



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Criteria and Procedure for NABL Medical (Entry Level) Testing Labs {NABL M(EL)T Labs} Program

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AMENDMENT SHEET

S. No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature CEO
1.	3	2 i	11-Jan-2021	Inclusion of requirements of legal identity	Internal Review	-Sd-	-Sd-
2.	3	2 vii		Inclusion of requirements of calibration/ AMC for equipment			
3.	5	5		Recommendation for Recognition by Review Committee is replaced by Recommendation by Reviewer and Approval of recognition is replaced with Approval of recognition Decision			
4.	5	5		Recommendation for continuation of Recognition by Review Committee is replaced with Recommendation for continuation of Recognition by Reviewer {Based on onsite (surveillance) assessment}			
5.	7	6 xi		CAB word is replaced with laboratories.			
6.	7	8		"Procedure for" word removed			
7.	7, 8	8.1 8.2		Actions by NABL and procedure for re-enrollment included.			
8.	8	8.3		Actions by NABL and note included.			
9.	9	9		Inclusion of Privileges Extended to the Laboratory upon approval			

CONTENTS

S. No.	Title	Page No.
	Amendment Sheet	1
	Contents	2
1.	Introduction	3
2.	Criteria	3
3.	Recognition process	4
4.	On-Site Assessment (Surveillance)	4
5.	Process Flow Diagram	5
6.	Terms and Conditions	6
7.	Monitoring of Proficiency Testing (PT) participation and performance	7
8.	Adverse Decision	7
9.	Privileges Extended to the Laboratory upon approval	9
	Annexure A	11

1. INTRODUCTION

NABL Medical (Entry Level) Testing Laboratories {NABL M(EL)T Lab} Program is an entry level program for medical laboratory under which laboratory shall be recognized for basic routine tests based on the satisfactory proficiency testing (PT) performance.

This scheme is:

- i. not covered under Asia Pacific Accreditation Co-operation (APAC) & International Laboratory Accreditation Co-operation (ILAC) MRA.
- ii. valid for one cycle of three years.
- iii. applicable only for basic routine tests as mentioned in **Annexure A**.
- iv. based on satisfactory performance in PT programs.

2. CRITERIA

- i. The laboratory shall have a valid legal identity as given below.

Type of Legal Identity	Document(s) to be submitted
Proprietorship	Bank passbook/ Account statement and PAN of the CAB
Partnership	Registration certificate under The Partnership Act, 1932
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

- ii. The applicant laboratory shall have satisfactorily participated in Proficiency Testing (PT) program conducted by accredited PT provider as per ISO/IEC 17043 before submission of application.
- iii. Test parameters covered in last six months in PT programs shall be considered for recognition. Six months shall be calculated from date of application submission.
- iv. Date of issue of PT result / report shall be considered as date for PT participation
- v. The laboratory shall continue participation for its scope in PT programs during recognition period (minimum 1 PT program per year).
- vi. On-site assessment (surveillance) shall be conducted once in three years cycle at any point of time.
- vii. Valid Calibration / AMC of the equipment required to test the parameters under the applied scope. For achieving traceability to the International System of Units (SI),