

NABL 219



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Assessment Forms and Checklist (Based on ISO/IEC 17025:2017)

Issue No.: 02
Issue Date: 16-Feb-2021

Amendment No.: 01
Amendment Date: 02-Jul-2021

AMENDMENT SHEET

Sl.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature CEO
1.	15 & 39, 21 & 45, 25 & 49, 28 & 52	6.3 7.2.1.3, 7.8.1, 7.8.6.2	02.07.2021	Clause no. corrected and missed clause included.	Typographical error	-Sd-	-Sd-
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							

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ASSESSMENT SCHEDULE

Name of the Laboratory:				
Authorized representative of Laboratory:			Date(s) of Visit:	
Type of Assessment: Final assessment / 1 st Surveillance / Re-Assessment / Supplementary Visit				
Field: Testing / Calibration		Discipline (s):		
Facility (s): Permanent / Site / Mobile				
Assessment Standard: ISO / IEC 17025: 2017				
Specific Criteria of NABL (If applicable):				
Assessment Timings		Opening/Closing Meeting Date/Time		Daily Debriefing Date / Time (at the end of each day)
Morning: AM to PM Afternoon: PM to PM		Opening Meeting: Closing Meeting:		Day 1: Day 2: Day 3:
Name and Expertise of the Assessor	Schedule of Locations/ 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 (only for observation)				
I declare that the assessment schedule has been prepared after discussing with the assessment team members.				
Signature of Lead Assessor				

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CALIBRATION(S) WITNESSED BY THE ASSESSMENT TEAM

(To be filled in by each Technical Assessor)

Name of the Laboratory:		Date(s) of Assessment:
Name of the Assessor:	Locations:	Discipline(s):
Calibration(s) witnessed	Calibration Method Used or Standard Referred	Remarks
Signature and Name of Assessor		

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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:		Location(s):	
Discipline:	Facility (Permanent / Site / Mobile):	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			
Uncertainty of Measurement (+) at 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 Assessor)

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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/IEC 17025: 2017 / NABL 133 Clause No. / 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 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 Assessor			
REMARKS BY LEAD ASSESSOR, IF ANY:			
Acceptance/Signature & Name of Lead Assessor			

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SUMMARY OF ASSESSMENT

Sl.	Item	Details														
1.	Name of the Laboratory															
2.	Date(s) of Assessment															
3.	Field															
4.	Discipline(s)															
5.	Facility	Permanent/ Site/ Mobile														
6.	Type of Assessment	Final Assessment/ Surveillance/ Re-assessment / Supplementary visit														
7.	Assessment Team/ Capacity															
8.	Date of earlier visit:	Non-Conformities during earlier visit 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 143*															
	NABL 163*															
	Specific Criteria* (wherever applicable)															
	*(Lead Assessor to comment on the basis of observations of Technical Assessor(s))															
11.	Assessment Summary															
12.	Recommendation of Assessment team as per ISO/IEC 17025: 2017															
13.	Only if accreditation is recommended, date by which the Corrective Action to be submitted by the CAB 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 CAB															
Enclosures	NAF 6	NAF 4	NAF 3/3A	NAF 1	NAF 1A	Checklist	Form 72	Form 74	Form 45	TA/DA Forms	PT/ILC records	Any other docs.				
No. of Pages																
Acknowledgement by Authorised Representative of CAB & Date							Signature of Lead Assessor & Date									

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RECOMMENDED SCOPE OF ACCREDITATION

[illegible]

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		
Organisation		
Address		
Capacity	Lead Assessor / Technical Assessor / Technical Expert / Observer	
CAB* Assessed		
Date of Assessment		
Type of Assessment	QM Adequacy / Pre-Assessment / Final assessment / Onsite Surveillance / Re-Assessment / 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, 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

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ASSESSOR CHECKLIST 1 (ISO/IEC 17025: 2017)

(To be filled in by the Lead Assessor)

The following pages present a checklist of the criteria from ISO/IEC 17025: 2017, which is the basis for NABL to decide accreditation for laboratories. The laboratory's policies and procedures must meet full requirements of ISO/IEC 17025: 2017, NABL 133, NABL 142, NABL 143, NABL 163 and NABL specific criteria where ever applicable. **The actual standard must be referred for the definitive language and interpretation.** The Assessor must complete this checklist.

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

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

The Lead Assessor must review the laboratory's documented system to verify compliance with the requirements of ISO/IEC 17025: 2017 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-4. 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.

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				DOCUMENTATION		
					IMPLEMENTATION	
REQUIREMENTS OF ISO/IEC 17025: 2017						REMARK
4	GENERAL REQUIREMENTS					
	4.1	Impartiality				
		4.1.1	Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality			
		4.1.2	The laboratory management shall be committed to impartiality.			
		4.1.3	The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality			
		4.1.4	The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality. 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 customers, etc.			
		4.1.5	If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.			
	4.2	Confidentiality				
		4.2.1	The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (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	When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.			
		4.2.3	Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source.			
		4.2.4	Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.			

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5	STRUCTURAL REQUIREMENTS			
5.1	The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities. NOTE: For the purposes of this document, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.			
5.2	The laboratory shall identify management that has overall responsibility for the laboratory			
5.3	The laboratory shall define and document the range of laboratory activities 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.			
5.4	Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.			
5.5	The laboratory shall:			
	a	define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;		
	b	specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;		
	c	document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.		
5.6	The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:			
	a	implementation, maintenance and improvement of the management system;		
	b	identification of deviations from the management system or from the procedures for performing laboratory activities;		
	c	initiation of actions to prevent or minimize such deviations;		
	d	reporting to laboratory management on the performance of the management system and any need for improvement;		
	e	ensuring the effectiveness of laboratory activities		
5.7	Laboratory management shall ensure that			
	a	communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;		
	b	the integrity of the management system is maintained when changes to the management system are planned and implemented		

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6	RESOURCE REQUIREMENTS				
6.1	General				
	The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.				
6.2	Personnel				
	6.2.1	All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.			
	6.2.2	The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.			
	6.2.3	The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.			
	6.2.4	The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities.			
	6.2.5	The laboratory shall have procedure(s) and retain records for:			
	a	determining the competence requirements;			
	b	selection of personnel;			
	c	training of personnel;			
	d	supervision of personnel;			
	e	authorization of personnel;			
	f	monitoring competence of personnel.			
	6.2.6	The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:			
	a	development, modification, verification and validation of methods;			
	b	analysis of results, including statements of conformity or opinions and interpretations;			
	c	report, review and authorization of results.			
6.3	Facilities and environmental conditions				
	6.3.1	The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results. NOTE: Influences that can adversely affect the validity of results can include, but are not limited to, microbial contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration.			
	6.3.2	The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented.			

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		6.3.3	The laboratory shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.			
		6.3.4	Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to:			
		a	access to and use of areas affecting laboratory activities;			
		b	prevention of contamination, interference or adverse influences on laboratory activities;			
		c	effective separation between areas with incompatible laboratory activities			
		6.3.5	When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met			
		6.4	Equipment			
		6.4.1	The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results.			
			NOTE 1: A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard reference materials and quality control materials. ISO 17034 contains additional information on reference material producers (RMPs). RMPs that meet the requirements of ISO 17034 are considered to be competent. Reference materials from RMPs meeting the requirements of ISO 17034 are provided with a product information sheet/certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their associated measurement uncertainty and metrological traceability. NOTE 2: ISO Guide 33 provides guidance on the selection and use of reference materials. ISO Guide 80 provides guidance to produce in-house quality control materials.			
		6.4.2	When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met			
		6.4.3	The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.			
		6.4.4	The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service.			

Comments of Assessor on compliance against: -

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		6.4.5	The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.			
		6.4.6	Measuring equipment shall be calibrated when - the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or - calibration of the equipment is required to establish the metrological traceability of the reported results. NOTE: Types of equipment having an effect on the validity of the reported results can include: - those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement; - those used to make corrections to the measured value, e.g. temperature measurements; - those used to obtain a measurement result calculated from multiple quantities			
		6.4.7	The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.			
		6.4.8	All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.			
		6.4.9	Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service. It shall be isolated to prevent its use or 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 the management of nonconforming work procedure (see 7.10).			
		6.4.10	When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.			
		6.4.11	When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.			
		6.4.12	The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results.			
		6.4.13	Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable:			
		a	the identity of equipment, including software and firmware version;			
		b	the manufacturer's name, type identification, and serial number or other unique identification;			
NABL 133			• Assessor to comment on compliance of NABL 133 by verifying few test report / test certificates			

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