



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Application Form for Medical Testing Laboratories

ISSUE NO.: 06
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AMENDMENT SHEET

S. No.	Amendment No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature Competent Authority
1.	01	9& 12	7& 9	22.03.2018	Change in Payment option	Development of NABL payment gateway/ Cheque/DD	-Sd-	-Sd-
2.	02	6	1.9	20.06.2018	a to d from a to c	typographical error	-Sd-	-Sd-
		11	Annexure-A		Changes as highlighted	Start of Recognition of SCF	-Sd-	-Sd-
3.	03	3	1	28-Apr-2020	Following content included 'fraudulent behaviour, false information and concealing the information may lead to rejection of application or termination of the assessment process.	In line with ISO/IEC 17011: 2017 requirements	-Sd-	-Sd-
		3	5		Reference to NABL 201 deleted	NABL 201 has been withdrawn		
		3	6		Type and evidence accepted in support of legal identity document included	Align with other application form		
		3	8		Word 'APLAC' is replaced with APAC	Due to merger of APALC in PAC, new organisation name is APAC		
		4, 7	11, 2.2		Alignment of Scope of Accreditation as highlighted	In-line with Cl. 7.8.3 of ISO/IEC 17011: 2017		
		4, 7	15, 3.2		Rearrangement in the text related to the Proposed person(s)	Policy decision		

					reviewing the results and authorizing the release of the report as highlighted			
		6	1.8		Inclusion of two new categories	Outcome of management review		
		6	2.1		Disciplines are aligned as per NABL 112	NABL 112 is implemented.		
		8	3.4.1		Requirements of 4 days training removed	Outcome of management review		
4.	04	4, 5	-	11.01.2022	As highlighted	For better clarity/ internal review	-Sd-	-Sd-
		7	1.3		Requirements for Mobile Van and Movable container included	Internal review		
		8	1.9		Text revised for better clarity			
		9	2.1		Medical imaging discipline included			
		10, 11, 12	3.2, 4, 5, 8		As highlighted			
		15	----		Declaration Form included			
5.	05	----	----	23.06.2023	Added ISO 15189: 2022	Release of ISO 15189: 2022 version	-Sd-	-Sd-
		6,7,8, 9	----		Segregation of requirements & instructions to be followed and information for testing laboratories	For more clarity		
		8, 9	1,		As highlighted	Internal Review		
					Addition of Point of Care testing (POCT) under medical testing facility	Release of ISO 15189: 2022 version		
					As highlighted	Internal Review		

		10	2		As highlighted	Internal Review		
					Included Point of Care testing (POCT) in 2.2	Release of ISO 15189: 2022 version		
					As highlighted	Internal Review		
		11	3.1, 3.2, 3.3 & 3.4.1		As highlighted	Internal Review		
		12	3.4.2		Addition of details regarding Medical Imaging Laboratories	Medical Imaging included under Medical field		
		12	4.1, 4.2		As highlighted	Internal Review		
		13	4.3 & 4.4		Addition of details regarding Medical Imaging Laboratories	Medical Imaging included under NABL 153		
			6.1		As highlighted	Internal Review		
			6.2		Addition of table for details of ILC participation			
		14	8		As highlighted	Internal Review		
		17	Declarati on Form		As highlighted	Internal review		
6.	06	11	3.3.2	21.02.2024	As highlighted	ISO 15189:2012 is under transition to ISO 15189: 2022	-Sd-	-Sd-
		14	8.11					
		16	Applicati on Form- Checklist - Sr. No. 15					

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Requirements to be fulfilled and instructions to be followed by the medical testing laboratories while applying for NABL Accreditation

1. Application shall be made in the prescribed form NABL 153 only. All applied disciplines of medical testing should be covered in the same application form. The application shall consist of the following:
 - Completed application form.
 - Management System Document (howsoever named)
 - Prescribed application fees
 - Duly signed NABL 131

Note: Incomplete application, false information, concealing the information and fraudulent behavior discovered any time during accreditation process may lead to rejection of application or termination of the assessment process by denial of accreditation.

2. The applicant/accredited laboratory shall undertake to carry out its testing activities in such a way so as to meet the requirements of ISO 15189: 2012 or ISO 15189: 2022, NABL Application Document, Specific criteria, other relevant requirements of NABL and the regulatory authorities, as applicable at all times.

Note: Other relevant requirements of NABL are mentioned in documents such as NABL 111, NABL 163, NABL 133 and NABL 142. The list of documents is available on NABL website under publication section.

3. Applicant/accredited laboratories are advised to ensure that the latest versions of NABL documents are available with them and are implemented.
4. Laboratories are advised to familiarize themselves with NABL 100A 'General Information Brochure' NABL 100B 'Accreditation Process & Procedure', NABL 216 'Procedures for Dealing with Adverse Decisions', NABL 131 'Terms & Conditions for Obtaining and Maintaining NABL Accreditation' and NABL 133 'Policy for Use of NABL Symbol and / or Claim of Accreditation by Accredited Conformity Assessment Bodies (CAB) & NABL Accredited CAB Combined ILAC MRA Mark' before filling up this form.
5. The applicant/accredited laboratory shall provide/upload copy of the following appropriate document(s) in support of the legal entity status claimed:

Type of Legal Entity	Document / to be submitted
One Person Company	Registration certificate under The Companies Act, 2013
Limited Liability Partnership	Registration certificate under The Limited Liability Partnership Act, 2008
Company	Registration certificate under The Companies Act, 1956 or 2013
Societies/ Trust	Registration certificate under Societies Registration Act, 1860/ Registration under The Indian Trusts Act, 1882
Government	Gazette or Government Notification or self-Declaration on Letter head by Head of the organization

6.
 - a. The applicant/accredited laboratory shall provide the complete address of the laboratory for which it is seeking accreditation including the PIN Code. In case the applicant laboratory is located as a part of a larger organization/institution, then the exact address where the laboratory is located (eg. name of the building or in which floor the laboratory is located or any other unique identification of the laboratory's address, etc.) shall be provided.
 - b. The applicant/accredited laboratory may also provide any document issued by Government/local authorities in support of the address of the laboratory.
 - c. The applicant/accredited laboratory shall provide the layout of the premises including the details of laboratories departments/section.