1.3. Document Control

QBO and QBA are responsible for quality document control, and ensuring documents are up to date timely manner, current version is in place and the obsoleted versions are appropriate treated refer to: LRM-DOC-SOP002 – Document Control Procedure.

a) All documents, including those maintained in a computerized system, issued as part of the quality management system are reviewed and approved by authorized personnel before issue.

b) All documents are identified to include:
   - laboratory name;
   - a title;
   - a document code control on each page;
   - the last reviewed date and version number;
   - page number to total number of pages (e.g., "Page 1 of 5," "Page 2 of 5,");
   - authority for issue.

c) All authorized documents (internal and external) are listed on the Master List and maintain by Quality Officer.

d) Only current authorized versions of appropriate documents are available for active use at relevant locations. Original copies are to be retained in a "ORIGINAL SOPs" folder and a soft version back-up in CILM server by the Quality Officer. Originals copies shall be used to make controlled copies for use by all authorized CILM personnel.

e) Where a laboratory's document control system allows for the amendment of **documents by hand**, pending the re-issue of documents, the procedures and authorities for such amendments are defined, amendments are clearly marked, initialed and dated, and a revised document is issued within a specified time period.

f) **Changes to documents are identified.** Documents are revised using LRM-DOC-SOP002-A01_Revision Database to ensure that only authorized changes are made to approved documents, all changes are reviewed and approved before use, and all copies of the documents in use reflect the change. The nature of changes within revised documents shall be clearly indicated in the section entitled History Medication Log. That indicated in the first or second page of each document.

g) Documents remain legible: All documents must be prepared using the appropriate template as specified in the Applying the LRM-DOC-SOP001: Master SOP (annexes).

   NOTE All personnel are responsible for notifying the Quality Officer if there is a need to update procedures or whenever actual procedures are permanently changed from documented procedures. The change is initiated using LRM-DOC-SOP002-A01_Revision database.

h) CILM Quality documents are reviewed every 2 years at least, revised when necessary, and approved by authorized personnel. Additionally, revision of all documents is done when a need arises (major changes in the document, or recommendation from corrective/preventive actions, management reviews).

i) **Obsolete controlled documents are dated and marked as obsolete.** All obsolete documents are promptly removed from all points and discard. The master copy of all superseded documents is dated

and marked OBSOLETE, then archived for reference according to LRM-REC-SOP001: Control of Record Procedure. Any copies of invalid documents are promptly shredded, with the original marked Invalid and attached to its accompanying LRM-NCE-SOP001-F01-NCE form.

j) At least one copy of an obsoleted version is retained for a specified time period or in accordance with applicable specified requirements.

k) Each document has a master file that contains the current (master document) and all previous versions of the document. When a document is changed, the new version becomes the new master document and the previous version is marked with OBSOLETE, along with the date on the upper right-hand corner of the header, and archived in the master file. Included with the master file are the forms for all author, reviewer, and approval signatures for each version, as well as the attestation sheets.

1.4. Service agreements

Any test request accepted by the laboratory is considered based on LRM-SERV-MAN001: Service Manual.

The accepted request form, constitutes the basis for an agreement between laboratory and customers to perform tests. Verbal requests are accepted, but results will not be released until a written request is made.

All test requests are reviewed against CILM resources and agreements to provide medical laboratory services taking into account factors affecting the request, the examination and the report generated.

CILM has made available the list of tests performed to customers and the procedure for reviewing Service Agreement through the LRM-SERV-MAN001: Service Manual. These includes ensuring that;

a. The requirements of the customer and users, and that of CILM including the examination processes to be used, are defined, documented and understood;

b. The laboratory has the capacity and resources to process requests. Once the request has been accepted by the laboratory, it is understood that the laboratory has the capacity (Machinery, Methods, Manpower, Materials and environment) to be able to carry out the test or has adequate options to refer the test;

1.5. Examination by referral laboratories

CILM can refer to laboratories, when necessary, as per LRM-REF-SOP001: Selecting and evaluating referral laboratories.

1.6. External services and supplies

The evaluation of external services and suppliers is carried out according to criteria defined in the SOP (Refer to: LRM-ESS-SOP002: Selection and evaluation for suppliers).

1.7. Advisory services

Laboratory scientific director and Laboratory Manager are available to answer questions or provide advice related to laboratory examinations performed in the CILM laboratory (Refer to: LRM-SERV-MAN001: Service Manual.

Advisory services are given to CILM staff or healthcare workers at sites either orally or in written, regarding the use of the CILM laboratory services and for the purpose of consultation on scientific matters.

The laboratory scientific director and Laboratory Manager have to provide advice on choice of examinations and use of services, including repeat frequency, required type of sample and interpretation of the results of the examinations. Information for advisory service for hospitals and clinics.

1.8. Resolution of complaints

CILM are caring claims with the complaint box, present at the information desk directly at the entrance. All claims are reviewed at least every quarterly as defined per SOP (Refer to LRM-COMP-SOP003- Complaint Handling Management).

1.9. Identification and control of nonconformities

All CILM staffs have the authorization to write a nonconformity for any event who occurred which is not compliant with SOPs, policies and ISO 15189: 2012. And will be report on the Lab weekly meeting.

Monitoring of corrective action will be done by quality officer by checking on every weekly meeting and or whenever the nonconformity is closed. (Refer to LRM-NCE-SOP001 – Nonconformity corrective and preventive action procedure).

1.10. Corrective action

Corrective action is the action that take to eliminate the cause(s) of nonconformities (NC). All NC will be determining the root cause and evaluate the need of corrective action to ensure the NC do not recur. (Refer to LRM-NCE-SOP001 – Nonconformity corrective and preventive action procedure).

1.11. Preventive action

Preventive action is the process of identifying opportunities for improvement to prevent recur of problem. CILM implement preventive action (Refer to LRM-NCE-SOP001 – Nonconformity corrective and preventive action procedure):

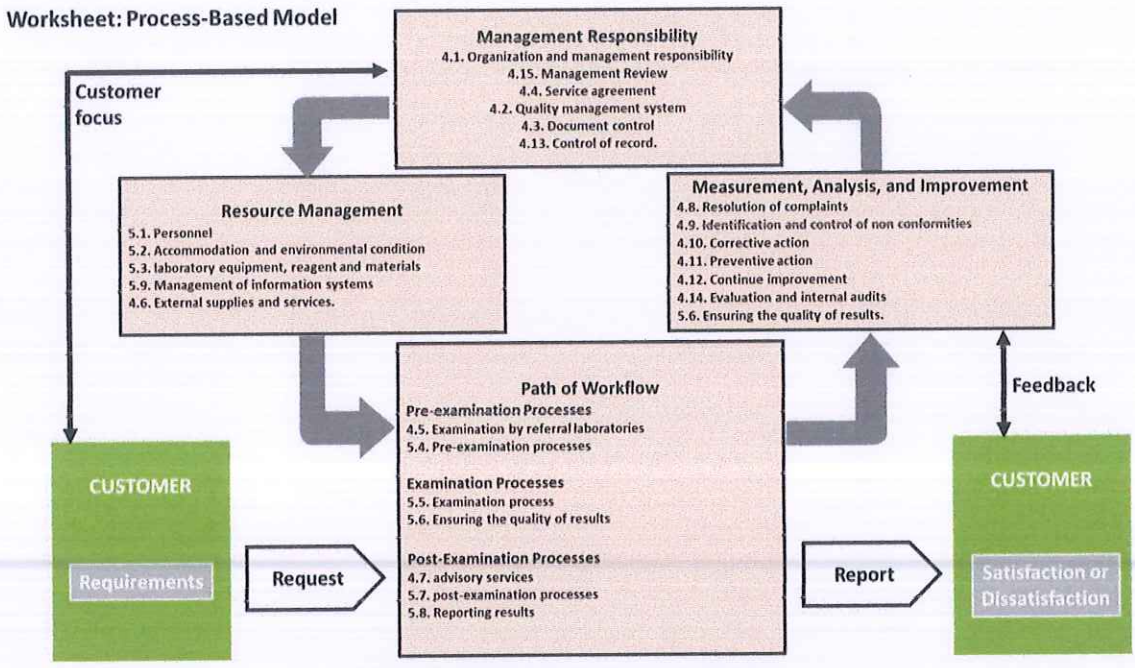
- To the impact of work process and potential failures on examination results.
- To nonconformities
- To the lacks or gaps from NC trend analysis

1.12. Continual improvement

CILM conducts continually improve the effectiveness of the quality management system, including the Pre-Examination, examination and post-examination processes, through the use of management reviews to compare the laboratory's actual performance in its evaluation activities, corrective actions and preventive actions with its intentions, as stated in the quality policy and quality objectives. Improvement activities shall be directed at areas of highest priority based on risk assessments.

Action plans for improvement should be developed, documented and implemented, as appropriate. The effectiveness of the actions taken should be determined through a focused review or audit of the area concerned.

Lab Management should ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care. When the continual improvement program identifies opportunities for improvement, the lab management shall address them regardless of where they occur. Laboratory management shall communicate to staff improvement plans and related goals. (Refer to: LRM-CON–SOP001: Continual improvement Procedure).



(Picture n°03: Process – Based Model)

1.13. Control of records

CILM documented procedure for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records. (Refer LRM-REC-SOP001 – Control of Record Procedure). Records is being created concurrently with performance of each activity that affects the quality of the examination.

CILM defines the time period that various records pertaining to the quality management system, including pre-examination, examination and post-examination processes, are to be retained. The length of time that records are retained may vary; however, reported results shall be retrievable for as long as medically relevant or as required by regulation. (Refer LRM-REC-SOP001 – Control of Record Procedure).

Facilities is providing a suitable environment for storage of records to prevent damage, deterioration, loss or unauthorized access.

1.14. Evaluation and audits

1.14.1. General

The results of evaluation and improvement activities of CILM over the process including pre-analytical, analytical and post-analytical process are included as input in the management review report.

1.14.2. Periodic review of requests, and suitability of procedures and sample requirements

CILM staff annually review the requests and verify the examinations provided by the laboratory to ensure that the examinations are appropriate.

for transportation and management of samples annually review the sample volume, collection device and preservative requirements for sample as applicable to ensure that neither insufficient nor excessive amount of sample are collected and the sample is collected per protocol requirement. (Refer to LRM-SERV-MAN001: Service Manual).

1.14.3. Assessment of user feedback

CILM assessing customer satisfaction, with all customers' using CILM services including: Conference room users, patients and medical personnel (Refer to LRM-SERV-SOP001 – Customer management). Collect customer feedback and take appropriate follow-up actions.

1.14.4. Staff Suggestions

CILM management encourages all staff to make suggestions for improvement of any aspect of the laboratory service through all meetings and staff yearly evaluation. Records of suggestions and action taken by the management are maintained.

1.14.5. Internal audit

Internal audit is conducted yearly based on ISO15189 and ISO15190 leads by the Quality Officer. The internal audit submits a full internal audit report, with achievements, findings and corrective action. (Refer to: LRM-AUD-SOP001- Assessment Procedure).

1.14.6. Risk management

The laboratory evaluated the impact of work processes and potential failures on examination results as they affect patient safety, and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken. (Refer to: LRM-SSM-SOP001: Risk Management Procedure and Risk Management reports)

1.14.7. Quality indicators

CILM established Quality Indicator (QI) to monitor and evaluate performance throughout critical aspects of Pre-Examination, examination and post-examination processes. (Refer to LRM-CON-SOP001 – Continual improvement).

Key Quality Indicators	How to measure:
1. Equipment Down Time;	• Quantify number of days per month that any specific piece of equipment is not functioning.
2. Stock Out;	• Quantify number of days per month that any specific reagent or supply is stocked out
3. Turn Around Time;	• Measure time from specimen receipt/log in to release of results.
4. External Quality Assessment Results;	• Indicate either Pass or Fail for each EQA program in which the laboratory is engaged.
5. Specimens Rejected;	• Quantify number of specimens rejected per month and qualify reason for rejection.
6. Customer Satisfaction;	• Quantify or qualify number of complaints, or change in points on a survey (Dependent on tool used for assessment)

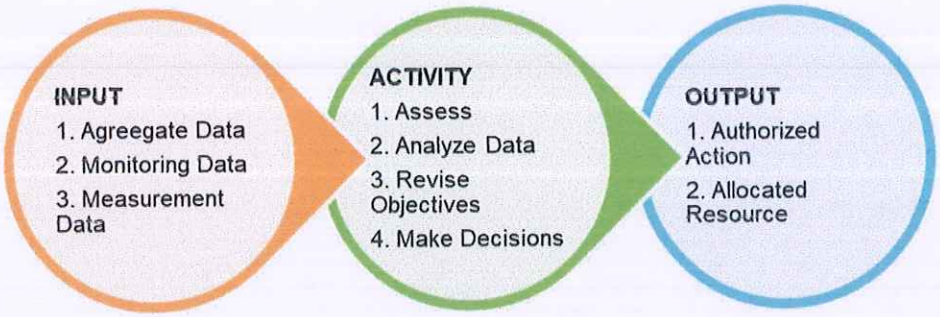
1.14.8. Reviews by external organizations.

External audits are conducted by a third party as part of ongoing laboratory monitoring process. When nonconformities or potential nonconformities are identified, appropriate action, corrective action or preventive actions are taken. The Quality officer maintains records of each audit, the associated findings and actions taken.

1.15. Management review (MR)

Top Management conducts MR yearly, to evaluate the suitability, adequacy, effectiveness, and efficiency of the QMS with respect to the Quality Policy and the Objectives. MR provides the cornerstone for laboratory's strategic planning. (Refer to LRM-MR-SOP001 – Management review Procedure).

MR process:



Review of activities:

The input information includes the results of evaluations of:

a) the periodic review of requests, and suitability of procedures and sample requirements;
b) assessment of user feedback;
c) staff suggestions;
d) internal audits;
e) risk management;
f) use of quality indicators;
g) reviews by external organizations;
h) results of participation in interlaboratory comparison programs (PT/EQA);
i) monitoring and resolution of complaints;
j) performance of supplies;
k) identification and control of nonconformities;
l) results of continual improvement including current status of corrective actions and preventive actions;
m) follow up actions from previous management review;
n) changes in the volume and scope of work, personnel, and premises that could affect the quality management system;
o) recommendations for improvement including technical requirements.

Review of activities

The review analyzes the input information for causes of nonconformities, trends and patterns that indicate process problems. The review includes assessing the opportunities for improvement and the need for changes to the quality management system including the policy and objectives.

Review of output

The output from the management review has been taken into a record that documents any decisions made and actions taken related to:

a) improvement of the effectiveness of the quality management system and its processes;
b) improvement of services to users;
c) resource needs.

During the management meeting, actions are allocated and minutes taken to record the development of the Laboratory's management system.

Findings and actions arising from management reviews are recorded and reported to laboratory staff and the laboratory management ensures that actions are completed within a defined timeframe.

2. TECHNICAL

2.1. Personnel

2.1.1. General

CILM policy is to ensure that all personnel are trained to undertake their assigned activities and responsibilities effectively (Refer to LRM-PER-SOP001 – Personnel Management Procedure).

2.1.2. Personnel qualifications

The personnel qualifications for each position are recorded in personal files with the CV which detail the education, training, experience to perform the assigned tasks.

2.1.3. Job descriptions

The job description for each position describes also the duties, responsibilities, and tasks.

2.1.4. Personnel introduction to the organizational environment

The CILM has defined and implemented a plan to introduce new staff to the organization, the department or area where the person will work, the terms and conditions of employment, staff facilities, health and safety requirements and occupational health services. Each new staff member or trainee requires a medical check-up within 30 days of arrival. (Refer to: LRM-PER-SOP001 – Personnel management Procedure).

2.1.5. Training

CILM provides training for all personnel which includes the following areas:

a) The Quality Management System – by self-reading or briefly explain on LRM-QMS-MAN001 Quality Manual;
b) Assigned work processes and procedures (SOPs related to Job Description);
c) The applicable Laboratory Information System (LIS) (software that processes, stores, and manages patient data related to laboratory processes and testing at: how to use FileMakers etc.);
d) Health and safety, including the prevention or containment of the effects of adverse incidence) ethics by self-reading or briefly explain by Safety Officer on LRM-SSM-MAN002-Safety Manual;
e) Confidentiality of patient information by self-reading or briefly explain on LRM-LIM-SOP001-Laboratory information management system procedure

Once training is done, "Training Record" must be documented.

NOTE: Personnel that are undergoing training will be supervised at all times and the effectiveness of the training program should be periodically reviewed. (Refer to LRM-PER-SOP003: Training Procedure).

2.1.6. Competency assessment

To ensure propriate training, the laboratory assess the competence of each person to perform assigned managerial or technical tasks according to established criteria. (Refer to: LRM-PER-SOP004: Staff competency assessments).

2.1.7. Review of staff performance

The laboratory director and/ or laboratory manager assesses the staff performances through the yearly evaluation (Refer to LRM-PER-SOP001 – Personnel management).

2.1.8. Continuing Education and professional development

CILM management considers to provide those training needs identified from audit findings, competency evaluation, staff yearly evaluation and or suggested by staff during meetings. When training is considered and available the related staff must follow and complete the training.

All staff is applying to the Staff Yearly Evaluation, in this activities staff will receive the improvement points from managers, staff should take part of continuing improvement their professional skill and Behavior

(Refer to: ISO15189:2012 / 5.1.8)

2.1.9. Personnel records

Records of the relevant educational and professional qualifications, training and experience and competency assessment are maintained in personal file and specific binder of each record. (Refer to: LRM-PER-SOP001 Personnel management Procedure).

2.2. Accommodation and environmental conditions

2.2.1. General

CILM laboratory has a space allocated for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel visitors. (Refer to LRM-SSM-MAN002: Safety manual).

2.2.2. Laboratory and office facilities

The laboratory and associated office facilities is provided an environment suitable for the tasks to be undertaken, to ensure the following conditions are met:

a) Access to areas affecting the quality of examinations is controlled.

NOTE Access control is taking into considering safety, confidentiality, quality and prevailing practices.

b) Medical information, patient samples, and laboratory resources are safeguarded from unauthorized access.
c) Facilities for examination allows for correct performance of examinations. These include, for example, energy sources, lighting, ventilation, noise, water, waste disposal and environmental conditions.
d) Communication systems within the laboratory are appropriate to the size and complexity of the facility to ensure the efficient transfer of information.
e) Safety facilities and devices are provided and their functioning regularly verified.

EXAMPLE Operation of emergency release, intercom and alarm systems for cold rooms and walk-in freezers; accessibility of emergency showers and eyewash, etc.

2.2.3. Storage facilities

Storage space and conditions are provided to ensure the continuing integrity of sample materials, documents, equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results.

Clinical samples and materials used in examination processes are stored in a manner to prevent the contamination.

Storage and disposal facilities for dangerous materials are appropriate to the hazards of the materials and as specified by applicable requirements.

2.2.4. Staff facilities

CILM has adequate access to washrooms, to a supply of drinking water and to facilities for storage of PPE and clothing. Including meetings room and quiet study and a rest area.

2.2.5. Patient sample collection facilities

Patient sample collection facilities is separate reception/waiting and collection areas. Appropriate accommodation of patient privacy, comfort and needs (e.g., disabled access, toilet facility) and accommodation of appropriate accompanying person (e.g., guardian or interpreter) during collection.

Facilities at which patient sample collection procedures are performed (e.g., phlebotomy) shall enable the sample collection to be undertaken in a manner that does not invalidate the results or adversely affect the quality of the examination. Sample collection facilities shall have and maintain appropriate first aid materials for both patient and staff need.

NOTE Some facilities may need equipment appropriate for resuscitation; local regulations may apply.

2.2.6. Facilities maintenance and environmental conditions

The facilities are maintained in a functional and reliable condition. Work area is cleaned and well maintained (Refer to LRM-SSM-MAN001: Safety Manual).

2.3. Laboratory equipment, reagents and consumables

2.3.1. Equipment

2.3.1.1. Equipment acceptance testing

Installation process and before use, the equipment has been verified that it is capable of achieving the necessary performance and complies with requirements relevant to any examinations concerned.

NOTE This requirement applies to: equipment used in the laboratory, equipment on loan or equipment used in associated or mobile facilities by others authorized by the laboratory.

Each item of equipment has been uniquely labelled, marked or otherwise identified (Refer to LRM-EQP-SOP030: Equipment Management Procedure).

2.3.1.2. Equipment instructions for use

Equipment has been operated at all times by trained and authorized personnel.

Current instructions on the use, safety and maintenance of equipment, including any relevant manuals and directions for use provided by the manufacturer of the equipment, are readily available.

NOTE: Excepted some equipment that arrived earlier the QMS is implemented so instruction of use missed but SOP of use is available.

SOP for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration is available (Refer to LRM-EQP-SOP030 Equipment Management Procedure).

2.3.1.3. Equipment calibration and metrological traceability

Equipment that directly or indirectly affects examination results must be calibrated over the entire range of use within the specifications required. Calibration certificates are verified and archived by QO. (Refer to LRM-EQP030 Equipment Management Procedure).

2.3.1.4. Equipment maintenance and repair

SOP of preventive maintenance which, at a minimum, follows the manufacturer's instructions is available: (Refer to LRM-EQP-SOP030 Equipment Management Procedure).

Equipment has been maintained in a safe working condition and in working order. This is included examination of electrical safety, emergency stop devices where they exist and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons. At a minimum, manufacturer's schedules or instructions, or both, shall be used.

Whenever equipment is found to be defective, it must be taken out of service and clearly labelled. The laboratory is ensured that defective equipment is not used until it has been repaired and shown by verification to meet specified acceptance criteria. The laboratory shall examine the effect of any defects on previous examinations and institute immediate action or corrective action (Refer to: SOP-NCE-SOP001: Non-conformity Corrective and Preventive action procedure).

Lab Management takes reasonable measures to decontaminate equipment before service, repair or decommissioning, provide suit able space for repairs and provide appropriate personal protective equipment.

When equipment is removed from the direct control of the laboratory, the lab management ensured that its performance is verified before being returned to laboratory use.

2.3.1.5. Equipment adverse incident reporting

Any adverse incidents and accidents attributed to specific equipment occurs, it is reported in a non-conformity where it is investigated. Major incident is reported to the manufacturer. (Refer to: LRM-NCE-SOP001: Non-conformity Corrective and Preventive action procedure).

Equipment records: Records has been maintained for each item of **equipment that contributes to the performance of examinations.**

- File name: Fixed Asset CILM 2009-2022
- Address in server: Z:\Equipment Management\Equipment_Inventory

These equipment records shall include, but not be limited to, the following:

- Name of the equipment;
- Brand (manufacturer), Model, Serial number;
- Location;
- Date of reception;
- Condition when received;

- Current condition;
- Maintenance date, frequency and type;
- Calibration date, frequency and type;
- Person in charge;
- Buying prize;
- Supplier and contacts.

Refer to (Refer to LRM-EQP-SOP030 Equipment Management Procedure).

2.3.2. Reagents, Chemicals and consumables

2.3.2.1. General

SOP for the reception, storage, acceptance testing and inventory management of reagents and consumables is available. (Refer to LRM-REA-SOP001-Inventory Management Procedure)

2.3.2.2. Reagents and consumables — Reception and storage

Where the laboratory is not the receiving facility, it shall verify that the receiving location has adequate storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration. CILM stored received reagents and consumables according to manufacturer's specifications.

2.3.2.3. Reagents and consumables — Acceptance testing

Each new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, must be verified for performance or lot-to-lot verification before use in examinations. Consumables that can affect the quality of examinations must be verified for performance before use in examinations.

2.3.2.4. Reagents and consumables — Inventory management

CILM inventory control system for reagents and consumables is implemented. The system for inventory control shall segregate uninspected and unacceptable reagents and consumables from those that have been accepted for use.

All reagent, chemicals and consumables are identified by a unique code and recorded in the Stock Management System called "BANSI.LA" to ensure thereby their traceability by the stock officer. (Refer to LRM-REA-SOP001-Inventory Management Procedure)

Every three months the stock officer is responsible for checking the inventory to ensure the proper status of the reagent, chemicals and consumables and anticipates the product availability for the laboratory.

2.3.2.5. Reagents and consumables — Instructions for use

Instructions for the use of reagents and consumables, including those provided by the manufacturers, are readily available (archived in Quality Cabinet).

2.3.2.6. Reagents and consumables — Adverse incident reporting

Adverse incidents and accidents that can be attributed directly to specific reagents or consumables must be investigated and reported to the manufacturer and appropriate authorities, as required.

2.3.2.7. Reagents and consumables — Records

Records shall be maintained for each reagent and consumable that contributes to the performance examinations. These records shall include but not be limited to the following:

a) Identity of the reagent or consumable;
b) Manufacturer's name and batch code or lot number;
c) Contact information for the supplier or the manufacturer;
d) Date of receiving, the expiry date, date of entering into service and, where applicable, the date the material was taken out of service;
e) Condition when received (e.g., acceptable or damaged);
f) Manufact user's instructions;
g) Records that confirmed the reagents or consumable's initial acceptance for use;
h) Performance records that confirm the reagents or consumable's ongoing acceptance for use.

Where the laboratory uses reagents prepared or completed in-house, the records shall include, in addition to the relevant information above, reference to the person or persons undertaking their preparation and the date of preparation.

2.3.2.8. Instruction for use

The instruction for use of reagents and consumables are readily available in examination area trough the related examination SOP or manufacturer manual in the original packaging of the reagent, chemicals or consumables.

2.3.2.9. Adverse incident reporting

Any adverse incidents and accidents attributed to specific reagent, chemicals or consumables occurs, it is reported in a non-conformity where it is investigated. Major incident are reported to the manufacturer. (Refer to SOP LRM-OCP001 Non conformity Corrective and Preventive action procedure).

2.3.2.10. Records

Reagent, chemicals and consumables are recorded into the Stock Management System "STOCKS CILM" which include the following information (Refer to LRM-REA-SOP001-Inventory Management Procedure).

1. The name of the reagent or consumable;
2. The manufacturer's name, batch number or lot number;
3. Date received, expiry date, date of starting to use;
4. Current location, where appropriate;
5. Condition when received and contact information;
6. Copy of the manufacturer's instructions, where available;
7. The preparation date and initials of responsible person (for in-house preparation reagents).

2.4. Pre-Examination

2.4.1. General

The procedure for Pre-Examination has been established and implemented as per (LRM-PRE-SOP001: Pre-Examination Procedure)

2.4.2. Information for patients and users

CILM information is available for patients and users that includes an explanation of the clinical procedure to be performed to enable informed consent. Importance of provision of patient and family information, where relevant (e.g., for interpreting genetic examination results), shall be explained to the patient and user (Refer to: LRM-SERV-MAN001: Service Manual).

2.4.3. Request form information

Request forms are available as annexes of LRM-SERV-MAN001: Service Manual is available at CILM's website and communicated to all clients or users through meetings, training, workshop.

2.4.4. Primary sample collection and handling

CILM has SOP for the proper collection and handling of primary samples. The SOP is available to those responsible for primary sample collection whether or not the collectors are laboratory staff. (Refer to LRM-PRE-SOP001: Pre-Examination Procedure).

2.4.5. Sample transportation

CILM has SOP for monitoring the transportations of samples to ensure they are transported refer to LRM-PRE-SOP001: Pre-Examination Procedure)

2.4.6. Sample reception

All specimens are inspected according to acceptance/rejection criteria. CILM rejects specimens which are not complied with its criteria as explained in the LRM-SERV-MAN001: Service Manual and LRM-PRE-SOP001: Pre-Examination Procedure.

2.4.7. Procedure handling, preparation and storage

The specimen/sample handling, preparation and storage are defined as per (LRM-PRE-SOP001: Pre-Examination Procedure procedure).

A unique registration number is assigned to each specimen/sample: **TEST (Year)(Month)(Day)-(No of sample of the day).** Laboratory staff responsible for sample labelling, aliquoting and storage sample in proper temperature and safety condition.

2.5. Examination processes

2.5.1. Selection, verification and validation of examination procedures

2.5.1.1. General

CILM selected examination procedures which have been validated for their intended use. The identity of persons performing activities in examination processes shall be recorded. The specified requirements (performance specifications) for each examination procedure shall relate to the intended use of that examination refer to: LRM-QC-SOP001: Method validation

2.5.1.2. Verification of Examination Procedures Validated

When the examination used are the same as the one provided by the manufacturer CE marked commercial reagent, is published in peer-reviewed journals, international or national guidelines; the laboratory check that the result obtained by the test in the laboratory are the same as given refer to: LRM-QC-SOP001: Method validation.

2.5.1.3. Validation of Examination Procedures

When the same examination procedures are performed in the same way on different machines, validation of results on both machines is needed. The laboratory will check that parallel testing is done to ensure that the results obtained by any one machine are identical to those obtained by any other machine refer to: LRM-QC-SOP001: Method validation.

2.5.1.4. Measurement Uncertainty of Measured Quality Values

CILM determines measurement uncertainly for each measurement procedure in the examination phase used to report measured quantity values on the patients' samples. Define the performance requirements for measurement uncertainly of each measurement procedure and regularly review estimates of measurement uncertainty refer to: LRM-QC-SOP001: Method validation.

2.5.2. Biological reference intervals or clinical decision values

Biological reference intervals and clinicals decisions are defined by the medical doctors of CILM according to the published in peer-reviewed journals, international or national guidelines.

If changes an examination procedure, CILM will review associated reference intervals and communicate to users.

2.5.3. Documentation of examination procedures

All SOP for examination phase is implemented by the laboratory staff and accessible by all staff refer to all examination SOPs:

1. LRM-EXAM-SOP006 HBV DNA Quantification by Abbott RealTime HBV assay
2. LRM-EXAM-SOP007 HCV RNA Quantification by Abbott RealTime HBV assay
3. LRM-EXAM-SOP009 Genotyping for ARV Drug Resistance of HIV-01
4. LRM-EXAM-SOP010 HIV-1 RNA Quantification by Abbott RealTime HIV-1 assay
5. LRM-EXAM-SOP012 Sputum and extra pulmonary specimens (CSF, lymph nodes and other tissues) for Xpert MTB/RIF
6. LRM-EXAM-SOP013 GenoType MTBDRsl
7. LRM-EXAM-SOP014 HIV-1 DNA Cell Procedure

If CILM intends to change an existing examination procedure such that results or their interpretations could be significantly different, the implications should be explained to users of the laboratory services after validating the procedure.

2.6. Ensuring quality of examination results

2.6.1. General

CILM is ensuring the quality of examinations by performing them under define conditions. Appropriate pre- and post-examination processes shall be implemented. Quality control procedures that verify the attainment of the intended quality of results. (Refer to: LRM-QC-SOP002: Ensuring quality of examination results).

2.6.2. Quality control

Each method used in the laboratory has a quality control process defined in the examination SOP related. (Refer to all the examination SOP) and LRM-QC-SOP002: Ensuring quality of examination results).

The quality control materials are examined as per examination SOP and according to the manufacturer requirement.

The internal QC checks may differ slightly for each individual procedure, If the quality control sample results fall within the acceptance criteria detailed in the procedure, the analytical data are considered valid or acceptable. The lab manager performs a scientific review of the data for final validation. The acceptance criteria for QC sample data are specified in each analytical procedure.

Quality control data should be reviewed by lab director at regular intervals to detect trends in examination performance that may indicate problems in the examination system. When such trends are noted, preventive actions shall be taken and recorded.

2.6.2.1. External Quality Assessment (EQA):

EQA procedure for participation, responsibilities, and instruction and performance criteria is described in each examination SOPs and LRM-QC-SOP002: Ensuring quality of examination results).

Evaluation of laboratory performance

The performance in external proficiency panels is reviewed by the laboratory director or lab manager and relevant staff.

1. The corrective action is used to document quality control results that fall outside the established ranges, inconsistency in results or problems with the test system (reagents, controls, instrument or equipment);
2. The testing technician is responsible for documenting any problems and corrective action taken on the corrective action log for that test system;
3. The laboratory Manager or designee is notified immediately of any problems and will review the corrective action.

2.7. Post-examination processes

2.7.1. Review of results

It is the responsible of every lab staff that should ensuring the test has been performed appropriate with the test SOPs and should review and signed the results report as performer.

Validation of lab results is the responsibility of Lab Managers and Lab Director to ensure the interpretation of results is reliable and accuracy. (Refer to LRM-POS-SOP001: Post Examination Process).

2.7.2. Storage, retention and disposal of clinical samples

Lab Director is responsible for the retention time follow up, and laboratory technician are responsible for proper disposal according. (Refer to LRM-PRE-SOP001: Pre-Examination Procedure procedure).

2.8. Reporting of results

2.8.1. Report content

All CILM results are recoded in to private database (File maker), and on paper base patient's form.
The final paper report result released from the laboratory includes at least the following:

- Name and Code of patient;
- Date of birth;
- Hospital name;
- Reason for the request of test;
- Cut off values;
- Treatment used;
- Date started of treatment;
- Sampling date;
- Lab code;
- Result values;
- Interpretation of result;
- Remarks;
- Date of publication of result;
- Signature.

2.9. Release of results

2.9.1. General

The final result report must always be validated by the Lab director and ready for release as: hard copy, phone application and emails.

The results of each examination is being reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures.

CILM test results must be originated based on appropriate formats and medium of the report including electronic or paper and the manner in which it is to be communicated from the laboratory. (Refer to LRM-POS-SOP001: Post Examination Process).

Reports shall include the information necessary for the interpretation of the examination results.

The procedure of notifying the requester when an examination is delayed that could compromise patient care. (Refer to LRM-POS-SOP001: Post Examination Process).

2.10. Laboratory information system

2.10.1. Information system management

CILM has access to the data and information needed to provide a service which meets the needs and requirements of the user. Ensure that the confidentiality of patient information is maintained at all times is refer to: LRM-LIM-SOP001-Information Management.

2.10.2. Authorities and Responsibilities

CILM ensures that the authorities and responsibilities for the management of the information system are defined, including the maintenance and modification system(s) that may affect patient care. refer to: LRM-LIM-SOP001-Information Management.

Defines the authorities and responsibilities of all personnel who use the system, in particular those who:

a. Access patient data and information;
b. Enter patient data and examination results;
c. Change patient data or examination results;
d. Authorize the release of examination results and reports

2.10.3. Information System Management

The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information is File-Maker and Lab-Book Software.

CILM verifies that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information (e.g., computer systems, e-mail, website, personal web devices). When a new examination or automated comments are implemented, the laboratory should verify that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory.

CILM has documented contingency plans to maintain services in the event of failure or downtime in information systems that affect the laboratory's ability to provide service refer to: LRM-SSM-MAN001-A02: Contingency plan

When information system(s) are managed and maintained off-site or subcontracted to an alternative provider, laboratory management should be responsible for ensuring that the provider or operator of the system complies with all applicable requirements of ISO15189.

DOCUMENTTATION

This SOP is archiving at "Quality Cabinet" accessible by all staff and responsible by QBO and QBA.

ANNEXES,

N/A