ສູນວິໄຈພະຍາດຊິມເຊື້ອ ລາວ-ຄຣິສຕຶຟ ເມຣິເອ
ສอลม
CILM
Center Infectiology Lao-Christophe Merieux

2020

LRM-MAN-001

QUALITY MANUAL

Center of Infectiology Lao-Christophe Merieux (CILM)

Version: 05

Application date: 30/02/2020

Center of Infectiology Lao-Christophe Merieux (CILM)
Samsenthai Road, Kaoyot Village, Sisathanak District, Vientiant Lao PDR
Email: contact@ccm-laos.org
Tel: +856 (0) 21 260 357 – fax: +586 (0) 21 260 358

Introduction

This quality manual provides guidance for CILM on writing policies and procedures that support the quality management system based on both ISO15189 and ISO15190 requirements.

It defines the general policy for quality assurance to be conducted at CILM.

A quality manual is required for implementing a quality management system. Such a system aims primarily at archiving customer satisfaction by meeting customer requirements through application of the system, continuous improvement of the system, and prevention of the occurrence of nonconformities.

CILM's QUALITY STANDARD

GOAL

"The main objective of CILM laboratory is to provide reliable, timely and accurate testing results (HIV_viral load). Including all the facilities and environments are meet the satifaction of clients."

POLICY STATEMENTS

1) To comply with ISO15189:2012 and ISO15190:2003 standard at all time for HIV Viral Load Testing;
2) Using standard technology and equipment;
3) To ensure compliance with the statutory services using standard technology;
4) To ensure adequate staff and competency, enabling effective professional services;
5) Ensuring accuracy and reliability of testing results and report on time;
6) To ensure excellence in medical laboratory services and meet client's satisfaction.

ETHICAL AND CONFEDENTIAL

The laboratory's obligation is to ensure that the patient's welfare is the highest priority. CILM team commits to conduct Good Clinical Laboratory Practice (GCLP) for diagnosis and research.
Confidential includes, but is not limited to, all information of a secret or confidential nature relating to the staff nature related to the affairs of any person whose information is held within the CILM. This will include: patient's relatives and friends, employees and any business or affairs of any other.

NON-CONFLICT INTEREST

Laboratory management and *CILM personnel* are free from any commercial, financial or other pressures and influences that may affect the quality if their work, if the potential conflicts in competing interests exist, they will be openly and appropriately declared.

CILM personnel must perform duties as per their job description, avoid involvement in any activities that diminish confidence in its competence, impartiality, judgment or operational integrity and must read and sign the declaration for conflict of interest form.

COMMIMENT

Our hard work on quality is to provide reliable testing results for all CILM is engaged to implement Quality Management System (QMS) per ISO 15189:2012 since 2014 with collaboration with Foundation Merieaux.

We at CILM commit to provide Quality Medical Laboratory service in terms of generating reliable patient test reports, on time, using appropriate technology of internal standards through committed and competent staff, who ensures to abide by the policies and procedures of the laboratory at all times with complete awareness of the required documentations.

And we would like to ensure that all staff and patients coming to the CILM are within safe environment.

Vientiane Capital, Date: 30 MAR 2020

Deputy Director of Center for Disease Control and Prevention
Executive Director of Center Infectiology Lao-Christophe Merieux

ดร.สีสะหวาด สุดทาบีละไซ
Dr.Sisavath SOUTTHANIRAXAY

DOCUMENT CONTROL INFORMATION

Activities	Name	Position	Date	Signature
Author	Mixivang XAYAOVONG	Quality/Biosafety Officer	30/02/20	
Review	Phimpha PABORIBOUNE	Laboratory Scientific Director	30.03.20	
Validators	Sisavath SOUTTHANIRAXAY	Executive Director	30/3/20	

History of modifications:

Version	Date	Comments
01	2017	Initial version.
02	15/12/2018	• Update template; • Summary reorganization to match witht the ISO 15189:2012 requierement; • Update the responsibles 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 "Organizarion 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 responsabilities.
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.

Copy needed and location

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

Next revision planned: 01/02/2022

Contents

SCOPE OF APPLICATION OF THE MANUAL

The quality manual is applied to all staff and all quality activities at Center of Infectiology Lao-Christophe Merieux (CILM) including pre-analysis, analysis and post-analysis. It should be reviewed at least **every 2 years**

DEFINITION

- **BSL** Biosafety Level;
- **CILM** Center Infectiology Lao-Christophe Mérieux;
- **CDC** Centres for Disease Control and Prevention, USA;
- **CISI** Clinical and Laboratory Standards Institute, Wayne, Pennsylvania, USA;
- **EQA** External Quality Assessment;
- **ISO** International Organization for Standardization;
- **LQMS** Laboratory Quality Management System;
- **QC** Quality Control;
- **QM** Quality Manual;
- **QMS** Quality Management System;
- **QSE** Quality System Essential;
- **SOP(s)** Standard Operating Procedure(s);
- **WHO** World Health Organization.

REFERENCE

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

I. Quality Management System (QMS)

1.1. Organizarion and management responsibility

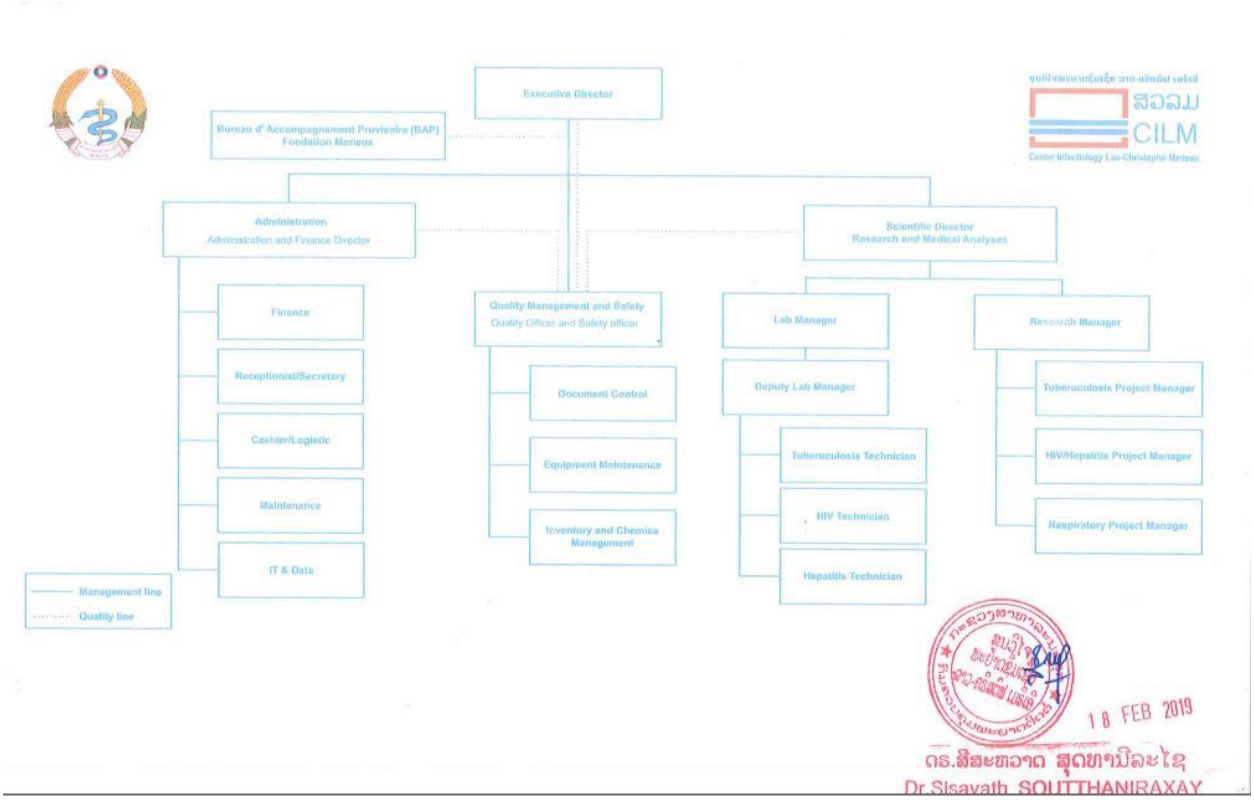
1.1.1. Organization

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's organization chart



ACTIVITIES:

To conduct its mission, the CILM follow dedicated activities:

- **Routine and specialized biology testing** of; HIV viral load measurement and ARV susceptibility testing; Hepatitis B on serological samples as well as plasma for viral load quantification; Hepatitis C viral load measurement and genotyping; *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.

MISSION AND VISION:

The CILM is a biomedical laboratory that provides research and testing for HIV, Tuberculosis, Hepatitis B and C to physicians, health care providers, and epidemiologists for the benefit of the patient and population of Lao PDR. Inaugurated in 2009, the CILM develop diagnostic tools for infectious diseases.

Since 2012, the laboratory has adopted a quality management system for the purpose of effective and efficient use of its resources. All employees are committed to the culture of quality.

Provide patient with quality diagnostic for improvement care.

Conduct project that address 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.

1.1.1.2. Legal entity

The Center of Infectiology Lao-Christophe Merieux (CILM) has been inaugurated in 2009 and belongs to the Ministry of Health of Lao PDR under the Communicable Diseases Control Department ***(Reffer to: document Authorization management - nº163/26th Jan 2009).***

1.1.1.3. Ethical conduct

CILM director ensuring the ethical conduct of CILM personnel and patient's welfare is of the highest priority. (Refer to page nº 3 of this manual).

1.1.1.4. Role and responsibilities of CILM management

Positions	Responsibilities
CILM General Director	1) Act as the laboratory director and ensure the ISO 15189:2012 and 15190:2003 compliance; 2) Delegate responsabilities to qualified personnel but remain the overall responsible for the operation and administration of the CILM; 3) Provide professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory and delegates tasks to qualified personnel; 4) Designs, approves, implements and maintains the CILM QMS; 5) Ensures adequate number of staff and training for all CILM staff. And provide opportunities to participate to developpement programmes 6) Ensures internal and external communication; 7) Plan and direct research and developpement.
Laboratory Scientific Director	1) Responsible and advice technically the laboratory for overall compliance of ISO 15189:2012 and 15190:2003; 2) Participates in management review of the QMS; 3) Designed responsibilities for the quality officer, lab manager and deputies; 4) Ensure the good research conduct and the scientific rightness of the laboratory activities. 5) Select and monitor referal laboratories.
Administrative Director	1) Ensure the budget planning, financial management, procurement, administrative and accounting management; 2) Responsible for the Hurman resource management; 3) Communicate with external funding partner; 4) Select and monitor laboratory supplier;
Laboratory Manager	1) Responsible to assist lab director for the overall ISO 15189:2012 and 15190:2003 compliance of laboratory and conducts as the lab director when the lab director can not be on duties; 2) Monitor all work performed in the laboratory to determine the clinical relevance information is generated; 3) Implement the applicable of good clinical laboratory practice ; 4) Ensures that the necessary human and material resources, as well as the necessary information, are available to enable effective operation and control of the processes of the QMS; 5) Provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with situational assignment of such responsibilities; 6) Participate in management review of the QMS and writing of laboratory documents; 7) Resolves the problem of the environment for CILM laboratory; 8) Ensure the lab is kept clean and tidy; 9) Ensure to controll internal and external quality assurance for laboratory tests.

	10) Select and monitor referal laboratories.
Quality Officer	1) Has completed the required level of training as specified in the ISO requirements; 2) Ensure the implementation of ISO 15189:2012. Responsible to develop, maintain and improve the laboratory quality system; 3) Supervise the quality activities of the laboratory; 4) Establishes and coordinate internal audit program; 5) Participates in available and relevant proficiency tests or interlaboratory; 6) Coordinates and participates in management review of the quality system; 7) Provides and control all laboratory quality procedure; becomes aware in daily practice; 8) Define, implement and monitor standards of performance and quality improvement.
Biosafety Officer	1) Ensure the implementation of ISO 15190:2003, monitoring, assessment the safety of the environnement for CILM staff and user.
Lab Technician	1) Follow the SOP and performs the laboratory testing; 2) Controls and maintains equipments, record logbooks; 3) Reports any significant problems of which he/she becomes aware in daily practice by recording nonconformity form; 4) Checks performance of internal Quality Control (QC) to validate the tests.
All CILM staff	1) Preform the assignments according to the job description and follow CILM procedure; 2) Document on time the tasks: author, review, validate SOP and record logbook; 3) Reports any significant problems of which he/she becomes aware in daily practice; by recording nonconformity form and sample rejection; 4) Follow meeting and training assigned; 5) Keep the environment safe; 6) Adress any complaint, request or suggestion.

(Table nº01: Role and responsible for the laboratory management)

1.1.1.5. Needs of users

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

Customer satisfation and requirements are identified, reviewed and promptly responded to ensure that the needs and requirements are fully understood and met. (Refer to SOP - LRM-ICP002 Custommer management).

1.1.1.6. Quality policy

To ensure that CILM activities performing is complying with CILM goal. The policy has been created to provide as a frame work for establishing and revewing quality objectives. (Refer to Quality Policy on page nº3 of this manual).

Quality policy is communicated and understood with the organization trough the quality bill board post, and present with the quality manual in the meeting and located in the server can access by all CILM staff.

1.1.1.7. Quality objective and plaing

To ensure CILM is functioning complying with the policy, the laboratory manager and quality officer has been create or draft as a plan for each year continuing year to year to ensure CILM is moving forward to the goal of the center. (Refer to SOP LRM-GQP002 - Quality Action Plan Management Procedure).

Quality year plan drafted or created based on the audit and assessments performed of the previous years. Which will summaries all nonconformity items and continuous improvements.

Implementing action plan following the rule of **SMART**:
S – Specific;
M – Measurement;
A – Agreement;
R – Realistic;
T – Time bound.

1.1.1.8. Responsibility, authority and interrelationships

This is written on the job description of each position in the personnel file. (Refer to: LRM-HRP001-Personnel Management Procedure).

1.1.1.9. Communication process

Internal communication:

Communication path	Participate	Objective	Means
Yearly board meetings	CILM Management.	Review CILM previous year activities and next year organization and planed activities.	Minute of meeting.
CILM Monthly meeting	CILM staff.	Review CILM previous month activities and plan for next upcomming month.	Minute of meeting.
Quality management review meeting	CILM staff.	Review the efficiency of the pre-analytical, analytical and post analytical process in CILM.	Management review report.
Lab weekly meeting	Laboratory Staff.	Review and plan the weekly Pre analytical, Analytical and Post analytical activities of the laboratory. Update of equipment problem; Quality activities and laboratory related informations.	Lab weekly meeting report (Annex 01: Lab weekly meeting report).
Computerized server	CILM staff.	Store and share safely all CILM documentation.	Share folders (\\192.168.1.3) (Z).
Email	CILM staff.	To communicate within the center and to external user according to CILM works and needs.	Emails.

Telecommunications	CILM staff.	Ensure good communication inbetween the CILM staff.	Email and intercom.
Quality billboard	CILM staff.	Ensure the communication on the quality activities inbetween the CILM staff	Quality billboard posted document.

External communication:

Communication path	Participates	Objectives	Means
CILM website	CILM staff.	Ensure good communication with the CILM user.	http://www.ccm-laos.org
Results reports	Laboratory staff.	Communicate the tests results to the requester.	Request forms, Result report.
Telecommincations	CILM staff and users.	Ensure good communication with the CILM user and provide medical advice.	Email, Phone, Fax, Brochure.
Seminars organization	CILM staff and users	Organize seminars, trainings and workshops.	Networking.

(Table nº02: Communication)

1.1.1.10. Quality Officer Resposible

1.) Establish Quality Management System at CILM with CILM managers to keep the standard of the laboratory as ISO 15189:2012 and ISO15190:2003;
2.) Acting as a catalyst for change and improve on quality activities in the CILM:
   - Implementing and ensuring the completeness of quality year plan;
   - Monitoring and coordination of the processes for all action points implemented until completion.
3.) Ensuring CILM staffs are working compliance with ISO requirements:
   - Perform internal quality audit.
4.) Monitoring, reporting and recording all nonconformity in CILM. Ensuring appropriate corrective and preventive action;
5.) Ensuring staff are trained as mandatory training needed on quality requirement;
6.) Ensuring good documentation management system:
   - Create all procedures and monitoring the process until the document is been completed. And coordinate with all staff to establish procedures related to his/her tasks;
   - Implement and update the Document Master List;
   - Manage, archived and organize all quality documents;
   - Control and update manuals, SOPs and annexe/forms to comply ISO 15189 requirement.
7.) Record, analyse and report statics of quality management system and report to the:
   - Monthly meeting, quarterly report, management review;
   - Implement, monitoring, summarize and report Quality indicators. And find the solution for the task outside of the target.

1.2. Quality management system

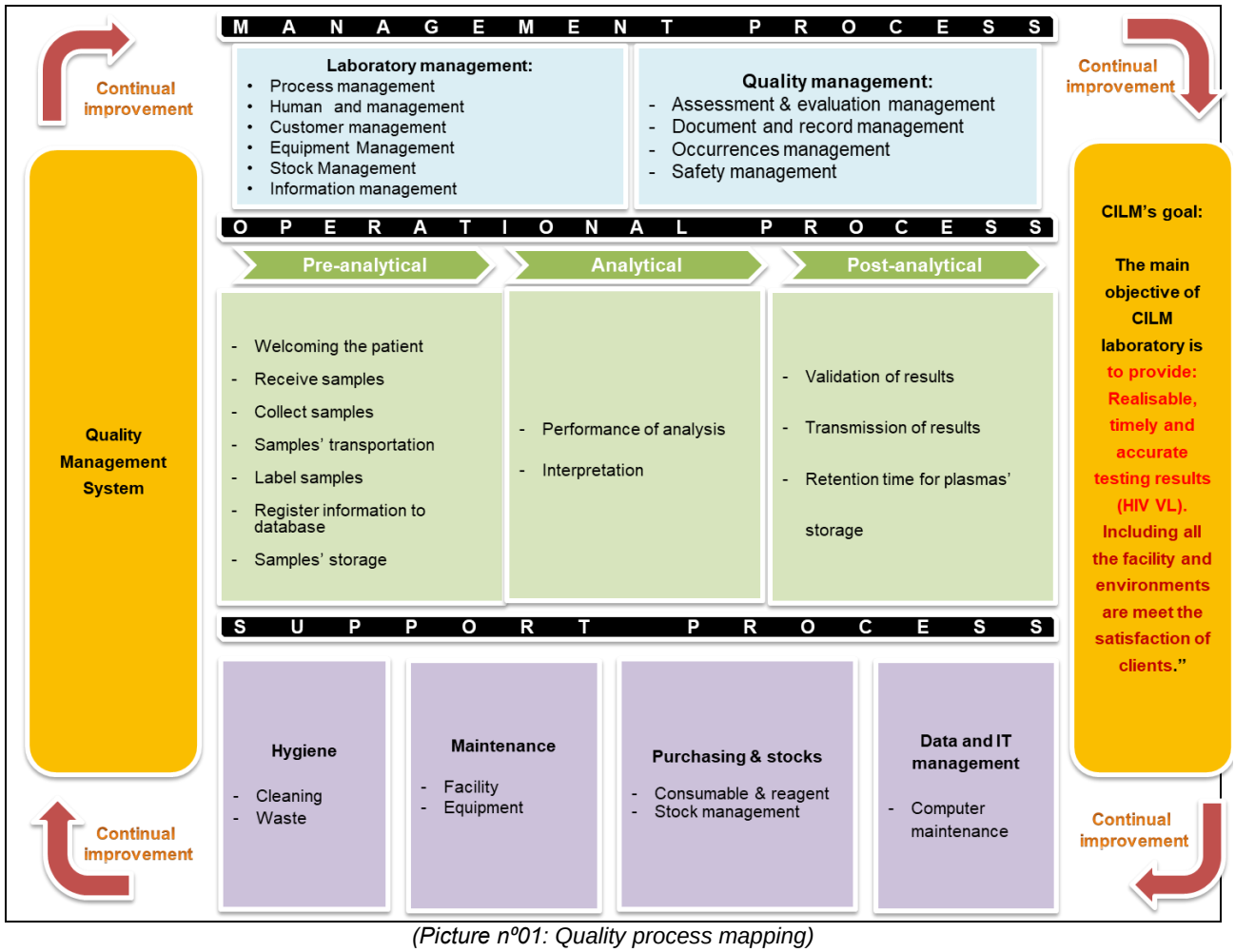
1.2.1. General

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

1.2.1.1. Mapping process

Quality Management System in the CILM it defined base on 3 objectives as:

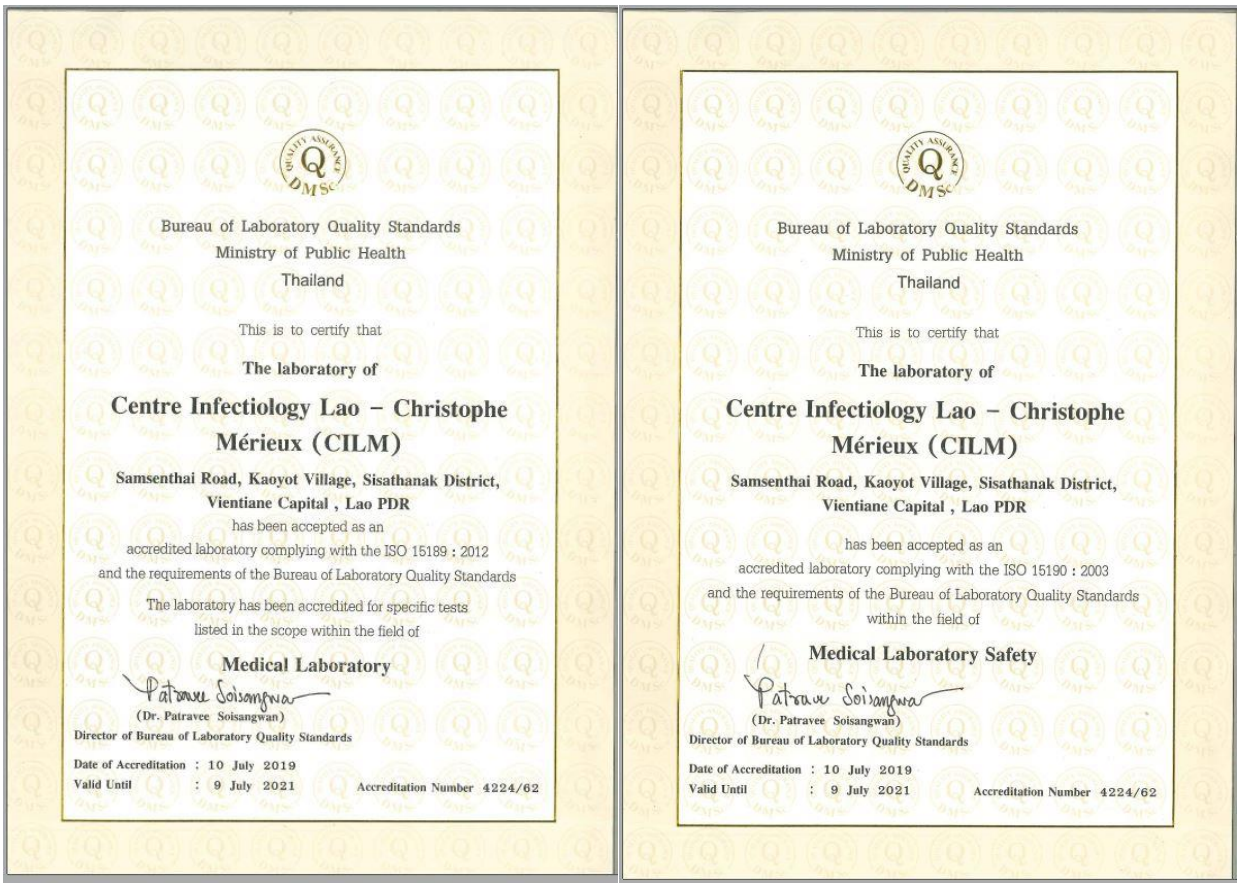
- **Management process:** all the general procedure, policy and means of CILM organization;
- **Operational process** : is the process of performing laboratory activities which cover pre-analytical, analytical and post-analytical process;
- **Support process:** is all the procedure that supports the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



(Picture nº01: Quality process mapping)

1.3. Accreditation

CILM is accredited for ISO15189:2012 and ISO15190:2003 on HIV Viral Load Testing on 10th July 2019, Accreditation Number: 4224/02.



Bureau of Laboratory Quality Standards
Ministry of Public Health
Thailand

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 : 10 July 2019
Valid Until : 9 July 2021 Accreditation Number 4224/62

Bureau of Laboratory Quality Standards
Ministry of Public Health
Thailand

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 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 : 10 July 2019
Valid Until : 9 July 2021 Accreditation Number 4224/62

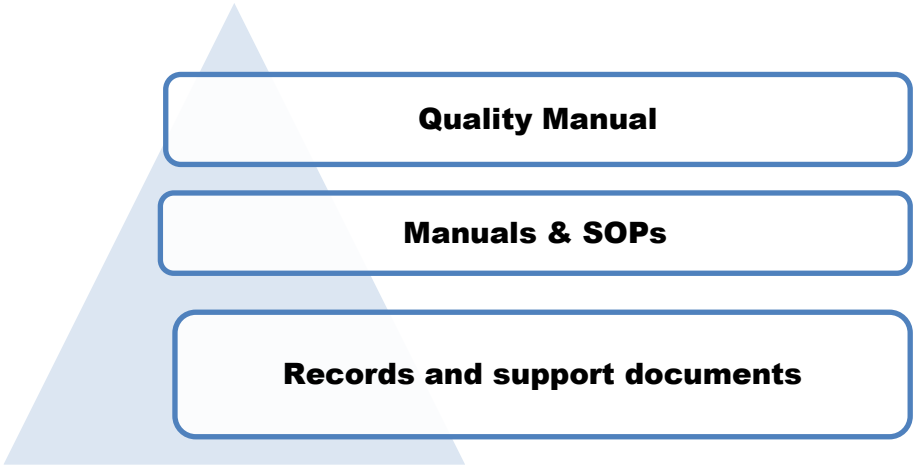
To get the accreditation CILM implementing LQSI_Tools, 4 phases of WHO *(https://extranet.who.int/lqsi/)* and follow the ISO15189:2012 requirements.

1.4. Documentation

Quality Officer is responsible for all quality documents, and ensuring documents are up to date on time, current version is in place and the obsoleted version is destroyed appropriately (Refer to: LRM-DIP002 – Document Management procedure).

1.4.1. Type of documents:

Rankings of quality documents management system similar to the pyramid:



(Picture nº02: Pyramid ranking of quality document)

Manuals

- LRM-MAN001 - Quality Manual: contains the Quality Policy and also all policies relating to the requirements of ISO 15189:2012.
- LRM-MAN002 - Service maual: contains all information related to CILM services;
- LRM-MAN003 - Safety manual: containts all information related to health and safety.
- LRM-MAN004 - Newcomer's manual: containts CILM general information and facilities.

Standard Operation Procedure (SOP):
SOP is the document that describing clearly how to perform the operation process of each activity ex: HIV VL testing SOP.

Short procedure or flowchart:
Is a document that describes the step by step of a specific task.

Supporting documents: are documents used to support the QMS including:

a. Record: is document that indicates that QMS checked is regularly performed;
b. Manufacture of equipment and reagents that use to be a reference;

1.4.2. Documents and record control

Quality documents are uniquely identified with at least the following included:

- Header: CILM logo, document title, sub process, document code, version, total number of pages and application date.
- Authorizing signatories and date;
- History of modification;

- Location of copy needed;
- Next revision planed;
- Table contain.

Document control database is maintained identifying the current valid versions and their distribution.

A secure master file is maintained of all documents to prevent unauthorized access, loss or damage. (Refer to SOP LRM-DIP002-Document control management).

1.4.3. Coding

Each SOP gets a unique code in the header of each page.

Process	Sub-process	SOP Code2	Meaning of code
Management	Laboratory Management	LRM-HRP001	Humen Resource Procedure
		LRM-GLP001	General Laboratory Procedure
		LRM-GQP002	General Quality Procedure
	Quality Management	LRM-OCP001	Occurrence Procedure
		LRM-ICP001	Internal Control Procedure
		LRM-DIP001	Document and Information Procedure
Operation Procedure	Pre-Examination	LRM-PAP001	Pre-Analytical Procedure
	Examination	LRM-DHP001	Diagnosis Hepatitis Procedure
		LRM-DVP001	Diagnosis HIV Procedure
		LRM-DTP001	Diagnosis Tuberculosis Procedure
		LRM-DRP002	Diagnosis Respiratory Procedure
		LRM-MVP001	Method Validation Procedure
	Post-Examination	LRM-RRP001	Results Reporting Procedure
Support Process	Hygiene, Safety and Environment	LRM-HSP001	Hygien and Safety Procedure
		LRM-SSP 002	Safety and Security Procedure
		LRM-EMP001	Environment Management Procedure
	Purchasing-stock and Selection-evaluation Procedure	LRM-PSP001	Purchasing-stock and Selection-evaluation Procedure
	Equipment and maintenance	LRM-EQP004	Equipment Procedure

(Table n° 03: Coding)

Example: **LRM-EQPxxx – Name of document**

Note: Codes will not be changed after they have been assigned to a specific document.

1.5. Service agreements

Laboratory Scientific Director and lab manager decided what tests and methods will be used to ensure that the test requirements and methods to be used are adequately defined, documented and understood

Any lab test request accepted by the laboratory is considered based on LRM-MAN003 – Service manual.

1.6. Refferal laboratory

CILM can refer to laboratories when necessary as per SOP: LRM-PSP004 Selecting and evaluating referral laboratories.

1.7. External services and supplies

The evaluation of external services and suppliers is carried out according to criteria defined in the SOP (Refer LRM-PSP002-Selection and evaluation for suppliers).

1.8. 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-MAN003 – 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.

Informatioan for advisory service for ART site, hospital and clinics.

1.9. 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 SOP LRM – ICP003 – Complaints Handling Management).

1.10. 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-OCP001 – Nonconformity corrective and preventive action procedure).

1.11. Corrective and preventive action

CILM Staff is responsible for identifying the nonconformity, finding the root cause and evaluating the need of corrective and preventive action.

The Quality Officer is responsible for the follow-up and the evaluation of the actions (the efficiency and effectiveness of the actions). When the problem is solved or the situation is improved, the nonconformity case can be closed. (Refer to LRM-OCP001 – Nonconformity corrective and preventive action procedure).

1.12. Continual improvement

The Laboratory continuously improves the effectiveness of the QMS through the conduct of management review. Continuous improvement activities are performed to achieve the targets related to quality policies. When opportunities for improvement are identified, the laboratory management will address them regardless of where they occur and communicate to CILM staff the plans and related goals. (Refer to: LRM-OCP002 – Continual improvement).

The Quality officer is responsible for quality service improvement and will perform the following tasks:

- Conduct a customer satisfaction survey once a year;
- Receive complaints from customers;
- Review the quality indicators quaterly, and report to laboratory management;
- Supervise and coordinate the annual review of quality procedures, work instructions and all quality documents.

The Lab managers is responsible for the technical aspects of the test he/she is responsible for, and will perform the following tasks:

- Review the EQA results;
- Review the work instructions and quality documents related to the test he/she is responsible for;
- Give advice to customers as needed.

Any CILM staff who has the responsibility to attend the meetings will report at the weekly lab meeting the issues discussed during the meetings they attended or as soon as possible by writing an email if an issue needs a prompt response.

1.13. Control of records

Quality Officer is responsible for the proper archiving of documents and records trough the Document Retention Matrix (Refer LRM-DIP002 – Document management procedure).

A copy of an obsolete document is kept to provide a means for review if the situation arises. The quality officer monitors the archives by the destruction of documents which passed the time determined in the Document Retention List.

Any documentation errors are corrected by **drawing a single line through the error so that it remains legible and is initialed by the responsible individual, along with the date of change**. The correction is written adjacent to the error.

All laboratory records are retained. (Refer LRM-DIP002 – Document management procedure).

Laboratory records include the following:

- Request forms;
- Analysis of results and reports;
- Analysis procedures;
- Laboratory workbooks and worksheets;
- Calibration certificates and maintenance reports/records (logbooks);
- Quality control records;
- Complaints and action taken;
- Records of internal and external audits;
- Management Review Report;
- Nonconformity forms records including accident and incidents action taken;
- External quality assessment records (EQA records);
- Lot documentation, certificates of supplies, package inserts;
- Personnel information documents and records;
- Meeting report/records;
- Vendor and supplier evaluation report and approved vendor list;
- Sample shipping records and sample arrival checking records;
- Risk assessment records and reports;
- Customer satisfaction survey forms and reports.

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-MAN003 – Service manual).

1.14.3. Assessment of user feedback

CILM performs customer satisfaction survey at least once per year with all customers' interacting within CILM services (Refer to LRM-ICP002 – Customer management):

- patients walk in;
- conference room users;
- doctors council and workshops.

1.14.4. Staff Suggestions

CILM management encourages staff to make suggestions for improvement of any aspect of the laboratory service.
The suggestions from CILM staff are collected and discussed in the weekly meeting and CILM meeting
The suggestions are evaluated, implemented as appropriate and feedback provided to the staff.
Records of suggestions and action taken by the management are maintained.

1.14.5. Internal audit

Once a year, CILM organize an internal audit, led by the quality officer. The internal audit submits a full internal audit report, with achievements, findings and corrective action.

Twice a year, the quality officer fill LQSI tool checklist to monitor the accreditation process for achievement of compliance, and evaluate the quality at CILM. (Refer to LRM-ICP001 - Assessment procedure).

1.14.6. Risk management

Biosafety officer performs the risk assessment at least once a year to be improved to reduce or eliminate the identified risks (Refer to LRM-MAN002 – Biosafety manual).

1.14.7. Quality indicators

The process of monitoring quality indicators is planned for monthly and reviewed in the quarterly meeting. (Refer to LRM-OCP002 – Continual improvement).

Policy	Target	Period of review
To comply with ISO15189:2012 and ISO15190:2003 standard at all time for HIV Viral Load Testing.	Internal audit and safety audit 2020 results must be: - Number of Corrective Action Request (CAR) must be < 15; - Number of Opportunity to improve (O) must be < 15; Action plan 2020 must completed >95%.	1 per year
Using standard technology and equipment;	Any equipment calibration results that is not in accepted range. Then the corrective action must be addressed. Results of Error + Uncertainty must be in accepted criteria: Accepted criteria of calibration is between ±10% to ±20% of Standard value. • Type A: <±10% = Ready to use; • Type B: >±10% to ±20% = Alarm to check the equipment; • Type C: >±20% = The equipment should be re-calibrate or DO NOT USE!	1 per year
To ensure compliance with the statutory services using standard	Results of LQSI_Tool: Number of “YES” total/phase of each element must be **> 90%**	1 per year

technology.	Including: all official document from Ministry of Health.	
To ensure adequate staff and competency, enabling effective professional services.	1. Conduct Staff evaluation and competency assessment once time per year; 2. Training needs from the both assessments must be provided/conducted >65%.	1 per year
Ensuring accuracy and reliability of testing results and report on time.	1. Number of samples that out of CILM's criteria must be: • **HIV** viral load samples must <5 samples / year; • **Early Infant Diagnosis** samples must < 10samples / year; • **Hepatitis B and C** samples must <50 samples / 6months; • **GeneXpert samples** must <30 samples / year. 2. Delay **TAT** must be **< 5 times** for each test / year . 3. **EQA:** results must be pass **95%** of each test that applied / year. 4. **IQC:** Nonconformity related must be **< 5 times** for each test / year.	1 per year Except: Hepatitis B and C samples/ 6months;
To ensure excellence in medical laboratory services and meet client's satisfaction.	➢ Satisfied survey results must **> 85%** ➢ Complaint form must **< 5 forms** ➢ Nonconformity event must be close **>95%**	1 per year

(Table n°04: Quality indicator)

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

At least once in the period of 12 months, the laboratory management conducts a review of the quality system to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements in the quality system and laboratory operations The information includes the results of evaluations of input, activities review and output. (Refer to LRM-GLP001 – Management review).

Review of input

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.

II. 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 SOP LRM-HRP001 – Personnel management).

2.1.2. Personnel qualifications

The personnel qualifications for each position are recorded in the each personal file 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 SOP LRM-HRP001 – Personnel management).

2.1.5. Training

All staff are responsible for recommending the training needs. Once training needs are identified these are provided under the responsibility of the CILM Management. The training have been recorded. (Refer to SOP LRM-DIP002 Document management procedure).

2.1.6. Competency assessment

All employees are checked for competency at least once a year. New employees have the evaluation for probation period and competency in the first year of employment.

Competency is checked by: direct observation, quality control results and proficiency testing reviews, oral/written exam, repeat testing and unusual patient or control results. (Refer to LRM-HRP002 Staff competency assessments).

Competency evaluations score should reach above 90% satisfactory results. If an employee fails his/her competency checks, he/she must complete a retraining procedure before they can test patient samples. All competency testing are documented and kept in competency assessment binder.

Staff orientation of all new employees is to be completed within 90 days of hire. Safety orientation occurs before an employee is assigned to duties.

All newly hired employees are trained comprehensively on all policies and procedures in the department that apply to their job description and assignments. (Refer to LRM-MAN004 – Newcomer's handbook).

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-HRP001 – Personnel management).

2.1.8. Continuing Education and professional development

Continuing education provides personnel an opportunity to review and expand their knowledge of laboratory procedures and policies.

1) Continuing education may be earned through reading, videos, cassette tapes, departmental lectures, and conferences, training seminars, workshops, tech sample reviews or safety training (fire safety, universal precautions, and blood borne pathogens).
2) Each employee should keep a record of his or her continuing education. Any supporting documents should be given to the quality officer to maintain in the personnel file.

The effectiveness of the training program and continuing education will be periodically reviewed by lab director or designee (Refer to LRM-HRP001 Personnel management).

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-HRP001 Personnel management).

2.2. Accommodation and environmental conditions

2.2.1. General

The 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-MAN004 Newcomer's Handboook and LRM-MAN002 Biosafety manual).

2.2.2. Laboratory and office facilities

The CILM is equipped with advanced instrumentation and computers. The CILM laboratory is dedicated to HIV, Tuberculosis research and studies on other viral co-infections and has been designed to comply with the principles of Biosafety described for Laboratory Biosafety level 2. Access to all facilities is restricted to authorized persons. Keycard scanners are used to restrict access of the laboratories to authorized persons. (Refer to LRM-MAN002 – Biosafety manual).

The communication system in the laboratory is appropriate to ensure the efficient transfer of information. The laboratory and associated office facilities provide an environment suitable for the tasks to be undertaken.

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.

2.2.4. Staff facilities

The CILM management ensures that the appropriate space is provided for washrooms and drinking and eating. Appropriate space for meetings, studying and arresting is provided.

2.2.5. Patient sample collection facilities

CILM laboratory has served for patient sample collection and samples are sent from the clinical research sites as well.

Sample collection facilities have and maintain the first aid materials for both patient and staff needs.

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-MAN002 – Biosafety manual).

2.3. Laboratory equipment, reagents and consumables

2.3.1. Equipment

2.3.1.1. General

The equipment used in the measurement or assessment of data and equipment used for facility environmental control is of appropriate design and adequate capacity to function according to the protocol, suitably located for operation, inspection, cleaning and maintenance. (Refer to SOP LRM-EQU30 .Equipment management procedure).

2.3.1.2. Equipment acceptance testing

New equipment will be installed by the vendor when defined as critical. The laboratory participates, to the installation and will be trained by the vendor. For the non-critical new equipment, the laboratory will perform the installation and the training.

The laboratory ensures prior installation that space, ventilation, humidity and electricity meet specifications for satisfactory performance for the use of the instruments and equipment.

The laboratory will evaluate that the satisfactory performances are met and the documentation is done properly. All equipment needs to meet all the required criteria prior its first use in the laboratory. (Refer to SOP LRM-EQP030 Equipment Management Procedure).

2.3.1.3. Equipment instructions for use

Equipment are operated by trained and authorized personnel. The 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. The procedure for safe handling and use of equipment to prevent the contamination have been established and implemented. (Refer to the related equipment SOP and manufacturer manual).

2.3.1.4. Equipment calibration and metrological traceability

Yearly, the critical laboratory equipment are calibrated over the entire range of use within the specifications required. All calibrations and working standards are documented and stored in the quality cabinet office room n°6. (Refer to SOP LRM-EQP030 Equipment Management Procedure).

Critical equipment includes: balances, refrigerators, freezers, incubators, temperature measuring devices, pipettes, centrifuge, PCR machine, extraction machine.

2.3.1.5. Equipment maintenance and repair

Maintenance programs have been established and tasks assigned to each member of the laboratory. Each instrument in use has a procedure for maintenance and the time frame for the performance of the maintenance. (Refer to SOP LRM-HSP001 General Maintenance and Cleaning Procedure).

Preventive maintenance is scheduled according to each manufacturer's recommendation. Major analysis instruments are under service contract with the manufacturer.

Corrective maintenance is performed when an instrument begins to degrade as evidenced by the degradation of peak resolution, shift in calibration curves, or failure to meet one or another of the quality control criteria.

When equipment is found defective, it will be clearly labelled as "OUT OF USE" to ensure that it is not used until it has been repaired. (Refer to SOP LRM-EQP030 Equipment Management Procedure).

2.3.1.6. 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 are reported to the manufacturer. (Refer to SOP LRM-OCP001 Non conformity Corrective and Preventive action procedure).

2.3.1.7. Equipment records

Refer to SOP LRM-EQP030 Equipment Management Procedure.

Equipment inventory:

A general equipment database is maintained for each piece of equipment and recorded on the server: *Z:\Exchange\Quality Management System\4. Equipment\Equipment Database.*

The following information are recorded for all the equipment:

- 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.

Equipment records:

Each equipment use and maintenance is recorded in its related SOP, manufacturer manual and maintenance log (including logbook). The equipment performance includes the reports/ certificates of calibrations and/ or verifications including date, and results, the acceptance criteria and due date of the next calibration and/ or verification.

- These records are reviewed periodically according the requierement;
- These records are retained for five years.

2.3.2. Reagents, Chemicals and consumables

2.3.2.1. General

The procedure for the reception, storage, and acceptance testing and inventory management of reagents, chemicals and consumables has been established and implemented. (Refer to LRM-PSP003 – Stock management procedure).

2.3.2.2. Reception and storage

When the order is received, the CILM staff is responsible for recording the date, received item(s), lot number, and transportation condition and storage location. The received reagents and consumables are stored according to the manufacturer's specifications. (Refer to LRM-PSP003 – Stock management procedure).

2.3.2.3. Acceptance testing

Reagent, chemicals and consumables that can affect the quality of examination are verified before use in examination. (Refer to LRM-PSP003 – Stock management procedure).

The laboratory director or designee will sign off the acceptance testing. Any variation needs to be investigated and documented.

2.3.2.4. Inventory management

All reagent, chemicals and consumables are identified by a unique code and recorded in the Stock Management System called “STOCKS CILM” to ensure thereby their traceability by the stock officer. (Refer to LRM-PSP003 Stock management).

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. 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.

2.3.2.6. 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).

2.3.2.7. Records

Reagent, chemicals and consumables are recorded into the Stock Management System “STOCKS CILM” which include the following information (Refer to LRM-PSP003 Stock management):

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 processes

2.4.1. General

The procedure for pre-examination has been established and implemented as per SOP LRM-SMP001 Pre-examination procedure)

2.4.2. Information for patients and users

The information of CILM organization and pre-examination process is available for users trough external communication path as the website, brochure, receptionist, request form.

The study protocol and service manual are used as supporting document in the quality document system with details from collecting blood samples from patients to the sample examination at the CILM laboratory. (Refer to LRM-MAN003 Service manual).

2.4.3. Request form information

Testing is performed according to the study protocol requirements and service manual. When needed, requests for sample examination are communicated to the CILM laboratory in paper. Verbal requests are not authorized. Request forms should contain information sufficient to identify the patient and the authorized requester, date and time of primary sample collection, and the requested examination procedure(s). (Refer to LRM-MAN003 Service manual).

2.4.4. Primary sample collection and handling

All specimens should be processed appropriately to ensure the best results for both individual patient management and completion of the collective protocol objectives. (Refer to SOP LRM-SMP001 Pre-examination procedure and LRM-MAN003 Service manual).

Samples for HIV and Tuberculosis testing are collected at ART sites. Samples for Hepatitis testing are collected at CILM laboratory. All samples processed according to the specific handling requirements, mentioned in service manual. It is the **responsibility of every lab technician** to ensure that primary samples as well as sample portions are correctly labeled with the patient code, the date and time of collection. (Refer to SOP LRM-SMP001 Pre-examination procedure).

In case of nonconformity, CILM staff in charge sample receipt and checking will record the event and initiate corrective action according to established procedures. (Refer to SOP LRM-OCP001 Non conformity Corrective and Preventive action procedure).

Processing of samples is performed only when proper information is provided.

2.4.5. Sample transportation

The procedure for sample transporatation and management are implemented through LRM-SMP001 Pre-examination procedure.

The CILM works in collaboration with many hospital laboratories throughout the country and receives samples as:

- Plasma;
- Whole blood;
- Dried blood spots (DBS);
- Sputum or extra pulmonary sample.

Samples are shipped on commercial company by ground transportation or air transportation depending the location and transportation availability.

To ensure the safe transportation and handling of these samples, packing follows the national regulations on dangerous goods transportation. To ensure that transportation from these remote sites is carried out correctly, the CILM laboratory has implemented a plan for blood collection using a temperature monitoring device to record the temperature during transportation for . Shipment conditions are traceable with the help of the temperature record and the shipment form indicating the date and time of shipments well as date and time of receipt. All records are kept. (Refer to LRM-SMP001 Pre-examination procedure).

2.4.6. Sample reception

The CIML has three ways to receive samples/specimen of bloods, plasmas and sputum:

- Direct sampling at CILM;
- Sending from Central hospitals < 6 hours;
- Sending from provincial hospitals.

All specimens/samples are inspected according to acceptance/rejection criteria. The laboratory rejects specimens/samples, which are not suitable for processing. In the case of critical specimens/samples, such as one of limited volume, the laboratory management consults with the requestor to prioritize testing. (Refer to LRM-SMP001 Pre-examination procedure).

2.4.7. Pre-examination handling, preparation and storage

The specimen/sample handling, preparation and storage are defined as per SOP LRM-SMP001 Pre-examination 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

The CILM laboratory's examination procedures include:

- HIV RNA Quantitation using Biocentric (LRM-DVP002 - Quantification of RNA HIV-1; plasmatic viral loads by real time RT-PCR);
- HIV Early infant diagnosis In-house (LRM-DVP003 - DBS Testing procedure);
- HIV Multi drugs Resistance Testing (LRM-DVP004 – MDR testing);
- HBV DNA Quantitation using Fast track (LRM-DHP001 – Hepatitis B Viral Load Assay Procedure);
- HBV serology by ELISA (HBsAg, Anti-HBs, Anti-HBc, HbeAg and Anti-HBe) : (LRM-DHP005 - Hepatitis B Monolisa Bioborad Procedure);
- HCV RNA Quantitation using Fast track: LRM-DHP002 - Hepatitis C Viral Load Assay Procedure;
- Hain test for Tuberculosis diagnosis: LRM-DTP002 - Sputum and extra pulmonary specimens (CSF, lymph nodes and other tissues) for Xpert MTB/RIF.

The CILM laboratory use validated procedures for HIV RNA Quantitation using Biocentric to ensure that the examination procedures in use is suitable for the intended use.

2.5.1.2. Verification and validation of examination procedures

The method used in the laboratory are evaluated trough verification or validation of the procedure. (Refer to SOP LRM-MVP001 Method validation).

The procedure for method verification and validation is documented and results obtained are recorded. The authority staff will review and record the validation results. The demonstration of method performance is performed each time there is a method implementation, significant change in instrument type, personnel or test method.

Method verification
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.

Method validation
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.

2.5.1.3. 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 the laboratory changes an examination procedure, the laboratory will review associated reference intervals and communicate to users.

2.5.1.4. Documentation of examination procedures

The procedures for examination in CILM laboratory have been established and implemented by the laboratory staff and available in the laboratory office n°6 and in the examination location related.

All documents that are associated with the performance of examinations are subjected to the document control. If the laboratory intends to change an existing examination procedure, the reasons and expected reasons will be explained to users.

2.6. Ensuring quality of examination results

2.6.1. General

The laboratory ensures the quality of examinations by performing them under specific and defined conditions and all results are not actual.

2.6.2. Quality control

Internal QC:
Each method used in the laboratory has a quality control process defined in the examination SOP related. (Refer to all the examination SOP).

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 tlab manager performs a scientific review of the data for final validation. The acceptance criteria for QC sample data are specified in each analytical procedure.

External QC:
The procedure for participation, responsibilities, and instruction and performance criteria is described in each examination.

The laboratory participate in external proficiency panels/surveys, which are blind assessments of the laboratory's performance:

1. HIV RNA Quantitation : UKNQAS from UK, Twice a year
2. HIV Early infant diagnosis In-house: CDC from US, twice a year
3. HIV Multi drugs Resistance Testing : ANRS, once a year
4. HBV DNA Quantitation using Fast track:
5. HBV serology by ELISA (HBsAg, Anti-HBs, Anti-HBc, HbeAg and Anti-HBe) :
6. HCV RNA Quantitation using Fast track:
7. Tuberculosis diagnosis using GeneXpert:
8. Hain test for Tuberculosis diagnosis:

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

1. The corrective action are 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 SOP LRM-RRP001-post examination process).

2.7.2. Storage, retention and disposal of clinical samples

Laboratory manager is responsible for the retention time follow up, and laboratory technician are responsible for proper disposal according. (Refer to LRM-SMP001 – Pre-examination 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 report is validated by the Lab director/project manager/lab manager of CILM.

Patient's reports are released:

- directly at CILM, send by E-mail or Fax;
- send to provincial reference sites;
- or exceptionally for TB test, it can be reported via telephone.

2.10. Laboratory information system

2.10.1. Information system management

Information system is describes in the SOP LRM-DIP001-Information Management.

CILM back up information are on computerized systems or paper base:

- CIML limit access to computerized information by setup user account for every staff for permission and privacy;
- Laboratory Information backup and scanning is performing daily;
- Patient's documents in hard copy version are stored in archives in lockable cabinet;
- All documents can be accessed only the authorized and who is concern or perform the test.

III.ANNEXES

Annex 01: LRM-MAN001 – A01 – Lab weekly meeting report.