



National Accreditation Board for Testing and Calibration Laboratories (NABL)

NABL 223

Assessment Forms and Checklist (Based on ISO 15189:2022)

Issue No.: 01
Issue Date: 21-Jun-2023

Amendment No.: --
Amendment Date: --

AMENDMENT SHEET

S. No.	Amendment No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature Competent Authority
1.								
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ASSESSMENT SCHEDULE

Name of the Laboratory:				
Head of the Laboratory (how so ever named):			Date(s) of Visit:	
Type of Assessment: <i>Initial assessment / Onsite Surveillance / Reassessment / Supplementary Visit</i>				
Field: Medical			Discipline (s):	
Facility (s): <i>Permanent / POCT / Mobile/ Site Facility</i>				
Assessment Standard: <i>ISO 15189: 2022</i> Specific Criteria of NABL (If applicable):				
Assessment Timings		Opening/Closing Meeting Date/Time		Daily Debriefing Date / Time (at the end of each day)
<i>Morning: AM to PM</i> <i>Afternoon: PM to PM</i>		<i>Opening Meeting:</i> <i>Closing Meeting:</i>		<i>Day 1:</i> <i>Day 2:</i> <i>Day 3:</i>
Name and Expertise of the Assessor	Schedule of Department/ Section/ Activity to be Assessed (date wise)			
	Day 1		Day 2	
	Morning	Afternoon	Morning	Afternoon
Lead Assessor				
Assessor 1				
Assessor 2				
Assessor 3				
Assessor 4				
Assessor 5				
Assessor 6				
Assessor 7				
Observer <i>(only for observation)</i>				
I declare that the assessment plan has been prepared after discussing with the assessment team members.				
Signature of Lead Assessor				

National Accreditation Board for Testing and Calibration Laboratories					Documents
Doc. No.: NABL 223		Assessment Forms and Checklist (based on ISO 15189: 2022)			 Document Sharing Hub
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DETAILS OF TESTING / RE-TESTING / REPLICATE WITNESSED DURING ASSESSMENT
(To be filled in by the Technical Assessor)

Name of the Laboratory:		
Discipline(s):	Facility (Permanent/ POCT/ Mobile/ Site facility):	Date(s) of Assessment:
Materials or Products tested		
Component, parameter or characteristic tested/ Specific Test Performed/ Tests or type of tests performed		
Test Method Specification against which tests are performed and/or the techniques/ equipment used		
Range of Testing / Limits of detection		
% CV/Measurement Uncertainty expressed as ($\pm$) of Observed Value		

1. Fresh Sample

Sample ID	
Tested by	
Results of Test Witnessed	

2. Re-testing/replicate testing of Retained Sample

Sample ID	
Date of Earlier Testing	
Earlier Tested by	
Earlier Reported Results	
Results of Test Witnessed	
Test conducted by (same person)	
Test conducted by (different person)	

3. Testing of CRM / SRM

Reference Material	
Specified Value	
Results of Test Witnessed	

Remarks:

Deviations observed, if any	
Conclusion on the technical competence of the lab for the test witnessed	

(Enclose/upload all supporting data sheets for tests witnessed)

(Signature & Name of Technical Assessor)

Summary on Non-Conformities

(Please use separate sheet for raising each Non-Conformity)

Name of the Laboratory			
Name of the Assessor			
Date(s) of Assessment		Discipline:	
NON-CONFORMITY STATEMENT:			
Cl. No. of ISO 15189:2022 / Cl. No. of NABL 133/ NABL Specific criteria (If applicable):			
Acceptance (Signature of laboratory's representative and propose the required corrective actions)		Signature & Name of Assessor	
CORRECTION PROPOSED BY THE LABORATORY			
Signature & Name of the Authorized Representative of Laboratory			
ASSESSOR'S COMMENTS ON CORRECTIVE ACTION PROPOSED BY THE LABORATORY: (Root cause analysis to be submitted along with the evidences of corrective actions)			
Acceptance/Signature of Technical Assessor			
REMARKS BY LEAD ASSESSOR, IF ANY:			
Acceptance/Signature & Name of Lead Assessor			

SUMMARY OF ASSESSMENT

Sl.	Item	Details																											
1.	Name of the Laboratory																												
2.	Date(s) of Assessment																												
3.	Field																												
4.	Discipline(s)																												
5.	Facility	Permanent/ POCT/ Mobile/ Site facility																											
6.	Type of Assessment	Initial Assessment/ Onsite Surveillance/ Reassessment / Supplementary visit																											
7.	Assessment Team/ Capacity																												
8.	Date of earlier visit:	Non-Conformities during earlier onsite assessment have/ have not been discharged. (Yes or No)																											
9.	Total no. of Non-conformities	<table border="1"> <thead> <tr> <th></th> <th>Number of NC(s)</th> </tr> </thead> <tbody> <tr> <td>Clause 4</td> <td></td> </tr> <tr> <td>Clause 5</td> <td></td> </tr> <tr> <td>Clause 6</td> <td></td> </tr> <tr> <td>Clause 7</td> <td></td> </tr> <tr> <td>Clause 8</td> <td></td> </tr> <tr> <td>Total</td> <td></td> </tr> </tbody> </table>															Number of NC(s)	Clause 4		Clause 5		Clause 6		Clause 7		Clause 8		Total	
	Number of NC(s)																												
Clause 4																													
Clause 5																													
Clause 6																													
Clause 7																													
Clause 8																													
Total																													
10.	Comment(s) of Assessment Team on compliance of CAB to:																												
	NABL 133*																												
	NABL 142*																												
	NABL 163*																												
	NABL 112*																												
	*(Lead Assessor to comment on the basis of observations of Technical Assessor(s))																												
11.	Assessment Summary																												
12.	Recommendation of assessment team as per ISO 15189: 2022																												
13.	Only if accreditation is recommended, date by which the corrective Action & root cause analysis to be submitted by the laboratory for the above Non-conformities (Max. 30 days):																												
14.	The requirements of NABL 133 have been explained by the Lead Assessor and understood by the laboratory																												
Enclosures	NAF 6	NAF 4	NAF 3A	NAF 1	NAF 1A	Check list 1	Check list 2	Check list 3	Form 72	Form 74	Form 45	TA/DA Forms	PT/ILC records	Comments on the competency of personnel	Any other docs.														
No. of Pages																													
Acknowledgement by Authorised Representative of Laboratory & Date									Signature of Lead Assessor & Date																				

RECOMMENDED SCOPE OF ACCREDITATION

[illegible]

DECLARATION OF IMPARTIALITY & CONFIDENTIALITY
(to be filled in by each Assessor and enclosed with the Assessment report)

Name		Assessor ID: (To be filled in by NABL Sect.)
Designation		
Organization		
Address		
Capacity	Lead Assessor / Technical Assessor / Technical Expert / Observer	
CAB* Assessed		
Date of Assessment		
Type of Assessment	Document Review / Pre-Assessment / Initial assessment / Onsite Surveillance / Reassessment / Supplementary visit	

*CAB – Conformity Assessment Body (Testing / Medical / Calibration laboratory / Proficiency Testing Provider (PTP) / Reference Material Producer (RMP))

I _____, hereby declare that I have not offered any consultancy, guidance, supervision or other services to the CAB (e.g. internal audit), in any way.

I am / am not* an ex-employee of the CAB and am/ am not* related to any person of the management of the CAB.

I got an opportunity to go through various documents like Quality Manual/Management System document, Procedural Manuals, Work instructions, Internal reports etc. of the above CAB and other related information that might have been given by NABL. I undertake to maintain strict confidentiality of the information acquired in course of discharge of my responsibility and shall not disclose to any person other than that required by NABL.

*Strike out which is not applicable

Date:

Place:

Signature

ASSESSOR CHECKLIST 1 (ISO 15189: 2022)

(To be filled in by the Lead Assessor)

The following pages present a checklist of the criteria from ISO 15189: 2022, which is the basis for NABL to decide accreditation for laboratories. The laboratory's policies and procedures must meet full requirements of ISO 15189:2022, NABL 133, NABL 142, NABL 163 and NABL specific criteria where ever applicable. **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
+	NON - COMPLIANCE
NA	NOT APPLICABLE
BLANK	NOT ASSESSED

The Lead Assessor must review the laboratory's documented system to verify compliance with the requirements of ISO 15189: 2022 assess to verify that the documented management system is indeed implemented as described, record conclusion/comments related to any requirements. All non-conformity(ies) must be identified and reported separately on NAF a4. This checklist be submitted as a part of the assessment report.

Name of the Laboratory	
City/ Town	
Date(s) of Assessment	
Lead Assessor's Name	
Signature	

#-Applicable for Offline Assessments

Assessor shall enter comment in "REMARK" box for each sub clause.

				DOCUMENTATION		
					IMPLEMENTATION	
REQUIREMENTS OF ISO 15189: 2022						REMARK
4.	GENERAL REQUIREMENTS					
4.1	Impartiality					
	a)	Laboratory activities shall be undertaken impartially. The laboratory shall be structured and managed to safeguard impartiality.				
	b)	The laboratory management shall be committed to impartiality.				
	c)	The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.				
	d)	The laboratory shall monitor its activities and its relationships to identify threats to its impartiality. This monitoring shall include relationships of its personnel. <i>NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new laboratory users, etc. Such relationships do not necessarily present the laboratory with a threat to impartiality.</i>				
	e)	If a threat to impartiality is identified, the effect shall be eliminated or minimized so that the impartiality is not compromised. The laboratory shall be able to demonstrate how it mitigates such threat.				
4.2	Confidentiality					
	4.2.1	Management of information The laboratory shall be responsible, through legally enforceable agreements, for the management of all patient information obtained or created during the performance of laboratory activities. Management of patient information shall include privacy and confidentiality. The laboratory shall inform the user and/or the patient in advance, of the information it intends to place in the public domain. Except for information that the user and/or the patient makes publicly available, or when agreed between the laboratory and the patient (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.				
	4.2.2	Release of information When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the patient concerned shall be notified of the information released, unless prohibited by law. Information about the patient from a source other than the patient (e.g. complainant, regulator) shall be kept confidential by the laboratory. The identity of the source shall be kept confidential by the laboratory and shall not be shared with the patient, unless agreed by the source.				

Comments of Assessor on compliance against: -

	4.2.3 Personnel responsibility	Personnel, including any committee members, contractors, personnel of external bodies, or individuals with access to laboratory information acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities.			
4.3	Requirements regarding patients				
		Laboratory management shall ensure that patients' well-being, safety and rights are the primary considerations. The laboratory shall establish and implement the following processes:			
	a)	opportunities for patients and laboratory users to provide helpful information to aid the laboratory in the selection of the examination methods, and the interpretation of the examination results;			
	b)	provision of patients and users with publicly available information about the examination process, including costs when applicable, and when to expect results;			
	c)	periodic review of the examinations offered by the laboratory to ensure they are clinically appropriate and necessary;			
	d)	where appropriate, disclosure to patients, users and any other relevant persons, of incidents that resulted or could have resulted in patient harm, and records of actions taken to mitigate those harms;			
	e)	treatment of patients, samples, or remains, with due care and respect;			
	f)	obtaining informed consent when required;			
	g)	ensuring the ongoing availability and integrity of retained patient samples and records in the event of the closure, acquisition or merger of the laboratory;			
	h)	making relevant information available to a patient and any other health service provider at the request of the patient or the request of a healthcare provider acting on their behalf;			
	i)	upholding the rights of patients to care that is free from discrimination.			
5	STRUCTURAL REQUIREMENTS				
5.1	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.			
		<i>NOTE For the purposes of this document, a government laboratory is deemed to be a legal entity on the basis of its government status.</i>			
5.2	Laboratory director				
	5.2.1	Laboratory director competence			
		The laboratory shall be directed by a person, or persons however named, with the specified qualifications, competence, delegated authority, responsibility, and resources to fulfil the requirements of this document.			
	5.2.2	Laboratory director responsibilities			
		The laboratory director is responsible for the implementation of the management system, including the application of risk management to all aspects of the laboratory operations so that risks to patient care and opportunities to improve are systematically identified and addressed.			
		The duties and responsibilities of the laboratory director shall be documented.			

	5.2.3	Delegation of duties The laboratory director may delegate either selected duties or responsibilities, or both, to qualified and competent personnel and such delegation shall be documented. However, the laboratory director shall maintain the ultimate responsibility for the overall operation of the laboratory.			
	5.3	Laboratory activities			
	5.3.1	General The laboratory shall specify and document the range of laboratory activities, including laboratory activities performed at sites other than the main location (e.g. POCT, sample collection) for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.			
	5.3.2	Conformance with requirements Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the users, regulatory authorities and organizations providing recognition. This applies to the complete range of specified and documented laboratory activities, regardless of where the service is provided.			
	5.3.3	Advisory activities Laboratory management shall ensure that appropriate laboratory advice and interpretation are available and meet the needs of patients and users.			
		The laboratory shall establish arrangements for communicating with laboratory users on the following when applicable:			
	a)	advising on choice and use of examinations, including required type of sample, clinical indications and limitations of examination methods, and the frequency of requesting the examination;			
	b)	providing professional judgments on the interpretation of the results of examinations;			
	c)	promoting the effective utilization of laboratory examinations;			
	d)	advising on scientific and logistical matters such as instances of failure of sample(s) to meet acceptability criteria.			
	5.4	Structure and authority			
	5.4.1	General The laboratory shall:			
	a)	define its organization and management structure, its place in any parent organization, and the relationships between management, technical operations and support services;			
	b)	specify the responsibility, authority, lines of communication and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;			
	c)	specify its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.			
	5.4.2	Quality management The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:			

NABL 133

• Assessor to comment on compliance of NABL 133 by verifying few test report / test certificates

		a)	implementation, maintenance and improvement of the management system;			
		b)	identification of deviations from the management system or from the procedures for performing laboratory activities;			
		c)	initiation of actions to prevent or minimize such deviations;			
		d)	reporting to laboratory management on the performance of the management system and any need for improvement;			
		e)	ensuring the effectiveness of laboratory activities.			
			<i>NOTE These responsibilities can be assigned to one or more persons.</i>			

5.5 Objectives and policies

	a)	Laboratory management shall establish and maintain objectives and policies (see 8.2) to:			
	1)	meet the needs and requirements of its patients and users;			
	2)	commit to good professional practice;			
	3)	provide examinations that fulfil their intended use;			
	4)	conform to this document.			
	b)	Objectives shall be measurable, and consistent with policies. The laboratory shall ensure that the objectives and policies are implemented at all levels of the laboratory organization.			
	c)	Laboratory management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.			
	d)	The laboratory shall establish quality indicators to evaluate performance throughout key aspects of pre-examination, examination, and post-examination processes and monitor performance in relation to objectives (see 8.8.2).			
		<i>NOTE Types of quality indicators include the number of unacceptable samples relative to the number received, the number of errors at either registration or sample receipt, or both, the number of corrected reports, the rate of achievement of specified turnaround times.</i>			

5.6 Risk management

	a)	Laboratory management shall establish, implement, and maintain processes for identifying risks of harm to patients and opportunities for improved patient care associated with its examinations and activities, and develop actions to address both risks and opportunities for improvement (see 8.5).			
	b)	The laboratory director shall ensure that these processes are evaluated for effectiveness and modified, when identified as being ineffective.			
		<i>NOTE 1 ISO 22367 provides details for managing risk in medical laboratories.</i>			
		<i>NOTE 2 ISO 35001 provides details for laboratory biorisk management.</i>			

- Assessor to also verify if any test reports/certificates has been issued by the laboratory during the non-accredited period (i.e break in accreditation cycle, if any)
- If lab uses NABL Accredited CAB Combined ILAC MRA Mark, assessor to verify its agreement with NABL.

6	RESOURCE REQUIREMENTS				
6.1	General The laboratory shall have available the personnel, facilities, equipment, reagents, consumables and support services necessary to manage and perform its activities.				
6.2	Personnel				
	6.2.1 General				
		a)			
		b)			
		c)			
		d)			
	6.2.2 Competence requirements				
		a)			
		b)			
		c)			
		d)			
	6.2.3 Authorization The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:				
		a)			

		b)	review, release, and reporting of results;			
		c)	use of laboratory information systems, in particular: accessing patient data and information, entering patient data and examination results, changing patient data or examination results.			
	6.2.4	Continuing education and professional development				
		A continuing education programme shall be available to personnel who participate in managerial and technical processes. All personnel shall participate in continuing education and regular professional development, or other professional liaison activities.				
		The suitability of the programmes and activities shall be periodically reviewed.				
	6.2.5	Personnel records				
		The laboratory shall have procedures and retain records for:				
		a)	determining the competence requirements specified in 6.2.2 a);			
		b)	position descriptions;			
		c)	training and re-training;			
		d)	authorization of personnel;			
		e)	monitoring competence of personnel.			
6.3	Facilities and environmental conditions					
	6.3.1	General				
		The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results, or the safety of patients, visitors, laboratory users, and personnel. This shall include pre-examination related facilities and sites other than the main laboratory premises where examinations are performed, as well as POCT.				
		The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be specified, monitored, and recorded.				
		<i>NOTE 1 ISO 15190 provides details for facility and environmental conditions.</i>				
		<i>NOTE 2 Environmental conditions that can adversely affect the validity of results include, but are not limited to: adventitious amplified nucleic acid, microbial contamination, dust, electromagnetic disturbances, radiation, lighting conditions (illumination), humidity, electrical supply, temperature, sound and vibration.</i>				
	6.3.2	Facility controls				
		Facility controls shall be implemented, recorded, monitored, periodically reviewed, and shall include:				
		a)	control of access, taking into consideration safety, confidentiality, quality, and safeguarding medical information and patient samples;			
		b)	prevention of contamination, interference, or adverse influences on laboratory activities that can arise from energy sources, lighting, ventilation, noise, water and waste disposal;			
		c)	prevention of cross-contamination, where examination procedures pose a risk, or where work can be affected or influenced by lack of separation;			

		d)	provision of safety facilities and devices, where applicable and regularly verifying their functioning; EXAMPLES The operation of emergency release, intercom and alarm systems for cold rooms and walk-in freezers, accessibility of emergency showers, eyewash and resuscitation equipment.			
		e)	maintenance of laboratory facilities in a functional and reliable condition.			
		6.3.3	Storage facilities			
		a)	Storage space, with conditions that ensure the continuing integrity of samples, equipment, reagents, consumables, documents and records, shall be provided.			
		b)	Patient samples and materials used in examination processes shall be stored in a manner that prevents cross contamination and deterioration.			
		c)	Storage and disposal facilities for hazardous materials and biological waste shall be appropriate to the classification of the materials in the context of any statutory or regulatory requirements.			
		6.3.4	Personnel facilities There shall be adequate access to toilet facilities and a supply of drinking water, as well as facilities for storage of personal protective equipment and clothing. Space for personnel activities, such as meetings, quiet study and a rest area, should be provided.			
		6.3.5	Sample collection facilities Sample collection facilities shall:			
		a)	enable collection to be undertaken in a manner that does not invalidate results or adversely affect the quality of examinations;			
		b)	consider privacy, comfort and needs (e.g. disabled access, toilet facility) of patients and accommodation of accompanying persons (e.g. guardian or interpreter) during collection;			
		c)	provide separate patient reception and collection areas;			
		d)	d) maintain first aid materials for both patients and personnel. <i>NOTE ISO 20658 provides details for sample collection facilities.</i>			
	6.4	Equipment				
	6.4.1	General The laboratory shall have processes for the selection, procurement, installation, acceptance testing (including acceptability criteria), handling, transport, storage, use, maintenance, and decommissioning of equipment, in order to ensure proper functioning and to prevent contamination or deterioration. <i>NOTE Laboratory equipment includes hardware and software of instruments, measuring systems, and laboratory information systems, or any equipment that influences the results of laboratory activities, including sample transportation systems.</i>				
	6.4.2	Equipment requirements				
		a)	The laboratory shall have access to equipment required for the correct performance of laboratory activities.			
		b)	Where the equipment is used outside the laboratory's permanent control, or equipment manufacturer's functional			

			specification, laboratory management shall ensure that the requirements of this document are met.			
		c)	Each item of equipment that can influence laboratory activities shall be uniquely labelled, marked or otherwise identified and a register maintained.			
		d)	The laboratory shall maintain and replace equipment as needed to ensure the quality of examination results.			
		6.4.3	Equipment acceptance procedure The laboratory shall verify that the equipment conforms to specified acceptability criteria before being placed or returned into service. Equipment used for measurement shall be capable of achieving either the measurement accuracy or measurement uncertainty, or both, required to provide a valid result (see 7.3.3 and 7.3.4 for details). <i>NOTE 1 This includes equipment used in the laboratory, equipment on loan, or equipment used in point of care settings, or in associated or mobile facilities, authorized by the laboratory.</i> <i>NOTE 2 The verification of equipment acceptance testing can be, where relevant, based on the calibration certificate of the returned equipment.</i>			
		6.4.4	Equipment instructions for use			
		a)	The laboratory shall have appropriate safeguards to prevent unintended adjustments of equipment that can invalidate examination results.			
		b)	Equipment shall be operated by trained, authorized, and competent personnel.			
		c)	Instructions for the use of equipment, including those provided by the manufacturer, shall be readily available.			
		d)	The equipment shall be used as specified by the manufacturer, unless validated by the laboratory (see 7.3.3).			
		6.4.5	Equipment maintenance and repair			
		a)	The laboratory shall have preventive maintenance programs, based on manufacturer's instructions. Deviations from the manufacturer's schedules or instructions shall be recorded.			
		b)	Equipment shall be maintained in a safe working condition and working order. This shall include electrical safety, any emergency stop devices and the safe handling and disposal of hazardous materials by authorized personnel.			
		c)	Equipment that is defective or outside specified requirements, shall be taken out of service. It shall be clearly labelled or marked as being out of service, until it has been verified to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate actions when non-conforming work occurs (see 7.5).			
		d)	When applicable, the laboratory shall decontaminate equipment before service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment.			
		6.4.6	Equipment adverse incident reporting Adverse incidents and accidents that can be attributed directly to specific equipment shall be investigated and reported to either the manufacturer or supplier, or both, and appropriate authorities, as required.			

- If any NC raised during previous onsite assessment for misuse of NABL symbol / Claim of Accreditation and/ or any complaint registered by NABL related to misuse of NABL symbol, Assessor to give a comment regarding the same.

		The laboratory shall have procedures for responding to any manufacturer's recall or other notice, and taking actions recommended by the manufacturer.			
	6.4.7	Equipment records Records shall be maintained for each item of equipment that influences the results of laboratory activities. These records shall include the following, where relevant:			
		a) manufacturer and supplier details, and sufficient information to uniquely identify each item of equipment, including software and firmware;			
		b) dates of receipt, acceptance testing and entering into service;			
		c) evidence that equipment conforms with specified acceptability criteria;			
		d) the current location;			
		e) condition when received (e.g. new, used or reconditioned);			
		f) manufacturer's instructions;			
		g) the program for preventive maintenance;			
		h) any maintenance activities performed by the laboratory or approved external service provider;			
		i) damage to, malfunction, modification, or repair of the equipment;			
		j) equipment performance records such as reports or certificates of calibrations or verifications, or both, including dates, times and results;			
		k) status of the equipment such as active or in-service, out-of-service, quarantined, retired or obsolete.			
		These records shall be maintained and shall be readily available for the lifespan of the equipment or longer, as specified in 8.4.3.			
6.5	Equipment calibration and metrological traceability				
	6.5.1	General The laboratory shall specify calibration and traceability requirements that are sufficient to maintain consistent reporting of examination results. For quantitative methods of a measured analyte, specifications shall include calibration and metrological traceability requirements. Qualitative methods and quantitative methods that measure characteristics rather than discrete analytes shall specify the characteristic being assessed and such requirements necessary for reproducibility over time. <i>NOTE Examples of qualitative methods and quantitative methods that may not allow metrological traceability include red cell antibody detection, antibiotic sensitivity assessment, genetic testing, erythrocyte sedimentation rate, flow cytometry marker staining, and tumour HER2 immunohistochemical staining.</i>			
	6.5.2	Equipment calibration The laboratory shall have procedures for the calibration of equipment that directly or indirectly affects examination results. The procedures shall specify:			
		a) conditions of use and manufacturer's instructions for calibration;			
		b) recording of the metrological traceability;			
		c) verification of the required measurement accuracy and the functioning of the measuring system at specified intervals;			
		d) recording the calibration status and date of re-calibration;			
		e) ensuring that, where correction factors are used, these are updated and recorded when re-calibration occurs;			

NABL 142

National Accreditation Board for Testing and Calibration Laboratories

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		f)	handling of situations when calibration was out of control, to minimize risk to service operation and to patients.			
	6.5.3	Metrological traceability of measurement results				
		a)	The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference. <i>NOTE Information of traceability to a higher order reference material or reference procedure can be provided by an examination system manufacturer. Such documentation is acceptable only when the manufacturer's examination system and calibration procedures are used without modification.</i>			
		b)	The laboratory shall ensure that measurement results are traceable to the highest possible level of traceability and to the International System of Units (SI) through: — calibration provided by a competent laboratory; or <i>NOTE 1 Calibration laboratories fulfilling the requirements of ISO/IEC 17025 are considered competent for performing calibrations.</i> — certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; <i>NOTE 2 Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.</i> <i>NOTE 3 Certified reference material fulfilling the requirements of ISO 15194 are considered suitable.</i>			
		c)	Where it is not possible to provide traceability according to 6.5.3 a), other means for providing confidence in the results shall be applied, including but not limited to the following: — results of reference measurement procedures, specified methods or consensus standards, that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison; — measurement of calibrator by another procedure. <i>NOTE ISO 17511 provides further information on how to manage the compromises in the metrological traceability of measurands.</i>			
		d)	For genetic examinations, traceability to genetic reference sequences shall be established.			
		e)	For qualitative methods, traceability may be demonstrated by testing of known material or previous samples sufficient to show consistent identification and, when applicable, intensity of reaction.			
	6.6	Reagents and consumables				
	6.6.1	General	The laboratory shall have processes for the selection, procurement, reception, storage, acceptance testing and inventory management of reagents and consumables. <i>NOTE Reagents include substances which are commercially supplied or prepared in-house, reference materials (calibrators and QC materials),</i>			

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		culture media; consumables include pipette tips, glass slides, POCT supplies etc.			
	6.6.2	Reagents and consumables — Receipt and storage The laboratory shall store reagents and consumables according to manufacturers' specifications and monitor the environmental conditions where relevant. When the laboratory is not the receiving facility, it shall verify that the receiving facility has adequate storage and handling capabilities to maintain supplies in a manner that prevents damage and deterioration.			
	6.6.3	Reagents and consumables — Acceptance testing Each reagent or new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, shall be verified for performance before placing into use, or before release of results, as appropriate. Consumables that can affect the quality of examinations shall be verified for performance before placing into use. <i>NOTE 1 Comparative IQC performance of new reagent lots and that of previous lots can be used as evidence for acceptance (see 7.3.7.2). Patient samples are preferred when comparing different reagent lots to avoid issues with commutability of IQC materials.</i> <i>NOTE 2 Verification can sometimes be based on the certificate of analysis of the reagent.</i>			
	6.6.4	Reagents and consumables — Inventory management The laboratory shall establish an inventory management system for reagents and consumables. The system for inventory management shall segregate reagents and consumables that have been accepted for use from those that have been neither inspected nor accepted for use.			
	6.6.5	Reagents and consumables — Instructions for use Instructions for the use of reagents and consumables, including those provided by manufacturers, shall be readily available. Reagents and consumables shall be used according to the manufacturer's specifications. If they are intended to be used for other purposes see 7.3.3.			
	6.6.6	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 either the manufacturer or supplier, or both, and appropriate authorities, as required. The laboratory shall have procedures for responding to any manufacturer's recall or other notice and taking actions recommended by the manufacturer.			
	6.6.7	Reagents and consumables — Records 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 information, including instructions, name and batch code or lot number;			

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(Wherever applicable)

		c)	date of receipt and condition when received, the expiry date, date of first use and, where applicable, the date the reagent or consumable was taken out of service;			
		d)	records that confirm the reagent's or consumable's initial and ongoing acceptance for use.			
		Where the laboratory uses reagents prepared, resuspended or combined in-house, the records shall include, in addition to the relevant information above, reference to the person or persons undertaking the preparation, as well as the dates of preparation and expiry.				
6.7	Service agreements					
	6.7.1	Agreements with laboratory users The laboratory shall have a procedure to establish and periodically review agreements for providing laboratory activities. The procedure shall ensure:				
		a)	the requirements are adequately specified;			
		b)	the laboratory has the capability and resources to meet the requirements;			
		c)	when applicable, the laboratory advises the user of the specific activities to be performed by referral laboratories and consultants.			
		Laboratory users shall be informed of any changes to an agreement that can affect examination results. Records of reviews, including any significant changes, shall be retained.				
	6.7.2	Agreements with POCT operators Service agreements between the laboratory and other parts of the organization using laboratory supported POCT, shall ensure that respective responsibilities and authorities are specified and communicated. <i>NOTE Established multidisciplinary POCT committees can be used to manage such service agreements as described in Annex A.</i>				
6.8	Externally provided products and services					
	6.8.1	General The laboratory shall ensure that externally provided products and services that affect laboratory activities are suitable when such products and services are:				
		a)	intended for incorporation into the laboratory's own activities;			
		b)	provided, in part or in full, directly to the user by the laboratory, as received from the external provider;			
		c)	used to support the operation of the laboratory.			
		It can be necessary to collaborate with other organizational departments or functions to fulfil this requirement. <i>NOTE Services include, e.g. sample collection services, pipette and other calibration services, facility and equipment maintenance services, EQA programs, referral laboratories and consultants.</i>				
	6.8.2	Referral laboratories and consultants The laboratory shall communicate its requirements to referral laboratories and consultants who provide interpretations and advice, for:				
		a)	the procedures, examinations, reports and consulting activities to be provided;			
		b)	management of critical results;			

		c)	any required personnel qualifications and demonstration of competence.			
			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. A list of all referral laboratories and consultants shall be maintained.			
		6.8.3	Review and approval of externally provided products and services The laboratory shall have procedures and retain records for:			
		a)	defining, reviewing, and approving the laboratory's requirements for all externally provided products and services;			
		b)	defining the criteria for qualification, selection, evaluation of performance and re-evaluation of external providers;			
		c)	referral of samples;			
		d)	ensuring that externally provided products and services conform to the laboratory's established requirements, or where applicable to the relevant requirements of this document, before they are used or directly provided to the user;			
		e)	taking any actions arising from evaluations of the performance of external providers.			
	PROCESS REQUIREMENTS					
7	7.1	General The laboratory shall identify potential risks to patient care in the pre-examination, examination and post-examination processes. These risks shall be assessed and mitigated to the extent possible. The residual risk shall be communicated to users as appropriate. The identified risks and effectiveness of the mitigation processes shall be monitored and evaluated according to the potential harm to the patient. The laboratory shall also identify opportunities to improve patient care and develop a framework to manage these opportunities (see 8.5).				
	7.2	Pre-examination processes				
	7.2.1	General The laboratory shall have procedures for all pre-examination activities and make them accessible to relevant personnel. <i>NOTE 1 The pre-examination processes can influence the outcome of the intended examination.</i> <i>NOTE 2 ISO 20658 provides detailed information for sample collection and transport.</i> <i>NOTE 3 ISO 20186-1, ISO 20186-2, ISO 20186-3, ISO 20166 (all parts), ISO 20184 (all parts), ISO 23118 and ISO 4307 provide detailed information for samples from particular sources and for specific analytes.</i>				
	7.2.2	Laboratory information for patients and users The laboratory shall have appropriate information available for its users and patients. The information shall be sufficiently detailed to provide laboratory users with a comprehensive understanding of the laboratory's scope of activities and requirements. The information shall include as appropriate:				
		a)	the location(s) of the laboratory, operating hours and contact information;			
		b)	the procedures for requesting and the collection of samples;			
		c)	the scope of laboratory activities and time for expected availability of results;			

		d)	the availability of advisory services;			
		e)	requirements for patient consent;			
		f)	factors known to significantly impact the performance of the examination or the interpretation of the results;			
		g)	the laboratory complaint process.			
	7.2.3	Requests for providing laboratory examinations				
	7.2.3.1	General				
		a)	Each request accepted by the laboratory for examination(s) shall be considered an agreement.			
		b)	The examination request shall provide sufficient information to ensure: — unequivocal traceability of the patient to the request and sample; - identity and contact information of requester; — identification of the examination(s) requested; — informed clinical and technical advice, and clinical interpretation can be provided.			
		c)	The examination request information may be provided in a format or medium as deemed appropriate by the laboratory and acceptable to the user.			
		d)	Where necessary for patient care, the laboratory shall communicate with users or their representatives, to clarify the user's request.			
	7.2.3.2	Oral requests The laboratory shall have a procedure for managing oral requests for examinations, if applicable, that includes the provision of documented confirmation of the examination request to the laboratory, within a given time.				
	7.2.4	Primary sample collection and handling				
	7.2.4.1	General The laboratory shall have procedures for the collection and handling of primary samples. Information shall be available to those responsible for sample collection. Any deviation from the established collection procedures shall be clearly recorded. The potential risk and impact on the patient outcome of acceptance or rejection of the sample shall be assessed, recorded and shall be communicated to the appropriate personnel. The laboratory shall periodically review requirements for sample volume, collection device and preservatives for all sample types, as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected, and samples are properly collected to preserve the analyte.				
	7.2.4.2	Information for pre-collection activities The laboratory shall provide information and instructions for pre-collection activities with sufficient detail to ensure that the integrity of the sample is not compromised. This shall include:				
		a)	preparation of the patient (e.g. instructions to caregivers, sample collectors and patients);			
		b)	type and amount of the primary sample to be collected with descriptions of the containers and any necessary additives, and when relevant the order of collecting samples;			
		c)	special timing of collection, where relevant;			