Summer Training at
Narayana Multispecialiy Hospital,
Jaipur

NABL Accredation at Narayana Multispeciality Hospital, Jaipur

By
Kshama Singh

Under the guidance of
Dr. S.D. Gupta

MBA Hospital and Health Management
2015-2017

The IIHMR University, Jaipur
2016

INSTITUTE OF HEALTH
MANAGEMENT RESEARCH
(WHO Collaborating Centre for District Health System Based on Primary Health Care)

IIHMR UNIVERSITY

TO WHOMSOEVER MAY CONCERN

This is to certify that **Dr. KSHAMA SINGH** student of MBA Hospital Management from The IIHMR University; Jaipur has undergone internship training at **NH JAIPUR**, from **1st April 2016** to **31st May 2016.**

The Candidate has successfully carried out the study designated to his during internship training and his approach to the study has been sincere, scientific and analytical.
The Internship is in fulfillment of the course requirements.

I wish her all success in all her future endeavors.

Col (Dr) Ashok Kaushik
Dean, Academics and Student Affairs
The IIHMR University, Jaipur

Dr S.D Gupta
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NH Narayana™
Multispeciality Hospital
Unit of Narayana Health

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DL No. - JPR/2012/24144-24145

NH/HRD-Off/2015/297

Date: 1st June 2016

TO WHOM SO EVER IT MAY CONCERN

This is to certify that **Ms. Kshama Singh** has completed her summer internship training in Operations on "NABL Accreditation" Successfully in Narayana Multispecialty Hospital, Jaipur from 1st April 2016 to 31st May 2016.

Her work during the Period was commendable and appreciable. Her character and conduct was good.

We wish her success in her future endeavors.

For Narayana Multispecialty Hospital, Jaipur

Vishnupriya Sharma
Deputy General Manager-Human Resources

PREFACE

Summer internship is an integral part of MBA-HM curriculum. As a part of the course, the students of first year are required to undergo summer placement at any reputed organization to get in depth exposure to various departments of the organization and understanding of health care delivery system and its functions.

The major objectives of the summer internship are as follows:

1. To understand and learn day to day operational management of a Hospital/ Health Care organization and its service contents.
2. To identify issues/problems with certain operational areas.
3. To acquire more knowledge on roles and responsibilities of key players and stakeholders in the hospital.
4. To gain perspective in the functions of various departments by interaction with key stakeholders, policy makers, academicians and researchers.
5. To work on a Project assigned by the summer training organization.

ACKNOWLEDGEMENT

The internship opportunity we had with Narayana Multispeciality Hospitals, Jaipur was a great chance for learning and professional development.

I feel deeply privileged in expressing our deep sense of gratitude to Dr.Devi Shetty (CMD Narayana Group), Mr.Arunesh Punetha (Facility Director) and Dr. Mala Airun (clinical director) Narayana Multispeciality Hospital , Jaipur for their expert guidance and encouragements which helped in the process of making this report. Without their support, exploring such a vast organisation could not have been possible

I would like to express our deepest gratitude to Mr Subhasis Bhattacharya, Ms Vishnupriya Sharma, Ms Mayuri Lokre who guided me and gave me the project and help throughout the work.

I am also grateful to all the department heads and staff for giving us time in spite of their hectic schedule. Without their active co operation and participations it would not have been possible to accomplish my task.

My sincere gratitude to my mentor **Dr. S.D Gupta**, for his constant encouragement.

Sincerely
Dr. Kshama Singh

1.ORGANISATIONAL PROFILE

Narayana Multispecialty Hospital, a branch of Narayana Health (Head Quartered in Bengaluru, India), a privately owned hospital in Jaipur, estd in 2010, is a perfect blend of technological excellence, complete infrastructure, competent care and heartfelt hospitality - this is how the people, whom the hospital has been fortunate to serve, define the hospital.
It is a 290 bedded multispecialty tertiary care hospital, located at Pratap Nagar within a sprawling campus of 4.7 acres offering high quality affordable medical care to the people within Rajasthan and bordering states as well.
Narayana Multispecialty Hospital, Jaipur was awarded the International accreditation from **Joint Commission International (JCI)** on 21st July 2012, making it the first hospital in Rajasthan to receive this prestigious recognition. It got reaccredited from JCI in 2015. A JCI accreditation provides assurance that the standards, training and processes at the hospital meet the highest international benchmarks.

1.1 Vision: "Our vision is affordable quality healthcare to the masses worldwide."

1.2 Mission: "To deliver high quality and affordable healthcare services to the broader population by leveraging our economies of scale, skilled doctors, and an efficient business model"

1.3 Values: Core values are represented by the simple acronyms **iCARE**

- i- Innovation & efficiency
  To continuously reduce the cost of delivery of high quality health care and improve our reach.
- C- Compassionate care
  In providing accessible service that makes a difference to our patients.
- A- Accountability
  To honour commitments to our patients, employees and investors with integrity and transparency.
- R- Respect for all
  Recognise the contribution of every employee and respect the rights as well as the dignity of every patient and employee.
- E- Excellence as a culture
  Where we individual excel to collectively ensure the highest quality of consistence and reliable services to our patients and sustainable values to all our stakeholders.

1.4 The ultimate goal of NH : Service Excellence

Patient satisfaction

1.4 Scope of Services:

- Anaesthesia & Critical Care
- Department of Cardiac Science
  - Minimally Invasive Cardiology
  - Cardiac Electrophysiology
  - Paediatric Cardiology
  - PTCA
  - Coronary Angiography
  - Cardiothoracic & Vascular Surgery
    Paediatric & Adult
- Department of ENT
- Department of Gastrointestinal Sciences
  - Medical Gastroenterology & Haematology
  - G.I & Laparoscopic Surgery
  - Bariatric Surgery
- Department of Neuro Sciences
  - Neurology
  - Neurosurgery
- Department of Paediatric
  - Neonatology
  - Paediatric
- Department of Paediatric Surgery
- Department of Renal Sciences
  - Dialysis
  - Nephrology
  - Urology
  - Transplant Services
- General & Laparoscopic Surgery
- Institute of Bone, Joint & Spine
  - Hand & Microvascular Surgery
  - Joint Replacement
  - Spine surgery
  - Sports Medicine & Arthroscopy
- Internal Medicine
- Obstetric & Gynaecology
- Pulmonary Medicine
- Department of Rheumatology
- Onco-Gynaecology

- Opthalmology
- Dermatology

ALLIED SERVICES

- Dietetics
- Emergency & Trauma
- Radiology & Imaging
  - 1.5 Tesla MRI
  - 64 Slice CT Scan
  - Cath lab
- Laboratory Sciences
- Physiotherapy

1.5 DEPARTMENTAL SERVICES:

1.Outpatient Department:

There are 4 decentralised OPD :

1. North OOD
2. South OPD
3. Cardiac OPD
4. Nephrology OPD

OPD Timings: 9am to 5pm.

Average no. of OPD patients 300-350 per day (Including old and new patients)

2.In Patient Department:

- Male Medical Ward:
  Location: Lower ground floor.
  Bed Capacity: 19 Beds
- Male Surgical ward:
  Location: Lower ground floor
  Bed Capacity: 16 Beds
- CCU
  Location: Ground floor
  Bed Capacity: 20Beds
- MICU
  Location: Ground floor
  Bed Capacity: 20 Beds including 2 bed 0063s for isolation
- Female Medical & Surgical ward
  Location: 1st Floor
  Bed Capacity: 36 (18+18) Beds
- ANC Ward
  Location: 1st Floor
  Bed Capacity: 8 Beds with 2 Beds in Labour Room
- Paediatric Ward
  Location: 1st Floor

Bed Capacity: 5 Beds

- PICU
  Location: 1st Floor
  Bed Capacity: 5 Beds
- NICU
  Location: 1st Floor
  Bed Capacity: 6 Cribs
- ITU
  Location: 1st Floor
  Bed Capacity: 21 beds plus 2 beds for isolation
- Semi Private Ward
  Location: 1st Floor
  Bed Capacity: 36 Beds including 4 day care beds.
- KTU
  Location: 1st Floor
  Bed Capacity: 3 Beds
- Private Ward
  Location: 2nd Floor
  Bed Capacity: 18 Beds
- CTVS Male & Female Ward
  Location : 2nd Floor
  Bed Capacity: 23 Beds
- Ortho General Ward
  Location: 2nd Floor
  Bed Capacity: 6 Beds
- Neuro General Ward
  Location: 2nd Floor
  Bed Capacity: 6 Beds

3.Emergency Services:

Location: Lower ground floor
Entrance : Separate entry from the main road
The Emergency Department is a well equipped 10 bedded department. 3 beds for each triage category Red , Yellow, Green and 1 bed for isolation
Staff: 1 Emergency Incharge, 2 MO , 1 Nursing Incharge, 9 Staff nurse, 2 House-Keeping staff
Ambulance service is outsourced.

4.Operation Theatre:

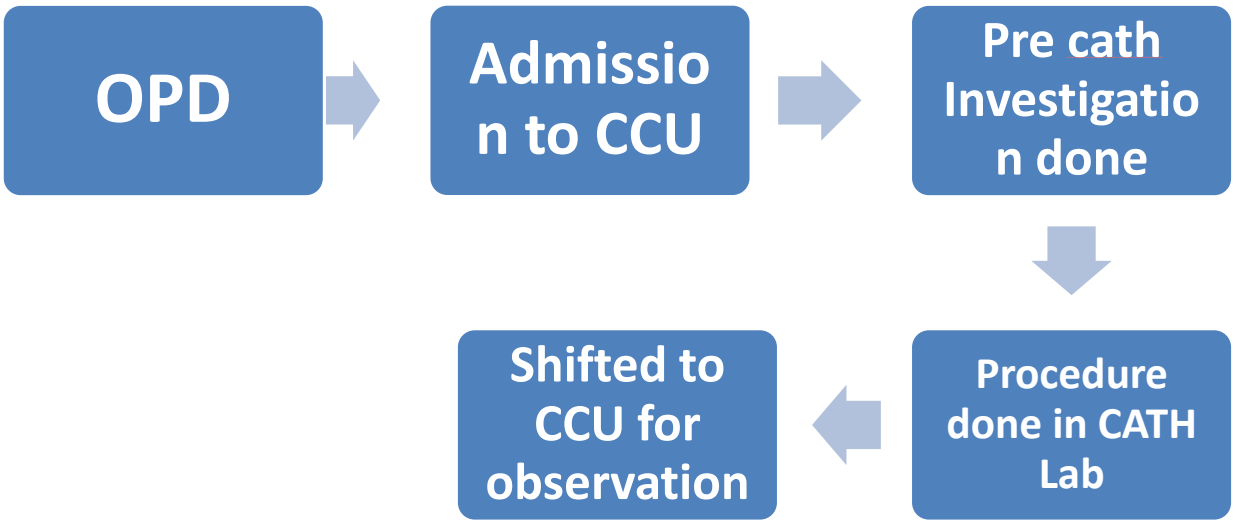
There are 5 functional OTs in the 1st floor and 3 functional OTs in the 2nd floor out of total 11 OTs
Location: 1st and 2nd Floor
Easy access to CCU, Blood Bank, Emergency and CSSD

ITU is attached to the the OTs located in the 1st floor
Manpower: 1 Chief Head of the Department, 21 Anaesthetists, 1 OT Manager, 3Perfusionists, 21 OT Technicians, 52 Staff Nurse, 5 House Keeping Staff.
No of Surgeries: 480-500 surgeries per month with around 150 cardiac surgeries every month.

5.Catheterisation Lab:

Location : Ground Floor
All Invasive Procedures are done in cath lab such as Angoigraphy, Angoiplasty , Cath Study, Electro Physiological Study.
Door to Balloon Time for emergency patients is 90 minutes.
Average patients – 10-12/day
Temperature: 17-20 degree Celsius.
TAT: In between 2 cases: 45-50 mins
Angiography : 10-15 mins
Angioplasty: variable
Maintenance is done regularly every 3 months.

Process Flow:



6.CSSD

Location: Lower Ground Floor
Total Area is divided into 4 Zones:

- Zone I. (Dirty Utility) Reception , Inspection and Documentation
- Zone II. (Clean Area) Assembly and Packing
- Zone III (Sterile Area) Sterilisation
- Zone IV (Issue Area) Storage and distribution

Check for proper sterilisation

- Bowie dick test

- Leak test
- Sterilisation test
- Batch monitoring test

7.Radiology Department:

Location: Lower Ground Floor

Area:

- Reception Area
- Console Room
- Imaging service room
- Changing room-2

Different rooms for X-Ray, Mammography, MRI, CT Scan.

8.Laboratory:

Location: Ground floor

All laboratory services related to Biochemistry, Microbiology, Histopathology and Haematology.

Blood Bank is attached with the laboratory.

9.Physiotherapy and Rehabilitation Centre:

Location: Lower ground floor

Well trained team of 6 physiotherapist managing the department and providing rehabilitation therapy for joint disease, stokes, trauma etc.

Other facilities :

- Wax Therapy
- Hydro collator- hot pack
- Interferential Therapy
- IFT- Pain Relief
- Ultrasound therapy- piezoelectric effect
- TENZ
- Muscle Stimulator
- SWD etc

10. Medical Record Department:

Scope of Services:

- Maintenance of all medical record
- Storage of records : 1) OPD: 3 years
  2) IPD: 5 years
  3) Death/MLCs: lifetime
- Maintaining the integrity and confidentiality of all medical record
- Maintenance of MLC cases

- Numbering and filing
- Completion of all incomplete records.
- Arrangement is according to Admission No.

11. Food and Beverages:

Location: Lower ground floor

Scope of services:

- To provide well balance nutritious food to all in patients as well as patients for dialysis as per their needs.
- To serve staff and patients attendants
- To helps in improving the patients condition by providing hygienic , proper and nutritious food as prescribed by the dieticians.

Provide 5 servings for the general ward patients and 8 servings to the semi private and private ward patients.

Types of diet:

- Normal full diet
- Liquid diet
- Soft diet
- Diet for diabetic patients
- Diet for renal patients
- Diet post cardiac surgery patients.

12. Housekeeping:

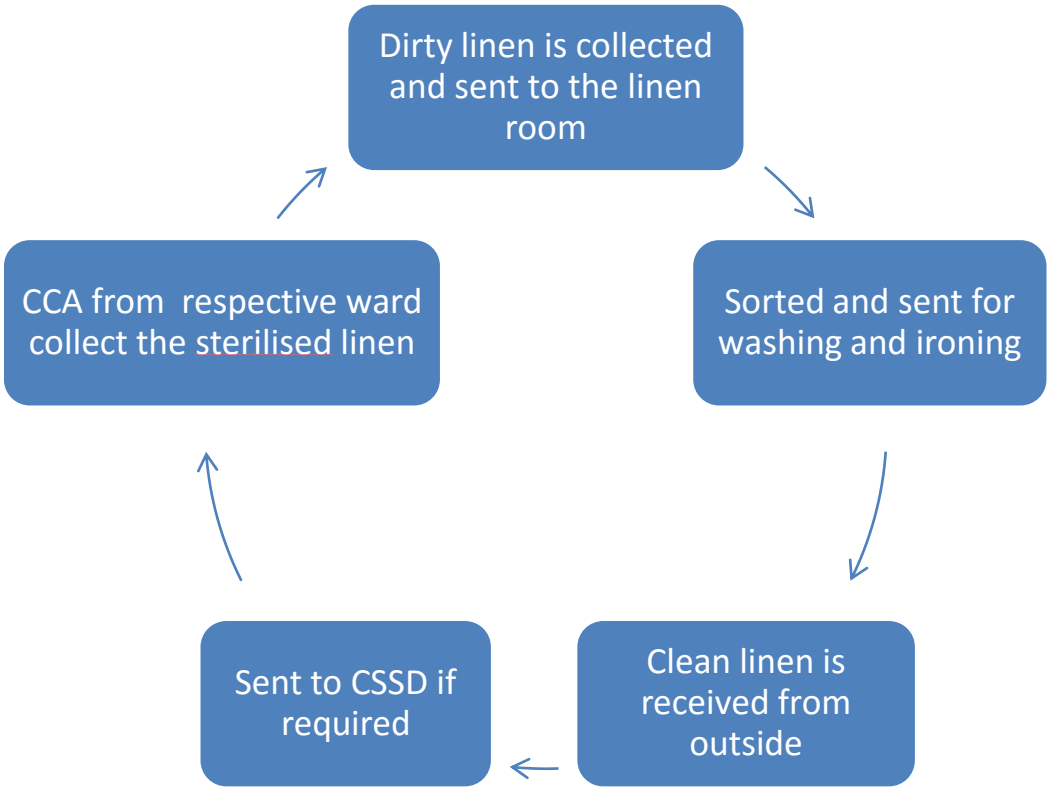
Housekeeping department is outsourced

Services provide:

- Maintain hygiene of the patients and the hospital
- Helping in patients preparation
- Infection control
- Waste disposal

13. Linen and Laundry:

Linen and laundry department is outsourced



Availability of coloured coded bags in each department. Orange colour is for serology positive patients and and green bags for serology negative patients.

14. Pharmacy:

The hospital 3 different types of pharmacy:

- OPD Pharmacy
- IPD Pharmacy
- OT Pharmacy

Functions:

Dispensing of drugs to all the admitted patients.

Dispensing of drugs for the OPD patients.

Demand estimation according to the formulary, in the absence of formulary, establishment of specification for drug procurement

Furnishing of new drug information to consultants and other professional staff
Quality control of drugs purchased

15. Diagnostic Services:

Location: Ground Floor
Scope of services:

- Ultrasonography
- TMT
- Electrocardiography
- Echocardiography
- Electroencephalography
- Uroflowmetry
- Electromyography
- Pulmonary function test

Operational timings: 9 am to 5 pm.

16. Dialysis Department:

Location: Lower ground floor
Machines: 30
Bed Capacity: 20 beds including 4 beds for serology positive patients
No. of procedures done per day: 55-60 dialyses per day
Manpower: 10 staff nurse, 7 Technicians, 2 MO, 4 HK
TAT: 15 mins Pre, 4 hrs Dialysis, 15 mins Post
Shift of dialysis: 7 am to 12 noon, 12 noon to 5 pm and 5pm to 8 pm.

Every patient is provided with a meal, included in tariff and the meal is prescribed by the dietician.

17. Mortuary:

Location: Lower ground floor
Temperature: 5-6 degree Celsius
Capacity: At a time four dead bodies can be kept together

Function:

- To keep the dead bodies in the hospital until the relatives claim them.
- To keep the dead bodies for post mortem (MLC Cases).

18. Security Services:

Security service department of the hospital is outsourced.
Functions:

- To provide security services to all the staff, patients, relatives and visitors
- To protect the hospital property within the premises
- To analyse threats and vulnerability in conjugation with the managements , police and others
- To control the movement of vehicular traffic inside the premises.

19. Billing and Finance Department:

Location: Ground floor
Operational timings: 9am to 5 pm for the finance department
24 hr IP billing service.
Functions:

- To provide salary to all the staff in a timely manner
- To provide payment to all the vendors and contractors
- Tracking the expenses of in patients on daily basis
- Timely discharge of patients related to financial clearance
- To provide accurate and timely financial information for decision making.

20.Maintainence Department:

Location: Lower ground floor
Functions:

- To maintain continuous electric supply to the hospital.
- To maintain the chilling plant room of the hospital
- To maintain the supply of medical gases
- To maintain the proper functioning of STP

Operational timings: 24hr.
Infrastructure:

Low tension room
Generator panel: 2 generator of 750 ampere each
Diesel tank- 24 kilolitres capacity
Sewerage treatment plan
Desk panel- control air handling unit
Chilling plant room
Gas manifold room

21. Human Resource Department:

Location: First floor, Admin Block
Functions:

- Recruitment based on requisition form from respective department duly signed by incharge of the department, HR and facility director
- Induction and training programs- 3 days induction program for all new employees
- Performance appraisal ones in a year in the month of March
- Employee engagement activities such as birthday celebration, open house, and also on the job trainings such as fire safety. BLS training
- Grievance Handling
- Conduct employee exist interview

22. Fire safety Department:

Location: Lower ground floor
The hospital has 7 fire exist door in each floor . A total 26 functional fire exist doors
Sprinklers are located in the entire hospital with a distance of 6 mts between two sprinklers and burst at 68 degree Celsius
Smokes detectors are also located in the entire hospital.
Fire Safety Equipments:

- Horse Reel Drums 21
- Jockey Pump 01
- Alarm Valve 05
- Double Hydrant Valve 28

Hospital follows “PASS” and “ RACE” protocols.
PASS: Pull Aim Squeeze Sweep for operating a fire extinguisher
RACE: Rescue Alarm Contain Extinguish, Evacuate.

PROJECT REPORT

NABL ACCREDATATION

ISO 15189-2012

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electro technical standardization. International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2. The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote. Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. ISO 15189 was prepared by Technical Committee ISO/TC 212, Clinical laboratory testing and in vitro diagnostic test systems. This third edition cancels and replaces the second edition (ISO 15189:2007), which has been technically revised. A correlation between the second and third editions of this International Standard is provided as Annex B. The third edition continues the alignment established in ISO/IEC 17025:2005

INTRODUCTION

This International Standard, based upon ISO/IEC 17025 and ISO 9001, specifies requirements for competence and quality that are particular to medical laboratories1). It is acknowledged that a country could have its own specific regulations or requirements applicable to some or all its professional personnel and their activities and responsibilities in this domain. Medical laboratory services are essential to patient care and therefore have to be available to meet the needs of all patients and the clinical personnel responsible for the care of those patients. Such services include arrangements for examination requests, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent interpretation, reporting and advice, in addition to the considerations of safety and ethics in medical laboratory work. Whenever allowed by national, regional or local regulations and requirements, it is desirable that medical laboratory services include the examination of patients in consultation cases, and that those services actively participate in the prevention of disease in addition to diagnosis and patient management. Each laboratory should also provide suitable educational and scientific opportunities for professional staff working with it. While this International Standard is intended for use throughout the currently recognized disciplines of medical laboratory services, those working in other services and disciplines such as clinical physiology, medical imaging and medical physics could also find it useful and appropriate. In addition, bodies engaged in the recognition of the competence of medical laboratories will be able to use this International Standard as the basis for their activities. If a laboratory seeks accreditation, it should select an accrediting body which operates in accordance with ISO/IEC 17011 and which takes into account the particular requirements of medical laboratories. This International Standard is not

intended to be used for the purposes of certification; however a medical laboratory's fulfilment of the requirements of this International Standard means the laboratory meets both the technical competence requirements and the management system requirements that are necessary for it to consistently deliver technically valid results. The management system requirements in Clause 4 are written in a language relevant to a medical laboratory's operations and meet the principles of ISO 9001:2008, Quality management systems — Requirements, and are aligned with its pertinent requirements (Joint IAF-ILAC-ISO Communiqué issued in 2009). The correlation between the clauses and subclauses of this third edition of ISO 15189 and those of ISO 9001:2008 and of ISO/IEC 17025:2005 is detailed in Annex A of this International Standard. Environmental issues associated with medical laboratory activity are generally addressed throughout this International Standard, with specific references in 5.2.2, 5.2.6, 5.3, 5.4, 5.5.1.4 and 5.7

NABL-National accreditation board for testing and caliberation laboratories

NABL Vision

To be the world's leading accreditation body and to enhance stakeholders' confidence in its services.

NABL Mission

To strengthen the accreditation system accepted across the globe by providing high quality, value driven services, fostering APLAC/ILAC MRA, empanelling competent assessors, creating awareness among the stake holders, initiating new programs supporting accreditation activities and pursuing organisational excellence.

INTRODUCTION NABL

National Accreditation Board for Testing and Calibration Laboratories (NABL) is an autonomous body under the aegis of Department of Science & Technology, Government of India. NABL has been established with the objective to provide Government, Regulators and Industry with a scheme of laboratory accreditation through third-party assessment for formally recognizing the technical competence of laboratories. The accreditation services are provided for testing, calibration and medical laboratories in accordance with International Organization for Standardization (ISO) Standards.

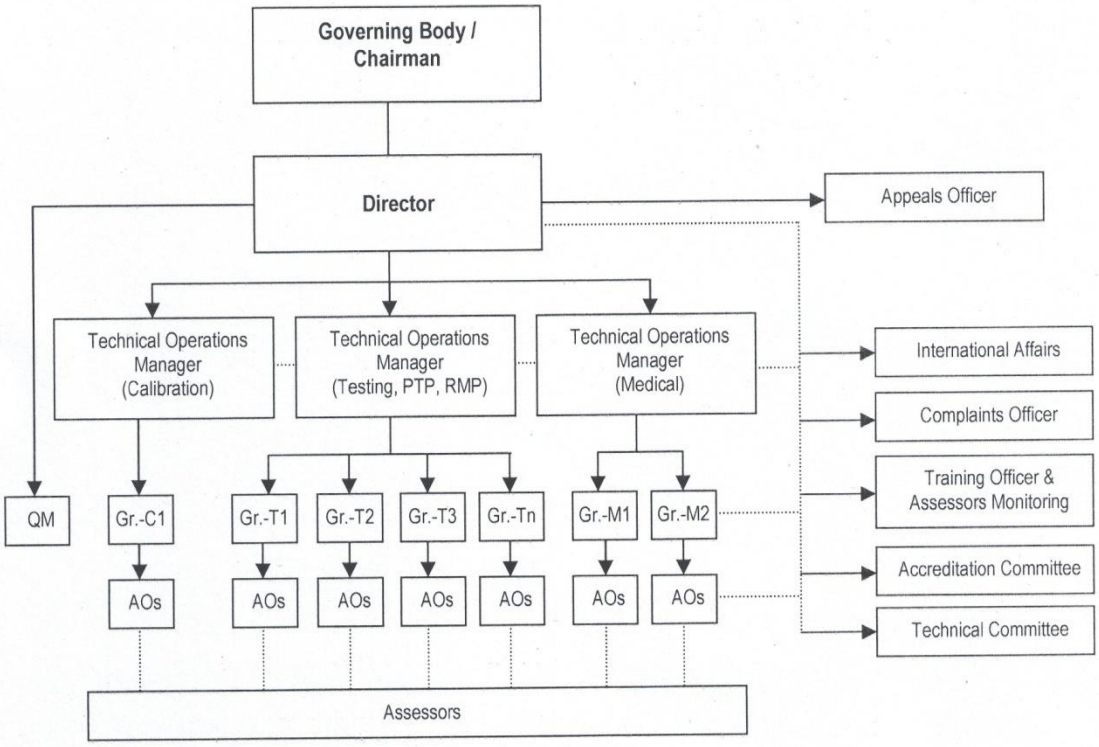
Accreditation assists the Indian industries to enhance the quality and reliability of Indian goods in the domestic market and exports, thereby, catalyses the growth of Indian economy. WTO has identified non-acceptance of test results and measurement data as Technical Barrier to Trade (TBT) and accreditation is considered to be the first essential step towards removing such technical barriers.

NABL went a step further in removing technical barriers to trade and achieved the status of signatory to Asia Pacific Laboratory Accreditation Cooperation (APLAC) Mutual Recognition Arrangement (MRA) and International Laboratory Accreditation Cooperation (ILAC) Arrangement based on a peer evaluation by APLAC in 2000. This was a major step towards mutual acceptance of test results and measurement data across Indian borders. NABL went through the peer APLAC evaluation in 2004 & 2008 and reaffirmed its APLAC / ILAC signatory status with extension of scope for Medical Testing as per the new standard ISO 15189. Today, the test results and measurement data produced by Indian accredited laboratories are acceptable amongst 64 economies. NABL accredited laboratories have therefore emerged members of global family of more than 40,000 accredited laboratories.

NABL provides accreditation in all major fields of Science and Engineering such as Biological, Chemical, Electrical, Electronics, Mechanical, Fluid-Flow, Non-Destructive, Photometry, Radiological, Thermal & Forensics under testing facilities and Electro-Technical, Mechanical, Fluid Flow, Thermal, Optical & Radiological under Calibration facilities. NABL also offers accreditation for medical testing laboratories.

The major sectors in which NABL has granted accreditation are Textiles, Automobiles, Power, Telecom, Petroleum, Food, Health and Environment. As on date, more than 1600 laboratories have NABL accreditation, out of which 20% are Government laboratories.

Organisation Structure of NABL (Technical)



NABL AUDIT

ASSESSOR CHECKLIST 1: (ISO 15189: 2012)

The following pages present a checklist of the criteria from ISO 15189: 2012, which is the basis for the NABL General requirements for accreditation of Medical laboratories. The laboratory's policies and procedures must meet full requirements of ISO 15189: 2012. **The actual standard must be referred for the definitive language and interpretation.**

The Lead Assessor must complete this checklist, put initials on each page. The following symbols may be used for completing this checklist.

++	=	COMPLIANCE
+	=	COMPLIANCE WITH REMARK
A	=	MAJOR NON-CONFORMITY
B	=	MINOR NON-CONFORMITY
NA	=	NOT APPLICABLE
BLANK	=	NOT ASSESSED

The Lead Assessor must review the laboratory's documented system to verify conformity with the requirements of ISO 15189: 2012, assess to verify that the documented quality system is indeed implemented as described, record conclusion/comments related to any requirements on the space provided or use the bottom of the page or use separate sheet(s). All non-conformities must be identified and reported separately on each sheet of NAF-4. This checklist be submitted as a part of the assessment report.

LABORATORY ASSESSED	
CITY/ TOWN	
ASSESSMENT DATE (S)	
LEAD ASSESSOR'S NAME	
SIGNATURE	

REQUIREMENTS OF ISO 15189: 2012					DOCUMENTATION	IMPLEMENTATION	REMARKS
4	**MANAGEMENT REQUIREMENTS**						
	4.1	**Organization and management responsibilities**					
		4.1.1	**Organization**				
			4.1.1.1	**General**			
				The medical laboratory (hereinafter referred to as 'the laboratory') shall meet the requirements of this International Standard when carrying out work at its permanent facilities, or in associated or mobile facilities.	++	++	ISO 15189, third edition
			4.1.1.2	**Legal entity**			
				The laboratory or the organization of which the laboratory is a part shall be an entity that can be held legally responsible for its activities.	++	++	Rajasthan Shop & Establishment Act, registration no.SH-276-R-10D/P-40/2010
			4.1.1.3	**Ethical conduct**			
				Laboratory management shall have arrangements in place to ensure the following:	++	++	
				a there is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgement or operational integrity;	++	++	
				b management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work;	++	++	
				c where potential conflicts in competing interests may exist, they shall be openly and appropriately declared;	++		
				d there are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements;	++	++	
				e confidentiality of information is maintained.	++	++	
			4.1.1.4	**Laboratory Director**			
				The laboratory shall be directed by a person or persons with the competence and delegated responsibility for the services provided. The responsibilities of the laboratory director shall include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory. The laboratory director may delegate selected duties and/or responsibilities to qualified personnel; however, the laboratory director shall maintain the ultimate responsibility for the overall operation and administration of the laboratory. The duties and responsibilities of the laboratory director shall be documented. The laboratory director (or the designates for delegated duties) shall have the necessary competence, authority and resources in order to fulfil the requirements of this International Standard. The laboratory director (or designate/s) shall:	++	++	Job description ANNEXURE- 2

REQUIREMENTS OF ISO 15189: 2012						DOCUMENTATION	IMPLEMENTATION	REMARKS
				a	provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities;	++	++	
				b	relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required;	++	++	
				c	ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users;	++	++	
				d	ensure the implementation of the quality policy;	++	++	
				e	implement a safe laboratory environment in compliance with good practice and applicable requirements;	++	++	
				f	serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate;	++	++	
				g	ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results;	++	++	
				h	select and monitor laboratory suppliers;	++	++	
				i	select referral laboratories and monitor the quality of their service (see also 4.5);	++	++	
				j	provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations;	++	++	
				k	define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services; *NOTE: This may be done within the context of the various quality improvement committees of the parent organization, as appropriate, where applicable.*	++	++	
				l	monitor all work performed in the laboratory to determine that clinically relevant information is being generated;	++	++	
				m	address any complaint, request or suggestion from staff and/or users of laboratory services (see also 4.8, 4.14.3 and 4.14.4);	++	++	
				n	design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable; *NOTE: Contingency plans should be periodically tested.*	++	++	
				o	plan and direct research and development, where appropriate.	++	++	
		4.1.2	**Management responsibility**					

REQUIREMENTS OF ISO 15189: 2012					DOCUMENTATION	IMPLEMENTATION	REMARKS
			4.1.2.1	**Management commitment**			
				Laboratory management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:	++	++	
				a communicating to laboratory personnel the importance of meeting the needs and requirements of users (see 4.1.2.2) as well as regulatory and accreditation requirements;	++	++	
				b establishing the quality policy (see 4.1.2.3);	++	++	
				c ensuring that quality objectives and planning are established (see 4.1.2.4);	++	++	
				d defining responsibilities, authorities and interrelationships of all personnel (see 4.1.2.5);	++	++	
				e establishing communication processes (see 4.1.2.6);	++	++	
				f appointing a quality manager, however named (see 4.1.2.7);	++	++	
				g conducting management reviews (see 4.15);	++	++	
				h ensuring that all personnel are competent to perform their assigned activities (see 5.1.6);	++	++	
				i ensuring availability of adequate resources (see 5.1, 5.2 and 5.3) to enable the proper conduct of pre-examination, examination and post-examination activities (see 5.4, 5.5, and 5.7)	++	++	
			4.1.2.2	**Needs of users**			
				Laboratory management shall ensure that laboratory services, including appropriate advisory and interpretative services, meet the needs of patients and those using the laboratory services. (See also 4.4 and 4.14.3).	++	++	
			4.1.2.3	**Quality Policy**			
				Laboratory management shall define the intent of its quality management system in a quality policy. Laboratory management shall ensure that the quality policy:	++	++	
				a is appropriate to the purpose of the organization;	++	++	
				b includes a commitment to good professional practice, examinations that are fit for intended use, compliance with the requirements of this International Standard, and continual improvement of the quality of laboratory services;	++	++	
				c provides a framework for establishing and reviewing quality objectives;	++	++	
				d is communicated and understood within the organization;	++	++	
				e is reviewed for continuing suitability.	++	++	
			4.1.2.4	**Quality objectives and planning**			
				Laboratory management shall establish quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and levels within the	++	++	

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				organization. The quality objectives shall be measurable and consistent with the quality policy. Laboratory management shall ensure that planning of the quality management system is carried out to meet the requirements (see 4.2) and the quality objectives. Laboratory management shall ensure that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.				
			4.1.2.5	**Responsibility, authority and interrelationships**				
				Laboratory management shall ensure that responsibilities, authorities and interrelationships are defined, documented and communicated within the laboratory organization. This shall include the appointment of person(s) responsible for each laboratory function and appointment of deputies for key managerial and technical personnel. *NOTE: It is recognized that in smaller laboratories individuals can have more than one function and that it could be impractical to appoint deputies for every function.*	++	++	
			4.1.2.6	**Communication**				
				Laboratory management shall have an effective means for communicating with staff (see also 4.14.4). Records shall be kept of items discussed in communications and meetings. Laboratory management shall ensure that appropriate communication processes are established between the laboratory and its stakeholders and that communication takes place regarding the effectiveness of the laboratory's pre-examination, examination and post-examination processes and quality management system.	++	++	
			4.1.2.7	**Quality manager**				
				Laboratory management shall appoint a quality manager who shall have, irrespective of other responsibilities, delegated responsibility and authority that includes:	++	++	Procedure for protection of confidential information, competence, impartiality, judgement, and operational integrity (QSP-1/4.1)
				a ensuring that processes needed for the quality management system are established, implemented, and maintained;	++	++	
				b Reporting to laboratory management, at the level at which decisions are made on laboratory policy, objectives, and resources, on the performance of the quality management system and any need for improvement;	++	++	

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				c	ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organization.	++	++	
	4.2	**Quality management system**						
		4.2.1	**General requirements**					
			The laboratory shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. The quality management system shall provide for the integration of all processes required to fulfil its quality policy and objectives and meet the needs and requirements of the users. The laboratory shall:			++	++	
			a		determine the processes needed for the quality management system and ensure their application throughout the laboratory;	++	++	
			b		determine the sequence and interaction of these processes;	++	++	
			c		determine criteria and methods needed to ensure that both the operation and control of these processes are effective;	++	++	
			d		ensure the availability of resources and information necessary to support the operation and monitoring of these processes;	++	++	
			e		monitor and evaluate these processes;	++	++	
			f		Implement actions necessary to achieve planned results and continual improvement of these processes.	++	++	
		4.2.2	**Documentation requirements**					
			4.2.2.1	**General**				
				The quality management system documentation shall include:		++	++	
				a	statements of a quality policy (see 4.1.2.3) and quality objectives (see 4.1.2.4);	++	++	
				b	a quality manual (see 4.2.2.2);	++	++	
				c	procedures and records required by this International Standard;	++	++	
				d	documents, and records (see 4.13), determined by the laboratory to ensure the effective planning, operation and control of its processes;	++	++	
				e	copies of applicable regulations, standards and other normative documents. *NOTE: The documentation can be in any form or type of medium, providing it is readily accessible and protected from unauthorized changes and undue deterioration*.	++	++	
			4.2.2.2	**Quality manual**				
				The laboratory shall establish and maintain a quality manual that includes		++	++	Structure and relationships of the documentation used in the quality management system (QSP-2/4.2)
				a	the quality policy (4.1.2.3) or makes reference to it;	++	++	
				b	a description of the scope of the quality management system;	++	++	
				c	a presentation of the organization and management structure of the laboratory and its place in any parent organization;	++	++	
				d	a description of the roles and responsibilities of laboratory management	++	++	

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					(including the laboratory director and quality manager) for ensuring compliance with this International Standard;			
				e	a description of the structure and relationships of the documentation used in the quality management system;	++	++	
				f	the documented policies established for the quality management system and reference to the managerial and technical activities that support them. All laboratory staff shall have access to and be instructed on the use and application of the quality manual and the referenced documents.	++	++	
	4.3	**Document control**						
		The laboratory shall control documents required by the quality management system and shall ensure that unintended use of any obsolete document is prevented. NOTE: 1 Documents that should be considered for document control are those that may vary based on changes in versions or time. Examples include policy statements, instructions for use, flow charts, procedures, specifications, forms, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software documentation, drawings, plans, agreements, and documents of external origin such as regulations, standards and text books from which examination procedures are taken. NOTE: 2 Records contain information from a particular point in time stating results achieved or providing evidence of activities performed and are maintained according to the requirements given in 4.13, Control of records. The laboratory shall have a documented procedure to ensure that the following conditions are met,				++	++	Quality system process for document control (QSP-3/4.3)
			a	All documents, including those maintained in a computerized system, issued as part of the quality management system are reviewed and approved by authorized personnel before issue.		++	++	
			b	All documents are identified to include: — a title; — a unique identifier on each page; — the date of the current edition and/or edition number; — page number to total number of pages (e.g. “Page 1 of 5,” “Page 2 of 5,”); — Authority for issue. NOTE: ‘Edition’ is used to mean one of a number of printings issued at separate times that incorporates alterations and amendments. ‘Edition’ can be regarded as synonymous with ‘revision or version’.	++	++	
			c	Current authorized editions and their distribution are identified by means of a list (e.g. document register, log or master index).		++	++	
			d	Only current, authorized editions of applicable documents are available at points of use.		++	++	
			e	Where a laboratory’s document control system allows for the amendment of documents by hand, pending the re-issue of documents, the procedures and authorities for such amendments are defined, amendments are clearly marked,		++	++	

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				initialled and dated, and a revised document is issued within a specified time period.			
			f	Changes to documents are identified.	++	++	
			g	Documents remain legible.	++	++	
			h	Documents are periodically reviewed and updated at a frequency that ensures that they remain fit for purpose.	++	++	
			i	Obsolete controlled documents are dated and marked as obsolete.	++	++	
			j	At least one copy of an obsolete controlled document is retained for a specified time period or in accordance with applicable specified requirements.	++	++	
	4.4	**Service agreements**					
		4.4.1	**Establishment of service agreements**				
				The laboratory shall have documented procedures for the establishment and review of agreements for providing medical laboratory services. Each request accepted by the laboratory for examination(s) shall be considered an agreement. Agreements to provide medical laboratory services shall take into account the request, the examination and the report. The agreement shall specify the information needed on the request to ensure appropriate examination and result interpretation. The following conditions shall be met when the laboratory enters into an agreement to provide medical laboratory services.	++	++	QSP for service agreements (QSP 4/4.4)
			a	The requirements of the customers and users, and of the provider of the laboratory services, including the examination processes to be used, shall be defined, documented and understood (see 5.4.2 and 5.5).	++	++	
			b	The laboratory shall have the capability and resources to meet the requirements.	++	++	
			c	Laboratory personnel shall have the skills and expertise necessary for the performance of the intended examinations.	++	++	
			d	Examination procedures selected shall be appropriate and able to meet the customers' needs (see 5.5.1).	++	++	
			e	Customers and users shall be informed of deviations from the agreement that impact upon the examination results.	++	++	
			f	Reference shall be made to any work referred by the laboratory to a referral laboratory or consultant.	++	++	
				NOTE: 1 Customers and users may include clinicians, health care organizations, third party payment organizations or agencies, pharmaceutical companies, and patients. *NOTE: 2 Where patients are customers (e.g. when patients have the ability to directly request examinations), changes in service should be reflected in explanatory information and laboratory reports.* *NOTE: 3 Laboratories should not enter into financial arrangements with referring practitioners or funding agencies where those arrangements act as an*			

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				inducement for the referral of examinations or patients or interfere with the practitioner's independent assessment of what is best for the patient.			
		4.4.2		**Review of service agreements**			
				Reviews of agreements to provide medical laboratory services shall include all aspects of the agreement. Records of these reviews shall include any changes to the agreement and any pertinent discussions. When an agreement needs to be amended after laboratory services have commenced, the same agreement review process shall be repeated and any amendments shall be communicated to all affected parties.	NA	NA	
	4.5	**Examination by referral laboratories**					
		4.5.1		**Selecting and evaluating referral laboratories and consultants**			
				The laboratory shall have a documented procedure for selecting and evaluating referral laboratories and consultants who provide opinions as well as interpretation for complex testing in any discipline. The procedure shall ensure that the following conditions are met.	++	++	Procedure for examination by referral laboratories (QSP-5/4.5)
			a	The laboratory, with the advice of users of laboratory services where appropriate, is responsible for selecting the referral laboratory and referral consultants, monitoring the quality of performance and ensuring that the referral laboratories or referral consultants are competent to perform the requested examinations.	++	++	
			b	Arrangements with referral laboratories and consultants are reviewed and evaluated periodically to ensure that the relevant parts of this International Standard are met.	++	++	
			c	Records of such periodic reviews are maintained.	++	++	
			d	A register of all referral laboratories, and consultants from whom opinions are sought, is maintained.	++	++	
			e	Requests and results of all samples referred are kept for a pre-defined period.	++	++	
		4.5.2		**Provision of examination results**			
				Unless otherwise specified in the agreement, the referring laboratory (and not the referral laboratory) shall be responsible for ensuring that examination results of the referral laboratory are provided to the person making the request. When the referring laboratory prepares the report, it shall include all essential elements of the results reported by the referral laboratory or consultant, without alterations that could affect clinical interpretation. The report shall indicate which examinations were performed by a referral laboratory or consultant. The author of any additional remarks shall be clearly identified. Laboratories shall adopt the most appropriate means of reporting referral laboratory results, taking into account turnaround times, measurement accuracy, transcription processes and interpretative skill requirements. In cases where the correct interpretation and application of examination results needs collaboration between	++	++	

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			clinicians and specialists from referring and referral laboratories, this process shall not be hindered by commercial or financial considerations.			
	4.6		**External services and supplies**			
			The laboratory shall have a documented procedure for the selection and purchasing of external services, equipment, reagents and consumable supplies that affect the quality of its service (see also 5.3). The laboratory shall select and approve suppliers based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratory's requirements; however, it may be necessary to collaborate with other organizational departments or functions to fulfil this requirement. Criteria for selection shall be established. A list of selected and approved suppliers of equipment, reagents and consumables shall be maintained. Purchasing information shall describe the requirements for the product or service to be purchased. The laboratory shall monitor the performance of suppliers to ensure that purchased services or items consistently meet the stated criteria.	++	++	QSP for external services and supplies (QSP-6/4.6)
	4.7		**Advisory services**			
			The laboratory shall establish arrangements for communicating with users on the following			Feedback analysis QSP for advisory services (QSP-7/4.7) Annexure 4
		a	advising on choice of examinations and use of the services, including required type of sample (see also 5.4), clinical indications and limitations of examination procedures and the frequency of requesting the examination;	++	++	
		b	advising on individual clinical cases;	++	++	
		c	professional judgments on the interpretation of the results of examinations (see 5.1.2 and 5.1.6);	++	++	
		d	promoting the effective utilization of laboratory services;	++	++	
		e	consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria.	++	++	
	4.8		**Resolution of complaints**			
			The laboratory shall have a documented procedure for the management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties. Records shall be maintained of all complaints and their investigation and the action taken (see also 4.14.3).	++	++	QSP for handeling of feedback and resolution of complaints (QSP-8/4.8)
	4.9		**Identification and control of non-conformities**			
			The laboratory shall have a documented procedure to identify and			QSP for identification

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		manage nonconformities in any aspect of the quality management system, including pre-examination, examination or post-examination processes. The procedure shall ensure that:				and control of non-conformity.(QSP-9/4.9)
		a	the responsibilities and authorities for handling nonconformities are designated;	++	++	
		b	the immediate actions to be taken are defined;	++	++	
		c	the extent of the nonconformity is determined;	++	++	
		d	examinations are halted and reports withheld as necessary;	++	++	
		e	the medical significance of any nonconforming examinations is considered and, where appropriate, the requesting clinician or authorized individual responsible for using the results is informed;	++	++	
		f	the results of any nonconforming or potentially nonconforming examinations already released are recalled or appropriately identified, as necessary;	++	++	
		g	the responsibility for authorization of the resumption of examinations is defined;	++	++	
		h	each episode of nonconformity is documented and recorded, with these records being reviewed at regular specified intervals to detect trends and initiate corrective action.	++	++	
		NOTE Nonconforming examinations or activities occur in many different areas and can be identified in many different ways, including clinician complaints, internal quality control indications, instrument calibrations, checking of consumable materials, interlaboratory comparisons, staff comments, reporting and certificate checking, laboratory management reviews, and internal and external audits. When it is determined that nonconformities in pre-examination, examination and post-examination processes could recur or that there is doubt about the laboratory's compliance with its own procedures, the laboratory shall take action to identify, document and eliminate the cause(s). Corrective action to be taken shall be determined and documented (see 4.10).				
	4.10	**Corrective action**				
		The laboratory shall take corrective action to eliminate the cause(s) of nonconformities. Corrective actions shall be appropriate to the effects of the nonconformities encountered. The laboratory shall have a documented procedure for:				QSP for corrective action (QSP-10/4.10)
		a	reviewing nonconformities;	++	++	
		b	determining the root causes of nonconformities;	++	++	
		c	evaluating the need for corrective action to ensure that nonconformities do not recur;	++	++	
		d	determining and implementing corrective action needed;	++	++	
		e	recording the results of corrective action taken (see 4.13);	++	++	
		f	Reviewing the effectiveness of the corrective action taken (see 4.14.5) *NOTE Action taken at the time of the nonconformity to mitigate its immediate effects is considered "immediate" action. Only action taken to remove the root cause of the problem that is causing the nonconformities is considered "corrective" action.*	++	++	
	4.11	**Preventive action**				
		The laboratory shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. The laboratory shall have a documented procedure for:				QSP for preventive actions. (QSP-11/4.11)
		a	reviewing laboratory data and information to determine where	++	++	

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			potential nonconformities exist;			
		b	determining the root cause(s) of potential nonconformities;	++	++	
		c	evaluating the need for preventive action to prevent the occurrence of nonconformities;	++	++	
		d	determining and implementing preventive action needed;	++	++	
		e	recording the results of preventive action taken (see 4.13);	++	++	
		f	Reviewing the effectiveness of the preventive action taken. *NOTE Preventive action is a proactive process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints (i.e. nonconformities). In addition to review of the operational procedures, preventive action might involve analysis of data, including trend and risk analyses and external quality assessment (proficiency testing).*	++	++	
	4.12	**Continual improvement**				
		The laboratory shall continually improve the effectiveness of the quality management system, including the pre-examination, examination and post-examination processes, through the use of management reviews to compare the laboratory's actual performance in its evaluation activities, corrective actions and preventive actions with its intentions, as stated in the quality policy and quality objectives. Improvement activities shall be directed at areas of highest priority based on risk assessments. Action plans for improvement shall be developed, documented and implemented, as appropriate. The effectiveness of the actions taken shall be determined through a focused review or audit of the area concerned (see also 4.14.5). Laboratory management shall ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care. When the continual improvement programme identifies opportunities for improvement, laboratory management shall address them regardless of where they occur. Laboratory management shall communicate to staff improvement plans and related goals..	++	++	QSP for continual improvement (QSP-12/4.12)
	4.13	**Control of records**				
		The laboratory shall have a documented procedure for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records. Records shall be created concurrently with performance of each activity that affects the quality of the examination. *NOTE 1 Records can be in any form or type of medium providing they are readily accessible and protected from unauthorized alterations.* The date and, where relevant, the time of amendments to records shall be captured along with the identity of personnel making the amendments (see 5.9.3). The laboratory shall define the time period that various records pertaining to the quality management system, including pre-examination, examination and post-examination processes, are to be retained. The length of time that records are retained may vary; however, reported results shall be retrievable for as long as medically relevant or as required by regulation. *NOTE 2 Legal liability concerns regarding certain types of procedures (e.g. histology examinations, genetic examinations, paediatric examinations) may require the retention of certain records for much longer periods than for other records.* Facilities shall provide a suitable environment for storage of	++	++	QSP for control of records. (QSP-13/4.13)

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		records to prevent damage, deterioration, loss or unauthorized access (see 5.2.6). *NOTE 3 For some records, especially those stored electronically, the safest storage may be on secure media and an offsite location (see 5.10.3).* Records shall include, at least, the following					
		a	supplier selection and performance, and changes to the approved supplier list;		++	++	
		b	staff qualifications, training and competency records;		++	++	
		c	request for examination;		++	++	
		d	records of receipt of samples in the laboratory;		++	++	
		e	information on reagents and materials used for examinations (e.g. lot documentation, certificates of supplies, package inserts);		++	++	
		f	laboratory work books or work sheets;		++	++	
		g	instrument printouts and retained data and information;		++	++	
		h	examination results and reports;		++	++	
		i	instrument maintenance records, including internal and external calibration records;		++	++	
		j	calibration functions and conversion factors;		++	++	
		k	quality control records;		++	++	
		l	incident records and action taken;		++	++	
		m	accident records and action taken;		++	++	
		n	risk management records;		++	++	
		o	nonconformities identified and immediate or corrective action taken;		++	++	
		p	preventive action taken;		++	++	
		q	complaints and action taken;		++	++	
		r	records of internal and external audits;		++	++	
		s	interlaboratory comparisons of examination results;		++	++	
		t	records of quality improvement activities;		++	++	
		u	minutes of meetings that record decisions made about the laboratory's quality management activities;		++	++	
		v	Records of management reviews.		++	++	
		All of these quality and technical records shall be available for laboratory management review (see 4.15).			++	++	
	4.14	**Evaluation and audits**					
		4.14.1	**General**				
			The laboratory shall plan and implement the evaluation and internal audit processes needed to:		++	++	QSP for evaluation and audits. (QSP-14/4.14)
			a	demonstrate that the pre-examination, examination and post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of users;	++	++	
			b	ensure conformity to the quality management system;	++	++	
			c	continually improve the effectiveness of the quality management system. The results of evaluation and improvement activities shall be included in the input to the management review (see 4.15). *NOTE For improvement activities, see 4.10, 4.11, and 4.12.*	++	++	
		4.14.2	**Periodic review of requests, and suitability of procedures and sample requirements**				
			Authorized personnel shall periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received. The laboratory shall periodically review its sample volume, collection device and preservative		++	++	

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			requirements for blood, urine, other body fluids, tissue and other sample types, as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected and the sample is properly collected to preserve the measurand.			
		4.14.3	**Assessment of user feedback**			
			The laboratory shall seek information relating to user perception as to whether the service has met the needs and requirements of users. The methods for obtaining and using this information shall include cooperation with users or their representatives in monitoring the laboratory's performance, provided that the laboratory ensures confidentiality to other users. Records shall be kept of information collected and actions taken.	++	++	
		4.14.4	**Staff suggestions**			
			Laboratory management shall encourage staff to make suggestions for the improvement of any aspect of the laboratory service. Suggestions shall be evaluated, implemented as appropriate and feedback provided to the staff. Records of suggestions and action taken by the management shall be maintained.	++	++	Feedback analysis Annexure 4
		4.14.5	**Internal audit**			
			The laboratory shall conduct internal audits at planned intervals to determine whether all activities in the quality management system, including pre-examination, examination, and post-examination:	++	++	
			a conform to the requirements of this International Standard and to requirements established by the laboratory, and	++	++	
			b are implemented, effective, and maintained.	++	++	
			NOTE 1 The cycle for internal auditing should normally be completed in one year. It is not necessary that internal audits cover each year, in depth, all elements of the quality management system. The laboratory may decide to focus on a particular activity without completely neglecting the others. Audits shall be conducted by personnel trained to assess the performance of managerial and technical processes of the quality management system. The audit programme shall take into account the status and importance of the processes and technical and management areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined and documented. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall, wherever resources permit, be independent of the activity to be audited. *NOTE 2 See ISO 19011 for guidance.* The laboratory shall have a documented procedure to define the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.13). Personnel responsible for the area being audited shall ensure that appropriate action is promptly undertaken when nonconformities are identified. Corrective action shall be taken without undue delay to eliminate the			

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			causes of the detected nonconformities (see 4.10).			
		4.14.6	**Risk management**			
			The laboratory shall evaluate the impact of work processes and potential failures on examination results as they affect patient safety, and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken.	++	++	
		4.14.7	**Quality indicators**			
			The laboratory shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes. EXAMPLE: Number of unacceptable samples, number of errors at registration and/or accession, number of corrected reports. The process of monitoring quality indicators shall be planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement. The indicators shall be periodically reviewed, to ensure their continued appropriateness. *NOTE 1 Quality indicators to monitor non-examination procedures, such as laboratory safety and environment, completeness of equipment and personnel records, and effectiveness of the document control system may provide valuable management insights.* *NOTE 2 The laboratory should establish quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care (see 4.12).* The laboratory, in consultation with the users, shall establish turnaround times for each of its examinations that reflect clinical needs. The laboratory shall periodically evaluate whether or not it is meeting the established turnaround times.	++	++	
		4.14.8	**Reviews by external organizations**			
			When reviews by external organizations indicate the laboratory has nonconformities or potential nonconformities, the laboratory shall take appropriate immediate actions and, as appropriate, corrective action or preventive action to ensure continuing compliance with the requirements of this International Standard. Records shall be kept of the reviews and of the corrective actions and preventive actions taken. *NOTE Examples of reviews by external accreditation organizations include: accreditation assessments, regulatory agencies' inspections, and health and safety inspections.*	++	++	
	4.15	**Management review**				
		4.15.1	**General**			
			Laboratory management shall review the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care.	++	++	QSP for management review (QSP-15/4.15)
		4.15.2	**Review input**			
			The input to management review shall include			

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			information from the results of evaluations of at least the following:				
			a	the periodic review of requests, and suitability of procedures and sample requirements (see 4.14.2);	++	++	
			b	assessment of user feedback (see 4.14.3);	++	++	
			c	staff suggestions (see 4.14.4);	++	++	
			d	internal audits (see 4.14.5);	++	++	
			e	risk management (see 4.14.6)	++	++	
			f	use of quality indicators (see 4.14.7);	++	++	
			g	reviews by external organizations (see 4.14.8);	++	++	
			h	results of participation in interlaboratory comparison programmes (PT/EQA) (see 5.6.3);	++	++	
			i	monitoring and resolution of complaints (see 4.8);	++	++	
			j	performance of suppliers (see 4.6);	++	++	
			k	identification and control of nonconformities (see 4.9);	++	++	
			l	results of continual improvement (see 4.12) including current status of corrective actions (see 4.10) and preventive actions (see 4.11);	++	++	
			m	follow-up actions from previous management reviews;	++	++	
			n	changes in the volume and scope of work, personnel, and premises that could affect the quality management system;	++	++	
			o	Recommendations for improvement, including technical requirements.	++	++	
		4.15.3	**Review activities**				
			The review shall analyse the input information for causes of nonconformities, trends and patterns that indicate process problems. This review shall include assessing these opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. The quality and appropriateness of the laboratory's contribution to patient care shall, to the extent possible, also be objectively evaluated.		++	++	
		4.15.4	**Review output**				
			The output from the management review shall be incorporated into a record that documents any decisions made and actions taken during management review related to:				
			a	improvement of the effectiveness of the quality management system and its processes;	++	++	
			b	improvement of services to users;	++	++	
			c	Resource needs.	++	++	
			NOTE The interval between management reviews should be no greater than 12 months; however, shorter intervals should be adopted when a quality management system is being established. Findings and actions arising from management reviews shall be recorded and reported to laboratory staff. Laboratory management shall ensure that actions arising from management review are completed within a defined timeframe.				

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5	**TECHNICAL REQUIREMENTS**					
	5.1	**Personnel**				
		5.1.1	**General**			
			The laboratory shall have a documented procedure for personnel management and maintain records for all personnel to indicate compliance with requirements.	++	++	QSP for personnel and training records. (QSP-16/5.1)
		5.1.2	**Personnel qualifications**			
			Laboratory management shall document personnel qualifications for each position. The qualifications shall reflect the appropriate education, training, experience and demonstrated skills needed, and be appropriate to the tasks performed. The personnel making judgments with reference to examinations shall have the applicable theoretical and practical background and experience. *NOTE Professional judgements can be expressed as opinions, interpretations, predictions, simulations and models and values, and should be in accordance with national, regional and local regulations and professional guidelines.*	++	++	Annexure 1
		5.1.3	**Job descriptions**			
			The laboratory shall have job descriptions that describe responsibilities, authorities and tasks for all personnel.	++	++	
		5.1.4	**Personnel introduction to the organizational environment**			
			The laboratory shall have a programme to introduce new staff 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 (including fire and emergency), and occupational health services.	++	++	
		5.1.5	**Training**			
			The laboratory shall provide training for all personnel which includes the following areas:			Job description annexure 2
			a the quality management system;	++	++	
			b assigned work processes and procedures;	++	++	
			c the applicable laboratory information system;	++	++	
			d health and safety, including the prevention or containment of the effects of adverse incidents;	++	++	
			e ethics;	++	++	
			f confidentiality of patient information.	++	++	
			Personnel that are undergoing training shall be supervised at all times. The effectiveness of the training programme shall be periodically reviewed.	++	++	
		5.1.6	**Competence assessment**			
			Following appropriate training, the laboratory shall assess the competence of each person to perform assigned managerial or technical tasks according to established criteria. Reassessment shall take place at regular intervals. Retraining shall occur when necessary. *NOTE 1 Competence of laboratory staff can be*			

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			assessed by using any combination or all of the following approaches under the same conditions as the general working environment:			
			a direct observation of routine work processes and procedures, including all applicable safety practices;	++	++	
			b direct observation of equipment maintenance and function checks;	++	++	
			c monitoring the recording and reporting of examination results;	++	++	
			d review of work records;	++	++	
			e assessment of problem solving skills;	++	++	
			f Examination of specially provided samples, such as previously examined samples, interlaboratory comparison materials, or split samples. *NOTE 2 Competency assessments for professional judgment should be designed as specific and fit for purpose.*	++	++	
		5.1.7	**Reviews of staff performance**			
			In addition to the assessment of technical competence, the laboratory shall ensure that reviews of staff performance consider the needs of the laboratory and of the individual in order to maintain or improve the quality of service given to the users and encourage productive working relationships. *NOTE Staff performing reviews should receive appropriate training.*	++	++	
		5.1.8	**Continuing education and professional development**			
			A continuing education programme shall be available to personnel who participate in managerial and technical processes. Personnel shall take part in continuing education. The effectiveness of the continuing education programme shall be periodically reviewed. Personnel shall take part in regular professional development or other professional liaison activities.	++	++	
		5.1.9	**Personnel records**			
			Records of the relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel shall be maintained. These records shall be readily available to relevant personnel and shall include but not be limited to:	++	++	
			a educational and professional qualifications;	++	++	
			b copy of certification or license, when applicable;	++	++	
			c previous work experience;	++	++	
			d job descriptions;	++	++	
			e introduction of new staff to the laboratory environment;	++	++	
			f training in current job tasks;	++	++	
			g competency assessments;	++	++	
			h records of continuing education and achievements;	++	++	
			i reviews of staff performance;	++	++	
			j reports of accidents and exposure to occupational hazards;	++	++	
			k Immunisation status, when relevant to assigned duties.	++	++	
			NOTE The records listed above are not required to be stored in the laboratory, but can be maintained in other specified locations, providing they remain accessible as			

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			needed.			
	5.2	**Accommodation and environmental conditions**				
		5.2.1	**General**			
			The laboratory shall have space allocated for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patients and visitors. The laboratory shall evaluate and determine the sufficiency and adequacy of the space allocated for the performance of the work. Where applicable, similar provisions shall be made for primary sample collection and examinations at sites other than the main laboratory premises, for example point-of-care testing (POCT) under the management of the laboratory.	++	++	QSP for accommodation and environmental conditions. (QSP-17/5.2)
		5.2.2	**Laboratory and office facilities**			
			The laboratory and associated office facilities shall provide an environment suitable for the tasks to be undertaken, to ensure the following conditions are met.			
			a Access to areas affecting the quality of examinations is controlled. *NOTE Access control should take into consideration safety, confidentiality, quality and prevailing practices*.	++	++	
			b Medical information, patient samples, and laboratory resources are safeguarded from unauthorized access.	++	++	
			c Facilities for examination allow for correct performance of examinations. These include, for example, energy sources, lighting, ventilation, noise, water, waste disposal and environmental conditions.	++	++	
			d Communication systems within the laboratory are appropriate to the size and complexity of the facility to ensure the efficient transfer of information.	++	++	
			e Safety facilities and devices are provided and their functioning regularly verified. *EXAMPLE Operation of emergency release, intercom and alarm systems for cold rooms and walk-in freezers; accessibility of emergency showers and eyewash, etc.*	++	++	
		5.2.3	**Storage facilities**			
			Storage space and conditions shall be provided that ensure the continuing integrity of sample materials, documents, equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results. Clinical samples and materials used in examination processes shall be stored in a manner to prevent cross contamination. Storage and disposal facilities for dangerous materials shall be appropriate to the hazards of the materials and as specified by applicable requirements.	++	++	
		5.2.4	**Staff facilities**			
			There shall be adequate access to washrooms, to a supply of drinking water and to facilities for storage of personal protective equipment and clothing.	++	++	

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			NOTE When possible, the laboratory should provide space for staff activities such as meetings and quiet study and a rest area.			
		5.2.5	**Patient sample collection facilities**			
			Patient sample collection facilities shall have separate reception/waiting and collection areas. Consideration shall be given to the accommodation of patient privacy, comfort and needs (e.g. disabled access, toilet facility) and accommodation of appropriate accompanying person (e.g. guardian or interpreter) during collection. Facilities at which patient sample collection procedures are performed (e.g. phlebotomy) shall enable the sample collection to be undertaken in a manner that does not invalidate the results or adversely affect the quality of the examination. Sample collection facilities shall have and maintain appropriate first aid materials for both patient and staff needs. *NOTE Some facilities may need equipment appropriate for resuscitation; local regulations may apply.*	++	++	
		5.2.6	**Facility maintenance and environmental conditions**			
			Laboratory premises shall be maintained in a functional and reliable condition. Work areas shall be clean and well maintained. The laboratory shall monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the sample, results, and/or the health of staff. Attention shall be paid to factors such as light, sterility, dust, noxious or hazardous fumes, electromagnetic interference, radiation, humidity, electrical supply, temperature, sound and vibration levels and workflow logistics, as appropriate to the activities concerned so that these do not invalidate the results or adversely affect the required quality of any examination. There shall be effective separation between laboratory sections in which there are incompatible activities. Procedures shall be in place to prevent cross-contamination where examination procedures pose a hazard or where work could be affected or influenced by not being separated. The laboratory shall provide a quiet and uninterrupted work environment where it is needed. *NOTE Examples of a quiet and uninterrupted work area include Cytopathology screening, microscopic differentiation of blood cells and microorganisms, data analysis from sequencing reactions and review of molecular mutations results.*	++	++	
	5.3	**Laboratory equipment, reagents, and consumables**				
			NOTE 1 For the purposes of this International Standard, laboratory equipment includes hardware and software of instruments, measuring systems, and laboratory information systems. *NOTE 2 Reagents include reference materials, calibrators and*			Annexure 3

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		quality control materials; consumables include culture media, pipette tips, glass slides, etc. *NOTE 3 See 4.6 for information concerning the selection and purchasing of external services, equipment, reagents and consumables.*					
		5.3.1	**Equipment**				
			5.3.1.1	**General**			
				The laboratory shall have a documented procedure for the selection, purchasing and management of equipment. The laboratory shall be furnished with all equipment needed for the provision of services (including primary sample collection, sample preparation, sample processing, examination and storage). In those cases where the laboratory needs to use equipment outside its permanent control, laboratory management shall ensure that the requirements of this International Standard are met. The laboratory shall replace equipment as needed to ensure the quality of examination results.	++	++	QSP for laboratory equipment- handling and maintainance (QSP-18/5.3)
			5.3.1.2	**Equipment acceptance testing**			
				The laboratory shall verify upon installation and before use that the equipment is capable of achieving the necessary performance and that it complies with requirements relevant to any examinations concerned (see also 5.5.1) *NOTE This requirement applies to: equipment used in the laboratory, equipment on loan or equipment used in associated or mobile facilities by others authorized by the laboratory.* Each item of equipment shall be uniquely labelled, marked or otherwise identified.	++	++	
			5.3.1.3	**Equipment instructions for use**			
				Equipment shall be operated at all times by trained and authorized personnel. Current instructions on the use, safety and maintenance of equipment, including any relevant manuals and directions for use provided by the manufacturer of the equipment, shall be readily available. The laboratory shall have procedures for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration.	++	++	
			5.3.1.4	**Equipment calibration and metrological traceability**			
				The laboratory shall have a documented procedure for the calibration of equipment that directly or indirectly affects examination results. This procedure includes:			

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				a	taking into account conditions of use and the manufacturer's instructions;	++	++	
				b	recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment;	++	++	
				c	verifying the required measurement accuracy and the functioning of the measuring system at defined intervals;	++	++	
				d	recording the calibration status and date of recalibration;	++	++	
				e	ensuring that, where calibration gives rise to a set of correction factors, the previous calibration factors are correctly updated;	++	++	
				f	safeguards to prevent adjustments or tampering that might invalidate examination results.	++	++	
					Metrological traceability shall be to a reference material or reference procedure of the higher metrological order available. *NOTE Documentation of calibration traceability to a higher order reference material or reference procedure may be provided by an examination system manufacturer. Such documentation is acceptable as long as the manufacturer's examination system and calibration procedures are used without modification.* Where this is not possible or relevant, other means for providing confidence in the results shall be applied, including but not limited to the following: — use of certified reference materials; — examination or calibration by another procedure; — Mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned.			
			5.3.1.5		**Equipment maintenance and repair**			
					The laboratory shall have a documented programme of preventive maintenance which, at a minimum, follows the manufacturer's instructions. Equipment shall be maintained in a safe working condition and in working order. This shall include examination of electrical safety, emergency stop devices where they exist and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons. At a minimum, manufacturer's schedules or instructions, or both, shall be used. Whenever equipment is found to be defective, it shall be taken out of service and clearly labelled. The laboratory shall ensure that defective equipment is not used until it has been repaired and shown by verification to meet specified acceptance criteria. The			

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				laboratory shall examine the effect of any defects on previous examinations and institute immediate action or corrective action (see 4.10). The laboratory shall take reasonable measures to decontaminate equipment before service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment. When equipment is removed from the direct control of the laboratory, the laboratory shall ensure that its performance is verified before being returned to laboratory use.			
			5.3.1.6	**Equipment adverse incident reporting**				
				Adverse incidents and accidents that can be attributed directly to specific equipment shall be investigated and reported to the manufacturer and appropriate authorities, as required.	++	++	
			5.3.1.7	**Equipment records**				
				Records shall be maintained for each item of equipment that contributes to the performance of examinations. These equipment records shall include, but not be limited to, the following:			
				a identity of the equipment	++	++	
				b manufacturer's name, model and serial number or other unique identification;	++	++	
				c contact information for the supplier or the manufacturer;	++	++	
				d date of receiving and date of entering into service;	++	++	
				e location;	++	++	
				f condition when received (e.g. new, used or reconditioned);	++	++	
				g manufacturer's instructions;	++	++	
				h records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory;	++	++	
				i maintenance carried out and the schedule for preventive maintenance;	++	++	
				j equipment performance records that confirm the equipment's ongoing acceptability for use;	++	++	
				k Damage to, or malfunction, modification, or repair of the equipment.	++	++	
				The performance records referred to in j) shall include copies of reports/certificates of all calibrations and/or verifications including dates, times and results, adjustments, the acceptance criteria and due date of the next calibration and/or verification, to fulfil part or all of this requirement. These records shall be maintained and shall			

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				be readily available for the lifespan of the equipment or longer, as specified in the laboratory's Control of Records procedure (see 4.13)			
		5.3.2	**Reagents and consumables**				
			5.3.2.1	**General**			
				The laboratory shall have a documented procedure for the reception, storage, acceptance testing and inventory management of reagents and consumables.	++	++	
			5.3.2.2	**Reagents and consumables — Reception and storage**			
				Where the laboratory is not the receiving facility, it shall verify that the receiving location has adequate storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration. The laboratory shall store received reagents and consumables according to manufacturer's specifications.	++	++	
			5.3.2.3	**Reagents and consumables — Acceptance testing**			
				Each new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, shall be verified for performance before use in examinations. Consumables that can affect the quality of examinations shall be verified for performance before use in examinations.	++	++	
			5.3.2.4	**Reagents and consumables — Inventory management**			
				The laboratory shall establish an inventory control system for reagents and consumables. The system for inventory control shall segregate uninspected and unacceptable reagents and consumables from those that have been accepted for use.	++	++	
			5.3.2.5	**Reagents and consumables — Instructions for use**			
				Instructions for the use of reagents and consumables, including those provided by the manufacturers, shall be readily available.	++	++	
			5.3.2.6	**Reagents and consumables — Adverse incident reporting**			
				Adverse incidents and accidents that can be attributed directly to specific reagents or consumables shall be investigated and reported to the manufacturer and appropriate authorities, as required.	++	++	
			5.3.2.7	**Reagents and consumables — Records**			
				Records shall be maintained for each reagent and consumable that contributes to the performance of examinations. These records shall include but not be limited to the following:	++	++	
				a identity of the reagent or consumable;	++	++	
				b manufacturer's name and batch code or lot number;	++	++	
				c contact information for the supplier or the manufacturer;	++	++	
				d date of receiving, the expiry date, date of	++	++	

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					entering into service and, where applicable, the date the material was taken out of service;			
				e	condition when received (e.g. acceptable or damaged);	++	++	
				f	manufacturer's instructions;	++	++	
				g	records that confirmed the reagent's or consumable's initial acceptance for use;	++	++	
				h	performance records that confirm the reagent's or consumable's ongoing acceptance for use.	++	++	
					Where the laboratory uses reagents prepared or completed in-house, the records shall include, in addition to the relevant information above, reference to the person or persons undertaking their preparation and the date of preparation.			
	5.4	**Pre-examination processes**						
		5.4.1	**General**					
			The laboratory shall have documented procedures and information for pre-examination activities to ensure the validity of the results of examinations.			++	++	QSP for sample handling (QSP-19/5.4)
		5.4.2	**Information for patients and users**					
			The laboratory shall have information available for patients and users of the laboratory services. The information shall include as appropriate:					
			a	the location of the laboratory;		++	++	
			b	types of clinical services offered by the laboratory including examinations referred to other laboratories;		++	++	
			c	opening hours of the laboratory;		++	++	
			d	the examinations offered by the laboratory including, as appropriate, information concerning samples required, primary sample volumes, special precautions, turnaround time, (which may also be provided in general categories or for groups of examinations), biological reference intervals, and clinical decision values;		++	++	
			e	instructions for completion of the request form;		++	++	
			f	instruction for preparation of the patient;		++	++	
			g	instructions for patient-collected samples;		++	++	
			h	instructions for transportation of samples, including any special handling needs;		++	++	
			i	any requirements for patient consent (e.g. consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed);		++	++	
			j	the laboratory's criteria for accepting and rejecting samples;		++	++	
			k	a list of factors known to significantly affect the performance of the examination or the interpretation of the results;		++	++	
			l	availability of clinical advice on ordering of examinations and on interpretation of examination results;		++	++	
			m	the laboratory's policy on protection of personal information;		++	++	
			n	the laboratory's complaint procedure		++	++	
			The laboratory shall have information available for patients and users that includes an explanation of the clinical procedure to be performed to enable informed consent. Importance of provision of patient and family			++	++	

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			information, where relevant (e.g. for interpreting genetic examination results), shall be explained to the patient and user.				
		5.4.3	**Request form information**				
			The request form or an electronic equivalent shall allow space for the inclusion of, but not be limited to, the following:				
			a	patient identification, including gender, date of birth, and the location/contact details of the patient, and a unique identifier; *NOTE Unique identification includes an alpha and/or numerical identifier such as a hospital number, or personal health number.*	++	++	
			b	name or other unique identifier of clinician, healthcare provider, or other person legally authorized to request examinations or use medical information, together with the destination for the report and contact details;	++	++	
			c	type of primary sample and, where relevant, the anatomic site of origin;	++	++	
			d	examinations requested;	++	++	
			e	clinically relevant information about the patient and the request, for examination performance and result interpretation purposes; *NOTE: Information needed for examination performance and results interpretation may include the patient's ancestry, family history, travel and exposure history, communicable diseases and other clinically relevant information. Financial information for billing purposes, financial audit, resource management and utilization reviews may also be collected. The patient should be aware of the information collected and the purpose for which it is collected.*	++	++	
			f	date and, where relevant, time of primary sample collection;	++	++	
			g	date and time of sample receipt.	++	++	
			NOTE The format of the request form (e.g. electronic or paper) and the manner in which requests are to be communicated to the laboratory should be determined in discussion with the users of laboratory services. The laboratory shall have a documented procedure concerning verbal requests for examinations that includes providing confirmation by request form or electronic equivalent within a given time. The laboratory shall be willing to cooperate with users or their representatives in clarifying the user's request				
		5.4.4	**Primary sample collection and handling**				
			5.4.4.1	**General**			
				The laboratory shall have documented **procedures** for the proper collection and handling of primary samples. The documented procedures shall be available to those responsible for primary sample collection whether or not the collectors are laboratory staff. Where the user requires deviations and exclusions from, or additions to, the	++	++	

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				documented collection procedure, these shall be recorded and included in all documents containing examination results and shall be communicated to the appropriate personnel. *NOTE :1 All procedures carried out on a patient need the informed consent of the patient. For most routine laboratory procedures, consent can be inferred when the patient presents himself or herself at a laboratory with a request form and willingly submits to the usual collecting procedure, for example, venipuncture. Patients in a hospital bed should normally be given the opportunity to refuse.* Special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, will need a more detailed explanation and, in some cases, written consent. In emergency situations, consent might not be possible; under these circumstances it is acceptable to carry out necessary procedures, provided they are in the patient's best interest. *NOTE 2: Adequate privacy during reception and sampling should be available and appropriate to the type of information being requested and primary sample being collected.*			
			5.4.4.2	**Instructions for pre-collection activities**				
				The laboratory's instructions for pre-collection activities shall include the following:				
				a	completion of request form or electronic request;	++	++	
				b	preparation of the patient (e.g. instructions to caregivers, phlebotomists, sample collectors and patients);	++	++	
				c	type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives;	++	++	
				d	special timing of collection, where needed;	++	++	
				e	clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs).	++	++	
			5.4.4.3	**Instructions for collection activities**				
				The laboratory's instructions for collection activities shall include the following:				
				a	determination of the identity of the patient from whom a primary sample is collected;	++	++	
				b	verification 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, etc.];	++	++	
				c	instructions for collection of primary blood and non-blood samples, with descriptions of the primary sample containers and any	++	++	

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					necessary additives;			
				d	in situations where the primary sample is collected as part of clinical practice, information and instructions regarding primary sample containers, any necessary additives and any necessary processing and sample transport conditions shall be determined and communicated to the appropriate clinical staff;	++	++	
				e	instructions for labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected;	++	++	
				f	recording of the identity of the person collecting the primary sample and the collection date, and, when needed, recording of the collection time;	++	++	
				g	instructions for proper storage conditions before collected samples are delivered to the laboratory;	++	++	
				h	safe disposal of materials used in the collection.	++	++	
		5.4.5	**Sample transportation**					
			The laboratory's instructions for post-collection activities shall include packaging of samples for transportation. The laboratory shall have a documented procedure for monitoring the transportations of samples to ensure they are transported:					
			a		within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned;	++	++	
			b		within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples;	++	++	
			c		in a manner that ensures the integrity of the sample and the safety for the carrier, the general public and the receiving laboratory, in compliance with established requirements. *NOTE: A laboratory which is not involved in primary sample collection and transportation is considered to have satisfied clause 5.4.5 c) above when, upon receipt of a sample whose integrity was compromised or which could have jeopardized the safety of the carrier or the general public, the sender is contacted immediately and informed about measures to be taken to eliminate recurrence.*	++	++	
		5.4.6	**Sample reception**					
			The laboratory's procedure for sample reception shall ensure that the following conditions are met.					
			a		Samples are unequivocally traceable, by request and labelling, to an identified patient or site.	++	++	
			b		Laboratory-developed and documented criteria for acceptance or rejection of samples are applied.	++	++	
			c		Where there are problems with patient or sample identification, sample instability due to delay in transport or inappropriate container(s), insufficient sample volume, or when the sample is clinically critical or irreplaceable and the laboratory chooses to process the sample, the final report shall indicate the nature of the problem and, where applicable, that	++	++	

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				caution is required when interpreting the result.			
			d	All samples received are recorded in an accession book, worksheet, computer or other comparable system. The date and time of receipt and/or registration of samples shall be recorded. Whenever possible, the identity of the person receiving the sample shall also be recorded.	++	++	
			e	Authorized personnel shall evaluate received samples to ensure that they meet the acceptance criteria relevant for the requested examination(s).	++	++	
			f	Where relevant, there shall be instructions for the receipt, labelling, processing and reporting of samples specifically marked as urgent. The instructions shall include details of any special labelling of the request form and sample, the mechanism of transfer of the sample to the examination area of the laboratory, any rapid processing mode to be used, and any special reporting criteria to be followed.	++	++	
				All portions of the primary sample shall be unequivocally traceable to the original primary sample.			
		5.4.7		**Pre-examination handling, preparation and storage**			
				The laboratory shall have procedures and appropriate facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities and during handling, preparation and storage. Laboratory procedures shall include time limits for requesting additional examinations or further examinations on the same primary sample.	++	++	
	5.5	**Examination processes**					
		5.5.1		**Selection, Verification And Validation Of Examination Procedures**			
			5.5.1.1	**General**			
				The laboratory shall select examination procedures which have been validated for their intended use. The identity of persons performing activities in examination processes shall be recorded. The specified requirements (performance specifications) for each examination procedure shall relate to the intended use of that examination. *NOTE Preferred procedures are those specified in the instructions for use of in vitro medical devices or those that have been published in established/authoritative textbooks, peer-reviewed texts or journals, or in international consensus standards or guidelines, or national or regional regulations*.	++	++	QSP for examination process (QSP-20/5.5)
			5.5.1.2	**Verification of examination procedures**			
				Validated examination procedures used without modification shall be subject to independent verification by the laboratory before being introduced into routine use. The laboratory shall obtain information from the manufacturer/method developer for confirming the performance characteristics of the procedure. The independent verification by the laboratory	++	++	

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				shall confirm, through obtaining objective evidence (in the form of performance characteristics) that the performance claims for the examination procedure have been met. The performance claims for the examination procedure confirmed during the verification process shall be those relevant to the intended use of the examination results. The laboratory shall document the procedure used for the verification and record the results obtained. Staff with the appropriate authority shall review the verification results and record the review.			
			5.5.1.3	**Validation of examination procedures**			
				The laboratory shall validate examination procedures derived from the following sources:			
				a non-standard methods;	++	++	
				b laboratory designed or developed methods;	++	++	
				c standard methods used outside their intended scope;	++	++	
				d Validated methods subsequently modified.	++	++	
				The validation shall be as extensive as is necessary and confirm, through the provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use of the examination have been fulfilled. *NOTE Performance characteristics of an examination procedure should include consideration of: measurement trueness, measurement accuracy, measurement precision including measurement repeatability and measurement intermediate precision; measurement uncertainty, analytical specificity, including interfering substances, analytical sensitivity, detection limit and quantitation limit, measuring interval, diagnostic specificity and diagnostic sensitivity.* The laboratory shall document the procedure used for the validation and record the results obtained. Staff with the authority shall review the validation results and record the review. When changes are made to a validated examination procedure, the influence of such changes shall be documented and, when appropriate, a new validation shall be carried out.	++	++	
			5.5.1.4	**Measurement uncertainty of measured quantity values**			
				The laboratory shall determine measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples. The laboratory shall define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty.	++	++	

REQUIREMENTS OF ISO 15189: 2012					DOCUMENTATION	IMPLEMENTATION	REMARKS
				NOTE 1 The relevant uncertainty components are those associated with the actual measurement process, commencing with the presentation of the sample to the measurement procedure and ending with the output of the measured value. *NOTE 2 Measurement uncertainties may be calculated using quantity values obtained by the measurement of quality control materials under intermediate precision conditions that include as many routine changes as reasonably possible in the standard operation of a measurement procedure, e.g. changes of reagent and calibrator batches, different operators, scheduled instrument maintenance.* *NOTE 3 Examples of the practical utility of measurement uncertainty estimates might include confirmation that patients' values meet quality goals set by the laboratory and meaningful comparison of a patient value with a previous value of the same type or with a clinical decision value.* The laboratory shall consider measurement uncertainty when interpreting measured quantity values. Upon request, the laboratory shall make its estimates of measurement uncertainty available to laboratory users. Where examinations include a measurement step but do not report a measured quantity value, the laboratory should calculate the uncertainty of the measurement step where it has utility in assessing the reliability of the examination procedure or has influence on the reported result.			
		5.5.2	**Biological reference intervals or clinical decision values**				
				The laboratory shall define the biological reference intervals or clinical decision values, document the basis for the reference intervals or decision values and communicate this information to users. When a particular biological reference interval or decision value is no longer relevant for the population served, appropriate changes shall be made and communicated to the users. When the laboratory changes an examination procedure or pre-examination procedure, the laboratory shall review associated reference intervals and clinical decision values, as applicable.	++	++	
		5.5.3	**Documentation of examination procedures**				
				Examination procedures shall be documented. They shall be written in a language commonly understood by the staff in the laboratory and be available in appropriate locations. Any condensed document format (e.g. card files or similarly used systems) shall correspond to the documented procedure. *NOTE 1 Working instructions, card files or similar systems that summarize key information are acceptable for use as*	++	++	

REQUIREMENTS OF ISO 15189: 2012					DOCUMENTATION	IMPLEMENTATION	REMARKS
			a quick reference at the workbench, provided that a full documented procedure is available for reference. *NOTE 2 Information from product instructions for use may be incorporated into examination procedures by reference.* All documents that are associated with the performance of examinations, including procedures, summary documents, condensed document format and product instructions for use, shall be subject to document control. In addition to document control identifiers, documentation shall include, when applicable to the examination procedure, the following:				
			a	purpose of the examination;	++	++	
			b	principle and method of the procedure used for examinations;	++	++	
			c	performance characteristics (see 5.5.1.2 and 5.5.1.3);	++	++	
			d	type of sample (e.g. plasma, serum, urine);	++	++	
			e	patient preparation;	++	++	
			f	type of container and additives;	++	++	
			g	required equipment and reagents	++	++	
			h	environmental and safety controls;	++	++	
			i	calibration procedures (metrological traceability);	++	++	
			j	procedural steps;	++	++	
			k	quality control procedures;	++	++	
			l	interferences (e.g. lipaemia, haemolysis, bilirubinemia, drugs) and cross reactions;	++	++	
			m	principle of procedure for calculating results including, where relevant, the measurement uncertainty of measured quantity values;	++	++	
			n	biological reference intervals or clinical decision values;	++	++	
			o	reportable interval of examination results;	++	++	
			p	instructions for determining quantitative results when a result is not within the measurement interval;	++	++	
			q	alert/critical values, where appropriate;	++	++	
			r	laboratory clinical interpretation;	++	++	
			s	potential sources of variation;	++	++	
			t	references	++	++	
			If the laboratory intends to change an existing examination procedure such that results or their interpretations could be significantly different, the implications shall be explained to users of the laboratory services after validating the procedure. *NOTE 3 This requirement can be accomplished in different ways, depending on local circumstances. Some methods include directed mailings, laboratory newsletters or part of the examination report itself.*				
	5.6	**Ensuring quality of examination results**					

REQUIREMENTS OF ISO 15189: 2012					DOCUMENTATION	IMPLEMENTATION	REMARKS
		5.6.1	**General**				
			The laboratory shall ensure the quality of examinations by performing them under defined conditions. Appropriate pre and post-examination processes shall be implemented (see 4.14.7, 5.4, 5.7 and 5.8). The laboratory shall not fabricate any results.		++	++	QSP for ensuring quality of examination results (QSP-21/5.6)
		5.6.2	**Quality control**				
			5.6.2.1	**General**			
				The laboratory shall design quality control procedures that verify the attainment of the intended quality of results. *NOTE In several countries, quality control, as referred to in this subclause, is also named "internal quality control."*	++	++	
			5.6.2.2	**Quality control materials**			
				The laboratory shall use quality control materials that react to the examining system in a manner as close as possible to patient samples. Quality control materials shall be periodically examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result. *NOTE 1 The laboratory should choose concentrations of control materials, wherever possible, especially at or near clinical decision values, which ensure the validity of decisions made.* *NOTE 2 Use of independent third party control materials should be considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer.*	++	++	
			5.6.2.3	**Quality control data**			
				The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure. When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, the results shall be rejected and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified. The laboratory shall also evaluate the results from patient samples that were examined after the last successful quality control event. Quality control data shall be reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system. When such trends are noted preventive actions shall be taken and recorded. *NOTE Statistical and non-statistical techniques*	++	++	

REQUIREMENTS OF ISO 15189: 2012					DOCUMENTATION	IMPLEMENTATION	REMARKS
				for process control should be used wherever possible to continuously monitor examination system performance.			
		5.6.3	**Interlaboratory comparisons**				
			5.6.3.1	**Participation**			
				The laboratory shall participate in an interlaboratory comparison programme(s) (such as an external quality assessment programme or proficiency testing programme) appropriate to the examination and interpretations of examination results. The laboratory shall monitor the results of the interlaboratory comparison programme(s) and participate in the implementation of corrective actions when predetermined performance criteria are not fulfilled. *NOTE The laboratory should participate in interlaboratory comparison programmes that substantially fulfil the relevant requirements of ISO/IEC 17043.* The laboratory shall establish a documented procedure for interlaboratory comparison participation that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the interlaboratory comparison programme. Interlaboratory comparison programme(s) chosen by the laboratory shall, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-examination procedures, and post-examination procedures, where possible.	++	++	
			5.6.3.2	**Alternative approaches**			
				Whenever an interlaboratory comparison is not available, the laboratory shall develop other approaches and provide objective evidence for determining the acceptability of examination results. Whenever possible, this mechanism shall utilize appropriate materials. *NOTE Examples of such materials may include:* *— certified reference materials;* *— samples previously examined;* *— material from cell or tissue repositories;* *— exchange of samples with other laboratories;* *— control materials that are tested daily in interlaboratory comparison programmes.*	++	++	
			5.6.3.3	**Analysis of interlaboratory comparison samples**			
				The laboratory shall integrate interlaboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples.	++	++	

REQUIREMENTS OF ISO 15189: 2012					DOCUMENTATION	IMPLEMENTATION	REMARKS
				Interlaboratory comparison samples shall be examined by personnel who routinely examine patient samples using the same procedures as those used for patient samples. The laboratory shall not communicate with other participants in the interlaboratory comparison programme about sample data until after the date for submission of the data. The laboratory shall not refer interlaboratory comparison samples for confirmatory examinations before submission of the data, although this would routinely be done with patient samples.			
			5.6.3.4	**Evaluation of laboratory performance**			
				The performance in Interlaboratory comparisons shall be reviewed and discussed with relevant staff. When predetermined performance criteria are not fulfilled (i.e. nonconformities are present), staff shall participate in the implementation and recording of corrective action. The effectiveness of corrective action shall be monitored. The returned results shall be evaluated for trends that indicate potential nonconformities and preventive action shall be taken.	++	++	
		5.6.4	**Comparability of examination results**				
				There shall be a defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals. This is applicable to the same or different procedures, equipment, different sites, or all of these. *NOTE In the particular case of measurement results that are metrologically traceable to the same reference, the results are described as having metrological comparability providing that calibrators are commutable*. The laboratory shall notify users of any differences in comparability of results and discuss any implications for clinical practice when measuring systems provide different measurement intervals for the same measurand (e.g. glucose) and when examination methods are changed. The laboratory shall document, record and, as appropriate, expeditiously act upon results from the comparisons performed. Problems or deficiencies identified shall be acted upon and records of actions retained.	++	++	
	5.7	**Post- examination processes**					
		5.7.1	**Review of results**				
				The laboratory shall have procedures to ensure that authorized personnel review the results of examinations before release and evaluate them against internal quality control and, as appropriate, available clinical information and previous examination results.	++	++	QSP for post-examination process

REQUIREMENTS OF ISO 15189: 2012				DOCUMENTATION	IMPLEMENTATION	REMARKS
			When the procedure for reviewing results involves automatic selection and reporting, review criteria shall be established, approved and documented (see 5.9.1)			
		5.7.2	**Storage, retention and disposal of clinical samples**			
			The laboratory shall have a documented procedure for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples. The laboratory shall define the length of time clinical samples are to be retained. Retention time shall be defined by the nature of the sample, the examination and any applicable requirements. *NOTE Legal liability concerns regarding certain types of procedures (e.g. histology examinations, genetic examinations, paediatric examinations) may require the retention of certain samples for much longer periods than for other samples*. Safe disposal of samples shall be carried out in accordance with local regulations or recommendations for waste management.	++	++	
	5.8	**Reporting of results**				
		5.8.1	**General**			
			The results of each examination shall be reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures. The laboratory shall define the format and medium of the report (i.e. electronic or paper) and the manner in which it is to be communicated from the laboratory. The laboratory shall have a procedure to ensure the correctness of transcription of laboratory results. Reports shall include the information necessary for the interpretation of the examination results. The laboratory shall have a process for notifying the requester when an examination is delayed that could compromise patient care	++	++	QSP for reporting of results (QSP-23/5.8)
		5.8.2	**Report attributes**			
			The laboratory shall ensure that the following report attributes effectively communicate laboratory results and meet the users' needs:			
			a comments on sample quality that might compromise examination results;	++	++	
			b comments regarding sample suitability with respect to acceptance/rejection criteria;	++	++	
			c critical results, where applicable;	++	++	
			d interpretive comments on results, where applicable, which may include the verification of the interpretation of automatically selected and reported results (see 5.9.1) in the final report	++	++	
		5.8.3	**Report content**			
			The report shall include, but not be limited to, the following:			
			a a clear, unambiguous identification of the examination including, where appropriate, the examination procedure;	++	++	

REQUIREMENTS OF ISO 15189: 2012					DOCUMENTATION	IMPLEMENTATION	REMARKS
			b	the identification of the laboratory that issued the report;	++	++	
			c	identification of all examinations that have been performed by a referral laboratory;	++	++	
			d	patient identification and patient location on each page;	++	++	
			e	name or other unique identifier of the requester and the requester's contact details;	++	++	
			f	date of primary sample collection (and time, when available and relevant to patient care);	++	++	
			g	type of primary sample;	++	++	
			h	measurement procedure, where appropriate;	++	++	
			i	examination results reported in SI units, units traceable to SI units, or other applicable units;	++	++	
			j	biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable; *NOTE Under some circumstances, it might be appropriate to distribute lists or tables of biological reference intervals to all users of laboratory services at sites where reports are received.*	++	++	
			k	interpretation of results, where appropriate; *NOTE Complete interpretation of results requires the context of clinical information that may not be available to the laboratory.*	++	++	
			l	other comments such as cautionary or explanatory notes (e.g. quality or adequacy of the primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure);	++	++	
			m	identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available;	++	++	
			n	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);	++	++	
			o	date of the report, and time of release (if not contained in the report, readily available when needed);	++	++	
			p	Page number to total number of pages (e.g. "Page 1 of 5", "Page 2 of 5", etc.).	++	++	
	5.9	**Release of results**					
		5.9.1	**General**				
				The laboratory shall establish documented procedures for the release of examination results, including details of who may release results and to whom. The procedures shall ensure that the following conditions are met.			QSP for release of results (QSP-24/5.9)
			a	When the quality of the primary sample received is unsuitable for examination, or could have compromised the result, this is indicated in the report.	++	++	
			b	When examination results fall within established "alert" or "critical" intervals: — a physician (or other authorized health professional) is notified immediately [this includes results received on samples sent to referral laboratories for examination (see 4.5)];	++	++	

REQUIREMENTS OF ISO 15189: 2012					DOCUMENTATION	IMPLEMENTATION	REMARKS
				— Records are maintained of actions taken that document date, time, responsible laboratory staff member, person notified and examination results conveyed, and any difficulties encountered in notifications.			
			c	Results are legible, without mistakes in transcription, and reported to persons authorized to receive and use the information.	++	++	
			d	When results are transmitted as an interim report, the final report is always forwarded to the requester.	++	++	
			e	There are processes for ensuring that results distributed by telephone or electronic means reach only authorized recipients. Results provided orally shall be followed by a written report. There shall be a record of all oral results provided. *NOTE 1 For the results of some examinations (e.g. certain genetic or infectious disease examinations) special counselling may be needed. The laboratory should endeavour to see that results with serious implications are not communicated directly to the patient without the opportunity for adequate counselling.* *NOTE 2 Results of laboratory examinations that have been separated from all patient identification may be used for such purposes as epidemiology, demography or other statistical analyses.* *See also 4.9.*	++	++	
		5.9.2	**Automated selection and reporting of results**				
			If the laboratory implements a system for automated selection and reporting of results, it shall establish a documented procedure to ensure that:		++	++	
			a	the criteria for automated selection and reporting are defined, approved, readily available and understood by the staff; *NOTE Items for consideration when implementing automated selection and reporting include changes from previous patient values that require review and values that require intervention by laboratory personnel, such as absurd, unlikely or critical values*.	++	++	
			b	the criteria are validated for proper functioning before use and verified after changes to the system that might affect their functioning;	++	++	
			c	there is a process for indicating the presence of sample interferences (e.g. haemolysis, icterus, lipaemia) that may alter the results of the examination;	++	++	
			d	there is a process for incorporating analytical warning messages from the instruments into the automated selection and reporting criteria, when appropriate;	++	++	
			e	results selected for automated reporting shall be identifiable at the time of review before release and include date and time of selection;	++	++	
			f	there is a process for rapid suspension of automated selection and reporting.	++	++	
		5.9.3	**Revised reports**				
			When an original report is revised there shall be written instructions regarding the revision so that:				
			a	the revised report is clearly identified as a revision and includes reference to the date and patient's identity in the original report;	++	++	

REQUIREMENTS OF ISO 15189: 2012					DOCUMENTATION	IMPLEMENTATION	REMARKS
			b	the user is made aware of the revision;	++	++	
			c	the revised record shows the time and date of the change and the name of the person responsible for the change;	++	++	
			d	the original report entries remain in the record when revisions are made.	++	++	
				Results that have been made available for clinical decision making and revised shall be retained in subsequent cumulative reports and clearly identified as having been revised. When the reporting system cannot capture amendments, changes or alterations, a record of such shall be kept.			
	5.10	**Laboratory information management**					
		5.10.1	**General**				
				The laboratory shall have access to the data and information needed to provide a service which meets the needs and requirements of the user. The laboratory shall have a documented procedure to ensure that the confidentiality of patient information is maintained at all times. *NOTE In this International Standard, "information systems" includes the management of data and information contained in both computer and non-computerized systems. Some of the requirements may be more applicable to computer systems than to non-computerized systems. Computerized systems can include those integral to the functioning of laboratory equipment and stand alone systems using generic software, such as word processing, spreadsheet and database applications that generate, collate, report and archive patient information and reports.*	++	++	QSP for laboratory information management (QSP-25/5.10)
		5.10.2	**AUTHORITIES AND RESPONSIBILITIES**				
				The laboratory shall ensure that the authorities and responsibilities for the management of the information system are defined, including the maintenance and modification to the information system(s) that may affect patient care. The laboratory shall define the authorities and responsibilities of all personnel who use the system, in particular those who:			
			a	access patient data and information;	++	++	
			b	enter patient data and examination results;	++	++	
			c	change patient data or examination results;	++	++	
			d	authorize the release of examination results and reports.	++	++	
		5.10.3	**Information system management**				
				The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information shall be:			
			a	validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented and verified before implementation; NOTE: Validation and verification include, where applicable, the proper functioning of interfaces between the laboratory information system and other systems such as with laboratory instrumentation,	++	++	

REQUIREMENTS OF ISO 15189: 2012					DOCUMENTATION	IMPLEMENTATION	REMARKS
				hospital patient administration systems and systems in primary care.			
			b	documented, and the documentation, including that for day to day functioning of the system, readily available to authorized users;	++	++	
			c	protected from unauthorized access;	++	++	
			d	safeguarded against tampering or loss;	++	++	
			e	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;	++	++	
			f	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;	++	++	
			g	in compliance with national or international requirements regarding data protection. The laboratory shall verify that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information (e.g. computer systems, fax machines, e-mail, website, personal web devices). When a new examination or automated comments are implemented, the laboratory shall verify that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory. The laboratory shall have documented contingency plans to maintain services in the event of failure or downtime in information systems that affect the laboratory's ability to provide service. When the information system(s) are managed and maintained off-site or subcontracted to an alternative provider, laboratory management shall be responsible for ensuring that the provider or operator of the system complies with all applicable requirements of this International Standard.	++	++	

ANNEXURE

1.TRAINING RECORD OF THE STAFF

Regular training is given to the laboratory staff in various fields like fire safety, different type of staining, duty protocols, about the maintenance of the instruments, lab safety, different types of tests, hand hygiene etc.

Record of which is as follows-

S. No	Date	Topic	Trainer
1	04-02-2014	Negative Stainng	Dr. Anil Sharma
2	04-03-2014	Night Duty Protocal	Dr. Anil Sharma
3	04-04-2014	Critical Value Information	Dr. Anil Sharma
4	04-05-2014	Interfacing Issue	Dr. Anil Sharma
5	04-08-2014	Tulip Turfidimetry	Dr. Anil Sharma
6	04-11-2014	V-250 Maintanance	Dr. Anil Sharma
7	04-12-2014	Histopathology	Dr. Anil Sharma
8	04-10-2014	Urine R/E	Dr. Anil Sharma
9	15/4/2014	Lab Saftey	Dr. Samiksha Sharma
10	16/4/2014	Centrifuge Protocal	Dr. Anil Sharma
11	19/4/2014	Benedict's Test	Dr. Anil Sharma
12	21/4/2014	APTT	Dr. Anil Sharma
13	23/4/2014	PT INR	Dr. Anil Sharma
14	26/4/2014	Pregnancy Test	Dr. Anil Sharma
15	28/4/2014	Fluid For Cell Count Sysmex Xsi- 800 I	Dr. Anil Sharma
16	29/4/2014	Hand Hygine	Shalini Jha
17	30/4/2014	Fire Safety	Jitendra Kummar
18	05-02-2014	Neu Bar Chamber	Dr. Anil Sharma
19	05-03-2014	Shali's HB Method	Dr. Anil Sharma
20	05-07-2014	Sample Collection	Dr. Anil Sharma
21	05-08-2014	Fluid For Cell Count Sysmex Xsi- 800 I	Dr. Anil Sharma
22	05-10-2014	Precath Profile Serology	Dr. Anil Sharma
23	05-12-2014	Urine C/S Method	Dr. Anil Sharma
24	05-12-2014	Hand Hygine	Shalini Jha
25	13/5/2014	Serology Profile Protocol	Dr. Anil Sharma
26	14/5/2014	PT, APTT - Critcal Value	Dr. Anil Sharma

27	15/5/2014	Lab Saftey	Dr. Samiksha Sharma
28	15/5/2014	Fluid For Cell Count	Dr. Anil Sharma
29	16/5/2014	Fire Safety	Jitendra Kummar
30	17/5/2014	Sample Collection Protocol	Dr. Anil Sharma
31	22/5/2014	TAT Report Type Method	Dr. Anil Sharma
32	23/05/2014	Biosafety Cabinet	Dr. Anil Sharma
33	23/5/2014	ABG Control	Dr. Anil Sharma
34	26/5/2014	Test by Card	Dr. Anil Sharma
35	28/5/2014	Microscopic	Dr. Anil Sharma
36	29/5/2014	Multiple Blood C/S	Dr. Anil Sharma
37	30/5/2014	Fluid Run Sysmex -800i	Dr. Anil Sharma
38	31/5/2014	Seman Analysis	Dr. Anil Sharma
39	06-02-2014	Blood C/S	Dr. Anil Sharma
40	06-03-2014	QC Plan	Dr. Anil Sharma
41	06-04-2014	L. J. Chart	Dr. Anil Sharma
42	06-05-2014	V-250 Daily Maintanance	Dr. Anil Sharma
43	06-05-2014	CSSD - Indicator	Shalini Jha
44	06-07-2014	Use of Neu Bar Chamber Counting	Dr. Anil Sharma
45	06-07-2014	Use of Centrifuge	Dr. Anil Sharma
46	06-09-2014	CSSD - Indicator	Dr. Anil Sharma
47	06-10-2014	Stool Occult Blood	Dr. Anil Sharma
48	06-11-2014	QC Plan	Dr. Anil Sharma
49	14/6/2014	Evaluation Weekly	Dr. Anil Sharma
50	18/6/2014	Urine C/S	Dr. Anil Sharma
51	19/6/2014	Blood C/S	Dr. Anil Sharma
52	21/6/2014	RFT Test	Dr. Anil Sharma
53	24/6/2014	T3.T4,TSH	Dr. Anil Sharma
54	24/6/2014	Biosafety Cabinet	Dr. Anil Sharma
55	26/6/2014	Biomedical Waste	Dr. Anil Sharma
56	27/6/2014	PCT Test	Dr. Anil Sharma
57	28/6/2014	Fire Safety	Jitendra Kummar
58	30/6/2014	PT INR	Dr. Anil Sharma
59	07-01-2014	Urine For Bile Salt & Bile Pigment	Dr. Anil Sharma
60	07-01-2014	CSSD - Indicator	Shalini Jha
61	07-02-2014	Stool RE/PH/RS	Dr. Anil Sharma
62	07-03-2014	PT INR	Dr. Anil Sharma
63	07-04-2014	Bacterial Culture Medium	Dr. Anil Sharma
64	07-05-2014	Sysmex Xsi- 800 CBC	Dr. Anil Sharma
65	07-09-2014	Blood Sugar Test V-250	Dr. Anil Sharma
66	07-10-2014	Haemoparasites	Dr. Anil Sharma
67	07-11-2014	New Bar Chamber	Dr. Anil Sharma
68	15/7/2014	BT CT	Dr. Anil Sharma

69	15/7/2014	lab Saftey	Dr. Samiksha Sharma
70	16/7/2014	Sample Collection	Dr. Anil Sharma
71	17/7/2014	Urine Routine & C/S	Dr. Anil Sharma
72	18/7/2014	Urine Routine	Dr. Anil Sharma
73	19/7/2014	Needlef Stick Injury	Dr. Anil Sharma
74	20/7/2014	Fire Safety	Dr. Anil Sharma
75	21/7/2014	Biosaftey Cabinet	Dr. Anil Sharma
76	22/7/2014	Dilution & Cell Count	Dr. Anil Sharma
77	23/7/2014	Urine C/S	Dr. Anil Sharma
78	24/7/2014	Lipid Profile	Dr. Anil Sharma
79	25/7/2014	LFT	Dr. Anil Sharma
80	26/7/2014	Urine Barcodes	Dr. Anil Sharma
81	28/7/2014	QC Plan	Dr. Anil Sharma
82	29/7/2014	PCT Card	Dr. Anil Sharma
83	31/7/2014	Urine For Creatine Ratio	Dr. Anil Sharma
84	08-01-2014	Sysmex Xsi- 800 CBC	Jitendra Kummar
85	08-01-2014	Malaria Parasite	Dr. Anil Sharma
86	08-02-2014	Cell Count	Dr. Anil Sharma
87	08-05-2014	PT-APTT	Dr. Anil Sharma
88	08-07-2014	LFT	Dr. Anil Sharma
89	08-09-2014	Sysmex Xsi- 800 CBC	Dr. Anil Sharma
90	14/8/2014	New Bar Chamber	Dr. Anil Sharma
91	15/8/2014	Eye Washer & PPE	Dr. Samiksha Sharma
92	18/8/2014	Urine R/E	Dr. Anil Sharma
93	19/8/2014	ECI-QC Plan	Dr. Anil Sharma
94	20/8/2014	Centrifuge Maintance	Dr. Anil Sharma
95	21/8/2014	LFT	Dr. Anil Sharma
96	22/8/2014	Lipid Profile	Dr. Anil Sharma
97	25/8/2014	BT CT	Dr. Anil Sharma
98	26/8/2014	Urine Routine	Dr. Anil Sharma
99	26/8/2014	Fire Safety	Jitendra Kummar
100	26/8/2014	Standard Precaution	Shalini Jha
101	27/8/2014	CA 50 Daily Maintance	Dr. Anil Sharma
102	29/8/2014	Cyst Giardia Lambia/MP Slide	Dr. Anil Sharma
103	15/9/2014	Urine Routine	Dr. Anil Sharma
104	16/9/2014	Microscopic	Dr. Anil Sharma
105	17/9/2014	PT INR	Dr. Anil Sharma
106	18/9/2014	New Bar Chamber	Dr. Anil Sharma
107	22/9/2014	CBC	Dr. Anil Sharma
108	23/9/2014	Paforming C/S Microbilogy	Dr. Anil Sharma
109	24/9/2014	Fire Safety	Jitendra Kummar

110	25/9/2014	Urine Routing	Dr. Anil Sharma
111	26/9/2014	Hand Hygine	Shalini Jha
112	28/9/2014	Biosaftey Cabinet	Dr. Anil Sharma
113	15/10/2014	Cardiac Panel	Dr. Anil Sharma
114	15/10/2014	Eye Washer & PPE	Dr. Anil Sharma
115	16/10/2014	Bio Medical Waste	Dr. Anil Sharma
116	18/10/2014	Bio Saftey Cabinet	Dr. Anil Sharma
117	20/10/2014	Fire Safety	Dr. Anil Sharma
118	11-10-2014	APTT	Dr. Anil Sharma
119	14/11/2014	Urine C/S	Dr. Anil Sharma
120	15/11/2014	Eye Washer & PPE	Dr. Samiksha Sharma
121	16/11/2014	Fire Safety	Jitendra Kummar
122	17/11/2014	Bio Medical Waste	Shalini Jha
123	18/1/2014	Bio Medical Cabinet	Shalini Jha
124	19/11/2014	PT INR	Dr. Anil Sharma
125	28/11/2014	Protein Creatinine Ratio	Dr. Anil Sharma
126	12-10-2014	Lipid Profile	Dr. Anil Sharma
127	16/12/2014	Stool Routine	Dr. Anil Sharma
128	17/12/2014	PPE & Eye Washer	Dr. Samiksha Sharma
129	18/12/2014	Fire Safety	Jitendra Kummar
130	21/12/2014	Bio Saftey Cabinet	Shalini Jha
131	22/12/2014	Vitros - 250 Maintanance	Poonam
132	23/12/2014	Hand Hygine	Shalini Jha
133	01-01-2015	Stool Routine	Jitendra Kummar
134	01-04-2015	Eci Maintance	Poonam
135	01-08-2015	Eci- TSH Calibation	Jitendra Kummar
136	15/1/2015	PPE & Eye Washer	Jitendra Kummar
137	16/1/2015	NSI	Shalini Jha
138	20/1/2015	Fire Safety	Jitendra Kummar
139	21/1/2015	HIV Calibration	Poonam
140	25/1/2015	Bio Saftey Cabinet	Dr. Anil Sharma
141	02-04-2015	Vitros - 250 Calibration	Jitendra Kummar
142	02-08-2015	Sysmex Xsi- 800 Control	Poonam
143	02-12-2015	HbsAg Control	Poonam
144	15/2/2015	PPE & Eye Washer	Dr. Samiksha Sharma
145	17/2/2015	Bio Medical Waste	Shalini Jha
146	19/2/2015	Fire Safety	Jitendra Kummar
147	22/2/2015	Standard Precaution	Shalini Jha
148	26/2/2015	Eci Maintance Pack	Jitendra Kummar
149	03-01-2015	ECI Calibration	Jitendra Kummar

150	03-04-2015	HIV Protocal	Jitendra Kummar
151	03-07-2015	Sample Collection	Jitendra Kummar
152	03-10-2015	Seman Analysis	Dr. Anil Sharma
153	14/3/2015	HCV Calibration	Poonam
154	15/3/2015	PPE & Eye Washer	Dr. Samiksha Sharma
155	16/3/2015	Fire Safety	Jitendra Kummar
156	04-10-2015	HIV Control	Poonam
157	15/4/2015	HbsAg Control	Poonam
158	16/4/2015	Lab Saftey	Dr. Samiksha Sharma
159	20/4/2015	Fire Safety	Jitendra Kummar
160	21/4/2015	HCV Control	Poonam
161	22/4/2015	Vitros - 250 Daily Maintance	Poonam
162	24/4/2015	Vitros-250 Control	Jitendra Kummar
163	25/4/2015	Reagent Maintance	Jitendra Kummar
164	28/4/2015	V-250 Weekly Maintance`	Poonam
165	05-05-2015	Reagen Reconstitution	Jitendra Kummar
166	05-08-2015	Control Reconstitution	Poonam
167	14/5/2015	PV II Reconstitution	Poonam
168	15/5/2015	Lab Saftey	Dr. Samiksha Sharma
169	16/5/2015	NSI	Shalini Jha
170	20/5/2015	Blood Culture Sensitivity	Shalini Jha
171	22/5/2015	Urine R/E	Dr. Anil Sharma
172	25/5/2015	ECI-Daily Maintanance	Poonam
173	25/5/2015	Fluids Run Sysmex -800i	Dr. Anil Sharma
174	26/5/2015	PBF	Dr. Anil Sharma
175	29/5/2015	Quality System Procedure	Dr. Anil Sharma
176	30/5/2015	PT/APTT Quality Control	Dr. Anil Sharma
177	06-04-2015	Aptt	Dr. Anil Sharma
178	06-05-2015	Seman Analysis	Dr. Anil Sharma
179	06-09-2015	Clinical Pathology	Dr. Anil Sharma
180	06-11-2015	Stool R/E Test	Dr. Anil Sharma
181	06-11-2015	KC4 Training	Neeraj
182	06-12-2015	CBC	Dr. Anil Sharma
183	06-12-2015	KC4 Training	Neeraj
184	13/6/2015	Lipid Profile	Dr. Anil Sharma
185	13/6/2015	Horiba Pentra xl 80 operational training	Manish Agarwal
186	13/6/2015	KC4 Training	Neeraj
187	14/6/2015	All Department Complain Log	Poonam
188	15/6/2015	Reticulocyte Count	Dr. Anil Sharma
189	15/6/2015	Lab Saftey	Dr. Samiksha

			Sharma
190	16/6/2015	KC4 Training	Mahesh Soni
191	16/6/2015	Stool R/E Test	Dr. Anil Sharma
192	16/6/2015	Horiba Pentra xl 80 operational training	Manish Agarwal
193	17/6/2015	KC4 Training	Mahesh Soni
194	18/6/2015	KC4 Training	Mahesh Soni
195	18/6/2015	V-250 Daily Maintanance	Poonam
196	19/6/2015	KC4 Training	Mahesh Soni
197	20/6/2015	KC4 Training	Mahesh Soni
198	20/6/2015	Hand Hygine	Vidhya
199	22/6/2015	PBF	Dr. Anil Sharma
200	07-07-2015	Biomedical Waste	Vidhya
201	07-09-2015	Fire Safety	Jitendra Kummar
202	07-11-2015	24 hrs urine protein	Dr. Anil Sharma
203	14/7/2015	Lab Saftey	Dr. Samiksha Sharma
204	15/7/2015	All Department Complain Log	Poonam
205	18/7/2015	Biomedical Waste	Vidhya
206	18/7/2015	V-250 Daily Maintanance	Poonam
207	20/7/2015	Biomedical Waste	Vidhya
208	21/7/2015	Turn Around Time	Dr. Anil Sharma
209	25/7/2015	Liver Function Test	Dr. Anil Sharma
210	28/7/2015	Blood Group Of Rh Typing Test	Dr. Anil Sharma
211	29/7/2015	Seman Analysis	Dr. Anil Sharma
212	30/7/2015	AFB Culture OR Stain	Dr. Anil Sharma
213	31/7/2015	V-250 Daily Maintanance	Dr. Anil Sharma
214	08-02-2015	V-250	Jitendra Kummar
215	08-03-2015	Horiba Pentra xl 80 operational training	Dr. Anil Sharma
216	5/8/2015	CRP V-250	Dr. Anil Sharma
217	7/8/2015	PT INR	Dr. Anil Sharma
218	08-08-2015	CRP Quantative	Dr. Anil Sharma
219	08-08-2015	NSI	Vidhya
220	08-11-2015	V-250 Maintanance	Poonam
221	08-11-2015	Lipid Profile	Dr. Anil Sharma
222	08-12-2015	Standard Precaution	Vidhya
223	08-12-2015	Urine Protein To Creatinine Ratio	Dr. Anil Sharma
224	13/8/2015	Centrifugetion	Dr. Anil Sharma
225	22/8/2015	Complain Log	Poonam
226	24/8/2015	Creatinine Clearence Test	Dr. Anil Sharma
227	24/8/2015	HIV Control Reconstitution	Poonam
228	27/8/2015	KC4 Training	B S Kataria
229	27/8/2015	Leving-Jennings Records	Dr. Anil Sharma
230	28/8/2015	Urine Protein To Creatinine Ratio	Dr. Anil Sharma

231	28/8/2015	Cleaning Of Pentra XL-80	Jitendra Kummar
232	31/8/2015	CBC	Dr. Anil Sharma
233	09-01-2015	Sample Collection Procedure	Dr. Anil Sharma
234	09-02-2015	APTT Examinatiopn	Dr. Anil Sharma
235	09-03-2015	KC4 Control	Poonam
236	09-03-2015	Centrifuge	Dr. Anil Sharma
237	09-03-2015	PT CONTROL	Poonam
238	09-04-2015	sample collection proccess	dr.anil Sharma
239	09-05-2015	new bar chembar	dr.anil Sharma
240	09-07-2015	urine for reducing sub.	dr.anil Sharma
241	09-08-2015	cbc* codes	dr.anil Sharma
242	09-10-2015	LFT	dr.anil Sharma
243	09-11-2015	24 hours urine protein examination	dr.anil Sharma
244	09-12-2015	horiba	dr.anil Sharma
245	14/9/2015	urine routine examination	dr.anil Sharma
246	17/9/2015	Turn Around Time	dr.anil Sharma
247	18/9/2015	Seman Analysis	dr.anil Sharma
248	19/9/2015	Critical Value Information	dr.anil Sharma
249	21/9/2015	fluid for amylase /lipase	dr.anil Sharma
250	22/9/2015	identification of bactrail	dr.anil Sharma
251	23/9/2015	electrolytes	dr.anil Sharma
252	24/9/2015	quality documentation in lab	dr.anil Sharma
253	25/9/2015	bile salt &pigment	dr.anil Sharma
254	26/9/2015	blood film staning	dr.anil Sharma
255	29/9/2015	ECI daily qc plan	dr.anil Sharma
256	30/9/2015	total protein a/g ratio	dr.anil Sharma
257	10-09-2015	quality process (two identifier	dr.anil Sharma
258	13/10/2015	Urine For Bile Salt & Bile Pigment	dr.anil Sharma
259	14/10/2015	identification of micro organisam	dr.anil Sharma
260	15/10/2015	Urine Protein To Creatinine Ratio	dr.anil Sharma
261	16/10/2015	newbar chembar	dr.anil Sharma
262	17/10/2015	blood c/s	dr.anil Sharma
263	19/10/2015	stool for reducing substance	dr.anil Sharma
264	20/10/2015	torch igg/igm	dr.anil Sharma
265	21/10/2015	urine routine exam.	dr.anil Sharma
266	23/10/2015	stool routine exam.	dr.anil Sharma
267	24/10/2015	use of microscope	dr.anil Sharma
268	26/10/2015	hpe process	dr.anil Sharma
269	27/10/2015	L.J. Charting	dr.anil Sharma
270	28/10/2015	blood c/s protocal	dr.anil Sharma
271	29/10/2015	victros 250 daily maintance	dr.anil Sharma
272	11-02-2015	centifuse maintenace	dr.anil Sharma

273	11-03-2015	v-250 training	harkesh Sharma
274	11-03-2015	Seman Analysis	dr.anil Sharma
275	11-04-2015	EQAS-Microbiology	dr.anil Sharma
276	11-05-2015	PT/APTT Exam.	dr.anil Sharma
277	11-06-2015	PBF Precaution	dr.anil Sharma
278	11-07-2015	urine for reducing sub.	dr.anil Sharma
279	11-10-2015	Work Flow Lab	dr.anil Sharma
280	13/11/2015	Serology Positive Protocol	dr.anil Sharma
281	14/11/2015	urine microscope	dr.anil Sharma
282	16/11/2015	LFT	dr.anil Sharma
283	17/11/2015	RBC INDEX	dr.anil Sharma
284	18/11/2015	A/G Ratio	dr.anil Sharma
285	19/11/2015	false Positive /False negative	dr.anil Sharma
286	20/11/2015	LFT	dr.anil Sharma
287	21/11/2015	Serum Creatinine and GFR	dr.anil Sharma
288	23/11/2015	stool for reducing substance &PH	dr.anil Sharma
289	24/11/2015	Serum electrolytes	dr.anil Sharma
290	25/11/2015	Urine routine	dr.anil Sharma
291	26/11/2015	APTT	dr.anil Sharma
293	27/11/2015	Kidney function test	dr.anil Sharma
294	28/11/2015	CSF Grams Stain	dr.anil Sharma
295	30/11/2015	Vit. B12	dr.anil Sharma
296	12-01-2015	Lipid Profile	dr.anil Sharma
297	12-02-2015	LFT	dr.anil Sharma
298	12-03-2015	24 hours urine protein examination	dr.anil Sharma
299	12-04-2015	P.S.A.	dr.anil Sharma
300	12-05-2015	Rapid Test	dr.anil Sharma
301	12-07-2015	Sample Collection Protocol	dr.anil Sharma
302	12-08-2015	victros 250 daily maintance	dr.anil Sharma
303	12-09-2015	measurement	dr.anil Sharma
304	12-10-2015	Lipid Profile	dr.anil Sharma
305	12-11-2015	Bilirubin	dr.anil Sharma
306	12-12-2015	Lipid Profile	dr.anil Sharma
307	14/12/2015	LFT	dr.anil Sharma
308	15/12/2015	URINE EXAMINATION	dr.anil Sharma
309	16/12/2015	STOOL FOR OCCULT BLOOD	dr.anil Sharma
310	17/12/2015	PBF	dr.anil Sharma
311	18/12/2015	newbar chembar	dr.anil Sharma
312	19/12/2015	Blood C/S	dr.anil Sharma
313	21-12-2015	Urine Protein To Creatinine Ratio	Dr. Anil Sharma
314	22-12-2015	CV%	dr.anil Sharma
315	23-12-2015	CSF Grams Stain	dr.anil Sharma

316	24-12-2015	urine c/s	dr.anil Sharma
317	26-12-2015	C.B.C run	dr.anil Sharma
318	28-12-2015	HIV Protocal/ NACO	dr.anil Sharma
319	29-12-2015	serum K+	dr.anil Sharma
320	30-12-2015	T3, T4,T5	dr.anil Sharma
321	31-12-2015	critical Value	dr.anil Sharma
322	01-01-2016	PT-INR test procedure	dr.anil Sharma
323	02-01-2016	PBF (peripheral smear examination	dr.anil Sharma
324	04-01-2016	stool (occuct blood)	dr.anil Sharma
325	05-01-2016	Urine Protein To Creatinine Ratio and bio red OC	dr.anil Sharma
326	06-01-2016	critical value/ stock inventory	dr.anil Sharma
327	07-01-2016	widal test	dr.anil Sharma
328	09-01-2016	serum potassium	dr.anil Sharma
329	11-01-2016	immunochromatography	dr.anil Sharma
330	12-01-2016	Centrifuge Maintance	dr.anil Sharma
331	13-01-2016	sample collecton order of draw	dr.anil Sharma
332	14-01-2016	stool RE/OB	dr.anil Sharma
333	16-01-2016	electrolytes	dr.anil Sharma
334	18-01-2016	LFT	dr.anil Sharma
335	19-01-2016	Lipid Profile	dr.anil Sharma
336	20-01-2016	bacterial c/s	dr.anil Sharma
337	21-01-2016	Urine R/E	dr.anil Sharma
338	22-01-2016	mantoux test	dr.anil sharma / jeetendra kumar
339	23-01-2016	Liver Function Test	dr.anil Sharma
340	25-01-2016	peripheral blood semen	dr.anil Sharma
341	27-01-2016	GTT	dr.anil Sharma
342	29-01-2016	semen analysis	dr.anil Sharma
343	30-01-2016	urine routine examination	dr.anil Sharma
344	01-02-2016	semen analysis	dr.anil Sharma
345	02-02-2016	quality manual	dr.anil Sharma
346	03-02-2016	PT-INR test procedure	dr.anil Sharma
347	04-02-2016	BT/CT process	dr.anil Sharma
348	05-02-2016	quality documentation in lab	dr.anil Sharma
349	06-02-2016	prothrombin time	dr.anil Sharma
350	08-02-2016	APTT	dr.anil Sharma
351	09-02-2016	Lipid Profile	dr.anil Sharma
352	10-02-2016	Blood Group Of Rh Typing Test	dr.anil Sharma
353	12-02-2016	urine r/e	dr.anil Sharma
354	13-02-2016	Seman Analysis	dr.anil Sharma
355	15-02-2016	H and E satin	dr.anil Sharma
356	16-02-2016	urine c/s	dr.anil Sharma
357	17-02-2016	CBC QC	dr.anil Sharma

358	18-02-2016	Urine C/S	dr.anil Sharma
359	19-02-2016	CAPD fluid routine examination	dr.anil Sharma
360	20-02-2016	L.F.T test	dr.anil Sharma
361	22-02-2016	NABL- quality control document	dr.anil Sharma
362	23-02-2016	urine for BS/BP	dr.anil Sharma
363	24-02-2016	GTT	dr.anil Sharma
364	25-02-2016	stool routine / blood examination	dr.anil Sharma
365	26-02-2016	biomedical Waste management	dr.anil Sharma
366	27-02-2016	blood culture	dr.anil Sharma
367	29-02-2016	internal audit	dr.anil Sharma
368	01-03-2016	Lipid Profile	dr.anil Sharma
369	02-03-2016	NABL/ DOC	dr.anil Sharma
370	03-03-2016	BMW	dr.anil Sharma
371	04-03-2016	Serum electrolytes	dr.anil Sharma
372	08-03-2016	HIV protocol	dr.anil Sharma
373	08-03-2016	Q.C. run	jeetendra kumar ji
374	09-03-2016	blood c/s	dr.anil Sharma
375	11-03-2016	haematology- CBC	dr.anil Sharma
376	12-03-2016	bile pigment circulation	dr.anil Sharma
377	14-03-2016	Lipid Profile	dr.anil Sharma
378	15-03-2016	KCU- quality control	dr.anil Sharma
379	22-03-2016	CBC	dr.anil Sharma
380	23-03-2016	urine protein ratio	dr.anil Sharma
381	25-03-2016	HIV protocol	dr.anil Sharma
382	26-03-2016	horiba 120 daily maintainance and concentrate cleaning	dr.anil Sharma
383	28-03-2016	total thyroid level	dr.anil Sharma
384	29-03-2016	CSF C/S	
385	29-03-2016	simens (dimensions RC may)	Er. Rohit
386	30-03-2016	GTT	Dr. Anil Sharma
387	30-03-2016	siemens (dimensions RI max)	Er. Rohit
388	30-03-2016	siemens (advanced)	Er. Rohit
389	31-03-2016	CBC in ITU	Dr. Anil Sharma
390	01-04-2016	Use of Centrifuge	Dr. Anil Sharma
391	02-04-2016	NABL documents	Dr. Anil Sharma
392	04-04-2016	PT. INR. APTT	Dr. Anil Sharma
393	05-04-2016	urine routine examination	Dr. Anil Sharma
394	07-04-2016	fluid run RGN/ HORIBA	Dr. Anil Sharma
395	09-04-2016	operation training on destiny plus	vineet bhati
396	09-04-2016	QSP	Dr. Anil Sharma
397	11-04-2016	sputum C/S	Dr. Anil Sharma
398	12-04-2016	Basic training on destiny plus	B.S katarya
399	13-04-2016	destiny plus	B.S katarya

400	14-04-2016	blood C/S BACTEC	Dr. Anil Sharma
401	16-04-2016	zeel nelson stain	Dr. Anil Sharma

2.JOB DESCRIPTION:

A **job description** is a list that a person might use for general tasks, or functions, and responsibilities of a position.

The work of the staff is designed taking into account of their duties and responsibilities according to the guidelines given by ISO 15189, 2012.

LABORATORY COORDINATOR (LC) & CHIEF EXECUTIVE OF LABORATORY

- Authorized to release Quality Manual.
- Responsible for all documents, including those maintained in a computerized system, issued as part of the quality management system shall be reviewed and approved by Laboratory Coordinator before issue.
- Person(s) with responsibility for, and authority over, a laboratory.
- The responsibilities of the laboratory coordinator shall include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory.
- Responsible to delegate selected duties and /or responsibilities to qualified personnel; however, the laboratory coordinator shall maintain the ultimate responsibility for the overall operation and administration of the laboratory.
- The laboratory coordinator shall have the necessary competence, authority and resources in order to fulfill the requirements of this International Standard.
- The laboratory coordinator shall provide effective leadership of the medical laboratory service.
- LC shall relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements when required;
- LC shall ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users;
- LC shall ensure the implementation of the quality policy;
- LC is responsible to implement a safe laboratory environment in compliance with good practice and applicable requirements;
- LC shall serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate;
- LC shall ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results;
- LC shall assist in Selection and monitoring of laboratory suppliers;
- LC is responsible to select referral laboratories and monitor the quality of the service.

- Responsible to provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations;
- Responsible to define; implement and monitor standards of performance and quality improvement of the medical laboratory service or services;
- Shall monitor all work performed in the laboratory to determine that clinically relevant information is being generated;
- Responsible to address any complaint, request or suggestion from staff and/or users of laboratory services.
- Responsible to ensure that essential services are available during emergency situations.
- Assist Quality Manager Responsible for conducting Management reviews.

QUALITY MANAGER

- Responsible to prepare the Quality Manual of the Laboratory Quality System.
- Authority to alter manual rests with the Quality Manager only.
- Responsible to ensure that processes needed for the quality management system are established, implemented and maintained;
- Responsible to laboratory management, at the level at which decisions are made on laboratory policy, objectives and resources, on the performance of the quality management system and any need for improvement;
- Responsible to ensure the promotion of awareness of users' needs and requirement throughout the laboratory organization.
- Responsible to plan and organize annual internal audits to ensure compliance with the Quality Management System and all sections of the laboratory including pre-examination, examination and post examination conform to the requirements of ISO 15189:2012 and to requirements established by the laboratory, and are implemented, effective, and maintained.
- Responsible to address and correct any nonconformity identified within agreed upon time.
- QM shall assume final responsibility for resolution of nonconformities.
- Shall determine the medical significance of nonconformity and, if necessary, keep the requesting clinician informed.
- Responsible for conducting Management review meetings apart from other departmental meetings and training programmes.

TECHNICAL MANAGER

- Overall responsible for technical operations of the laboratory as a whole or its sub-section their off and provision of resources to ensure the required quality.
- Assisting in accreditation systems relating to laboratory accreditation as per ISO/ IEC 17025 and ISO 15189.
- Responsible in helping management of NABL in development and maintaining an information system for accreditation operations.
- Interact with various external and internal personnel/bodies for continuing regular function.
- Organize and assist in organizing different awareness programs on laboratory accreditation.
- Responsible for attend Management reviews and other departmental meetings and trainings.

DEPUTY TECHNICAL MANAGER

- Responsible to assist Technical Manager for technical operations of the laboratory as a whole or its sub-section their off and provision of resources to ensure the required quality.
- Assisting in accreditation systems relating to laboratory accreditation as per ISO/ IEC 17025 and ISO 15189.
- Responsible in helping management of NABL in development and maintaining an information system for accreditation operations.
- Assisting Technical Manager in interacting with various external and internal personnel/bodies for continuing regular function.
- Responsible in assisting , organizing and coordinating different awareness programs on laboratory accreditation.
- Responsible for attend Management reviews and other departmental meetings and trainings.

DEPUTY QUALITY MANAGER

- Assist Quality manager in issuance of Quality Manual of the Laboratory Quality System.
- Assist Quality Manager in ensuring that processes needed for the quality management system are established, implemented and maintained;
- Responsible to laboratory management, at the level at which decisions are made on laboratory policy, objectives and resources, on the performance of the quality management system and any need for improvement;
- Responsible to ensure the promotion of awareness of users' needs and requirement throughout the laboratory organization.
- Responsible to assist Quality Manager in planning and organizing annual internal audits to ensure compliance with the Quality Management System and all sections of the laboratory including pre-examination, examination and post examination conform to the requirements of ISO 15189:2012 and to requirements established by the laboratory, and are implemented, effective, and maintained.
- Deputy QM shall be responsible to investigate the non conformity and report their findings to QM.
- Responsible in assisting Quality Manager to address and correct any nonconformity identified within agreed upon time.
- Responsible for attend Management reviews and other departmental meetings and trainings.

3. INSTRUMENTS:

There are different types of instruments used in laboratory .

Documentation for the instruments includes:

- Asset form
- Installation report
- Invoice
- Preventive maintenance
- Calibration reports

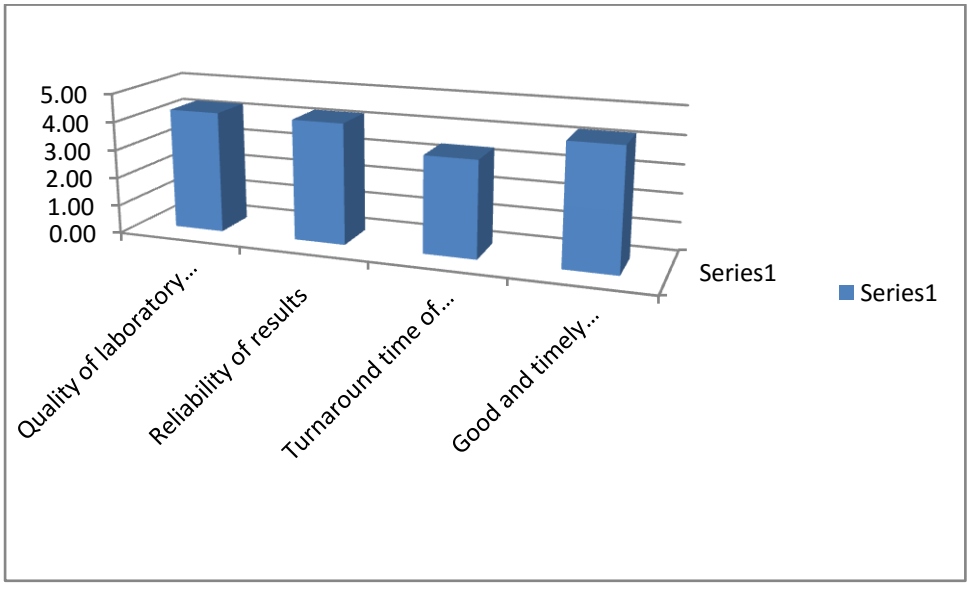
s. no	Name	sr.no
1	analyzers,lab, mmunology automated	R3100368
2	Scales	758539
3	blood mixer lab	1182
4	centrifuges, tabletop	Zban-01331
5	analyzers,lab, hematology,coagulation, semiautomated	10121906*
6	analyzers,lab, hematology,cell counter,automated	502pxl6628
7	sterlizing unit, steam, tabletop	839645*
8	counters cell differential	527805*
9	analyzers lab immuno automated	30001726
10	analyzers lab clinical chemistry automated	25014906
11	analyzers lab clinical chemistry automated	25010717
12	microscopes, light, lab	I10h054
13	microscopes, light, lab	I10h072
14	microscopes, light, lab	I10h075
15	incubators lab, thermocycling	20
16	Pipettes	Fj82602
17	Pipettes	Gh90453
18	Pipettes	Fj78998
19	Pipettes	Fj71333
20	centrifuges, tabletop	Gflc-8533
21	incubators lab, thermocycling	21
22	hot air oven	1869
23	blood mixer lab	2981
24	cabinets biological safety	2642
25	centrifuges, tabletop	Ghlc-10877
26	analyser heamatology	509pdx0183
27	test tube roller lab	2051391836
28	Pipettes	Fk20111
29	Pipettes	Fj82041

30	Pipettes	Gh64391
31	Pipettes	Gh79549
32	analyser lab, clinical chemistry, automated	222683-ax
33	analyzer lab, immunology, automated	Rob30002171
34	analyzers lab, hematology,coagulation, automated	Tcoag

4.FEEDBACK ANALYSIS:

Feedback analysis is done So that advice of the consulting doctors can advise on choice of examinations and use of services, individual clinical cases, can give professional judgement on the interpretation of the results of examinations, etc and help to improve services given by the laboratory.

s.no	Subject	Average score
1	**Quality of laboratory Investigation results**	4.29
2	**Reliability of results**	4.26
3	**Turnaround time of investigation**	3.40
4	**Good and timely responsiveness**	4.26



Reference:

- ISO Website:: http://www.iso.org/
- NABL website: http://www.nabl-india.org/
- Quality manual of NH, jaipur

LIST OF ABBREVIATIONS

JCI- joint commission international

OT- Operation theatre

TPA- Third party administrator

ICU-Intensive care Unit

MICU-Medical intensive care unit

SICU-Surgical Intensive care unit

MRN –Medical Record Number

AO – Admission Officer

HK – House Keeping

MGW- male general ward

FGW- female general ward

CTVS- cardio thoracic vascular system

MMW-male medical ward

PVT- private ward

SEMI PVT- semi private ward

HDU- high deficiency ward

ANC- antenatal care ward

CCU- Coronary care unit

CATH LAB- catheterization lab

PICU- paediatric intensive care unit

NICU- neonatal intensive care unit

F&B- food and beverages

KTU- kidney transplant unit

CSSD- central sterile supply department

QSP-Quality supply procedure