NABL 112

NABL

NATIONAL ACCREDITATION
BOARD FOR TESTING AND
CALIBRATION LABORATORIES

SPECIFIC CRITERIA *for* ACCREDITATION OF MEDICAL LABORATORIES

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AMENDMENT SHEET

Sl	Page No.	Clause No.	Date of Amendment	Amendment Made	Reasons	Signature QO	Signature Director
1	35/45	6	01.09.2008	Guidelines & Checklist for Operating Collection Centres and page numbers changed subsequently	Improvement on concern raised by APLAC Evaluation		
2	37/45	6	02.07.2012	Sampling plan assessment of collection centre	Withdrawal of NABL 023		
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PREFACE

Specific Criteria for Accreditation of Medical Laboratories (NABL 112) Issue No. : 02 was prepared by a Technical Committee, in accordance with ISO 15189:2003, and issued on 11.05.2005. Thereafter, Issue No. : 02 has gone through a few amendments. This document, Issue No. : 03 has been brought to align NABL 112 with the second edition of 15189, version 2007.

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ABBREVIATIONS

AERB	-	Atomic Energy Regulatory Board
APLAC	-	Asia Pacific Laboratory Accreditation Cooperation
AS	-	Australian Standards
ASTM	-	American Society for Testing & Materials
BARC	-	Bhabha Atomic Research Centre
CBC	-	Complete Blood Count
CLSI	-	Clinical & Laboratory Standards Institute
CSF	-	Cerebrospinal Fluid
CV	-	Coefficient of Variation
DNA	-	Deoxyribo Nucliec Acid
EDTA Acid	-	Ethylene Diamine Tetra Acetic Acid
ELISA	-	Enzyme Linked Immunosorbent Assay
EM	-	Electron Microscopy
EQAS	-	External Quality Assessment Scheme
ESR	-	Erythrocyte Sedimentation Rate
FNA	-	Fine Needle Aspiration
FNAC	-	Fine Needle Aspiration Cytology
GUM	-	Guide to the Expression of Uncertainty in Measurement
h	-	Hour(s)
H&E Staining	-	Haematoxylin & Eosin Staining
HBV	-	Hepatitis B Virus
HIV	-	Human Immunodeficiency Virus
HLA	-	Human Leukocyte Antigen
HPLC	-	High Performance Liquid Chromatography
ICSH	-	International Council for Standardization in Haematology
ILAC	-	International Laboratory Accreditation Cooperation
INR	-	International Normalized Ratio
ISO	-	International Organization for Standardization
LJ Chart	-	Levy-Jehning Chart
LJ Medium	-	Lowenstein – Jensen Medium

MCH	-	Mean Corpuscles Haemoglobin
MCV	-	Mean Corpuscles Volume
MNPT	-	Mean Normal Prothrombin Time
MRA	-	Mutual Recognition Arrangement
NACO	-	National AIDS Control Organization
NCCLS	-	National Committee for Clinical Laboratory Standards
NIH	-	National Institute of Health
PAP Staining	-	Papanicolaou Staining
PCR	-	Polymerase Chain Reaction
QBC	-	Quantitative Buffy Coat
QC	-	Quality Control
RBC	-	Red Blood Cells
RIA	-	Radio Immuno Assay
RTPCR	-	Real Time Polymerase Chain Reaction
SD	-	Standard Deviation
UV	-	Ultra Violet
WBC	-	White Blood Cells
WHO	-	World Health Organization

1. INTRODUCTION

Laboratory accreditation activities are administered under the direction of the National Accreditation Board for Testing and Calibration Laboratories (NABL), involving Assessment Team and Accreditation Committee as recommending bodies. NABL is a signatory to Asia Pacific Laboratory Accreditation Cooperation (APLAC) and International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangements (MRA). These are based on mutual evaluation and acceptance of other MRA partner laboratory accreditation systems. Such international arrangements allow acceptance of test/ calibration results between MRA partner countries.

The laboratories are required to comply with all the requirements listed in the international standard ISO 15189:2007 (Medical laboratories - Particular requirements for quality and competence).[1] The Specific Criteria document must be used in conjunction with ISO 15189. It provides an interpretation of the latter document and describes specific requirements for those clauses of ISO 15189 which are general in nature. Further, the laboratory shall follow the national, regional and local laws and regulations as applicable.

2. SCOPE

The scope of the accreditation is applicable to the following medical laboratory services:

i. Clinical Biochemistry
ii. Clinical Pathology
iii. Haematology and Immunohaematology
iv. Microbiology and Serology
v. Histopathology
vi. Cytopathology
vii. Genetics
viii. Nuclear Medicine (*in-vitro* tests only)

Note: Immunological techniques are common to many disciplines. Therefore, the immunological tests can be listed under respective disciplines.

The accreditation shall be considered only for those tests, which the laboratory is in itself equipped and competent to carryout. In case of Histopathology, however, a laboratory may use the services of another NABL-accredited laboratory for tissue processing (block making, sectioning and staining). The reporting laboratory itself nonetheless, shall perform gross examination and tissue sampling. To be eligible for accreditation for Histopathology and Cytopathology, a laboratory should receive at least 300 specimens every year.

The facility for primary sample collection at sites other than its main laboratory shall also comply with the relevant requirements of ISO 15189. A representative sample of these facilities shall be assessed by NABL for their compliance with the requirements.

3. DESCRIPTION AND TYPE OF LABORATORY

The requirements given in this document are applicable to all medical laboratories applying for NABL accreditation regardless of the level at which they function (small/ medium/ large) or the place in which they are located (village/ district/ city) or whether they are private/ government/ quasi-government attached to a hospital/ stand-alone. Following classification shall be used for determining fee structure:

Small Laboratory: A laboratory receiving up to 100 patients per day

Medium Laboratory: A laboratory receiving up to 101-400 patients per day

Large Laboratory: A laboratory receiving above 400 patients per day

4. MANAGEMENT REQUIREMENT

4.1 Organization and management

(The main text of this clause is the text of the same clause of ISO 15189:2007)

A laboratory operating at more than one location within a city having the same legal identity will be considered as a single laboratory and will be issued a single certificate. However, if the laboratory requires separate certificates for individual locations, the application for accreditation should be submitted separately for each location. The laboratory operating at more than one location having separate legal identities will be treated as independent laboratories even though they are part of same the organization.

The laboratory having same legal identity but operating in different cities will be treated as independent laboratories even though they are part of the same organization.

4.2 Quality management system

(The main text of this clause is the text of the same clause of ISO 15189:2007)

4.3 Document control

(The main text of this clause is the text of the same clause of ISO 15189:2007)

4.4 Review of contracts

(The main text of this clause is the text of the same clause of ISO 15189:2007)

4.5 Examination by referral laboratories

(The main text of this clause is the text of the same clause of ISO 15189:2007)

Laboratory shall have documented policy and procedure for selecting and referring tests to other laboratories and for second opinion to consultants. The accredited tests can be referred only to a laboratory accredited by NABL or its MRA partner. In the test report the accredited laboratory shall specify the name of referral laboratory and identify the tests performed and the results obtained by such referral laboratory.

4.6 External services and supplies

(The main text of this clause is the text of the same clause of ISO 15189:2007)

Each lot of reagents shall be checked against earlier tested in-use reagent lots or with a suitable reference material before being placed in service and the results should be recorded. Each lot of antibiotic sensitivity discs shall be checked for activity/ potency before being placed in service.

4.7 Advisory Services

(The main text of this clause is the text of the same clause of ISO 15189:2007)

4.8 Resolution of complaints

(The main text of this clause is the text of the same clause of ISO 15189:2007)

4.9 Identification and control of nonconformities

(The main text of this clause is the text of the same clause of ISO 15189:2007)

4.10 Corrective action

(The main text of this clause is the text of the same clause of ISO 15189:2007)

4.11 Preventive action

(The main text of this clause is the text of the same clause of ISO 15189:2007)

4.12 Continual improvement

(The main text of this clause is the text of the same clause of ISO 15189:2007)

The laboratory must have the comprehensive program for Quality Improvement, which shall incorporate salient quality indicators for monitoring laboratory's performance. This shall describe the evaluation of various aspects such as, but not limited to, the following

- sample collection and identification
- transportation and processing
- analysis and reporting of results
- turnaround time

- complaints
- equipment downtime
- uncertainty of measurements (monthly % CV)
- performance in EQAS

4.13 Quality and technical records

(The main text of this clause is the text of the same clause of ISO 15189:2007)

The laboratory shall decide the retention time of records as per the national, regional and local regulations. However, NABL requires following minimum retention time for ensuring the quality service and patient care:

Particle Cell counter data	– one week
Molecular diagnostic gel pictures	– 5 years
Flow cytometry/ Immunophenotyping data	– 6 months (values only)
Electrophoretogram	– 1 year
Haemoglobin HPLC data	– 1 year
Coagulation calibration/ standard graph	– 1 week
Table/ chart of daily values of internal quality control	– 1 year

The minimum period for retention of test reports issued shall be 5 years for Histopathology and Cytopathology and 1 year for other disciplines.

4.14 Internal audits

(The main text of this clause is the text of the same clause of ISO 15189:2007)

4.15 Management review

(The main text of this clause is the text of the same clause of ISO 15189:2007)

5. TECHNICAL REQUIREMENT

5.1 Personnel

(The main text of this clause is the text of the same clause of ISO 15189:2007)

5.1.1 Personnel

The authorized signatories shall demonstrate knowledge and competence in the concerned specialty.

5.1.1.1 Qualification norms for Director/ Chairman/ Head (howsoever named)

Same qualifications as given in 5.1.1.2 with 5 years experience

5.1.1.2 Qualification norms for authorized signatories (Refer Annex – I for routine and special tests) are given in Table 1.

Table 1

Sl. No.	Qualifications	Disciplines for being authorized signatory
A	M.D. (Pathology)	Histopathology, Cytopathology, Clinical Pathology, Haematology, Clinical Biochemistry, Nuclear Medicine (*in-vitro* tests), routine Microbiology and Serology, Genetics, Flow Cytometry and Molecular Biology
B	M.D. (Microbiology)	Microbiology and Serology, Flow Cytometry, Molecular Biology, Clinical Pathology, routine Haematology and routine Biochemistry
C	Ph.D. (Microbiology) with M.Sc. (Medical Microbiology)	Microbiology and Serology, Clinical Pathology, Flow Cytometry, Molecular Biology
D	M.D. (Biochemistry)	Clinical Biochemistry, Clinical Pathology, Nuclear Medicine (*in-vitro* tests), Flow Cytometry, Molecular Biology, Routine Haematology, Routine Microbiology and Serology
E	Ph.D. (Biochemistry) with M.Sc. (Biochemistry)	Clinical Biochemistry, Clinical Pathology, Nuclear Medicine (*in-vitro* tests), Flow Cytometry, Molecular Biology

Sl. No.	Qualifications	Disciplines for being authorized signatory
F	M.S. (Anatomy)/ Ph.D. with M.Sc. (Human Anatomy)/ Ph.D. (Genetics)/ Ph.D. (Applied Biology)	Genetics
G	Medical Degree with specialized (post graduate) qualification in nuclear medicine such as Diploma in Radiation Medicine (DRM), M.D./ Ph.D./ M.Sc. in Nuclear Medicine	Nuclear Medicine. It is necessary that the person concerned holds a certificate from BARC on the use of radioisotopes and RIA, this is the mandatory requirement of AERB
H	M. D. in Lab Medicine	Clinical Pathology, Haematology, Clinical Biochemistry, Nuclear Medicine (*in-vitro* tests), routine Microbiology and Serology
I	DCP with 7 years experience	Histopathology, Cytopathology, Clinical Pathology, Haematology, Clinical Biochemistry, Nuclear Medicine (*in-vitro* tests), routine Microbiology and Serology
J	MBBS with three years experience in medical laboratory	Routine Clinical Biochemistry, routine Haematology, routine Microbiology and Serology, and Clinical Pathology.
K	M.Sc. in Medical Biochemistry with 5 years experience or M.Sc. in Biochemistry with 7 years experience in Medical laboratory	Clinical Biochemistry, Clinical Pathology, routine Haematology, routine Microbiology and Serology.

Sl. No.	Qualifications	Disciplines for being authorized signatory
L	M.Sc. in Medical Microbiology with 5 years experience or M.Sc. in Microbiology with 7 years experience in Medical laboratory	Microbiology and Serology, Clinical Pathology, routine Clinical Biochemistry, routine Haematology.

Note: 1. *DNB is equivalent to M.D./M.S. in the respective discipline as stated above.*

2. *D.M. in Haematological disciplines can be a supervisor and authorized signatory for Haematological tests, Flow Cytometry and Molecular Biology.*
3. *NABL may relax qualifications in those exceptional cases where persons have demonstrated competence and established their credentials.*

In addition to the above, the persons supervising and performing the following tests should demonstrate evidence of adequate training, competence and experience: bone marrow examination, tests for coagulation, flow cytometry, molecular biology, karyotyping, HLA typing and special biochemistry.

5.1.1.4 Qualification norms for technical staff

The technical person performing the tests should have one of the following qualifications:

a. Graduate in Medical Laboratory Technology
b. Diploma in Medical Laboratory Technology with the course of at least two years duration
c. Diploma/ certificate in Medical Laboratory Technology with the course of at least one year duration and two years of experience in a medical laboratory.
d. Graduate in Science with one year experience in a medical laboratory.
e. Diploma in medical radiation and radioisotope technology (DMRIT)
f. Cytotechnologist – ‘a, b, c and d’ with additional certification in cytotechnology by the Indian Academy of Cytology for screening of exfoliative cytology.
g. A laboratory may employ up to 25 % of the staff with science in matriculation having at least 10 years experience in a medical laboratory.

Note:

i. The qualifications and experience for the phlebotomist shall be same as above. In addition, trained nurses may collect blood samples.

ii. The laboratory shall have a system of imparting necessary training to technical staff at various levels. There shall be a system so that a technical person receives adequate training in the operation of new analytical equipment and/ or performance of new test before he/ she is assigned such work.

5.2 Accommodation and environmental conditions

(The main text of this clause is the text of the same clause of ISO 15189:2007)

Towards effectiveness of operations, the laboratory shall ensure adequate space in relation to the following:

- Patient reception
- Sample collection
- Workbench
- Equipment
- Storage of volatile and inflammable reagents
- Radioisotope related work as per the regulatory agency (AERB) requirement
- Washing
- Isolation for biohazardous materials

The laboratory should have adequate lighting, power plugs and uninterrupted power supply. The use of exposed cables should be minimum.

The laboratory shall ensure that adequate electrical service is available so that there is no interruption in power supply that may lead to compromise of stored data. All computers, peripherals, equipments and communication devices should be supported in such a way that service is not likely to be interrupted. The laboratory shall have procedures in place to ensure the integrity of refrigerated and/or frozen stored samples/reagents/consumables in the event of an electrical failure.

The accommodation and environmental conditions are also applicable to primary sample collection facilities at sites other than the permanent laboratory facility.

Histopathology - Electron Microscopy

A. A separate room shall be allotted for tissue processing with a fume hood for handling osmium tetroxide.

B. A separate dust-free facility, with air-conditioning shall be available for preparation of specimen and performing electron microscopy.

C. The electron microscopy room shall have:

   i. facilities in place for temperature control and chilled water supply

   ii. insulated cabling kept away from the work areas

   iii. proper seating available to allow for optimal ergometric positioning of the person using the microscope

   iv. dark room with adequate ventilation.

   v. warning light on the door of the dark room indicating usage.

Cytopathology

The laboratory shall have a dedicated space for FNAC procedure.

5.3 Laboratory equipment

(The main text of this clause is the text of the same clause of ISO 15189:2007)

All reagents, consumables, stains, media, kits and antimicrobials should be stored as recommended by the manufacturer and used within their indicated expiry dates. The label should bear the following information: content and quantity, concentration or titer, date received/prepared, date of opening, storage requirements and expiry dates, wherever applicable.

The laboratory shall use adequate controls for reagents, stains, media, kits, antimicrobials, etc to check their performance where a built-in control does not exist. For use of commercial reagents and controls manufacturer's instructions should be complied. All reagents/ stains/ media/ kits/ antimicrobial discs shall be procured from standard reputed sources. Each lot of reagents shall be checked against earlier tested in-use reagent lots or with suitable reference material before being placed in service and the results should be recorded. Each lot of antibiotic sensitivity discs should be checked for activity/potency before being placed in service and at least weekly thereafter with reference strains. Reusable specimen containers should

be inspected regularly, especially the caps of bottles and tubes for missing or worn out liners. Anaerobic jars, autoclaves and hot air oven should be checked by chemical and/or biological controls.

For policy on calibration and traceability of measurements NABL 142 shall be followed. The equipment shall be calibrated from NPL, India or NABL accredited calibration laboratory or accredited by its MRA partners having accreditation for the specific scope.

In the case of analytical systems such as automated analyzers the frequency of calibration shall refer to the manufacturer's guidelines. The laboratory shall have a written procedure for calibration of automated instruments. All automated analytical systems such as cell counters, clinical biochemistry autoanalyzers, automated coagulometers and ELISA readers etc., shall be calibrated at least once a year.

Many types of equipment may be calibrated in-house by using reference materials or comparative techniques. In such cases, reference materials should demonstrate traceability to SI units or the appropriate measurement standards.

Automated haematology analyzers should be calibrated using 'calibrators' provided by the manufacturers. Controls often lack absolute accuracy and are not recommended for use as calibrators. Sometimes, however, calibrators are not readily available and controls with assigned values may have to be used as calibrators. In such cases the laboratory must ensure that the values of the controls have been assigned reliably by a reference method.[2]

Certain items of equipment may be calibrated by laboratory itself without the service of external calibration bodies, provided the laboratories have the necessary reference standards and materials and such calibration procedures do not demand specialist techniques which are outside the capabilities and experience of the laboratory staff.

The nominal maximum periods between successive calibrations of general equipment are illustrated in Table 2.

It must be stressed that these calibration intervals depend upon:

a. Ruggedness of the equipment
b. Frequency of use
c. Life of the equipment
d. Quality and periodicity of maintenance, etc.,

Table 2: Calibration requirements

Item	Maximum period between successive calibration & checks	Procedure and comments
Autoclaves	One year	*Check on effectiveness of sterilization with each cycle
Balances and scales	One year	Balances with in-built calibration check facility must also have six monthly checks Electronic balances with more than one range must have six monthly checks carried out on all ranges Checks include repeatability checks and one-point check using a known mass close to balance capacity
Biological safety cabinet	One year	*Colony count at least once in a week
Centrifuge	Every six months (where operating speed is specified)	Tachometer (mechanical stroboscope or light cell type) calibration of the timing device and, where appropriate, the temperature measurement device will be required. In addition, performance testing is recommended for specific applications.
Manometers: Reference Working	Five years One year	Check Fluid every three years Check against reference
Masses	One year	ASTM E617
Piston-operated volumetric apparatus pipettes and dispensers	Initial and every six months	AS 4163 For gravimetric checks, volume delivery and weighing under specified conditions must be repeated at least ten times. For adjustable devices check volume delivered at several settings. Delivery of volumes less than 100 microlitre may be verified by spectrometry using a dye solution.

Item	Maximum period between successive calibration & checks	Procedure and comments
Diluters	Six months	*Check volume delivered at settings in use. Check sample and diluent volumes or dilution ratio and total volume
Thermometers Working (Liquid in glass, resistance, electronic)	One year	Check against a calibrated reference * Initial check at sufficient points to cover the expected working range followed by six monthly checks at ice-point within the working range

* Calibrations commonly performed by laboratory staff

The following is the list of analytical instruments that can be calibrated primarily in-house by use of certified reference materials traceable to national/international standards

pH meter

Calibrate on use with at least two standard buffer solutions appropriate to the expected pH of the sample being tested. A record of the calibration must be kept.

Spectrophotometer and colorimeter

Calibration checks on all spectrophotometers or colorimeters shall be performed at six months interval. Such calibration shall include checks on absorbance, linearity, matching of cells and must be carried out in accordance with the manufacturer's instructions and/or appropriate procedures using standard/reference materials. A blank and at least two points on the calibration curve must also be checked. These calibrations should be compared over time to detect any system deterioration.

Chromatograph

a. Gas chromatograph: performance shall be routinely monitored during use with certified reference materials.
b. Liquid chromatograph, including high performance liquid chromatograph (HPLC): The total system must be monitored during use with certified reference materials. Loss of efficiency may be detected by chronological comparison of reference material measurements. System components (e.g. pumping system and detectors) shall be subject to periodic checks and details shall be recorded.

Electrophoresis

Instrument performance shall be routinely monitored during use with appropriate controls. System components (e.g. electrodes, tank and power supply), must be checked periodically.

Microscopes

Regular cleaning and maintenance of microscopes is essential for satisfactory operation. The stage and lenses shall be cleaned after use and maintenance and servicing shall be carried out by competent personnel.

Temperature-controlled equipment

The performance of temperature-controlled equipment such as water baths, incubators, ovens and refrigerators etc., shall be monitored routinely to ensure compliance with the temperature requirements of test methods. Accordingly, daily recorded checks of the temperature within the load space of these items of equipment shall be maintained. The use of continuous temperature monitors is strongly recommended where temperature control is critical. The thermometers used to monitor the performance of temperature-controlled equipment shall be of sufficient accuracy to ensure that this equipment complies with the temperature tolerances specified in the test methods. The spatial distribution of temperatures throughout the load space of temperature-controlled equipment shall be checked following installation of equipment and at appropriate intervals thereafter. Temperature recording devices shall be checked at six monthly intervals against a reference thermometer and the results recorded.

Microbiology

A separate biological safety cabinet, certified at least annually to ensure that filters are functioning properly and that air flow rates meet specifications, must be available for mycobacteriological work and for mycological work.

The laboratory performing fungus culture shall be equipped with heating and cooling (BOD) incubator to meet with the environmental conditions for the isolation of fungi.

Media

Laboratory shall ensure that in-house prepared media are sterile, able to support growth and are appropriately reactive bio-chemically. Therefore, the laboratory must maintain the stock of reference organisms. These should be used to test the media. Blood-based media shall be prepared using appropriate animal blood procured from an authorized source.

Reagents/ Kits/ Antibiotic discs

Stains and reagents must be labeled, dated and stored properly and not used beyond their expiry date or if they show signs of deterioration, such as abnormal turbidity and/or discoloration. At regular intervals and whenever new stain is prepared, control smears should be stained.

Appropriate controls should be used for all stains as per the following table:

Stain	**Control Organism/ material**	**Expected result**
Ziehl-Neelsen	*Mycobacterium sp.* *Escherichia coli*	Pink red bacilli Blue bacilli
Acridine Orange	*Escherichia coli* *Staphylococcus aureus*	Fluorescent bacilli/ cocci
Romanowsky stain	Thin film blood Smear	Distinct staining of WBCs and RBCs
Gram	*Escherichia coli* *Staphylococcus aureus*	Gram negative bacilli Gram positive cocci
Iodine Solution	Formalin treated stool specimen with cysts	Visible cyst nuclei
Spores	*Bacillus sp.*	Spores stain one colour and bacillus stains with counterstain

Histopathology

i) Tissue Processing

a. Depending on the workload the laboratory shall develop a procedure to change the tissue processing fluids and maintain a record of it.

b. A log recording of the ‘time setting schedule’ for an automatic tissue processor shall be maintained.

c. Temperature of the wax bath shall be checked and recorded daily.

ii) Microtome

a. The setting of the microtome indicating the thickness of sections shall be checked before use.

b. Microtome with non-disposable knife shall have a safety shield.

iii) Slide warming stage

a. Temperature of slide warming stage shall be checked weekly

iv) Flotation bath

a. The fluid in the flotation bath shall be changed at least once a day.

b. The surface of the water bath shall be skimmed regularly during section cutting to remove floaters.

Cytopathology

A. Microscopes used for screening shall have 10 X and 40 X objectives. Spare bulbs and fuses shall be available in the laboratory.

B. All equipment such as centrifuges capable of creating bio-hazardous aerosols should be used in extractor cabinets or rooms fitted with extractor facilities.

C. The laboratory performing Cytopathology tests on CSF must use cytocentrifuge for processing the samples.

Flow Cytometry

Diagnostic flow cytometry should be performed on flow cytometers made by standard companies that provide precise and verifiable procedures for operating and evaluating the performance of the machine. This would include procedures for calibration of the flow cytometer for instrument setup, optical alignment, test specific settings, colour compensation and daily performance, monitoring and verification. The flow cytometers must be operated and maintained exactly as per the standard operating procedures prescribed by the manufacturers.

Some important points regarding the instrument hardware and software that is being used for diagnostic work are as follows:

The instrument should be optically pre-aligned and pre-calibrated for optimal fluorescence and scattered light outputs i.e. the operator should not be able to change the alignment or calibration of the instrument without factory trained experts of the instrument.

The laboratory should use an optimal number and combination (panel) of antibodies that are able to distinguish between the major types and subtypes of leukemia/ lymphoproliferative disorders. The laboratory should determine the optimal concentration/dilution of an antibody for each assay before using it as a reagent for diagnosis. Laboratory should have documented procedure for reducing the effects of non-specific binding of antibodies to cells being tested.

5.4 Pre-examination procedures

(The main text of this clause is the text of the same clause of ISO 15189:2007)

Specific instructions for the proper collection and handling of primary samples shall be documented in a primary sample collection manual. This shall be applicable for the collection facility at main laboratory and the sites other than the main laboratory viz., collection centres. Additional requirements related to collection centres are provided in Chapter 6: Guidelines for Operating Collection Centre (s) of the Medical Laboratories, of this document.

The laboratory as a policy shall not accept samples, with labile analyte such as ammonia, acid phosphatase and lactate, not collected in-house.

Haematology

For the tests for monitoring anticoagulant therapy the request forms must have a column for the physician ordering the test to indicate the purpose of the test e.g. monitoring heparin/ low molecular weight heparin and/or oral anticoagulant therapy as applicable.

Indwelling Lines or Catheters:

Phlebotomists drawing blood from indwelling (arterial, central venous) or umbilical lines should have thorough training. While drawing blood form indwelling lines or catheters errors due to dilution and or contamination from flushing solution should be avoided.[3]

When an intravenous solution is being administered in a patient's arm, blood should be drawn from the opposite arm. If an intravenous infusion is running in both arms, samples may be drawn after the intravenous infusion is turned off for at least two minutes before venipuncture and applying the tourniquet below the intravenous infusion site.

Relevant clinical data are necessary for most specialized tests. Request forms should be designed so that the requesting physician provides this information.

Blood specimens for coagulation tests should be collected in 3.2% buffered sodium citrate

There must be guidelines for rejection of samples especially for under- or over- filled collection tubes for coagulation tests. Reasons for rejection of sample must be stated or communicated in writing to the nursing staff/ physician/ laboratory personnel responsible for sample collection.

Microbiology

Specimens for culture and sensitivity must be processed immediately after collection. In case of delay in processing the specimen may be stored in refrigerator except CSF and anaerobic culture. In situations where the sample has to be transported it must be collected in an appropriate transport medium.

Cytopathology

i) The procedure describing the sampling requirement for each specimen shall be readily available at all submitting locations (laboratory/ clinic/ hospital) and shall contain the following information:
   a. Preparation of patient for sampling.
   b. Consent form for Fine-Needle Aspiration (FNA).
   c. Collection techniques.
   d. Specimen identification and labeling.
   e. Fixation requirement e.g. anticoagulant used, fixative (wet fixed and/ or air dried) and storage requirements.
   f. Transportation instructions.

g. Safety precaution for all of the above (with special reference to HIV and Hepatitis).

h. All laboratory staff handling infected material shall be vaccinated against HBV.

ii) Where possible, FNA shall be carried out by the Pathologist. In the absence of a Pathologist, a clinician/radiologist may perform FNA, following documented procedures as provided by the laboratory and sign the requisition form.

iii) A request form should accompany every specimen and contain the following information:

a. Full demographic data

b. Relevant clinical history and clinical findings with provisional diagnosis

c. Anatomical site of collected specimen

d. Date and time of specimen collection

e. Information regarding previous cytology report

iv) For gynecological cytology the request form shall also contain:

a. Details of menstrual phase and hormonal status

b. Details of hormone therapy

c. Details of contraception

d. Details of previous surgery

v) For intra-operative imprint/ aspiration cytology, the request form shall also contain detailed surgical information observed at the time of procedure.

Flow Cytometry

Sample Handling

Blood/ bone marrow specimens collected in EDTA are stable up to 24h and in heparin up to 72h at room temperature. Samples must be transported and stored at ambient temperature (10-30^{0}C).

Sub-optimal and unacceptable samples include:

- Presence of clot, hemolysis, improper container
- Samples received beyond 48h after collection or if inappropriately labeled
- Samples received beyond 24h showing <80% viability on being tested by trypan blue test.

Presence of malignant cells should be verified microscopically by a pathologist prior to analyzing for suspected malignancies.

Storage period of examined specimen

The examined specimens shall be stored for re-examination and/ or additional tests for a minimum period as specified bellow:

Clinical Biochemistry: 1 day at 2-8^{0}C

Haematology:

Complete Blood Counts: 24 hours at 2-8^{0}C

Coagulation screening test – 6-8 hours at 2-8^{0}C

Haemoglobin electrophoresis and HPLC – 1 week at 2-8^{0}C or longer below -20^{0}C

Bone Marrow slides – 5 years *

HLA typing cell preparation – 3 days

Clinical Pathology:

Semen morphology slides – 1 week

Serology: Three days at 2-8^{0}C

Histopathology:

Specimens – 15 days

Slides/ Blocks – 5 years*

Bone marrow aspirate and corresponding blood film and biopsy – 5 years

Cytopathology:

Fluids – 24 hours at 2-8^{0}C

Slides – 5 years*

Genetics:

Blood samples for karyotyping – 6 days at 2-8^{0}C

Extracted DNA – 5 years at -20^{0}C

Extracted RNA – 5 years at -70^{0}C

Molecular diagnostic gel pictures – 5 years

Flow Cytometry:

Lysed stained samples can be re-suspended in buffered-formaldehyde solution (fixative) and stored at 2-8°C until analysis.

PCR: Blood with EDTA – up to 7 days at -20^{0}C or indefinitely at -70^{0}C

RT PCR: Extracted RNA - indefinitely at -70^{0}C

* The laboratory may consider giving the original slides to its patients on specific request for obtaining second opinion or for treatment elsewhere. The laboratory shall have a documented procedure and maintain records of the same. However, attempt should be made to retain at least one representative primary slide on which the diagnosis was based for review during the follow up.

5.5 Examination procedures

(The main text of this clause is the text of the same clause of ISO 15189:2007)

Haematology

CBC specimens must be checked for clots (visually, by applicator sticks, or by automated analyzer histogram inspection or flags), significant *in-vitro* haemolysis and interfering lipaemia before reporting results. CBC processing, either automated or manual, should be done within 8 hours.

Specimens for coagulation tests must be checked for presence of clots. Coagulation tests must be performed within 4 h of collection. If delay is expected plasma should be made platelet-free and kept frozen until test can be performed (at -20^{0}C for up to 2 weeks or at -70^{0}C for up to 6 months)

Packed Cell Volume Determination: The centrifuge shall be calibrated and capable of reaching at least 10000*g* for 5 minutes. The constant packing time (minimum spin-time to reach maximum packing of cells) shall be determined and recorded for each instrument.

ESR: Westergren or an equivalent method approved by ICSH or CLSI (Formerly NCCLS) shall be followed. ESR is to be performed within 6 h of collection. Sample kept at 4^0C can be processed up to 24 h.

Manual platelet count and white cell count: The haemocytometer shall be examined regularly to ensure that the lines are bright and free from scratch marks and dust particles. The correct standard thickness cover slips shall be used. The diluting fluid shall be filtered before use and checked periodically for background count. The fluid should be changed when required.

Blood film examinations: The blood film shall exhibit satisfactory quality for, staining properties, minimal debris and distribution plus morphology of cells. Where appropriate an estimation of cell counts should be made from the blood film and correlated with abnormal counts reported. Routine blood films need not be reviewed by resident trainees/ pathologist/ haematologist and the rules related to these shall be documented.

Bone marrow Examination: The bone marrow film should exhibit satisfactory quality for, staining properties, cell morphology and their distribution. A pathologist or medical specialist in haematology shall report all bone marrow slides.

Reticulocyte count (manual or automated) must be performed within 24h of collection. Stain should be filtered before use. The reticulocyte percentage should be based on the count of at least 1000 red blood cells.

Malarial parasites: Thick and thin films stained by Romanowsky is the method of choice. Quantitative Buffy Coat (QBC) used as a screening test must be followed up by thin film microscopy to identify the species. Ensure that the Buffer for the Romanowsky dye is at pH 7.0-7.2. At least 100 oil immersion fields should be screened before reporting negative. All samples should be double checked, one being performed by an experienced staff, in the areas where malaria is endemic. Positive *P. falciparum* should be reported with parasite index on at least 1000 red cells and parasitaemia reported immediately.

Manual Haemoglobin (Cyanmethaemoglobin method): At least four concentrations must be used to construct a calibration curve.

Coagulation Tests: All reagents and test samples shall be incubated at 37^0C immediately prior to testing to ensure reaction temperature. Water-baths must be temperature controlled. Timers shall be checked for accuracy at least annually.

HLA typing: For cytotoxicity testing procedures: There must be established limits for defining positive and negative results by approximate percentage of cell death. Each batch of complement must be evaluated to determine that it can mediate cytotoxicity when a specific antibody is present, and is not cytotoxic in the absence of a specific antibody. Complement cytotoxicity studies must be performed to with optimal dilution of anti lymphocyte globulin. The HLA antigen assignment in written reports must conform to the most current World Health Organization (WHO) nomenclature. Determination of HLA class II antigen typing must be performed on B-cell preparations where the percentage of B-lymphocytes is documented by a method that is at least 80% B-cell enriched. Class I antigens must be defined by at least 3 antisera, or by 2 antisera that are operationally monospecific. Class II antigen assignment by the use of operationally monoclonal antibodies to each DR and DQ antigen must be determined by (a) 2 antibodies directed to private epitope specificity, or (b) 1 antibody having private epitope specificity and 2 antibodies with public epitope specificity, or (c) 3 antibodies with partially non-overlapping antibodies directed at public epitope determinants. Techniques for HLA crossmatching in transplantation must use a method that is more sensitive than the basic NIH lymphocytotoxicity procedure. A policy must define what patient's sera are used in the final crossmatch, dilutions and nature of serum, i.e, frozen sera etc. Cellular targets for transplant crossmatches must include donor T-cells, and may include donor B-cells when appropriate.

Molecular Testing:

i) Sample identification must be assured through all applicable phases of analysis, including all of the following:

   Specimen receipt, nucleic acid extraction, nucleic acid quantification, endonuclease digestion, electrophoresis, transfer, hybridization, detection, *in-situ* hybridization, enzymatic amplification, photography, storage.

ii) Autoradiographs or electrophoretic gels should be interpreted independently by at least two qualified readers using an objective method

iii) Positive, negative and sensitivity controls must be run for each assay, when available and appropriate

iv) DNA contamination must be monitored in different areas by swipe tests, using the regular detection for testing. Results of monitoring and corrective action taken when contamination is detected must be documented

Flow Cytometry:

Clinical and morphological correlation with flow cytometric data should be carried out and should be taken into consideration when developing gating strategies.

Clinical Pathology

Urinalysis:

i) Refractometers or dipsticks with specific gravity capability must be checked periodically with appropriate controls. Distilled water (sp. gr. = 1.0000) and 5% NaCl (sp. gr. = 1.0225) can verify total solids meter calibration. For dipsticks, manufacturers' recommendations should be followed.

ii) Criteria must be documented for identifying urine samples that may give erroneous results by the dipstick reader, and thus require visual evaluation. Intensely colored urine samples may result in false positive dipstick reactions with automated reflectance readers.

Microbiology

The number of antibiotic discs applied on the Petri dish to test antibiotic sensitivity shall be as per CLSI (formerly NCCLS) recommendation.

The laboratory located in the hospital shall test against the antibiotics as per the hospital antibiotic policy, wherever possible. The stand-alone laboratory shall have an antibiotic sensitivity testing policy on the basis of site of infection, antibiotic susceptibility pattern, availability of drug and cost.

Enrichment and selective media should be used for isolation of organisms from stools, sputum, throat/urethral/cervical swabs, etc. For urine samples, the laboratory should perform and report quantitative cultures and use media and procedures that permit isolation of Gram positive, Gram negative bacteria and fungi.

For identification of *M. tuberculosis* the laboratory will at least consider the following:

Slow growth rate, growth temperature 35-37^{0}C only, no pigmentation, niacin positive, catalase negative at 68^{0}C and no growth on LJ medium containing *p*-nitro benzoic acid. At least 10 ml of CSF is recommended for recovery of *Mycobacteria.*

HIV testing

Laboratories performing HIV testing shall follow National AIDS Control Organization (NACO), Government of India guidelines for testing which includes pre and post test counseling. The laboratory shall not perform HIV test unless the individual has been given pre-test counseling and post-test counseling is ensured. In case the laboratory does not have its own counseling facility the individual must bring a certificate from the referring physician or the counselor of the hospital that she/he has been counseled before the test and will be counseled after the test. Informed consent of the individual will be taken before the blood sample is collected. In such a situation, the individual should be explained that the test report will be sent directly to the referring physician or the counselor, who shall inform the individual tested about his/ her HIV status and give post-test counseling. The results of the HIV test shall be kept strictly confidential.

Histopathology:

i) The specimens shall be grossed and the findings recorded by a pathologist or trainee pathologist deemed competent for the procedure.

ii) Staining
   a. The frequency of changing the deparafinizing solutions (xylene/ chloroform/ alcohol) and stains should be recorded. This is based on workload.
   b. Special Stains: A positive control should be stained with each batch. The control slides shall be filed and retained for the same time period as the test slides.

iii) Frozen section/squash smear:
   a. A specific area should be demarcated for performing frozen sections.
   b. Fresh tissue received for frozen section should be treated as infective and universal precautions should be taken.
   c. Frozen sections/squash smears should be recorded like other specimens in the request form. Left over tissue must be processed for permanent section.

d. The turnaround time for frozen section/squash smears should not exceed 30 minutes.

e. Frozen section/squash smears shall be retained and filed along with the permanent sections for the stipulated time.

Prion disease suspected specimens:

In a suspected case of prion disease, facilities should be available for safe handling of specimens. The biopsy specimen shall be considered as bio-hazardous and transferred to concentrated formic acid (96%) for 48 hours, subsequently to 10% formalin for 24 hours and then processed. The blocks should be labeled biohazardous. The trimmings of the block shall be disposed by incineration. All instruments used for sectioning be left in 2M NaOH for 1 hour and washed in running water for 15 minutes and reused. The microtome should be wiped clean with 2M NaOH and left for 1 hour. Subsequently the instrument should be wiped clean with tap water followed by alcohol before reuse.[4,5]

Electron Microscopy:

1. Processing of specimens shall be done by a trained technician under supervision/authorization of the Officer-in-charge of electron microscope laboratory.
2. A procedure manual shall be readily available with detailed procedure for the safe handling of epoxy resins.

Cytopathology

All exfoliative cytology slides shall be stained by Papanicolaou technique. FNAC slides shall be stained with May-Grundwald Giemsa with or without PAP/H&E staining for interpretation.

Flow Cytometry

Laboratory should have procedures in place to distinguish leukemic/ lymphoma cells based on their light scatter properties and differential expression of antigens and to distinguish fluorescent cells from nonfluorescent cells in flow cytometry analysis.

5.6 Assuring quality of examination procedures

(The main text of this clause is the text of the same clause of ISO 15189: 2007)

Clinical Biochemistry

The Laboratory must establish and document procedures for monitoring and evaluating analysis of testing processes including procedures for resolving 'out-of-control' situations. The laboratory is encouraged to use control material similar to or identical with patient sample matrix. The laboratory shall incorporate in the procedure, the multi-control QC rules used to detect systematic (trends or shifts) and random errors.

The laboratory shall include a minimum of one level QC at least once a day. However, where the number of patient samples analysed for any parameter exceeds 25 per day, the laboratory shall employ 2 levels of QC at least once a day for such parameters. Further, if the number of patient samples analysed for any parameter exceeds 75 per day, the laboratory shall employ 2 levels of QC at least twice a day at appropriate intervals.

The daily QC values shall be documented along with the calculation of %CV from the monthly QC data. The laboratory shall maintain control charts to demonstrate stability of the analytical measuring systems.

The laboratory shall follow the multi control QC rules as described below:

The rules to follow when one level QC material is used:

Reject QC if:

a. it is outside 3 SD (1_3s)
b. two consecutive values obtained are outside 2 SD on the same side but within 3 SD (2_2s)
c. ten consecutive values are above or below the mean, but within 2 SD (10_x)

The rules to follow when 2 level QC materials are used:

Reject QC if:

a. either QC values is outside 3 SD (1_3s)
b. both QC values are outside 2 SD on the same side, but within 3 SD (2_2s)

c. difference between both QC values is >4 SD i.e. one level QC is > 2 SD and other level QC is <2SD (R_4s).

d. ten consecutive values of the same level QC are >/< the mean, but within 2 SD (10_x).

e. five consecutive values of one level QC and five consecutive values of other level QC are >/< the mean but within 2 SD (10_x)

The laboratory shall have step-by-step flow chart to manage 'out-of-control situation' such as:

- Search for recent events that could have caused changes
- Examine environmental conditions.
- Follow manufacturer's troubleshooting guide.
- Refer to manufacturers of equipment, reagents or QC/calibrator.

The laboratory shall employ suitable reference material traceable to international standards for calibration of measuring systems and methods. Traceability certificates for calibrators shall be obtained from kit suppliers and appropriately documented.

Alternate methods shall be employed for verifying accuracy of results of such of those tests for which calibration and control materials are not available.

Haematology

Internal quality control is necessary to ensure precision and repeatability. It is desirable to use stable controls (prepared in-house or procured from commercial sources) for this. The data should be plotted on Control Charts (L.J. Charts or Cusum Charts). In a small laboratory stable controls may not be available. In these situations, precision of routine work can be monitored by performing duplicate tests on patient samples. SD of differences between results on 10 duplicate samples is determined and $\pm$2SD limits specified. Subsequent duplicate values should be within these defined limits. Patient data can also be used to monitor precision in a laboratory performing $\geq$100 samples a day. Day-to day variation in MCV, MCH and MCH should be between the 2SD limits determined on 400 samples. This facility is available in software of many autoanalysers. The use of stable controls, however, is the method of choice.[2]

Microbiology

The laboratory shall practice quality control of various procedures as under:

Procedure Test	Control organism	Expected Result	Expected reaction
Catalase	*Staphylococcus aureus* *Streptococcus species*	+ -	Bubbling reaction No bubbling
Coagulase	*Staphylococcus aureus* *Staphylococcus epidermidis*	+ -	Clot formation in 4 hours No clot
Indole	*Escherichia coli* *Enterobacter aerogenes*	+ -	Red ring at surface Yellow ring at surface
Methyl red	*Escherichia coli* *Enterobacter aerogenes*	+ -	Instant red colour No colour change
Oxidase test	*Pseudomonas aeruginosa* *Escherichia coli*	+ -	Purple colour in 20 seconds No colour in 20 seconds
Voges Proskauer	*Enterobacter aerogenes* *Escherichia coli*	+ -	Red Colour No colour change
Bacitracin disc	*Streptococcus group A* *Enterobacter faecalis*	+ -	Zone of inhibition No zone of inhibition
Optochin disc	*Streptococcus pneumoniae* *Streptococcus viridans*	+ -	Zone of inhibition No zone of inhibition
ONPG disc	*Escherichia coli* *Proteus vulgaris*	+ -	Yellow fever No change in colour
Oxidase disc	*Psuedomonas aeruginosa* *Escherichia coli*	+ -	Purple colour in 30 seconds No change in colour

Control strains of known susceptibility should be used along with the test sample while performing drug susceptibility testing. In case of susceptibility testing against *Mycobacterium*, a standard strain of *M. tuberculosis* with known resistance pattern to different drugs shall be used with each batch of tests as a check on procedures.

Stains for acid fast bacilli should be checked with the known positive and negative control organisms and the results recorded for each new batch. Control smears for acid fast stain should include smears with few to moderate number of acid fast bacilli. Positive and negative control smears should be included daily.

Histopathology

When repeat specimen for Histopathology from a patient is received, all previous slides must be reviewed and reflected in the final report. Frozen section results must be compared with the final assessment and both results must be reflected in the final report.

Cytopathology

1. Screening current work shall include
   a. Re-screening by the consultant of at least 10% of the gynecologic smears reported negative by the cyto-technologist.
   b. Re-screening of previously reported slides on receiving fresh smears from the same patient, during follow up.
   c. Checking for staining quality.

2. Volume of workload for each screener shall be recorded. The laboratory shall avoid overloading the screener.

3. Procedures and records for follow up shall comply with:
   a. Reviewing all previous slides for an individual patient.
   b. Matching previously reported abnormal smears with histopathology sections submitted for examination from the patient.
   c. Comparison of all abnormal cytological findings with results of colposcopy or biopsy.

4. The laboratory shall have procedures for following up discrepancies identified between biopsy result and cytology report

5. For gynecological cytology the ASCUS:SIL ratio shall comply with the latest Bethesda recommendations

6. The laboratory may implement a system to notify the state cancer registry of patients diagnosed with malignancy. This list may be maintained and updated regularly

Note: The above criteria/procedures shall be applied to fluids cytology/ FNAC where applicable.

Uncertainty of Measurement:

The laboratory shall determine the uncertainty of results, where relevant and possible. The uncertainty evaluation follows the general principle in the Guide to the expression of Uncertainty in Measurement (GUM)[6] and in the Eurachem/CITAC Guide Quantifying Uncertainty in Analytical Measurement.[7]

For calibration of equipment policies have been defined in 5.3 of this document.

Proficiency Testing:

The laboratory shall participate in External Quality Assessment Scheme (EQAS)/ Interlaboratory comparison as defined in NABL 163. The laboratory shall document any corrective actions taken based on the EQAS evaluation report.

For those analytes where a formal EQAS is not available the laboratory shall exchange samples with other NABL accredited laboratories. The laboratory shall adopt alternate methods to validate performance for certain tests for which inter-laboratory comparisons are not possible.

For some rare analytes where such comparisons are not possible the laboratory will ensure accuracy and precision by one or more of the following: replicate testing, examination of split samples, testing of retained samples and use of reference of materials, where available.

EQAS samples must be integrated within the routine laboratory workload, and analyzed by personnel who routinely test patient samples, using primary method systems. Rotate personnel for analysis in case of one time sampling on EQAS sample. If slides are to be reported it has to be reported by all the appropriate level of staff involved in the department with no sharing of data. Then they should be discussed collectively before the results are dispatched.

If the laboratory uses more than one measuring system as well as alternate methods for specific reasons towards proper laboratory management, it is essential to perform a

comparability study between the systems and prove the agreement in performance through appropriate statistical evaluation from the data generated. Such exercise shall be conducted as and when this is warranted. For the above comparability study, the laboratory can use a built-in statistical programme or the well established manual statistical procedure. A written procedure and complete record of all such data shall be retained for a reasonable period of time as decided by the laboratory.[2]

5.7 Post-examination procedures

(The main text of this clause is the text of the same clause of ISO 15189: 2007)

5.8 Reporting results

(The main text of this clause is the text of the same clause of ISO 15189: 2007)

The laboratory shall establish critical limits for tests which require immediate attention for patient management. Test results in the critical limits shall be communicated to the concerned after proper documentation.

Biological Reference Interval should be age- and sex- specific and established by the laboratory for the method used. If it is not practical to establish the biological reference interval for a particular analyte the laboratory should carefully evaluate the published data for its own reference intervals, and retain documentation of this evaluation.

Prothrombin Time results should contain the time taken by the patient specimen to clot and mean normal prothrombin time (MNPT) and the International Normalized Ratio (INR). MNPT (geometric/arthematic mean of prothrombin time of 20 normal healthy individuals) should be determined for every new lot of reagent, type of reagent and the instrument used. The INR must be appropriately adjusted for every new lot of prothrombin time reagent, types of reagent and the instrument used. Biological Reference Intervals show significant differences with each lot of reagent, type of reagent, technique and the instrument used and should be determined for each of the situations if the laboratory uses more than one system. The BRI stated in the literature is unsuitable for reporting the prothrombin time results.

Histopathology

1. The names of the person reporting the macroscopic and microscopic findings along with signatures shall be entered on each report.

2. There shall be adequate description of the macroscopic/ microscopic findings.
3. Report should be in accordance with recent terminology/ classification, grading, scoring, nature of lesion and relevant information necessary for disease management. Report shall also mention all additional tests performed such as special stains, immuno-histochemistry etc.
4. All reports shall be checked for accuracy by a pathologist before authorizing and issuing printed or electronic reports.
5. The turn around time for issue of reports should not exceed 4 days. In case any special procedures are carried out to further characterize the pathology, a interim report should be issued to facilitate immediate management of the patient. Final report should be issued after carrying out the special procedures in a reasonable amount of time depending upon the degree of specialization and consultancy needed.
6. National cancer Registry may be notified in cases where malignancy is diagnosed.
7. When the examination of a permanent section is preceded by frozen section and/or followed by other diagnostic modalities like immuno-histochemistry, *in-situ* hybridization, the final report shall also include these results with interpretation.

Cytopathology

1. A pathologist shall review and sign all reports screened by a cyto-technologist recorded as abnormal.
2. Explanatory notes shall accompany any unsatisfactory or equivocal report.
3. The turnaround time shall not exceed 3 working days.
4. All malignancies or suspected malignancies shall be reported immediately in writing.
5. For intra-operative cytology, the smears will be stained and interpreted within 30 minutes and the result immediately communicated to the surgeon.
6. In case of reports with abnormal cytologic findings, the pathologist should make recommendations regarding further clinical/histological evaluation, where relevant.

6 Guidelines for Operating Collection Centre(s) of the Medical Laboratories

Maintaining the integrity of the test sample at all stages of collection, handling and transportation to the main laboratory plays a vital role in the reliability of test results. Therefore, it is important to ensure quality at the collection centres.

Collection centres are classified under three categories:

(a) Ownership: Collection centres owned by the laboratory or its parent organization and personnel are employees of the laboratory.

(b) Management: Laboratory or its parent organization does not own the collection centre but is entirely responsible for day to day operations and its employees.

(c) Franchisee: Laboratory or its parent company does not own the collection centre but has an arrangement for sample collection under a legal agreement with the franchisee.

The laboratories shall have collection centres as per the above three categories only and declare them to NABL. The collection centres shall meet the following guidelines:

Collection centres to be included for scope under accreditation shall be fully operational. Only those collection centres which are declared to NABL shall be claimed by the laboratory as a part its laboratory system.

All issues related to the operation of collection centres and maintenance of quality shall be addressed by the laboratory in the quality system of the main laboratory. Specific instructions for proper collection and handling of primary samples at the collection centre and transportation of these samples to the laboratory shall be documented in a primary sample collection manual, which shall be a part of the quality system of the laboratory. A copy of this manual shall be available at the collection centre.

Laboratory shall document policies and procedures for proper hygiene, lighting, environmental conditions and privacy in its collection centres. It is the responsibility of the laboratory to ensure that its collection centres maintain adequate hygiene, lighting and environmental conditions such that the integrity of the samples is not affected during collection, storage and transportation. Special care should be taken to ensure that the work area is clean and well maintained. Collection centres should have adequate space to avoid any cross contamination. During the sample collection in collection centres, laboratory shall ensure the safety, comfort and privacy of the patients. Collection centres shall ensure that the environmental conditions are maintained as required during the transportation of sample to avoid deterioration of sample.

Records of environmental conditions in the collection centres shall be maintained. Record of temperature and condition of the sample on receipt by the laboratory shall also be maintained. Laboratory shall ensure that its collection centres dispose waste as per the national laws (eg. Biomedical Waste Act) and the local regulations on waste disposal.

The staff employed in collection centres shall be adequately trained. The training shall include but not be restricted to issues as:

(a) Policies, procedures and guidelines,
(b) Maintenance of proper hygiene and environmental conditions,
(c) Methodology for collection of sample and the amount required,
(d) Handling of collected samples,
(e) Packaging of samples,
(f) Proper transportation of the samples / specimen,
(g) First aid measures to be taken, in case of abnormal events,
(h) Safety and waste disposal.

Main laboratory shall ensure the evaluation of the training imparted to staff in collection centres and maintain records.

Laboratory shall have a plan to conduct internal audit of its collection centres so that they meet NABL guidelines. Laboratory shall conduct internal audit of each of its collection centre at least once a year. Management review of the laboratory shall also include the internal audit of its collection centres.

Only those collection centres which are declared to NABL shall be claimed by the laboratory as a part its laboratory system. The laboratory shall include the name and address of its collection centre in the test reports. Neither the laboratory nor the Collection Centres shall claim that collection centres are accredited.

Collection centre(s) of the laboratories within the city and also across the country will be assessed by NABL on a random sample basis as specified below. The collection centre(s) may or may not be assessed by the same assessor who has conducted assessment of the laboratory. Their assessment may be conducted separately by another assessor at a different time.

Assessment plan for Medical Laboratories with multiple collection centres shall include assessment of the collection centres on a sampling basis as per plan given below.

a) Laboratories with 1-5 collection centres in the same city, a minimum of one collection centre shall be audited.
b) Laboratories with 6-10 collection centres in the same city, a minimum of two collection centres shall be audited. However, the choice of centres to be audited shall be communicated to the laboratory only on the day of the audit.
c) Laboratories with 11-30 collection centres in the same city, a minimum three collection centres shall be audited. However, the choice of centres to be audited shall be communicated to the laboratory only on the day of the audit.
d) Laboratories with 31-100 collection centres in the same city, a minimum of four centres shall be audited on random basis.
e) Laboratories with more than 100 collection centres in the same city or all over the country, a minimum of 5% of randomly selected centres shall be audited.

NABL will charge an audit fees per collection centre audited. Refer NABL 153 for details .

During the assessment of a collection centre, the assessors shall check how the primary samples are transported from the collection centre to the main laboratory and the efficacy of containers used for transportation, so that the integrity of the samples is maintained. Assessors shall assess the records maintained by the collection centres, including the internal audit records of collection centres.

If there are major non-conformities or a total system failure during the assessment of a collection centre, the laboratory shall be asked to take corrective actions within two weeks time. In case the laboratory fails to take corrective actions or there is a consistent system failure, an appropriate and proportionate action against the laboratory will be taken.

The following pages present a checklist for auditing the collection centres, which form the additional requirements for accreditation of Medical laboratories operating collection centres.

CHECKLIST FOR MEDICAL LABORATORY COLLECTION CENTRES

Collection Centre: _____
_____

Premises

			Remarks
1.	Type of the Collection Centre	Owned / Managed / Franchise	
2.	Size of premises	____ Sq. Feet	
3.	Collection Centre is operational from (date)		
4.	Does it meet the requirement of the workload	Yes / No	
5.	Reception and waiting area separate from collection area	Yes / No	
6.	Hand washing facilities	Yes / No	
7.	Clean toilet facility	Yes / No	
8.	Provision of privacy during collections	Yes / No	
9.	Hours of operation have been displayed	Yes / No	

Accommodation and Environmental Conditions

1.	Is it adequately lit and clean	Yes / No	
2.	Is the humidity and temperature suitable	Yes / No	
3.	Are cleaning policies available	Yes / No	
4.	Is it adequately ventilated and prevented from dust	Yes / No	
5.	Does it have adequate space & separation to avoid cross contamination	Yes / No	
6.	Is the house keeping adequate	Yes / No	

Equipment

1.	Refrigerator	Yes / No	
2.	Centrifuge, if needed	Yes / No	
3.	Proper storage of supplies	Yes / No	
4.	Suitable chair and/ or couch for collection of blood, etc.	Yes / No	
5.	Basic first-aid materials	Yes / No	
6.	Telephone	Yes / No	
7.	AC for controlling temperature, if needed	Yes / No	
8.	Power backup for equipments	Yes / No	

Materials

1.	Material required for specimen collection eg. evacuated blood collection tubes, syringes, tubes, swabs etc.	Yes / No	
2.	No expired material in the premises	Yes / No	

Staffing

1.	Staff members	____ nos.	
2.	Is it appropriate to the workload?	Yes / No	
3.	Initial training records	Yes / No	
4.	Ongoing training records	Yes / No	
5.	Does the staff possess knowledge of first-aid measures to deal with situations they are likely to encounter in the course of specimen collection?	Yes / No	
6.	Appropriate identification to be worn by the staff	Yes / No	

Documentation

1.	List of services provided	Yes / No	
2.	List of services excluded	Yes / No	
3.	Sample collection manual available	Yes / No	
4	Records of Internal audit (available at laboratory)	Yes / No	

Health and Safety

1.	Collection staff to observe universal precautions (to wear gloves, lab coat & protective mask)	Yes / No	
2.	Vaccinated against Hepatitis B	Yes / No	
3.	Vaccinated against other preventive disease	Yes / No	

Safety and Waste Disposal

1.	Approved receptacles for sharps and for contaminated waste available	Yes / No	
2.	Transport and disposal of waste is in accordance with applicable regulatory requirements	Yes / No	

Transport of Pathology Specimens

1.	Does the collection centre follow national/ international regulations for the transport of infectious and other diagnostic specimens by air and by surface so that in the event of an accident occurring, courier staff and the general public may not be exposed to blood and body fluids	Yes / No	
2.	Has the specimen collection staff participated in training in specimen collection, transport, handling of emergencies etc?	Yes / No	
3.	Has the above staff participated in retraining undertaken at not greater than two year interval?	Yes / No	
4.	Is the parcel of infectious substances attached with a plastic envelope containing document – '**Bio-hazardous diagnostic specimens**'?	Yes / No	

Packing

1.	Is the primary container containing specimen leak proof tube or vial?	Yes / No	
2.	Does the secondary container possess sufficient absorbent material to absorb the contents if the primary container leaks?	Yes / No	
3.	Are both the above containers properly labelled?	Yes / No	
4.	Is the secondary container packed into appropriate outer packing and labelled appropriately?	Yes / No	
5.	Is cooling agent included in the outer package if cold chain is to be maintained?	Yes / No	
6.	Is the outer package labelled, addressed and taped securely	Yes / No	
7.	Are the pap smears mailed in rigid slide mailers to prevent breakage of the slide?	Yes / No	

Complaints / Feedback

1.	Does the collection centre has provision for receiving of complaints / feedback	Yes / No	
2	Are the complaints / feedback reviewed and resolved by the laboratory	Yes / No	

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Annex - I

List of routine and special tests
(This list is not exhaustive but only indicative)

Clinical Biochemistry

Routine tests:

Plasma/ Serum: glucose, urea, creatinine, total protein, albumin, bilirubin, AST, ALT, LDH, alkaline phosphatase, acid phosphatase, CK & CK MB, electrolytes, calcium, phosphorus, cholesterol, triglycerides, HDL cholesterol, uric acid, amylase, T3, T4, TSH, FSH and LH (except by RIA).

Urine: 24 hours calcium, phosphorous, creatinine, sodium, potassium, uric acid.

CSF: glucose, protein, chloride

Effusion fluid and Ascitic fluid: glucose, protein

Calculi analysis

Special tests

The tests other than those mentioned above.

Haematology

Routine tests

Complete Blood Count (CBC), Reticulocyte count, Erythrocyte Sedimentation Rate (ESR), Peripheral smear, Malarial/Filarial Parasite, Blood grouping, Compatibility testing for transfusion, D-Dimer/FDP, PT, APTT, Fibrinogen, Bleeding time, Anti gloubulin (Coombs) test (direct and indirect), G-6 PD screen, sickling test,

Special tests

The tests other than those mentioned above.

Clinical Pathology

Routine tests

Urine Chemistry - Urine microscopy, Body fluids - Cell count, microscopy, Stool examination - Cysts/Trophozoites/Ova/Larva, Occult blood, Semen examination – Counts, morphology, motility.

Special tests

The tests other than those mentioned above.

Microbiology and Serology

Routine Tests

Examination of direct smear and stain preparation under microscope in bacteriology, mycology and parasitology.

Slide and agglutination reaction and ELISA

Special tests

The tests other than those mentioned above.

Histopathology

All tests are considered special.

Cytopathology

All tests are considered special.

Genetics

All tests are considered special.

Nuclear Medicine (*in-vitro* tests)

All tests are considered special.

COMPOSITION OF TECHNICAL COMMITTEE

The following committee contributed towards the development of the Specific Criteria for Accreditation of Medical Laboratories in accordance with ISO 15189:2003.

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5	**Dr. Kusum Verma** Professor and Head, Department of Pathology All India Institute of Medical Sciences (AIIMS), New Delhi	Member
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7	**Dr. D.R. Arora** Professor and Head, Department of Microbiology Maharaja Agarsen Medical College, Agroha, Hisar, Haryana	Member
8	**Dr. S.K. Shankar** Professor and Head, Department of Neuropathology National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore	Member

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9	**Dr. Arti Bhatia Chacko** Professor, Department of Pathology University College of Medical Sciences & GTB Hospital, Delhi	Member
10	**Dr. Sukesh Nair** Associate Professor, Department of Clinical Pathology & Blood Bank Christian Medical College, Vellore	Member
11	**Dr. R.L. Ichhpujani** OSD, Directorate General of Health Services, New Delhi	Member
12	**Dr. B.K. Rana** Manager-Proficiency Testing National Accreditation Board for Testing & Calibration Laboratories (NABL), New Delhi	Convener
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