QUALITY MANAGEMENT SYSTEMS MANUAL

Based on ISO 15189:2022 Standards for Medical Laboratories

RELEASE AUTHORISATION

This quality management systems manual is released under the authority of

NAME: DR. ANIL MALLESHAPPA

DESIGNATION: LABORATORY DIRECTOR

And is the property of

KLES DR.PRABHAKAR KORE HOSPITAL & MRC, HI-TECH LABORATORY
Nehru Nagar
Belagavi -590010

Signature: 

Name: Dr. Anil Malleshappa

Designation: Laboratory Director

A. INDEX PAGE

List of Authorized copy holder:

AUTHORISED COPY HOLDER	
Laboratory Director	Soft copy
Quality manager	Soft copy/Hard copy
Consultants	Soft copy
Technical Staff	Soft copy
Phlebotomy section	Soft copy
NABL	Soft copy
Auditors	Soft copy

Quality manual is issued as a password protected read only PDF soft copy available in the intranet to all concerned by the Quality manager. The number of soft copies of respective holders depends upon on the number of desktop available in the sections.

C. Amendment / Revision record sheet

S. No.	Section/ Page	Clause no.	Amendment Date	Amendment Details	Signature Laboratory Director
1.	64	5.4.1	12.03.2025	Re-Structuring of the Organogram	

Quality Policy

Our laboratory is committed to providing accurate, reliable, and timely medical testing services in compliance with ISO 15189:2022, NABL (National Accreditation Board for Testing and Calibration Laboratories) guidelines and state-specific regulations.We aim to maintain the highest standards of quality, ethical conduct, and patient safety while ensuring continual improvement in our processes.

We achieve this by:

1. *Ensuring all laboratory tests are conducted with **precision, accuracy, and reliability**.*
2. *Complying with **national and international regulatory requirements**.*
3. *Implementing a **risk-based approach** to identify and mitigate potential errors.*
4. *Ensuring **confidentiality, impartiality, and integrity** in all operations.*
5. *Continually improving our **Quality Management System (QMS)**.*
6. *Encouraging **staff competency and professional development** through training and assessment.*
7. *Providing **exceptional patient care** by ensuring clear communication of results and maintaining laboratory safety.*

D. LIST OF ABBREVIATIONS:

ISO	- International Organization for Standardization
QM	- Quality Manager
QMSM	- Quality management systems manual
NABL	- National Accreditation Board for Testing and Calibration Laboratories
QSP	- Quality System Procedures
SOP	- Standard operating procedures
QRF	- Quality records & forms
No.	- Number
Ref.	- Reference
S. No.	- Serial number
SI	- System International
LIS	- Laboratory Information system
VIM	- Vocabulary in metrology
BSI	- British Standards Institution
MD	- Doctor in medicine
SAM	- Sample
IQ	- Installation qualification
OQ	- Operator qualification
PQ	- Performance qualification
ID	- Identification
HIV	- Human immunodeficiency virus
PUR	- Purchase
AMC	- Annual maintenance contract
FIFO	- First come first out
CAPA	- Corrective action and preventive action
CV	- Coefficient of variation

EQAS - External quality assurance services

HR - Human resource

TDS - Tax deducted at source

CSF - Cerebrospinal fluid

REG - Registration

TRG - Training

FNA - Fine needle aspiration

MSDS - Material safety data sheet

EQPT - Equipment

ICSH - International Council for Standardization in Hematology

IFCC - International Federation for Clinical Chemistry

CRIT - Critical

CUS - Customer

LIS - Laboratory information system

MOU - Memorandum of understanding

UPS - Power distribution unit

A/G - Albumin /globulin

QI - Quality Indicator

REP - Reports

FMS - Facility management system

CD - Compact disc

ILQA - Inter laboratory quality assurance

HDL - High density lipoprotein

GTT - Glucose tolerance test

TIBC - Total iron binding capacity

LDH - Lactate dehydrogenase

RBC - Red blood cell count

WBC - White blood cell count

ESR - Erythrocyte sedimentation rate

P.R.O – Public Relation Officer

HR - Human Resource

ISH - International Society of Hematology

IUMS - International Union of Microbiological societies

IUIS - International Union of Immunological societies

IUBMB - International Union of Biochemistry and Molecular Biology

POCT – Point-of-care testing

E. Introduction to Quality Management Systems Manual

This Quality management systems manual defines the established policies of KLES Dr. Prabhakar Kore Hospital & MRC, Hi-Tech Laboratory and is prepared in accordance with the requirements of ISO 15189:2022: Medical Laboratories –requirements for quality and competence & NABL 112. The Quality Manager is responsible for preparation; correct interpretation of the policies contained in this manual and their compliance to the requirement of ISO 15189:2022 Quality Management Systems. The laboratory utilizes this manual to demonstrate quality, technical competence, and appropriateness of results.

Manual Amendment

Amendments to this manual are identified by an amendment number of the page(s) of the affected sections and the effective date for each amendment is included (in the Amend Status in footer). The amendment number of each section is identical to that listed in the index page and the amendment status sheet. The first issue of this Quality management systems manual is '01' and amendment '00', with all subsequent amendments to the sections incremented consequently.

An Amendment record sheet is included as a part of the manual. Whenever a minor change is made, the brief nature of the amendments is identified and recorded in Amendment record sheet of this manual. This sheet lists the sections amended; amend numbers, and effective date of amendments and the brief nature of change.

This Quality management systems manual is reviewed once a year. Whenever the whole manual has to be re-issued, the manual will be issued with the incremented Issue No. (available as 'issue no' in the footer) and the amend Nos. of all sections of the manual will be reset to '00'.

Manual Approval and Issue

The Chief of Laboratory is the review and approval authority for this manual.

The Quality Manager is the issue authority for this manual.

Whenever any staff member requests an amendment, the Quality Manager ensures that the relevant staffs are consulted; the amendment is reviewed and approved by the Chief of Laboratory before releasing the amendment.

In case of hand amendments request, the amendments are clearly marked, initiated and dated by the quality manager. Such hand amended Manual is re-issued within 10days from the date of amendment.

Upon amendments all the pages of the Section amended is reissued with an incremented amendment number and effective date for implementation. (In amend no in footer). The Quality Manager records the amendment status sheet of amended Documents to the master copy and his / her copy of this manual before issuing the amended or modified documents along with updated Amendment record Sheet (QMSM B) to copy holders. The copy holder, upon receipt of the amendment intimation and the amended documents will incorporate the amended documents in their copy, remove the obsolete copies and acknowledge the amendment updating to Quality Manager.

Quality Manager maintains the latest and at least 1 copy of all previous amendments as historical documentation.

Each holder of the controlled copy is responsible for maintaining his / her manual complete and current with latest amendment.

Distribution

The Quality Manager will authorize the documents for issue, arrange to get soft copies installed in the system (as per distribution list) and is stamped 'CONTROLLED COPY' as Watermark.

1.0 Scope of The Quality Management System

Departments

The quality management systems manual is applicable to the following departments of laboratory services of **KLES ' Dr. Prabhakar Kore Hospital & MRC**, **Hi-Tech Laboratory** , Belagavi.

a) Clinical Biochemistry
b) Hematology and Clinical Pathology
c) Clinical Microbiology & Infectious disease Serology
d) Histopathology and Cytopathology
e) Molecular Testing

The list of examination procedures under the scope of the quality management system of each department is mentioned in the Directory of services (KLELAB/DOS) and Primary sample collection manual (KLELAB/PSM/O4)

2.0 Normative references

Reference list

1. ISO/IEC Guide 99:2007, International vocabulary of metrology — Basic and general concepts and associated terms (VIM)
2. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories
3. ISO 15189:2022 – Medical Laboratories –Requirements for Quality and competence.
4. NABL 112 A & B – Specific criteria for Medical Laboratories.
5. NABL 160- Guide Preparing a Quality Manual
6. NABL 161- Guide for Internal Audit and Management Review for Laboratories

3.0 Terms and definitions

3.1 bias measurement bias:
estimate of a systematic measurement error

3.2 biological reference interval /reference interval
specified interval of the distribution of values taken from a biological reference population.

3.3 clinical decision limit
examination result that indicates a higher risk of adverse clinical outcomes, or is diagnostic for the presence of a specific disease.

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

3.5 competence
demonstrated ability to apply knowledge and skills to achieve intended results.

3.6 complaint
expression of dissatisfaction by any person or organization to a laboratory relating to the activities or results of that laboratory, where a response is expected.

3.7 consultant
person who provides expert advice professionally.

3.8 examination
set of operations having the objective of determining the numerical value, text value or characteristics of a property.

3.9 examination procedure
specifically described set of operations used in the performance of an examination according to a given method.

3.10 external quality assessment- EQA
evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons. Also known as proficiency testing (PT).

3.11 impartiality

objectivity with regard to the outcome of tasks performed by the medical laboratory

Objectivity can be understood as freedom from bias or freedom from conflicts of interest.

Other terms that are useful in conveying the element of impartiality include “independence”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.

3.12 interlaboratory comparison

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

3.13 internal quality control -IQC

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

3.14 in vitro diagnostic medical device -IVD medical device

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

3.15 laboratory management

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

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

3.16 laboratory user

individual or entity requesting services of the medical laboratory

Users can include patients, clinicians, and, other laboratories or institutions that send samples for examination.

3.17 management system

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

3.18 measurement accuracy /accuracy of measurement /accuracy

closeness of agreement between a measured quantity value and a true quantity value of a measurand.

3.19 measurement uncertainty -MU

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

MU includes components arising from systematic effects, as in the case of corrections to the assigned quantity values of measurement standards. Sometimes estimated systematic effects are not corrected for, but instead, the associated MU components are incorporated.

3.20 medical laboratory /laboratory

entity for the examination of materials derived from the human body for the purpose of providing information for the diagnosis, monitoring, management, prevention and treatment of disease, or assessment of health.

3.21 patient

person who is the source of material for an examination.

3.22 point-of-care testing /POCT

examination performed near or at the site of a patient.

3.23 post-examination processes

processes following the examination including review of results, formatting, releasing, reporting and retention of examination results, retention and storage of clinical material, sample and waste disposal.

3.24 pre-examination processes

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

3.25 primary sample/specimen

discrete portion of a body fluid or tissue or other sample associated with the human body taken for examination , study or analysis of one or more quantities or characteristics to determine the character of the whole.

3.26 quality indicator

measure of the degree to which a large number of characteristics of an object fulfils requirements. Quality indicators can measure how well an organization meets the needs and requirements of the users.

3.27 referral laboratory

external laboratory to which a sample or data is submitted for examination

A referral laboratory is one to which laboratory management chooses to submit a sample or

sub sample for examination, data for analysis or interpretation, or when routine examinations cannot be carried out.

3.28 sample

one or more parts taken from a primary sample.

3.29 trueness /measurement trueness

closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value

3.30 turnaround time

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

3.31 validation

confirmation of plausibility for a specific intended use or application through the provision of objective evidence that specified requirements have been fulfilled.

3.32 verification

confirmation of truthfulness, through the provision of objective evidence that specified requirements have been fulfilled.

4.0 General requirements

4.1 Impartiality

a) Laboratory activities are undertaken impartially. The laboratory is structured and managed to safeguard impartiality.

b) The laboratory management is committed to impartiality.

c) The laboratory will be responsible for the impartiality of its laboratory activities and will not allow commercial, financial or other pressures to compromise impartiality.

d) The laboratory monitors its activities and its relationships to identify threats to its impartiality. This monitoring will include relationships of its personnel. The laboratory does not pay any commission or other inducement for the referral of new laboratory users, or to the technical staff for the work performed.

e) If a threat to impartiality is identified, the effect will be eliminated or minimized so that the impartiality is not compromised.

Reference Documents:- KLELAB/QSPM/02 - QSP 02 Procedure for Impartiality.

4.2 Confidentiality

4.2.1 Management of information

The laboratory is responsible, for all legally enforceable agreements, for the management of all patient information obtained or created during the performance of laboratory activities. Management of patient information includes privacy and confidentiality. The laboratory will inform the user and/or the patient in advance, of the information it intends to place in the public domain. Except for information that the user and/or the patient makes publicly available, or when agreed between the laboratory and the patient (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and will be regarded as confidential.

4.2.2 Release of information

When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the patient concerned will be notified of the information released, unless prohibited by law.

Information about the patient from a source other than the patient (e.g. complainant, regulator) will be kept confidential by the laboratory. The identity of the source will be kept confidential by the laboratory and will not be shared with the patient, unless agreed by the source.

4.2.3 Personnel responsibility

Personnel, including any committee members, contractors, personnel of external bodies, or individuals with access to laboratory information acting on the laboratory's behalf, will keep confidential all information obtained or created during the performance of laboratory activities.

Reference Documents:-
KLELAB/QSPM/02 - QSP 01Policy for confidentiality.

4.3 Requirements regarding patients

Laboratory management will ensure that patients' well-being, safety and rights are the primary considerations. The laboratory has established the following processes:

a) opportunities for patients and laboratory users to provide helpful information to aid the laboratory in the selection of the examination methods, and the interpretation of the examination results, through the test request form (TRF) by providing relevant Clinical history.
b) Directory of Services/ Price list has information on the examination process, including costs when applicable, and when to expect results;
c) All the examinations are periodically reviewed by the laboratory to ensure they are clinically appropriate and necessary;
d) where appropriate, disclosure to patients, users and any other relevant persons, of incidents that resulted or could have resulted in patient harm, and records of actions taken to mitigate those harms;
e) patients, samples, or remains are treated with due care and respect;
f) informed consent are taken when required;
g) integrity of retained patient samples and records in the event of the closure, acquisition or merger of the laboratory will be maintained;
h) Laboratory will make relevant information available to a patient and any other health service provider at the request of the patient or the request of a healthcare provider acting on their behalf;
i) Laboratory will uphold the rights of patients to care that is free from discrimination.

Reference documents:- KLE/POP-29- Policy and procedure on patient and patient's family rights and education

5.0 Structural and governance requirements

5.1 Legal entity

The laboratory which is a part of KLES Dr Prabhakar Kore Hospital & MRC Super Specialty Hospital is run by Karnataka Lingayat Education Society which is a registered society. It can be held legally responsible for all its activities. The hospital is registered under Karnataka private medical establishment authority; vide the certificate of registration No. BLG00476ALAL4. (Annexure VII)

The laboratory which is a part of the hospital carries out its work from its permanent facility at the address given below:
Hi-Tech Laboratory.
KLES Dr Prabhakar Kore Hospital & MRC
Nehru Nagar, Belagavi- 590010.
The legal identity of the organization is demonstrated through: Certificate of registration

5.2 Laboratory director

5.2.1 Laboratory director competence

The laboratory is directed by a laboratory director with the MD qualification, is competent, is the delegated authority with responsibility, and has the resources to fulfil the requirements of this document.

5.2.2 Laboratory director responsibilities

The laboratory director is responsible for the implementation of the management system, including the application of risk management to all aspects of the laboratory operations so that risks to patient care and opportunities to improve are systematically identified and addressed.

The duties and responsibilities of the laboratory director is documented.

Reference Documents:- Annexure III

5.2.3 Delegation of duties

The laboratory director may delegate the duties and responsibilities, to qualified and competent personnel and such delegation will be documented. However, the laboratory director maintains the ultimate responsibility for the overall operation of the laboratory.

Reference Documents:- KLELAB/QSPM/02 - QSP 14 Procedure for Personnel policies and job description.

5.3 Laboratory activities

5.3.1 General

KLES Dr. Prabhakar Kore Hospital & MRC, Hi-Tech Laboratory functions in accordance with the requirements of ISO 15189:2022: Medical Laboratories –requirements for quality and competence & NABL 112.

Laboratory services of **KLES' Dr. Prabhakar Kore Hospital & MRC**, **Hi-Tech Laboratory** Belagavi includes:

1. Clinical Biochemistry
2. Hematology and Clinical Pathology
3. Clinical Microbiology & Infectious disease Serology
4. Histopathology and Cytopathology
5. Molecular Testing

5.3.2 Conformance with requirements

Laboratory activities are carried out in such a way as to meet the requirements of ISO 15189:2022, NABL 112 A and B, the users, regulatory authorities and organizations providing recognition. This applies to the complete range of specified and documented laboratory activities, regardless of where the service is provided.

5.3.3 Advisory activities

Laboratory management ensures that appropriate laboratory advice and interpretation are available and meet the needs of patients and users.

The laboratory has established arrangements for communicating with laboratory users on the following when applicable:

a) The directory of services lists the lists of tests along with the type of sample required and special precautions if any. The clinical indications/ limit of testing and frequency of retesting are mentioned in the final report wherever applicable.

b) Wherever required the respective Consultants give an additional note or remarks in the test report towards advising on any case. The Consultants also holds verbal communication with the clinician / user to advise on any finding. This may be done via teleconference or during CME meets, conferences etc.

c) The Laboratory Consultants promote effective utilization of laboratory examinations by means of circulars and by meeting the Clinicians;

d) Wherever appropriate the interpretation of the tests is given as a part of the report.

Reference Documents:- Advisory services file - KLELAB/REP/04/ Biochemistry,
KLELAB/REP/04/ Pathology,
KLELAB/REP/04/ Microbiology,
KLELAB/REP/04/ Histopathology.
KLELAB/REP/04/ Molecular.

5.4 Structure and authority

5.4.1 General

The laboratory has:

a) Organization and management structure, its place in any parent organization, and the relationships between management, technical operations and support services are shown in the Organogram chart;(Annexure II)

b) The Chart specifies the responsibility, authority, lines of communication and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;

C)Laboratory management has ensured that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the Quality Management System. All communications are done by letters, circulars, e-mail and record of all such events are maintained.

5.4.2 Quality management

The laboratory has delegated Quality Manager who, irrespective of other responsibilities, has the authority and resources needed to carry out his duties, including:

a) implementation, maintenance and improvement of the management system;

b) identification of deviations from the management system or from the procedures for performing laboratory activities;

c) initiation of actions to prevent or minimize such deviations;

d) reporting to laboratory management on the performance of the management system and any need for improvement and ensuring the effectiveness of laboratory activities.

e) The Quality Manager ensures that the regular Management Reviews, internal audit, corrective action,preventive action,and risk analysis are carried out as per schedule at least once year and in interim period in case of any major event like change of technical head, change in instrument or any other similar situation that affects the Quality SystemManagement.

Reference document:- Annexure III

5.5 Objectives and policies

a) Laboratory management has established and maintains objectives and policies to:

1) meet the needs and requirements of its patients and users;
2) commit to good professional practice;
3) provide examinations that fulfil their intended use;
4) conform to this document as per ISO 15189:2022.

Laboratory Quality Objectives are met as follows:-

1. Technical Competence & Accreditation Compliance
   Adhere to ISO 15189:2022 and NABL accreditation requirements.
   Ensure all tests are conducted following standardized Standard Operating Procedures (SOPs).
2. Quality Assurance & Continuous Improvement
   Implement internal quality control (IQC) and participate in external quality assurance programs (EQAP).
   Review and analyze non-conformities to implement corrective and preventive actions (CAPA).
3. Patient Safety & Ethical Practices
   Ensure confidentiality and ethical handling of patient data.
   Maintain a patient-centered approach, ensuring clarity in test results and reports.
4. Risk Management & Error Reduction
   Identify, document, and address potential risks as part of a risk management framework.
   Monitor laboratory processes using Key Performance Indicators (KPIs) for continuous improvement.
5. Staff Competency & Training
   Conduct regular training and competency assessments for all personnel.
   Promote a culture of quality, safety, and teamwork.
6. Turnaround Time (TAT) & Efficiency
   Ensure timely and accurate reporting of test results, optimizing turnaround times.
   Use Lean and Six Sigma principles to enhance operational efficiency.
7. Equipment & Resource Management
   Maintain and calibrate all laboratory instruments as per manufacturer guidelines.
   Ensure availability of high-quality reagents and consumables.
8. Customer Satisfaction & Feedback
   Establish a system for patient and clinician feedback.
   Address complaints and suggestions to enhance service quality.

a) By implementing this policy and objectives, our laboratory commits to maintaining excellence in medical testing, ensuring patient safety, and achieving continual improvement in quality and efficiency.

b) Objectives are measurable, and consistent with policies. The Quality Policy is displayed at all relevant places and communicated to all contracted clients /agencies. There is dissemination of programs, procedures, and instructions to all concerned as per the document control.

c) Laboratory management ensures that the integrity of the management system is maintained when changes to the management system are planned and implemented.

d) The laboratory has established quality indicators to evaluate performance throughout key aspects of pre-examination (Sample rejection,labelling errors,Haemolysed samples,clotted sample), examination (IQC outliers, EQAS, Coefficient of variation,Equipment downtime) and post-examination processes (TAT,reporting errors,complaints) and monitor performance in relation to objectives as detailed in KLELAB/QSPS/02- QSP 10.

Reference Document:- Annexure I - Quality Policy

5.6 Risk management

a) Laboratory management has established, implements, and maintains processes for identifying risks of harm to patients and opportunities for improved patient care associated with its examinations and activities, and develop actions to address both risks and opportunities for improvement.

b) The laboratory director ensures that these processes are evaluated for effectiveness and modified, when identified as being ineffective.

Reference document:- KLELAB/QSPM/02 - QSP 26 Procedure for Risk management.

6.0 Resource requirements

6.1 General

The laboratory has available the personnel, facilities, equipment, reagents, consumables and support services necessary to manage and perform its activities.

6.2 Personnel

6.2.1 General

a) The laboratory has access to a sufficient number of competent persons to perform its activities.

b) All personnel of the laboratory, either internal or external, that could influence the laboratory activities will act impartially, ethically, be competent and work in accordance with the laboratory's management system.

c) The laboratory communicates to laboratory personnel the importance of meeting the needs and requirements of users as well as the requirements of this document through training.

d) The laboratory has a programme to introduce personnel to the organization, the department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safety requirements, and occupational health services.

Reference document:- KLELAB/QSPM/02- QSP 15
QRF/KLELAB/TRG/01

6.2.2 Competence requirements

a) The laboratory has specified the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, re-training, technical knowledge, skills and experience.

b) The laboratory ensures all personnel have the competence to perform laboratory activities for which they are responsible by training and re-training under the guidance of competent Personnel.

c) The laboratory manages the competence of its personnel, by frequent competence assessment.

d) All records of the competency evaluation are maintained by the Section In charge.
The competency is assessed by one or more of the following ways:

1. direct observation of an activity,
2. monitoring the recording and reporting of examination results,
3. review of work records,
4. assessment of problem-solving skills,
5. examination of specially provided samples, e.g. previously examined samples, interlaboratory comparison materials, or split samples.

Reference documents:- QRF/KLELAB/HR/05/Evaluation of Technicians
QRF/KLELAB/HR/06/Evaluation of Consultants
QRF/KLELAB/HR/07/Evaluation of Laboratory Director
QRF/KLELAB/HR/08/Evaluation of Quality Manager

6.2.3 Authorization

The laboratory has defined rights and authorities for every personnel working in the laboratory. This includes but is not limited

a)The section In-charge is authorized to review, release of reports access rights in the laboratory information system and selection, development, modification, validation, and verification of methods.

b)The Consultants are authorized to review, release and report results

c) The authorities include accessibility to the instrument in the section and LIS.

Based on Job description of the personnel, his/her respective section in charge decides the extend of authority to access and operate the LIS; the details of the are maintained by the IT section.Job descriptions and authorities have been defined in Annexure III and disseminated to all the employees. A copy of the same is filed in the personal records of the employees.

6.2.4 Continuing education and professional development

The laboratory encourages the personnel to participate in the managerial and technical continuing education program. The records for the same are maintained in the personnel file of every individual.

The respective section in charges / technical heads ensure that all the personnel are trained and assessed at regular intervals as indicated in the yearly training program; if required the yearly training program is revised to include the new incumbents or to accommodate new techniques or tests.

Reference documents:- KLELAB/QSPM/02 - QSP 15 Procedure for staff training.

6.2.5 Personnel records

The laboratory has procedures and retain records of all Personnel.

The records include but are not limited to:

a) determining the competence requirements specified in 6.2.2 a);
b) position descriptions;
c) training and re-training;
d) authorization of personnel;
e) monitoring competence of personnel.

Reference documents:- KLELAB/HR/01/DEPT/Employee name.

6.3 Facilities and environmental conditions

6.3.1 General

The facilities and environmental conditions of the laboratory is maintained in such a way that it is

suitable for the laboratory activities and will not adversely affect the validity of results, or the safety of patients, visitors, laboratory users, and personnel. The conditions include pre-examination related facilities and sites and the main laboratory premises where examinations are performed. The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities will be specified, monitored, and recorded.

Adequate provision is made to ensure appropriate environmental conditions like lighting conditions (illumination), humidity, electrical supply, temperature, vibration are monitored .

The laboratory has adequate space in relation to the following areas-

a. Patient Reception.
b. Phlebotomy room with all the facilities for patient comfort.
c. Adequate laboratory space for carrying out testing, staining, storage of samples, reporting and dispatch of reports.
d. Instruments and equipment are adequately spaced to avoid any interference and cross contamination.

Reference document:- Annexure VI

6.3.2 Facility controls

Facility controls will be implemented, recorded, monitored, periodically reviewed, and will include:

a) control of access of the laboratory facilities, taking into consideration safety, confidentiality, quality, and safeguarding medical information and patient samples;

b) prevention of contamination, interference, or adverse influences on laboratory activities that can arise from energy sources, lighting, ventilation, noise, water and waste disposal;

c) prevention of cross-contamination, where examination procedures pose a risk, or where work can be affected or influenced by separation of sections that can affect the safety;

d) provision of safety facilities and devices like Personal protective equipment, fire extinguishers, eye wash station and first aid box, where applicable and regularly verifying their functioning;

The operation of emergency release, intercom and alarm systems for cold rooms and walk-in freezers, accessibility of emergency showers, eyewash and resuscitation equipment.

e) maintenance of laboratory facilities in a functional and reliable condition.

Reference document:- QRF/KLELAB/TEMP/section name,
QRF/KLELAB/TEMP/EQPT No.,
QRF/KLELAB/ELT,
QRF/KLELAB/HK.

6.3.3 Storage facilities

a) The laboratory has adequate storage space, with conditions that ensure the continuing integrity of samples, equipment, reagents, consumables, documents and records,

b) Patient samples and materials used in examination processes are stored in refrigerator and the temperature of the same is monitored in a manner that prevents cross contamination and deterioration of the samples.

c) Storage and disposal facilities for hazardous materials and biological waste is appropriate to the classification of the materials in the context of statutory or regulatory requirements.

Reference document:- QRF/KLELAB/Autoclave

6.3.4 Personnel facilities

There is adequate access to toilet facilities and a supply of drinking water, as well as facilities for storage of personal protective equipment and clothing for all the Personnel.

Space for personnel activities, such as meetings, quiet study and a rest area, are provided.

6.3.5 Sample collection facilities

a) The sample collection facility has all the provisions to enable collection in a manner that does not invalidate the results or adversely affect the quality of the examination.

b) The phlebotomy area is located on the ground floor as indicated in the layout and is a dedicated room with privacy and equipped with comfortable phlebotomy chair and examination table. Adequate facilities for transporting patients with disabilities or on wheelchair is available in the premises; the phlebotomy area is equipped with washroom facilities as well.

c) Separate patient reception and collection area is provided.

d) Collection area has First aid material for both patient and Personnel.

The phlebotomy is performed by experienced and trained personnel by best means available like vacutainer in a manner that does not invalidate the results or adversely affect the quality of the examination; detailed guidelines have been laid down in the specimen collection and handling manual of the laboratory.
The specimen collection room is equipped with first Aid Box.

Reference documents:- KLELAB/PSM/04 Primary sample collection manual.

6.4 Equipment

6.4.1 General

The laboratory has processes for the selection, procurement, installation, acceptance testing (including acceptability criteria), handling, transport, storage, use, maintenance, and decommissioning of equipment, in order to ensure proper functioning and to prevent contamination or deterioration. (QSP 16)

6.4.2 Equipment requirements

a) The laboratory has access to equipment required for the correct performance of laboratory activities.
b) Where the equipment is used outside the laboratory's permanent control, or equipment manufacturer's functional specification, laboratory management will ensure that the requirements of this document are met.
c) Each item of equipment that can influence laboratory activities will be uniquely labelled, marked or otherwise identified and a register maintained.
d) The laboratory will maintain and replace equipment as needed to ensure the quality of examination results.

6.4.3 Equipment acceptance procedure

The laboratory will verify that the equipment conforms to specified acceptability criteria and meets the need of the laboratory in giving quality performance as per standards/guidelines before being placed or returned into service after major repair.

Equipment used for measurement will be capable of achieving either the measurement accuracy or measurement uncertainty, or both, required to provide a valid result

Reference document:- KLELAB/QSPM/02- QSP 16 Procedure for equipment
KLELAB/EQPT/01/ Dept name/name of the instrument

6.4.4 Equipment instructions for use

a) The equipment has appropriate passwords to start the equipment to prevent unintended adjustments of the equipment that can invalidate the examination results.
b) Equipment will be operated by trained, authorized, and competent personnel as evident in the work and LIS Authorization letter.
c) Instructions for the use of equipment, including those provided by the manufacturer will be readily available in the form of flow charts, equipment manual and SOPs.
d) The equipment will be used as specified by the manufacturer, unless validated by the laboratory.

6.4.5 Equipment maintenance and repair

a) The laboratory has preventive maintenance programmes, based on manufacturer's instructions. Deviations from the manufacturer's schedules or instructions will be recorded.
b) Equipment will be maintained in a safe working condition and working order. This will include electrical safety, any emergency stop devices and the safe handling and disposal of hazardous materials by authorized personnel.
c) Equipment that is defective or outside specified requirements, will be taken out of service. It will be clearly labelled or marked as being out of service, until it has been verified to perform correctly. The laboratory will examine the effect of the defect or deviation from specified requirements and will initiate actions when non-conforming work occurs.
d) When applicable, the laboratory will decontaminate equipment before service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment.
e) The biological wastes generated because of testing are disposed as per the laid down WI for the disposal of wastes.

6.4.6 Equipment adverse incident reporting

Adverse incidents and accidents that can be attributed directly to specific equipment will be investigated and reported to either the manufacturer or supplier, or both, and appropriate authorities, as required.

The laboratory has procedures for responding to any manufacturer's recall or other notice, and taking actions recommended by the manufacturer.

6.4.7 Equipment records

Records will be maintained for each item of equipment that influences the results of laboratory activities.(QRF/KLELAB/EQPT/01/Name of the equipment)

These records will include the following, where relevant:

a) manufacturer and supplier details, and sufficient information to uniquely identify each item of equipment, including software and firmware;
b) dates of receipt, acceptance testing and entering into service;
c) evidence that equipment conforms with specified acceptability criteria;
d) the current location;
e) condition when received (e.g. new, used or reconditioned);
f) manufacturer's instructions;
g) the programme for preventive maintenance;
h) any maintenance activities performed by the laboratory or approved external service provider;
i) damage to, malfunction, modification, or repair of the equipment;
j) equipment performance records such as reports or certificates of calibrations or verifications, or both, including dates, times and results;
k) status of the equipment such as active or in-service, out-of-service, quarantined, retired or obsolete.

These records will be maintained and will be readily available for the lifespan of the equipment or longer.

6.5 Equipment calibration and metrological traceability

6.5.1 General

The laboratory maintains the calibration and traceability requirements for all equipment being used for testing quantitative and qualitative parameters.

6.5.2 Equipment calibration

The laboratory has procedures for the calibration of equipment that directly or indirectly affects examination results. The frequency of calibration of equipment is decided based upon the following criteria:

- NABL 112
- Manufacturer's instructions

The procedures specifies:

a) conditions of use and manufacturer's instructions for calibration;
b) recording of the metrological traceability;
c) verification of the required measurement accuracy and the functioning of the measuring system at specified intervals;
d) recording the calibration status and date of re-calibration;
e) ensuring that, where correction factors are used, these are updated and recorded when re-calibration occurs;
f) handling of situations when calibration was out of control, to minimize risk to service operation and to patients.

Reference document:-KLELAB/EQPT/05/name of instrument

6.5.3 Metrological traceability of measurement results

a) The laboratory establishes and maintains metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

NOTE:Information of traceability to a higher order reference material or reference procedure can be provided by an examination system manufacturer. Such documentation is acceptable only when the manufacturer's examination system and calibration procedures are used without modification.

b) The laboratory ensures that measurement results are traceable to the highest possible level of traceability and to the International System of Units (SI) through:

--calibration provided by a competent laboratory; or

NOTE 1:Calibration laboratories fulfilling the requirements of ISO/IEC 17025 are considered competent for performing calibrations.

--certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI;

NOTE 2:Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.

NOTE 3:Certified reference material fulfilling the requirements of ISO 15194 are considered suitable.

c) Where it is not possible to provide traceability according to 6.5.3 a), other means for
d) providing confidence in the results will be applied, including but not limited to the following:

--results of reference measurement procedures, specified methods or consensus standards,

that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison;
--measurement of calibrator by another procedure.

NOTE ISO 17511 provides further information on how to manage the compromises in the metrological traceability of measurands.

e) For genetic examinations, traceability to genetic reference sequences shall be established when applicable. At present laboratory doesn't carry out any genetic examination.

f) For qualitative methods, traceability is demonstrated by testing of known material or previous samples sufficient to show consistent identification and, when applicable, intensity of reaction.

6.6 Reagents and consumables

6.6.1 General

The laboratory has processes for the selection, procurement, reception, storage, acceptance testing and inventory management of reagents and consumables. (QRF/KLELAB/RGT/01/Dept). It is the responsibility of the respective section in charge to ensure that the reagents and consumables selected are of the desired quality to give consistent results. Records of all purchases are maintained centrally by the Purchase Section.

Note:- Reagents include substances which are commercially supplied or prepared in-house, reference materials (calibrators and QC materials), culture media; consumables include pipette tips, glass slides, etc.

6.6.2 Reagents and consumables — Receipt and storage

The laboratory stores reagents and consumables according to manufacturers' specifications and monitor the environmental conditions where relevant.

The laboratory is not the receiving facility, it verifies that the receiving facility has adequate storage and handling capabilities to maintain supplies in a manner that prevents damage and deterioration.

6.6.3 Reagents and consumables — Acceptance testing

Each reagent or new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, is verified for performance before placing into use, or before release of results, as appropriate. Consumables that can affect the quality of examinations will be verified for performance before placing into use.

Comparative IQC performance of new reagent lots and that of previous lots is used as evidence for acceptance. Patient samples are preferred when comparing different reagent lots to avoid issues with commutability of IQC materials. Verification are sometimes based on the certificate of analysis of the reagent.

Reference document:- KLELAB/QSPM/02 - QSP 17 Procedure for reagent handling.
QRF/KLELAB/RGT/01/name of Department

6.6.4 Reagents and consumables — Inventory management

The laboratory has established an inventory management system for reagents and consumables in HIS. The system for inventory management will segregate reagents and consumables that have been accepted for use from those that have been neither inspected nor accepted for use.

6.6.5 Reagents and consumables — Instructions for use

Latest version of Instructions for the use of reagents and consumables, including those provided by manufacturers, is readily available as soft copy on desktop. Reagents and consumables are used according to the manufacturer's specifications.

6.6.6 Reagents and consumables — Adverse incident reporting

Adverse incidents and accidents that can be attributed directly to specific reagents or consumables will be investigated and reported to either the manufacturer or supplier, or both, and appropriate authorities, as required.
The laboratory has procedures for responding to any manufacturer's recall or other notice and taking actions recommended by the manufacturer.

6.6.7 Reagents and consumables — Records

All reagents, consumables, stains, and kits are stored as recommended by the manufacturer and used within their indicated expiry dates. These records will include the following:

a) identity of the reagent or consumable;
b) manufacturer's information, including instructions, name and batch code or lot number;
c) date of receipt and condition when received, the expiry date, date of first use and, where applicable, the date the reagent or consumable was taken out of service;
d) records that confirm the reagent's or consumable's initial and ongoing acceptance for use.

Where the laboratory uses reagents prepared, resuspended or combined in-house, the records include, in addition to the relevant information above, reference to the person or persons undertaking the preparation, as well as the dates of preparation and expiry.

Reference documents:- Records are in the LIS - Inventory management

6.7 Service agreements

6.7.1 Agreements with laboratory users

The laboratory has a procedure to establish and periodically review agreements for providing laboratory activities.

The procedure will ensure:

a) the requirements are adequately specified;
b) the laboratory has the capability and resources to meet the requirements;
c) when applicable, the laboratory advises the user of the specific activities to be performed by referral laboratories and consultants.

Laboratory users will be informed of any changes to an agreement that can affect examination

results. Records of reviews, including any significant changes, are retained.

Reference document:- QRF/KLELAB/TRF/dept name,

6.7.2 Agreements with POCT operators

The laboratory doesn't support any POCT equipment in hospital and is not under scope of laboratory.

6.8 Externally provided products and services

6.8.1 General

The laboratory ensures that externally provided products and services that affect laboratory activities are suitable when such products and services are:

a) intended for incorporation into the laboratory's own activities;
b) provided, in part or in full, directly to the user by the laboratory, as received from the external provider;
c) used to support the operation of the laboratory.

Services include, e.g. sample collection services, pipette and other calibration services, facility and equipment maintenance services, EQA programs, referral laboratories and consultants.

6.8.2 Referral laboratories and consultants

Laboratory, is self-sufficient to conduct tests under the scope defined and usually does not need any other external consultation. If needed referral services of only NABL & CAP accredited Laboratories that are competent will be used for Inter Laboratory Comparison(ILC) and few specialized tests. The laboratory will communicate its requirements to referral laboratories and consultants who provide interpretations and advice, for:

a) the procedures, examinations, reports and consulting activities to be provided;
b) management of critical results;
c) any required personnel qualifications and demonstration of competence.

The laboratory on an annual basis evaluate and review the list of referral laboratories and the consultants who provide interpretations and advice. A list of all referral laboratories and consultants is maintained.

Reference documents:- KLELAB/QSPM/02 - QSP 05 Procedure for referral laboratory.

6.8.3 Review and approval of externally provided products and services

The laboratory has procedures and retain records for:

a) defining, reviewing, and approving the laboratory's requirements for all externally provided products and services;
b) defining the criteria for qualification, selection, evaluation of performance and re-evaluation of external providers;
c) referral of samples;
d) ensuring that externally provided products and services conform to the laboratory's established requirements, or where applicable to the relevant requirements of this document, before they are used or directly provided to the user;
e) taking any actions arising from evaluations of the performance of external providers.

Reference documents:- KLELAB/QSPM/02 - QSP 25 Procedure for external services.

7.0 Process requirements

7.1 General

The laboratory identifies the potential risks to patient care in the pre-examination, examination and past-examination processes via Internal Audits and Risk Assessment process. The records for the same are maintained.

The laboratory identifies the opportunities to improve patient care and develop the framework to manage these opportunities.

7.2 Pre-examination processes

7.2.1 General

The laboratory will have procedures for all pre-examination activities and make them accessible to relevant personnel.

7.2.2 Laboratory information for patients and users

Laboratory has **Directory of Services and primary sample collection manual** in place which covers all the information which is required by the users and patients The manual is made available to those who are responsible for primary sample collection and is also made available at collection centre and desktops of all wards. The information is sufficiently detailed to provide laboratory users with a comprehensive understanding of the laboratory's scope of activities and requirements.

The information includes:

a) the location(s) of the laboratory, operating hours and contact information;
b) the procedures for requesting and the collection of samples;

c) the scope of laboratory activities and time for expected availability of results;
d) the availability of advisory services;
e) requirements for patient consent;
f) factors known to significantly impact the performance of the examination or the interpretation of the results;
g) the laboratory complaint process.

7.2.3 Requests for providing laboratory examinations

7.2.3.1 General

a) Each request accepted by the laboratory for examination(s) is considered an agreement.

b) The examination request provides sufficient information to ensure:

— unequivocal traceability of the patient to the request and sample;
— identity and contact information of requester;
— identification of the examination(s) requested;
— informed clinical and technical advice, and clinical interpretation can be provided.

c) The examination request information may be provided in a format or medium as deemed appropriate by the laboratory and acceptable to the user.
d) Where necessary for patient care, the laboratory will communicate with users or their representatives, to clarify the user's request.

7.2.3.2 Oral requests

The laboratory has a procedure for managing oral requests for examinations that includes the provision of documented confirmation of the examination request to the laboratory, within a given time. (KLELAB/PSM/04)

7.2.4 Primary sample collection and handling

7.2.4.1 General

The laboratory has procedures for the collection and handling of primary samples. Information is available to those responsible for sample collection. (KLELAB/PSM/04)
Any deviation from the established procedure is recorded as non-conformity. The potential risk and impact on the patient outcome of acceptance or rejection of the sample is accessed and communicated to the appropriate personnel.
The laboratory periodically reviews the requirement for sample volume, collection device and preservatives for all sample types as applicable to ensure that neither excessive nor insufficient amount of samples are collected to preserve the analyte.

7.2.4.2 Information for pre-collection activities

The laboratory has provided all information and instructions for pre-collection activities with sufficient detail to ensure that the integrity of the sample is not compromised.

This includes the following:

a) preparation of the patient (e.g. instructions to caregivers, sample collectors and patients);
b) type and amount of the primary sample to be collected with descriptions of the containers and any necessary additives, and when relevant the order of collecting samples;
c) special timing of collection, where relevant;
d) provision of clinical information relevant to, or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs);
e) sample labelling for unequivocal identification of the patient, as well as source and site of sample, and labelling, when several samples from the same patient are to be collected, including multiple pieces of tissue or slides;
f) the laboratory's criteria for acceptance and rejection of samples specific to the examinations requested.

7.2.4.3 Patient consent

a) The laboratory obtains the informed consent of the patient for all procedures carried out on the patient. For most routine laboratory procedures, consent is inferred when the patient willingly submits to the sample collecting procedure, for example, venipuncture.
c) Written consent is taken for all invasive procedures such as FNAC or for patients opting for HIV testing as per Govt. guidelines. The form is designed such that it gives detailed explanation of the procedure.
c) If obtaining consent is not possible in emergency situations, the laboratory carries out necessary procedures, provided they are in the patient's best interest.

7.2.4.4 Instructions for collection activities

The documented procedure for specimen collection and handling has instructions for phlebotomist /sample collectors to ensure completion of test request forms and verification of test details including:

a) verification of the identity of the patient from whom a primary sample is collected;
b) verification and when relevant, recording that the patient meets pre-examination requirements [e.g. fasting status, medication status (time of last dose, cessation), sample collection at predetermined time or time intervals];
c) collection of primary samples, with descriptions of the primary sample containers and any necessary additives, as well as the order of sample collection, where relevant;
d) labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected;
e) recording of the identity of the person collecting the primary sample and the collection date, and, when relevant, recording of the collection time;

f) requirements for separating or dividing the primary sample when necessary;
g) stabilization and proper storage conditions before collected samples are delivered to the laboratory;
h) safe disposal of materials used in the collection process.

Reference documents:- KLELAB/PSM/04 Primary sample collection manual
KLELAB/DOS-Directory of services

7.2.5 Sample transportation

a) To ensure the timely and safe transportation of samples, the laboratory will provide instructions for:
1) packaging of samples for transportation;
2) ensuring the time between collection and receipt in the laboratory is appropriate for the requested examinations;
3) maintaining the temperature interval specified for sample collection and handling;
4) any specific requirements to ensure integrity of samples, e.g. use of designated preservatives.

b) If the integrity of a sample has been compromised and there is a health risk, the organization responsible for the transport of the sample will be notified immediately and action taken to reduce the risk and to prevent recurrence.
c) The laboratory periodically evaluates adequacy of sample transportation systems.

7.2.6 Sample receipt

7.2.6.1 Sample receipt procedure

The instruction laid in specimen collection and handling manual for sample reception and all technical work instruction laid down ensures that:
a) the unequivocal traceability of samples by request and labelling, to a uniquely identified patient and when applicable, the anatomical site;
b) criteria for acceptance and rejection of samples;
c) recording the date and time of receipt of the sample, when relevant;
d) recording the identity of the person receiving the sample, when relevant;
e) evaluation of received samples, by authorized personnel, to ensure compliance with acceptability criteria relevant for the requested examination(s);
f) instructions for samples specifically marked as urgent, which include details of special labelling, transport, any rapid processing method, turnaround times, and special reporting criteria to be followed;
g) ensuring that all portions of the sample will be unequivocally traceable to the original sample.

7.2.6.2 Sample acceptance exceptions

a) The laboratory has a process that considers the best interests of the patient in receiving care, when a sample has been compromised due to
   1) incorrect patient or sample identification,
   2) sample instability due to, for example, delay in transport,
   3) incorrect storage or handling temperature,
   4) inappropriate container(s), and
   5) insufficient sample volume.

b) When a compromised clinically critical or irreplaceable sample is accepted, after consideration of the risk to patient safety, the final report will indicate the nature of the problem and where applicable, advising caution when interpreting results that can be affected.

7.2.7 Pre-examination handling, preparation, and storage

7.2.7.1 Sample protection

The laboratory has procedures and appropriate facilities for securing patient samples, ensuring sample integrity and preventing loss or damage during, handling, preparation and storage.

7.2.7.2 Criteria for additional examination requests

Laboratory has procedure of time limits for requesting additional examinations on the same sample.

7.2.7.3 Sample stability

In the case of certain tests where stability of the analyte is very crucial the time between the sample collection and performing the examination is monitored.

Related Documents:-
KLELAB/PSM/04 Primary sample collection manual.

7.3 Examination processes

7.3.1 General

a) The laboratory selects and uses examination methods which have been validated for their intended use to assure the clinical accuracy of the examination for patient testing. Preferred methods are those specified in the instructions for use of in vitro diagnostic medical devices or those that have been published in established/authoritative textbooks, peer-reviewed texts, or journals, or in international and national consensus standards or guidelines, or national or regional regulations.

b) The performance specifications for each examination method will relate to the intended use of that examination and its impact on patient care.

c) All procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, are kept up to date and be readily available to personnel.

d) Personnel will follow established procedures and the identity of persons performing significant activities in examination processes be recorded.
e) Section In-charges will periodically evaluate the examination methods provided by the laboratory to ensure they are clinically appropriate for the requests received.

7.3.2 Verification of examination methods

a) The laboratory has a procedure to verify that it can properly perform examination methods before introducing into use, by ensuring that the required performance, as specified by the manufacturer or method, can be achieved.
b) The performance specifications for the examination method confirmed during the verification process will be those relevant to the intended use of the examination results.
c) The laboratory ensures the extent of the verification of examination methods is sufficient to ensure the validity of results pertinent to clinical decision making.
d) Personnel with the appropriate authorization and competence (respective section Heads) will review the verification results and record whether the results meet the specified requirements.
e) If a method is revised by the issuing body, the laboratory will repeat verification to the extent necessary.
f) The following records of verification are retained:
1) performance specifications to be achieved,
2) results obtained, and
3) a statement of whether the performance specifications were achieved and if not, action taken.
Reference document:- KLELAB/EQPT/01/name of instrument

7.3.3 Validation of examination methods

The laboratory is using all standard methods. No modified methods are used.

7.3.4 Evaluation of measurement uncertainty (MU)

For practical purposes, imprecision data obtained from the routine application of internal quality control is recommended as the quantitative estimate of the uncertainty of measurement
The laboratory measures MU using the formula: Lab CV*1.96.It is recommended that a minimum of six months IQC data should be used to calculate routine imprecision. The value is to be updated annually where possible.

a) The MU of measured quantity values is evaluated and maintained for its intended use, where relevant. The MU is compared against performance specifications and documented.
b) MU evaluations will be regularly reviewed by section In-charge.
c) For examination procedures where evaluation of MU is not possible or relevant, the rationale for exclusion from MU estimation will be documented.
d) MU information will be made available to laboratory users on request.
e) When users have inquiries on MU, the laboratory's response will take into account other sources of uncertainty, such as, but not limited to biological variation.

f) If the qualitative result of an examination relies on a test which produces quantitative output data and is specified as positive or negative, based on a threshold, MU in the output quantity will be estimated using representative positive and negative samples.
g) For examinations with qualitative results, MU in intermediate measurement steps or IQC results which produce quantitative data should also be considered for key (high risk) parts of the process.
h) MU will be taken into consideration when performing verification or validation of a method, when relevant.
For qualitative set of tests, the laboratory enlists the factors which could contribute to the uncertainty of the results and ensure that they were given due attention while performing the test.

7.3.5 Biological reference intervals and clinical decision limits

Biological reference intervals and clinical decision limits, when needed for interpretation of examination results, is defined and communicated to users.

a) Biological reference intervals and clinical decision limits are defined based on the data published in national guidelines or as per kit inserts wherever applicable, and their basis recorded, to reflect the patient population served by the laboratory, while considering the risk to patients.
b) Biological reference intervals and clinical decision limits will be periodically reviewed by section in-charge based on the data published in national guidelines or as per kit inserts wherever applicable., and any changes communicated to users. If during review it is observed that the interval is no longer appropriate the process of updating the reference interval is initiated wherever required.
c) When changes are made to an examination or pre-examination method, the laboratory will review the impact on associated biological reference intervals and clinical decision limits and communicate to the users when applicable.
d) For examinations that identify presence or absence of a characteristic, the biological reference interval is the characteristic to be identified.

7.3.6 Documentation of examination procedures

a) The laboratory has documented its examination procedures to the extent necessary to ensure the consistent application of its activities and the validity of its results.
b) Procedures is written in a language understood by laboratory personnel and be available in appropriate locations.

c) Any abbreviated document content corresponds to the procedure.Working instructions, flow process diagrams or similar systems that summarize key information are used as a quick reference at the workbench.
d) Information from product instructions for use, that contain sufficient information, will be incorporated into procedures by reference.

e) When the laboratory makes a validated change to an examination procedure which could affect interpretation of results, the implications of this will be explained to users.

f) All documents associated with the examination process will be subject to document control. Information from product instructions for use that contain sufficient information is added to the procedure as reference.

Reference documents:-

S.No	Document No.	Document Title
1.	KLELAB/DPM/BIO/05	Biochemistry Department Procedure Manual
2.	KLELAB/DPM/HEM & PATH/06	Pathology Department Procedure Manual
3.	KLELAB/DPM/MICRO/07	Microbiology Department Procedure Manual
4.	KLELAB/DPM/HISTO/08	Histopathology Department Procedure Manual
5.	KLELAB/EPM/BIO/09	Biochemistry Equipment Procedure Manual
6.	KLELAB/EPM/HEM & PATH/10	Pathology Equipment Procedure Manual
7.	KLELAB/EPM/MICRO/11	Microbiology Equipment Procedure Manual
8.	KLELAB/EPM/HISTO/12	Histopathology Equipment Procedure Manual
9.	KLELAB/SOP/BIO/13	Biochemistry Examination Procedure Manual
10.	KLELAB/SOP/HEM & PATH/14	Pathology Examination Procedure Manual
11.	KLELAB/SOP/HISTO/15	Histopathology Examination Procedure Manual
12.	KLELAB/SOP/MICRO/16	Microbiology Examination Procedure Manual

7.3.7 Ensuring the validity of examination results

7.3.7.1 General

The laboratory has a procedure for monitoring the validity of results. The resulting data is recorded in such a way that trends and shifts are detectable and, where practicable, statistical techniques are applied to review the results. This monitoring is planned and reviewed.

Reference documents:- KLELAB/QSPM/02 - QSP 18 Procedure for Quality control

7.3.7.2 Internal quality control (IQC)

a) The laboratory has an IQC procedure for monitoring the ongoing validity of examination results, according to specified criteria, that verifies the attainment of the intended quality and ensures validity pertinent to clinical decision making.

1) The intended clinical application of the examination is considered, as the performance specifications for the same measurand can differ in different clinical settings.
2) The procedure also allows for the detection of either lot-to-lot reagent or calibrator variation, or both, of the examination method. To enable this, the laboratory procedure will avoid lot change in IQC material on the same day/run as either lot-to-lot reagent or calibrator change, or both.
3) The use of third-party IQC material is considered, either as an alternative to, or in addition to, control material supplied by the reagent or instrument manufacturer. Monitoring of interpretations and opinions is achieved through regular peer review of examination results.

b) The laboratory selects IQC material that is fit for its intended purpose. When selecting IQC material, factors considered include:

1) stability with regard to the properties of interest;
2) the matrix is as close as possible to that of patient samples;
3) the IQC material reacts to the examination method in a manner as close as possible to patient samples;
4) the IQC material provides a clinically relevant challenge to the examination method, has concentration levels at or near clinical decision limits and when possible, covers the measurement range of the examination method.

c) If appropriate IQC material is not available, the laboratory will consider the use of other methods for IQC. Examples of such other methods include:

1) trend analysis of patient results, e.g. with moving average of patient results, or percentage of samples with results below or above certain values or associated with a diagnosis;
2) comparison of results for patient samples on a specified schedule to results for patient samples examined by an alternative procedure validated to have its calibration metrologically traceable to the same or higher order references.
3) retesting of retained patient samples.

d) IQC will be performed at a frequency that is based on the stability and robustness of the

examination method and the risk of harm to the patient from an erroneous result.

e) The resulting data will be recorded in such a way that trends and shifts are detectable and, where applicable, statistical techniques will be applied to review the results.

f) IQC data will be reviewed with defined acceptability criteria at regular intervals, and in a time-frame that allows a meaningful indication of current performance.

g) The laboratory prevents the release of patient results in the event that IQC fails the defined acceptability criteria.

1) When IQC defined acceptability criteria are not fulfilled and indicate results are likely to contain clinically significant errors, the results will be rejected and relevant patient samples re-examined after the error has been corrected.

2) The results from patient samples that were examined after the last successful IQC event will be evaluated.

Reference documents:-
KLELAB/QSPM/02 - QSP 18 Procedure for Quality control

7.3.7.3 External quality assessment (EQA)

a) The laboratory monitors its performance of examination methods, by comparison with results of other laboratories. This includes participation in EQA programmes appropriate to the examinations and interpretation of examination results

b) The laboratory has established a procedure for EQA enrollment, participation and performance for examination methods used, where such programmes are available.

Related Documents:-
KLELAB/QSPM/02 - QSP 18 Procedure for Quality control

c) EQA samples is processed by personnel who routinely perform pre-examination, examination, and post-examination procedures.

d) The EQA programme(s) selected by the laboratory will, to the extent possible:

1) have the effect of checking pre-examination, examination, and post-examination processes;
2) provide samples that mimic patient samples for clinically relevant challenges;
3) fulfill ISO/IEC 17043 requirements.

e) When selecting EQA programme(s), the laboratory will consider the type of target value offered.

Target values are:

1) independently set by a reference method, or
2) set by overall consensus data, and/or
3) set by method peer group consensus data, or
4) set by a panel of experts.

When method-independent target values are not available, consensus values can be used to determine whether deviations are laboratory- or method-specific.

Where lack of commutability of EQA materials can hamper comparison between some methods,

it can still be useful for comparisons to be made between methods for which it is commutable, rather than relying only on within-method comparisons.

f) When an EQA programme is either not available, or not considered suitable, the laboratory will use alternative methodologies to monitor examination method performance. The laboratory will justify the rationale for the chosen alternative and provide evidence of its effectiveness.

Acceptable alternatives include:

— participation in sample exchanges with other laboratories;
— interlaboratory comparisons of the results of the examination of identical IQC materials, which evaluates individual laboratory IQC results against pooled results from participants using the same IQC material;
— analysis of a different lot number of the manufacturer's end-user calibrator or the manufacturer's trueness control material;
— analysis of microbiological organisms using split/ blind testing of the same sample by at least two persons, or on at least two analyzers, or by at least two methods;
— analysis of reference materials considered to be commutable with patient samples;
— analysis of patient samples from clinical correlation studies;
— analysis of materials from cell and tissue repositories.

g) EQA data will be reviewed at regular intervals with specified acceptability criteria, in a time frame which allows for a meaningful indication of current performance.

h) Where EQA results fall outside specified acceptability criteria, appropriate action will be taken, including an assessment of whether the non-conformance is clinically significant as it relates to patient samples.

i) Where it is determined that the impact is clinically significant, a review of patient results that could have been affected and the need for amendment will be considered and users advised as appropriate.

Reference documents:- KLELAB/QSPM/02 - QSP 18 Procedure for Quality control.

7.3.7.4 Comparability of examination results

a) For those examinations performed using different procedures or equipment or at different sites, or all these, procedures have been defined for verifying the comparability of results throughout the clinically intervals. When patient samples are either not available or impractical, QC material is used.

b) The laboratory records the results of comparability performed and its acceptability.
Reference documents:- KLELAB/MV/department name

c) The laboratory annually reviews the comparability of results.

d) Where differences are identified, the impact of those differences on biological reference intervals and clinical decision limits will be evaluated and acted upon.

e) The laboratory will inform users of any clinically significant differences in comparability of results.

7.4 Post-examination processes

7.4.1 Reporting of results

7.4.1.1 General

a) Examination results are reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedure. The report will include all available information necessary for the interpretation of the results.
b) The laboratory has a procedure to notify users when examination results are delayed, based on the impact of the delay on the patient.
c) All information associated with issued reports will be retained in accordance with management system requirements.

Reports are issued as hard copies or by electronic (soft copy) means.

7.4.1.2 Result review and release

Results are reviewed and authorized by the respective section Consultants prior to release.
The laboratory ensures that authorized personnel review the results of examinations and evaluate them against IQC and, as appropriate, available clinical information and previous examination results.
Responsibilities and procedures for how examination results are released for reporting, including by whom and to whom, is specified.

Reference documents:- KLELAB/QSPM/02 - QSP 19 Procedure for release of reports.

7.4.1.3 Critical result reports

When examination results fall within established critical decision limits:

a) the user or other authorized person is notified as soon as relevant, based on clinical information available;
b) actions taken are documented, including date, time, responsible person, person notified, results conveyed, verification of accuracy of communication, and any difficulties encountered in notification;
c) the laboratory has an escalation procedure for laboratory personnel when a responsible person cannot be contacted.

Reference documents:- KLELAB/QSPM/02 - QSP 20 Procedure for reporting Critical values

7.4.1.4 Special considerations for results

a) The results are reported in a simplified way. Any information listed in 7.4.1.6 and 7.4.1.7 that is not reported to the user will be readily available.
b) When results are transmitted as a provisional, the final report is always forwarded to the user.
c) Records will be kept of all results which are provided orally, including details of verification of accuracy of communication, as in 7.4.1.3 b. Such results will always be followed by a report.
Reference documents:- QRF/KLELAB/CRIT/Department
d) Special counselling for examination results with serious implications for the patient (e.g. for genetic or certain infectious diseases) is given
e) Results of laboratory examinations that have been anonymized may be used for such purposes as epidemiology, demography, or other statistical analyses, provided that all risks to patient privacy and confidentiality are mitigated and in accordance with any either legal or regulatory requirements, or both.

7.4.1.5 Automated selection, review, release and reporting of results

At present the laboratory does not have facility for automated reporting of results; in case if future inclusion it shall establish a documented procedure and it shall be ensured that:

a) the criteria for automated selection, review and release are specified, approved, readily available and understood by personnel responsible for authorizing the release of results;
b) the criteria are validated and approved before use, regularly reviewed and verified after changes to the reporting system that can affect their proper functioning and place patient care at risk;
c) results selected by an automated reporting system for manual review are identifiable; and as appropriate, date and time of selection and review, as well as identity of the reviewer are retrievable;
d) when necessary, rapid suspension of automated selection, review, release and reporting is applied.

7.4.1.6 Requirements for reports

All test reports are computer generated and the format of the report is made to include but not limited to the following:

a) unique patient identification, the date of primary sample collection and the date of the issue of the report, on each page of the report;
b) identification of the laboratory issuing the report;
c) name or other unique identifier of the user;
d) type of primary sample and any specific information necessary to describe the sample (e.g. source, site of specimen, macroscopic description);
e) clear, unambiguous identification of the examinations performed;
f) identification of the examination method used, where relevant, including, where possible and necessary, harmonized (electronic) identification of the measurand and measurement principle;

g) examination results with, where appropriate, the units of measurement, reported in SI units, units traceable to SI units, or other applicable units;
h) biological reference intervals, clinical decision limits, likelihood ratios or diagrams/nomograms supporting clinical decision limits as necessary;
i) identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available;
j) identification of the person(s) reviewing the results and authorizing the release of the report (if

not contained in the report, readily available when needed);
k) identification of any results that need to be considered as preliminary;
l) indications of any critical results;
m) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end (e.g. page number to total number of pages).

Reference documents:- KLELAB/QSPM/02 - QSP 19 Procedure for releasing reports

7.4.1.7 Additional information for reports

a) When necessary for patient care, the time of primary sample collection will be included.
b) Time of report release, if not contained in the report, will be readily available when needed.
c) Identification of all examinations or parts of examinations performed by a referral laboratory, including information provided by consultants, without alteration, as well as the name of the laboratory performing the examinations.
d) When applicable, a report will include interpretation of results and comments on:
1) sample quality and suitability that can compromise the clinical value of examination results;
2) discrepancies when examinations are performed by different procedures (e.g. POCT) or in different locations;
3) possible risk of misinterpretation when different units of measurement are in use regionally or nationally;
4) result trends or significant changes over time.

7.4.1.8 Amendments to reported results

If the report is to be altered due to transcription error the same is done by the section in-charge or authorized personnel of the lab. Detailed procedure for revoking of released report has been laid down. It will include

a) The reason for the change is recorded and included in the revised report, when relevant.
b) Revised results will be delivered only in the form of an additional document or data transfer, and clearly identified as having been revised, and the date and patient's identity in the original report will be indicated.
c) The user is made aware of the revision.
d) When it is necessary to issue a completely new report, this will be uniquely identified and will contain a reference and traceability to the original report that it replaces.

e) When the reporting system cannot capture revisions, a record of such will be kept.

Reference documents:- KLELAB/QSPM/02 - QSP 23 Procedure for alteration of reports

7.4.2 Post-examination handling of samples

The laboratory has the storage criteria for all tests defined post -examination of the patient samples. The procedure for identification, collection, retention, indexing, access, maintenance, and storage

of the primary sample after the test procedure and disposal is documented as defined specimen collection & Handling manual. The remnants of primary samples after the retention period are as described in NABL 112. The laboratory ensures that after the examination, the

a) patient and source identification of the sample are maintained,
b) suitability of the sample for additional examination is known,
c) sample is stored in a manner that optimally preserves suitability for additional examination,
d) sample can be located and retrieved, and
e) sample is discarded appropriately as per guidelines laid down for the purpose issued by State Government/ Waste Management Guidelines and latest National Bio-medical waste management guidelines.

7.5 Nonconforming work

The Laboratory staff perform their activities in the laboratory as per the laid down SOPs and Work Instructions. Any noncompliance or nonconformity observed while performing the examination or during reporting is immediately reported and recorded in the non-conformity handling form.

Corrective and Preventive action (CAPA) form is duly filled and analysis done by Quality Manger and Section In-Charge. The process will ensure that:

a) the responsibilities and authorities for the management of nonconforming work are specified;
b) immediate and long-term actions are specified and based upon the risk analysis process established by the laboratory;
c) examinations are halted, and reports withheld when there is a risk of harm to patients;
d) an evaluation is made of the clinical significance of the nonconforming work, including an impact analysis on examination results which were or could have been released prior to identification of the non conformance;
e) a decision is made on the acceptability of the nonconforming work;
f) when necessary, examination results are revised, and the user is notified;
g) the responsibility for authorizing the resumption of work is specified.

The laboratory will implement corrective action commensurate with the risk of recurrence of the nonconforming work.

The laboratory retains records of nonconforming work and actions.

Reference documents:-KLELAB/QSPM/02 - QSP 08 Procedure for Corrective action
KLELAB/QSPM/02 - QSP 09 Procedure for Preventive action

7.6 Control of data and information management

7.6.1 General

The laboratory has access to the data and information in the HIS and LIS needed to perform laboratory activities.

7.6.2 Authorities and responsibilities for information management

The laboratory will ensure that the authorities and responsibilities for the management of the information systems are specified, including the maintenance and modification to the information systems that can affect patient care. The laboratory is ultimately responsible for the laboratory information systems. The procedure laid down in QSP 28 defines authorities and responsibilities of personnel who:

1. Access patient data and information.
2. Enter Patient data and examination results.
3. Change patient data or examination results.
4. Authorize the release of examination results and reports.

7.6.3 Information systems management

The system(s) and software of LIS used for the collection, processing, recording, reporting, storage or retrieval of examination data and information is:

a) validated by the supplier and verified for functionality by the laboratory before introduction. Any changes to the system, including laboratory software configuration or modifications to commercial off-the-shelf software, will be authorized, documented and validated before implementation; sufficiently validated (e.g. word processing and spreadsheet software, and quality management software programs).

Reference documents:- KLELAB/LIS/Validation and Verification

b) documented, and the documentation readily available to authorized users, including that for day to day functioning of the system;

c) implemented taking cybersecurity into account, to protect the system from unauthorized access and safeguard data against tampering or loss;

d) operated in an environment that complies with supplier specifications or, in the case of non computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;

e) maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions.

Calculations and data transfers will be checked in an appropriate and systematic manner

7.6.4 Downtime plans

The laboratory has planned processes to maintain operations in the event of failure or during downtime in information systems that affects the laboratory's activities. This includes reporting of results.

7.6.5 Off site management

The laboratory Information system is managed and maintained by the onsite IT department.

Reference documents:- KLELAB/QSPM/02 - QSP 28 Procedure for Laboratory information system
KLELAB/QSPM/02 - QSP 30 Procedure for Contingency plan

7.7 Complaints

7.7.1 Process

The laboratory has a process for handling complaints that includes the following:

a) a description of the process for receiving, substantiating and investigating the complaint, and deciding what actions will be taken in response;
b) tracking and recording the complaint, including the actions undertaken to resolve it;
c) ensuring appropriate action is taken.

7.7.2 Receipt of complaint

a)The laboratory Upon receipt of the complaint the laboratory confirms and resolves the complaints
b)The laboratory will gather all necessary information to determine whether the complaint is substantiated
c)acknowledges the complainant with the outcome and if applicable with outcome and progress report to the complainant if applicable .

7.7.3 Resolution of complaint

Investigation and resolution of complaints will not result in any discriminatory actions.

The respective section In-charge, Quality Manager and the Lab Director have the overall responsibility for ensuring enough resources are made available to close such complaints of customers. All feedback and complaints received written, telephone. email or through other communication methods are registered in the Patient Complaint Register as described earlier. Each complaint is closed upon ensuring that the concerned issue has been resolved. These are analysed at regular intervals as a quality indicator. Where resources do not permit this, any alternative approach will not compromise impartiality.

Reference documents:- KLELAB/QSPM/02 - QSP 06 Procedure for resolution of complaints

7.8 Continuity and emergency preparedness planning

The laboratory ensures that risks associated with emergency situations or other conditions when laboratory activities are limited, or unavailable, have been identified, and a coordinated strategy exists that involves plans, procedures, and technical measures to enable continued operations after a disruption as detailed in contingency plan.

Plans will be periodically tested and the planned response capability exercised, where practicable.

The laboratory has:

a) established a planned response to emergency situations, taking into account the needs and capabilities of all relevant laboratory personnel;

b) provides information and training as appropriate to relevant laboratory personnel;

c) responds to actual emergency situations;

d) take action to prevent or mitigate the consequences of emergency situations, appropriate to the magnitude of the emergency and the potential impact.

Reference documents:- KLELAB/QSPM/02 - QSP 30 Procedure for Contingency plan

8.0 Management system requirements

8.1 General requirements

8.1.1 General

The laboratory has established, documented, implemented the following: and maintain a management system to support and demonstrate the consistent fulfilment of the requirements of this document. As a minimum, the management system of the laboratory includes the following:

- responsibilities
- objectives and policies
- documented information
- actions to address risks and opportunities for improvement.
- continual improvement
- corrective actions
- evaluations and internal audits
- management reviews

8.1.2 Fulfilment of management system requirements

The laboratory meets 8.1.1 by establishing, implementing, and maintaining a quality management system. This quality management system will support and demonstrate the consistent fulfilment of the requirements of Clauses 4 to 7 and the requirements specified in 8.2 to 8.9.

8.1.3 Management system awareness

The laboratory ensures that persons doing work under the laboratory's control are aware of:

a) relevant objectives and policies;
b) their contribution to the effectiveness of the management system, including the benefits of improved performance;
c) the consequences of not conforming with the management system requirements.

8.2 Management system documentation

8.2.1 General

Laboratory management has established, documented, and maintained objectives and policies for the fulfilment of the purposes of this document and ensures that the objectives and policies are acknowledged and implemented at all levels of the laboratory organization.

8.2.2 Competence and quality

The objectives and policies address the competence, quality, and consistent operation of the laboratory.

8.2.3 Evidence of commitment

Laboratory management has evidence of commitment to the development and implementation of the management system.

The lab head, with assistance from Technical Section in charges and other administrative functional heads ensures that adequate steps are taken towards development and implementation of Quality Management System and continuously improve its effectiveness.

8.2.4 Documentation

All documentation, processing systems and records related to fulfilment of the requirement of this document are referenced or linked to the management system.

Level	Document Type	Purpose	Examples
Level 1	Quality Manual	Defines QMS, scope, and policies	Laboratory Quality Manual
Level 2	Policies & SOPs	Guides testing and operational procedures	SOP for Sample Collection, Equipment Calibration Policy
Level 3	Work Instructions & Forms	Step-by-step tasks & documentation	Sample Requisition Form, Equipment Log
Level 4	Records & Evidence	Proof of quality control and compliance	Test Reports, Audit Findings, Training Records

Reference document:- QRF/KLELAB/QM/01(Master list of records and formats)
QRF/KLELAB/QM/01A (Master list of Internal Documents)

8.2.5 Personnel access

All personnel involved in laboratory activities has access to the parts of the management system documentation and related information.

8.3 Control of management system documents

8.3.1 General

The laboratory controls the document internal and external. Document includes policy statements, procedures, job flows, flow charts, posters etc.

8.3.2 Control of documents

The laboratory has ensured that:

a) documents are uniquely identified;
b) documents are approved for adequacy before issue by authorized personnel who have the expertise and competence to determine adequacy;
c) documents are periodically reviewed and updated as necessary;
d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;
e) changes and the current revision status of documents are identified;
f) documents are protected from unauthorized changes and any deletion or removal;
g) documents are protected from unauthorized access;
h) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose;
i) at least one paper or electronic copy of each obsolete controlled document is retained for a specified time period or in accordance with applicable specified requirements.

Reference documents:- KLELAB/QSPM/02 - QSP 03 Procedure for document control

8.4 Control of records

8.4.1 Creation of records

The laboratory has established and retains legible records to demonstrate fulfilment of the requirements of this document.
Records will be created at the time each activity that affects the quality of an examination is performed. Records are in different forms or type of medium (soft or hard copy).

8.4.2 Amendment of records

The laboratory ensures that amendments to records are traceable to the previous version. The original record is stored for traceability and amended data and files are stored. Both the amended and original data are filed and kept along with the date, time of alteration and identity of the personnel making alterations.

8.4.3 Retention of records

a) The laboratory has a procedure for the identification, storage, protection from unauthorized access and changes, back-up, archive, retrieval, retention time, and disposal of its records.
b) The retention times for records is specified.
c) Reported examination results is retrievable for as long as necessary or as required.
d) All records are accessible throughout the entire retention period, legible in whichever medium the laboratory keeps records, and available for laboratory management review.

Reference documents:- Master list of documents and records.(KLELAB/QM/OI)
KLELAB/QSPM/02 - QSP - Procedure for Document control

8.5 Actions to address risks and opportunities for improvement

8.5.1 Identification of risks and opportunities for improvement

The laboratory has performed risk assessment to identify the risks and opportunities for improvement associated with the laboratory activities.

1. Prevent or reduce undesired impacts.
2. Achieve improvement.
3. Assure that the management system achieves the intended results.
4. Mitigate risks to the patients.
5. Help achieve the purpose and objectives of the laboratory.

8.5.2 Acting on risks and opportunities for improvement

The laboratory prioritizes and acts on identified risks. The laboratory records the action taken on risks and opportunities. The laboratory records the decision made and actions taken on risks and opportunities.

Reference documents:- KLELAB/QSPM/02 - QSP - Procedure for Risk management
QRF/KLELAB/RA-Risk analysis

8.6 Improvement

8.6.1 Continual improvement

a) The laboratory continually improves the effectiveness of the management system, including the pre-examination, examination and post-examination processes as stated in the objectives and policies.
c) The laboratory identifies and select opportunities for improvement and develop, document, and implement any necessary actions. Improvement activities will be directed at areas of highest priority based on risk assessments and the opportunities identified through the analysis of non-conformances, complaints, feedback and performance in external and internal audits.
c) The laboratory will evaluate the effectiveness of the actions taken.
d) Laboratory management will ensure that the laboratory participates in continual improvement activities by training and CME, that encompass relevant areas and outcomes of patient care.
e) Continual improvement plans are discussed in the Management review meetings and communicates to personnel about its improvement plans and related goals.

Referenece document:-QRF/KLELAB/CI/Plan

8.6.2 Laboratory patients, user, and personnel feedback

The laboratory seeks feedback from its patients, users, and personnel. The feedback is analysed and used to improve the management system, laboratory activities and services to users.

The feedback is reviewed by the quality manager, Section In-charges and Laboratory Director at appropriate frequency and corrective action is taken in case of any complaint or feedback that requires immediate corrective action. The feedback is analysed to observe any area of improvisation and preventive action is taken accordingly.

The lab staff is encouraged to provide feedback and suggestions for improvisation in the quality management system including pre-analytical, analytical, and post-analytical activities. All such feedback and suggestions are discussed during a review meeting with the management and if found appropriate they are implemented.

Records of feedback are maintained including the actions taken. Communication is provided to personnel on actions taken arising from their feedback.

Reference Documents:- QRF/KLELAB/CUS/01
QRF/KLELAB/CUS/02
QRF/KLELAB/CUS/03

8.7 Non-conformities and corrective actions

8.7.1 Actions when nonconformity occurs

Whenever any non-conformity occurs the laboratory responds to the non-conformity and takes appropriate corrective action to correct the non -conformity.

a) Respond to the nonconformity and, as applicable:
   1) take immediate action to control and correct the nonconformity;
   2) address the consequences, with a particular focus on patient safety including escalation to the appropriate person.
b) Determine the cause(s) of the nonconformity.
c) Evaluate the need for corrective action to eliminate the cause(s) of the nonconformity, in order to reduce the likelihood of recurrence or occurrence elsewhere, by:
   1) reviewing and analyzing the nonconformity;
   2) determining whether similar non-conformities exist, or could potentially occur;
   3) assessing the potential risk(s) and effect(s) if the nonconformity recurs.
d) Implement any action needed.
e) Review and evaluate the effectiveness of any corrective action taken.
f) Update risks and opportunities for improvement, as needed.
g) Make changes to the management system, if necessary.

8.7.2 Corrective action effectiveness

The records of the non-conformities and the corrective actions taken are maintained and is checked for their effectiveness.

8.7.3 Records of non-conformities and corrective actions

The laboratory retains records as evidence of the

a) nature of the non-conformities, cause(s) and any subsequent actions taken, and
b) evaluation of the effectiveness of any corrective action.

Reference documents:-KLELAB/QSPM/02 - QSP 08 Procedure for Corrective action
KLELAB/QSPM/02 - QSP 09 Procedure for Preventive action

8.8 Evaluations

8.8.1 General

The QM plans Internal Quality Audits (IQA) under QMS practice at planned intervals to demonstrate that the management, support, and pre-examination, examination, and post-examination processes meet the needs and requirements of patients and laboratory users, and to ensure conformity to the requirements of this document.

8.8.2 Quality indicators

The laboratory has laid down procedure for monitoring and analysis of the quality indicators in QSP 10. The procedure mentions of monitoring acquired data throughout the laboratory processes like pre-examination (Sample rejection,labelling errors,Haemolysed samples,clotted sample), examination (IQC outliers, EQAS, Coefficient of variation,Equipment downtime) and post-examination processes (TAT,reporting errors,complaints) apart from monitoring other aspects like daily non-conformances that include reagent failure, instrument breakdowns, Personnel safety records, etc. Turnaround time for tests has been established in consultation with the clinicians as a part of Quality Indicators.
Reference documents:- KLELAB/QSPM/02 - QSP 10 Procedure for Quality indicator

8.8.3 Internal audits

8.8.3.1 The laboratory conducts internal audits at planned intervals to provide information on whether the management system

a) conforms to the laboratory's own requirements for its management system, including the laboratory activities,
b) conforms to the requirements of this document, and
c) is effectively implemented and maintained.

8.8.3.2 The laboratory plans, implement and maintain an internal audit programme that includes:

a) priority given to risk to patients from laboratory activities;
b) a schedule which takes into consideration identified risks; the outcomes of both external evaluations and previous internal audits; the occurrence of non-conformities, incidents, and complaints; and changes affecting the laboratory activities;
c) specified audit objectives, criteria and scope for each audit;
d) selection of auditors who are trained, qualified and authorized to assess the performance of the laboratory's management system, and, whenever resources permit, are independent of the activity to be audited;
e) ensuring objectivity and impartiality of the audit process;
f) ensuring that the results of the audits are reported to relevant personnel;
g) implementation of appropriate correction and corrective actions without undue delay;
h) retention of records as evidence of the implementation of the audit programme and audit results.

Reference documents:- KLELAB/QSPM/02 - QSP 12 Procedure for Internal Audits

8.9 Management reviews

8.9.1 General

Laboratory management reviews its management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.

MRM is conducted with a multi-disciplinary approach to ensure continual suitability and effectiveness in satisfying the requirements defined by quality policy and objectives, as well as that of latest ISO 15189:2022 standards.

8.9.2 Review input

The inputs of management review are recorded and includes evaluations of the following:

a) status of actions from previous management reviews, internal and external changes to the management system, changes in the volume and type of laboratory activities and adequacy of resources;
b) fulfilment of objectives and suitability of policies and procedures;
c) outcomes of recent evaluations, process monitoring using quality indicators, internal audits, analysis of non-conformities, corrective actions, assessments by external bodies;
d) patient, user and personnel feedback and complaints;
e) quality assurance of result validity;
f) effectiveness of any implemented improvements and actions taken to address risks and opportunities for improvement;
g) performance of external providers;
h) results of participation in interlaboratory comparison programmes;
i) No Evaluation of POCT activity as it is not under laboratory scope.
j) other relevant factors, such as monitoring activities and training.

8.9.3 Review output

The management ensures that actions arising from the MRM and the necessary changes are implemented within an agreed upon time frame and Records against the action required generated to: -

a) the effectiveness of the management system and its processes;
b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;
c) provision of required resources;
d) improvement of services to patients and users;
e) any need for change.

Laboratory management will ensure that actions arising from management review are completed within a specified time, frame.

Conclusions and actions arising from management reviews will be communicated to laboratory Personnel.

Reference documents:- KLELAB/QSPM/02 - QSP 13 Procedure for management review

Annexure I

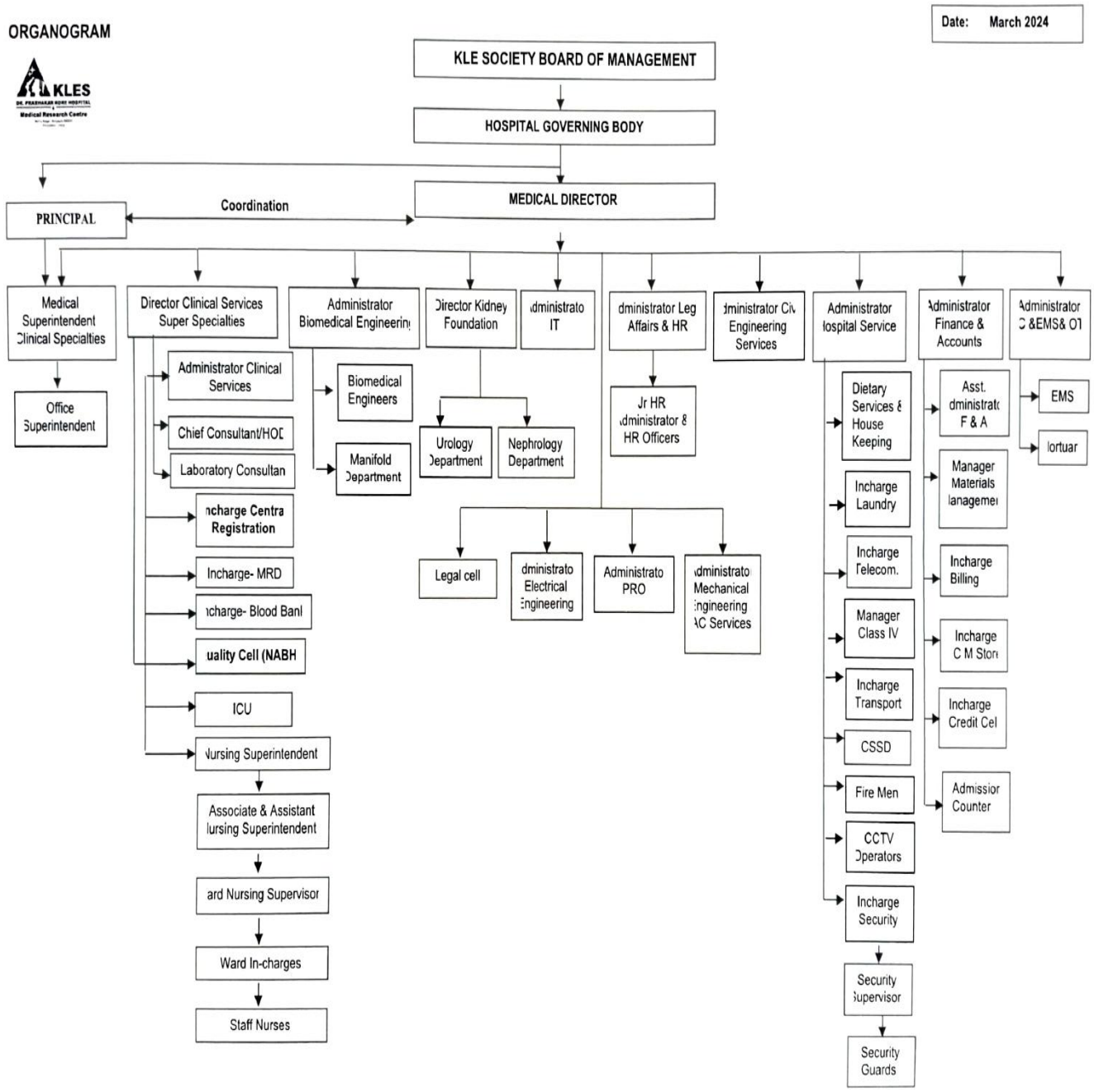
Quality Policy

Our laboratory is committed to providing accurate, reliable, and timely medical testing services in compliance with ISO 15189:2022, NABL (National Accreditation Board for Testing and Calibration Laboratories) guidelines and state-specific regulations.

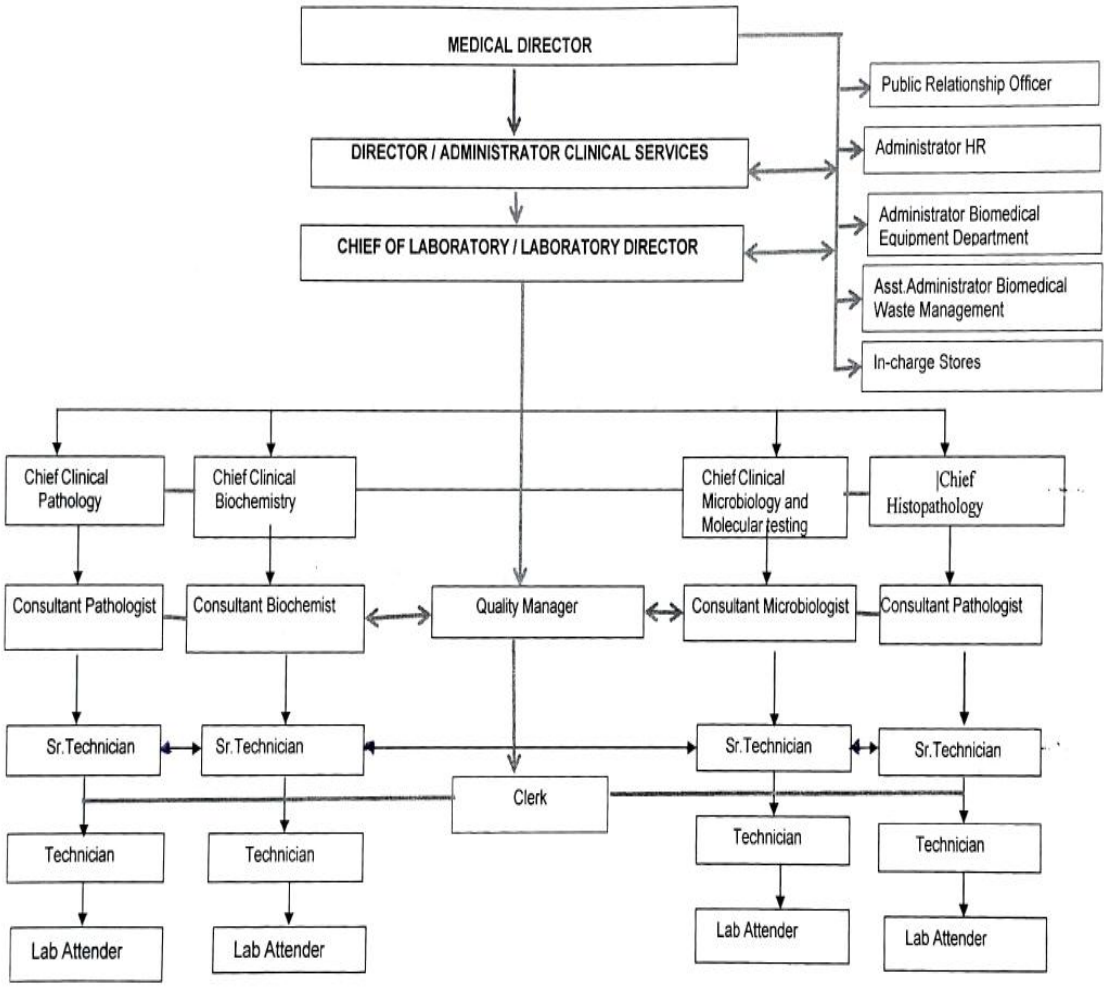
We aim to maintain the highest standards of quality, ethical conduct, and patient safety while ensuring continual improvement in our processes.

Annexure – II Organization Chart

A. Hospital Organization Chart



B. Laboratory Organization Chart



Annexure – III

Responsibilities & authority of laboratory personnel and other staff having influence of activities of laboratory

Laboratory Director authorized and responsible for

- providing advice to clinicians, hospitals and laboratories referring the patients to the laboratory about the choice of tests, the use of the laboratory services and the interpretation of laboratory data, along with technical management;
- relate and function effectively with (including contractual agreements) with quality manager and parent organization; NABL, Clinicians referring the patients to the facility, Patients visiting the facility;
- Define, implement and monitor standards of performance and quality improvement of the medical laboratory services as an approval authority of all documents related to quality management system and as an authority for initiating corrective actions.
- Implement the quality management system along with quality manager and technical management;
- Monitor all work performed in the laboratory to determine that reliable data are being generated as a part of authorized signatory for all the laboratory reports along with technical management;
- Ensure that there are sufficient qualified (as defined in QSP 14 & NABL 112) personnel with adequate documented training and experience to meet the needs of the laboratory;
- Plan, set goals, develop and allocate resources appropriate to the medical environment through action points of management review or as a part of initiation of corrective and preventive action;
- Provide effective and efficient administration of the laboratory service, including budget planning and control with responsible financial management, in accordance with institutional assignment of such responsibilities;
- Provide suitable educational training programs for the staff and participate in educational programs of the laboratory (QSP 15);
- Select and monitor all referral laboratories for quality of service;
- Implement a safe laboratory environment in compliance with good practice and applicable regulations (laboratory safety manual) along with technical management;
- Address any complaint, request or suggestion from users of laboratory services in coordination with quality manager (QSP 06);
- Ensure good staff morale in coordination with the parent organization

Reference : Personnel files KLELAB/HR/01/DEPT/Employee name.

Technical Management (In-charge Of Various Sections And Consultants) are responsible for :

- Organization and development of the operational system of the respective operations.
- As the functional in charge, responsible for developing procedures and standards for conducting examinations.
- Responsible for training of all technicians assigned under her / him.
- Performing critical investigations.
- Authorized to review the raw data and issue of the reports of the department
- Responsible for monitoring of the non-conformances in the procedures followed in the department.
- Overall responsibility for ensuring relevant good laboratory practices and safety.
- Write the standard operational procedure (SOP) for their respective section and ensure that it is been followed in the department.
- Review the SOP and QSP Periodically.
- Ensure that the department participates in Internal Quality Control and External Quality Programme.
- Ensure that the departmental functions are carried out in a smooth and efficient manner.
- Ensure that all documents pertaining to NABL are read and understood by the staff, and the requirements mentioned therein are implemented.
- Ensure that the tests are carried using documented procedures only, after ensuring that the quality control process is satisfactory.
- Ensure that the records are promptly updated and authenticated.
- Monitor QC data and report to the Quality Manager / Joint Quality Manager.
- Authentication and release of Test Reports.

Reference : Personnel files KLELAB/HR/01/DEPT/Employee name.

Biochemists/Microbiologist/Jr.Consultants are responsible for

- Should allot work to technicians, see that the reports are printed, signed and dispatch at the earliest.
- Monitor work during their duty hour.
- Maintain inventory stock register and indent items from store.
- Authorization of reports.

Reference : Personnel files KLELAB/HR/01/DEPT/Employee name.

Quality Manager (QM) is authorized and responsible for

- The designated Quality Manager (QM) is responsible for the implementation and maintenance of Quality management System of KLESH & MRC Laboratory in accordance with the requirements of the standard ISO 15189: 2022 and NABL.

- He / She is responsible for and has the authority for ensuring the establishment, implementation and maintenance of Quality management System in addition to his or her regular / routine responsibilities.
- He / She is responsible for any liaison activities with outside agencies regarding implementation and maintenance of the Quality System Standard.
- He / She is responsible for and has the authority for ensuring the periodic Internal Quality Audits and convening the Management Review Meeting.
- The Quality Manager (QM) will also apprise the Management about the status of Quality System in the organization periodically and shall provide the required inputs for the Management Review.
- Document control and maintenance.
- Check on record control.
- Monitoring proper execution of Quality control (Internal, External Quality Control and inter-laboratory) results.
- Monitoring Calibration and traceability.
- Ensure prompt and proper conduct of internal audit, and follow up correctives and preventive actions.
- Organize periodic management review meeting under the authority of the director.
- Interface between NABL and laboratory.
- Maintenance of corporate / insurance and other contracts, and correspondence.

Reference : Personnel files KLELAB/HR/01/DEPT/Employee name.

Deputy Quality Manager :

- Co-ordinate with Quality Manager.
- Responsible for daily maintenance of quality records, as well as monitoring records maintained by technical staff.
- Responsible for actual conduct of planned and incidental audit, in consultation with the QM.
- Updating of quality control data and reporting to the management about the results.
- Shall actively participate in management review meetings. Responsible for maintenance of quality system of laboratory in accordance with the requirements of the standard ISO 15189: 2022 and NABL.
- Document control and maintenance.
- Check on record control.
- Monitoring proper execution of Quality control (Internal, External Quality Control and inter-laboratory) results.
- Monitoring Calibration and traceability.
- Ensure prompt and proper conduct of internal audit, and follow up correctives and preventive actions.
- Organize periodic management review meeting under the authority of the director.

Reference : Personnel files KLELAB/HR/01/DEPT/Employee name.

Technicians are:

- Responsible for performing procedures / investigations assigned by the technical management.
- Responsible for undertaking various maintenance / upkeep protocols during and between procedure runs.
- Responsible for the equipments / reagents / chemicals / consumables under their operations.
- Responsible for proper inventory management system.
- Understand the documented procedures and policies.
- Carry out procedures of testing as per documented methods.
- Operate equipment of their department, and ensure that regular maintenance is being done.
- Follow instructions given by the divisional head.
- Maintain all quality systems records as per requirements of the standard.
- Receive the samples from OPD and IPD by proper identification.
- Analyze the samples.
- Enter results into the LIS.
- Maintain day-to-day patients requisition file and results log register.
- Regularly update the inventory stock register.
- Monitor the Bio Medical waste disposal as per the Hospital policy

Reference : Personnel files KLELAB/HR/01/DEPT/Employee name.

Collection Person

- Responsible for transporting the samples to the laboratory in time and deliver the reports to the requester.

Typing Staff

Follow instructions given by the divisional head.

- Responsible for transcription of reports into LIS and the accuracy.
- Responsible for updating all the quality records of the laboratory.
- Responsible for reports of the referral laboratory.
- Attending phone quarries, typing reports and clerical work of respective sections.
- Maintain all quality systems records as per requirements of the standard.
- Receive the samples from OPD and IPD by proper identification.
- Enter results into the LIS.
- Maintain day-to-day patients requisition file and results log register.
- Regularly update the inventory stock register.
- Monitor the Bio Medical waste disposal as per the Hospital policy

Reference : Personnel files KLELAB/HR/01/DEPT/Employee name.

Public Relations Officer

- Authorized to address client complaints / grievances and shall report to the Chief of Laboratory to define and implement appropriate corrective measures.
- Responsible for overall functioning of the Out patient reception.
- Responsible for obtaining / recording patient feedback and complaints.
- Responsible for maintaining the Patient Records and ensuring their privacy.
- Authorized to interact with the patients or their attenders.

Reference : Personnel files KLELAB/HR/01/DEPT/Employee name.

Lab Attender (Housekeeping):

- Maintain cleanliness in the department
- Washing lab glassware.
- Dispatch of reports to respective wards / OPD and other departmental correspondence.
- Disposal of Bio Medical waste as per the hospital policy

Reference : Personnel files KLELAB/HR/01/DEPT/Employee name.

Appointment of Deputies

1. Laboratory Director:
   In the absence of Laboratory Director, the administrative responsibilities related to laboratory will be managed by one Head of Department.

2. Quality Manager:
   In the absence of Quality Manager, the responsibilities are carried out by the deputy Quality Manager.

3. Public Relation Officer:
   In the absence of PRO, customer relations will be handled by his/her immediate Junior staff.

4. Section Heads:
   In the absence of Divisional heads the next senior most departmental member as designated by the management, shall take over the responsibilities.

Reference : Personnel files KLELAB/HR/01/DEPT/Employee name.

Annexure – IV

Employee Confidentiality And Ethics Agreement

Ethics

Medical Council of India, through Code of Ethics, has established protections to preserve the confidentiality of various medical and personal information and specify that such information may not be disclosed except as authorized by law or the patient or individual.

Confidential Patient Care Information includes: Any individually identifiable information in possession or derived from a provider of health care regarding a patient's medical history, test results, conversations, records and financial information. Examples include, but are not limited to:

- Records including paper, diagnostic and therapeutic reports, laboratory and pathology samples;
- Patient billing records;
- Computerized patient data and,
- Verbal information provided by or about a patient.

Confidential Employee and Business Information includes, but is not limited to, the following:

- Employee home telephone number and address;
- Information related to evaluation of performance; or
- Disclosure of Confidential business information that would cause harm to the organization.

I understand and acknowledge that:

1. I shall respect and maintain the confidentiality of all discussions, deliberations, patient reports and any other information generated in connection with reporting.
2. It is my legal and ethical responsibility to protect the privacy, confidentiality and security of all records, proprietary information and other confidential information relating to KLES Dr Prabhakar Kore Hospital & MRC, including business, employment and medical information relating to our patients, members, employees and Doctors.
3. I shall only access or disseminate patient information in the performance of my assigned duties, and in a manner which is consistent with officially adopted policies of KLES Dr Prabhakar Kore Hospital & MRC, or where no officially adopted policy exists, only with the express approval of Laboratory in charge. I shall make no voluntary disclosure of any discussion, deliberations, patient records except to persons authorized to receive it.
4. Undue pressure policy:- Management and Personnel are to be free from any undue internal and external commercial financial and other pressures that may adversely effect the work. The integrity of test results is responsibility of all Personnel. Management ensures that employees
5. are never instructed or forced to alter or forge data.

6. I undertake that where potential conflicts in competing interests may exist, they shall be openly and appropriately declared.
7. I undertake there are appropriate procedures to ensure staff treat human samples ,tissues or remains according to relevant legal requirements.
8. My user ID is recorded when I access LIS (Laboratory information software) and that I am the only one authorized to use my user ID. Use of my user ID is my responsibility whether by me or anyone else. I will only access the minimum necessary information to satisfy my job role or the need of the request.
9. I agree to discuss confidential information only in the work place and only for job related purposes and to not discuss such information outside of the work place or within hearing of other people who do not have a need to know about the information.
10. My obligation to safeguard patient confidentiality continues after my termination of employment with the KLES Dr Prabhakar Kore Hospital & MRC

I hereby acknowledge that I have read and understand the foregoing information and that my signature below signifies my agreement to comply with the above terms.

In the event of a breach or threatened breach of the Confidentiality Agreement.I acknowledge that the KLES Dr Prabhakar Kore Hospital & MRC may, as applicable and as it deems appropriate, pursue disciplinary action up to and including my termination from the KLES Dr Prabhakar Kore Hospital & MRC.

Employee Name:-_____ Designation:-_____

Signature:-_____ Date:- _____

Annexure – V

Organization Information

1. A designation is given for each employee
2. Salary is fixed for each employee.
3. Each new employee joining the company will be in a Trainee for period of two year and probationary period for two more years effective from the date of joining.
   A. During this time period, the employee can avail only the limited benefits.
   B. On successful completion of the probationary period, the employee can be / will be absorbed as a permanent working staff, based on the decision of the board of directors after evaluating his/her performance during the said period.

4. An employee is appointed to the company with the understanding that the information furnished by him/her, is correct and complete in every aspect and shall hold complete liability for the same. Necessary proof in support for the claim has to be furnished in original at the time of appointment along with a photocopy of the same which shall be retained by the company for official purpose.
5. In-case, the company finds any discrepancy in the information furnished by the employee, his/her appointment shall be withdrawn before he/she joins for the service or his/her service may be terminated at any time after the employee has taken up employment with the company and strict penal actions shall be taken as deemed fit by the management board of directors.
6. Working hours are applicable to all the employees. Minimum working hour is eight hours.
7. The decision of the management is final for the disbursement of benefits/allowances if any to its employees.
8. Annual increment of the employee will depend upon his/her overall performance, including work, conduct and attendance.
9. On scale Employees are entitled for leave as per Society rules:
   Earned leaves - 24 days
   Casual leave - 12 days
   Medical/ sick leave - 10 days/year
   Earned leave can be accumulated.
10. Employees have to get their leave sanctioned by their laboratory In charge and the leave applications have to be counter signed by the Medical Director.
11. Tax deducted at source for various categories.
12. Employees shall not disclose any information about the company to anyone.
13. During the employment tenure, employees shall not carry on any business of their own.
14. Employees shall have to provide the notice of resignation one month in advance, else will have to relinquish his/her last month salary and other employee benefits .
15. During duty hours Employees must have to wear his/her designated badge/uniform.

16. Employees must log in their duty entry and exit time by daily punching on the Biometric punching machine kept near the entrance.

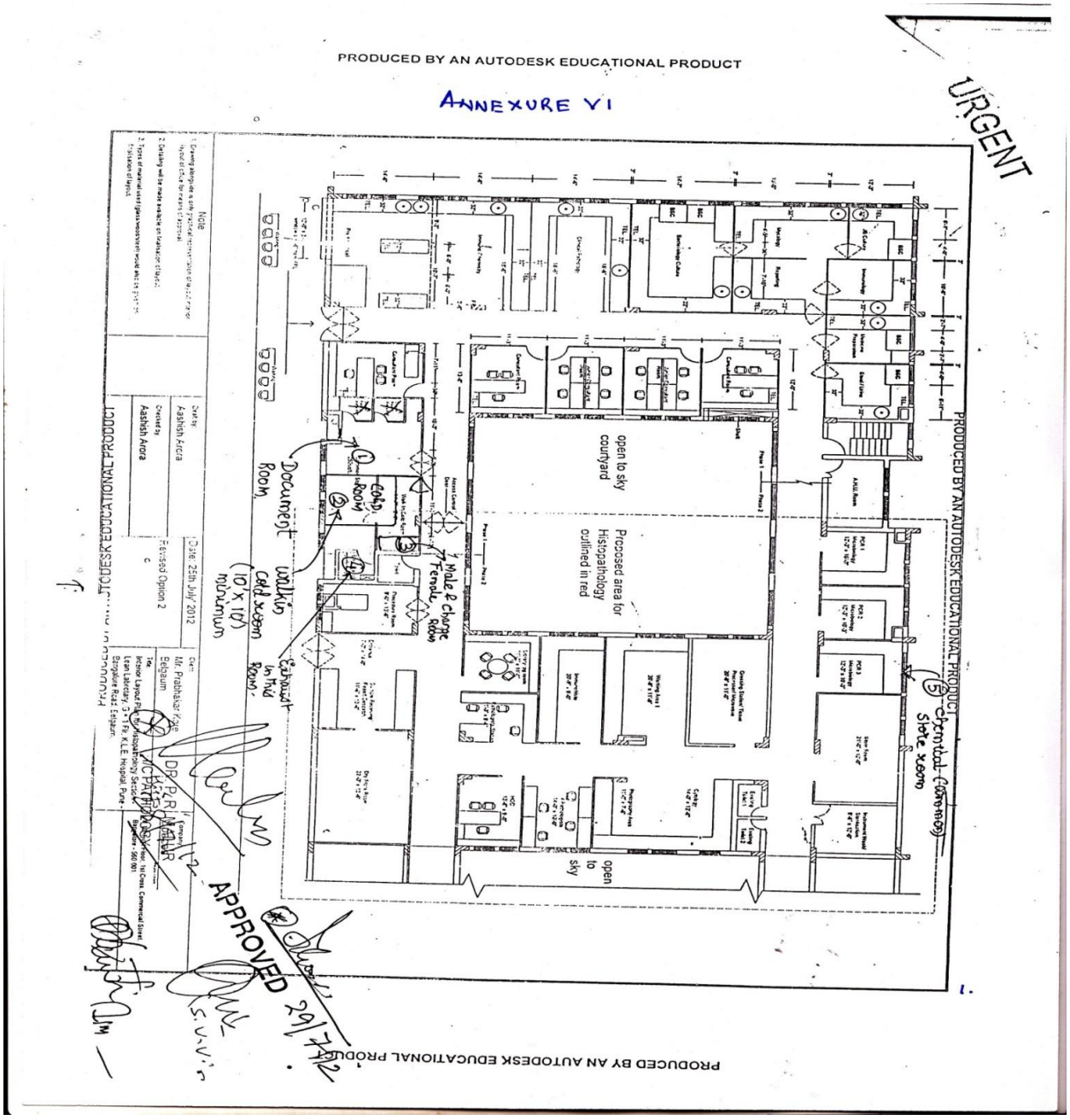
17. On scale Employees are entitled for Maternity leaves as per statutory terms only two times.

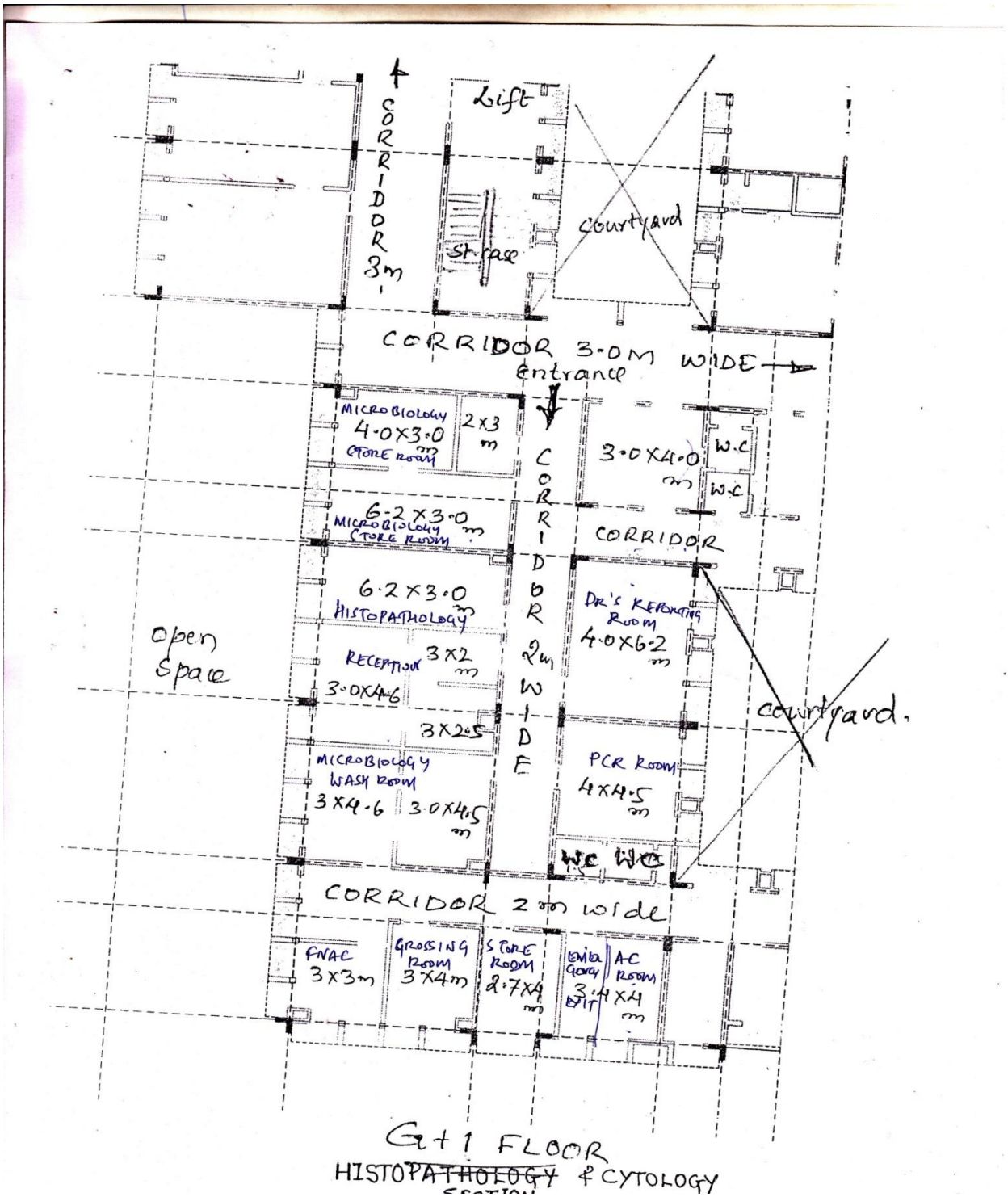
I have read and understood the organization information

Name:- _____ Designation:-_____

Signature:- _____

Annexure – VI Layout of the laboratory

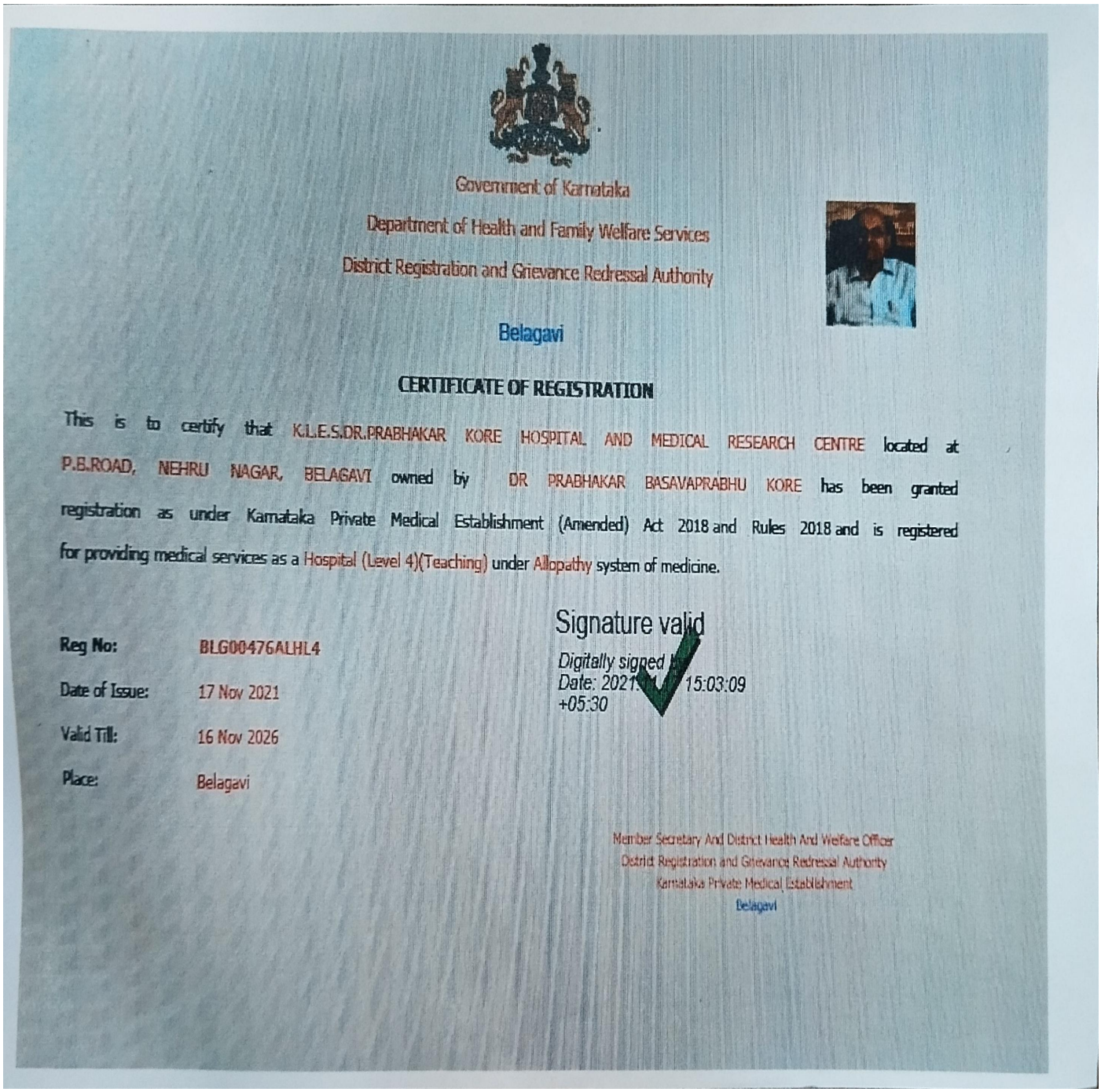




G+1 FLOOR

HISTOPATHOLOGY & CYTOLOGY

Annexure – VII - Hospital Registration



Government of Karnataka

Department of Health and Family Welfare Services

District Registration and Grievance Redressal Authority

Belagavi

CERTIFICATE OF REGISTRATION

This is to certify that K.L.E.S.DR.PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE located at P.B.ROAD, NEHRU NAGAR, BELAGAVI owned by DR PRABHAKAR BASAVAPRABHU KORE has been granted registration as under Karnataka Private Medical Establishment (Amended) Act 2018 and Rules 2018 and is registered for providing medical services as a Hospital (Level 4)(Teaching) under Allopathy system of medicine.

Signature valid

Digitally signed

Date: 2021 15:03:09 +05:30

Reg No: BLG00476ALHL4

Date of Issue: 17 Nov 2021

Valid Till: 16 Nov 2026

Place: Belagavi

Member Secretary And District Health And Welfare Officer
District Registration and Grievance Redressal Authority
Karnataka Private Medical Establishment
Belagavi