

AMENDMENT SHEET

S. No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature CEO
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							

CONTENTS

S. No.	Title	Page No.
	Amendment Sheet	1
	Contents	2
1.	Introduction	3
2.	Criteria	3
3.	Recognition process	3
4.	On-Site Assessment (Surveillance)	4
5.	Process Flow Diagram	4
6.	Terms and Conditions	5
7.	Monitoring of Proficiency Testing (PT) participation and performance	6
8.	Procedure for Adverse Decisions	6
	Annexure A	8

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 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.
- ii. 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.
- iii. Date of issue of PT result / report shall be considered as date for PT participation
- iv. The laboratory shall continue participation for its scope in PT programs during recognition period (minimum 1 PT program per year).
- v. On-site assessment (surveillance) shall be conducted once in three years cycle at any point of time.
- vi. Scope once recognized cannot be changed during recognition period. There is no provision for extension in scope in this scheme.

3. Recognition Process

- i. Laboratory shall apply through web-portal only (<http://nablmelt.qci.org.in>).
- ii. Laboratory location and its equipment shall be geo-tagged with the help of mobile app.
- iii. Laboratory application shall be reviewed along with PT results.
- iv. Decision on recognition shall be taken on the basis of satisfactory PT performance in last six months and communicated to the laboratory.
- v. Recognition certificate along with scope shall be visible to the laboratory after payment.

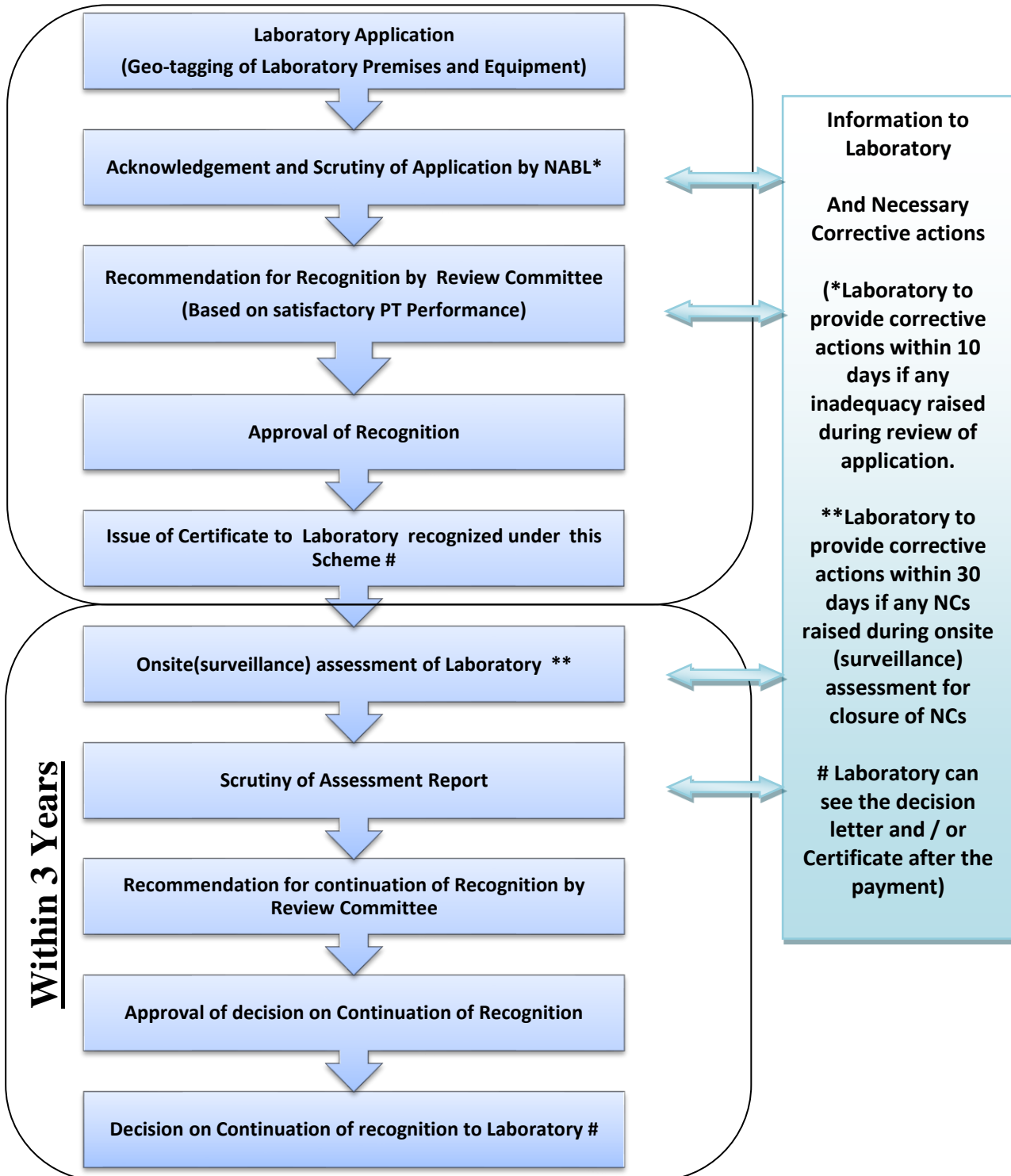
Note: Laboratory may switch over to ISO 15189 Accreditation program at any time during application stage or recognition period.

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 128	Criteria and Procedure for NABL Medical (Entry Level) Testing Laboratories {NABL M(EL)T Labs} Program			
Issue No.: 03	Issue Date: 30-Jul-2020	Amend. No.: --	Amend. Date: --	Page No.: 3 of 8

4. On-Site Assessment (Surveillance)

During recognition period (at any point of time) on-site assessment (Surveillance) shall be conducted to assess laboratory operations.

5. Process Flow Diagram



6. Terms and Conditions

The applicant and recognized laboratories under the scheme shall require to fulfill the following terms & conditions:

- i. The laboratory shall meet the requirements of regulators (local/ regional/ state/ national regulations).
- ii. The laboratory shall meet the criteria as defined in clause no. 2 of this document.
- iii. The laboratory shall offer cooperation to NABL or its representative in undergoing assessments and on the following whenever NABL considers it as necessary:
 - a) Access to all laboratory areas of operations
 - b) Undertaking any assessment to verify the capability of the laboratory for the applied scope.
 - c) Witnessing the activities being performed relevant to this scheme.
 - d) Assessing the competence of the staff during assessment.
 - e) Access to all relevant information, documentation and records.
 - f) Access to those documents that provide insight into the level of independence and impartiality to the laboratory from its related bodies, if applicable.
 - g) Access to all records pertaining to relevant personnel.
 - h) Investigating any complaints against the laboratory.
- iv. The laboratory shall pay the stipulated fee to NABL.
- v. If performance in two successive PT samples (for same parameter) is not satisfactory, the laboratory shall be de-recognized for that particular parameter(s).
- vi. The laboratory shall not involve in any kind of activity(ies) which may bring NABL to disrepute.
- vii. The recognized laboratories can relinquish recognition through a written notice to NABL by clearing any outstanding payment and surrendering the certificates along with scope.
- viii. The laboratory shall respond promptly to the changes initiated by NABL in its criteria and procedure (i.e. NABL 128). The lab shall inform NABL when such alterations under the agreed time frame have been completed.
- ix. NABL absolves itself of any legal or financial liability arising out of activities of any of its lab covered under this scheme involving any accidental or consequential damages to personnel / equipment / products at any time.
- x. The Laboratory shall inform NABL within 15 days of significant changes affecting the Lab's activities and operations relevant to recognition, such as:
 - a) change in physical location of laboratory

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 128	Criteria and Procedure for NABL Medical (Entry Level) Testing Laboratories (NABL M(EL)T Labs) Program			
Issue No.: 03	Issue Date: 30-Jul-2020	Amend. No.: --	Amend. Date: --	Page No.: 5 of 8

- b) change in its name / legal identity,
 - c) the organization, top management and key personnel
 - d) resources (equipment)
- xi. Laboratory shall offer co-operation to NABL assessment team in carrying out unannounced visit as a part of continuous monitoring activity by NABL for its recognized CABs.

Any violation of above terms and conditions shall result in denial of recognition in case of applicant laboratories or derecognition in case of recognized laboratories.

All disputes, arising out of NABL decisions that remain unresolved through mechanism provided by NABL are subject to the exclusive jurisdiction of the Courts at New Delhi and none other.

7. Monitoring of Proficiency Testing (PT) participation and performance

The recognized laboratories shall submit the reports of Proficiency Testing (PT) participation annually from date of issue of recognition certificate and the same shall be reviewed by NABL.

8. Procedure for Adverse Decision

8.1 Closure of Application

Conditions:

- a) Not addressing the inadequacies within stipulated time communicated during review of application.
- b) When the laboratory voluntarily withdraws application.

8.2 Denial of Recognition

Conditions:

- a) When the laboratory has not successfully participated in any test/ parameter of applied scope.
- b) Any Violation of terms and conditions.

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 128	Criteria and Procedure for NABL Medical (Entry Level) Testing Laboratories (NABL M(EL)T Labs) Program			
Issue No.: 03	Issue Date: 30-Jul-2020	Amend. No.: --	Amend. Date: --	Page No.: 6 of 8

8.3 De-recognition of Laboratory

Conditions:

- a) When laboratory does not participate in PT programs conducted by accredited PT providers after its recognition decision.
- b) PT performance is not satisfactory in two consecutive PT samples.
- c) When laboratory does not undergo on-site assessment (Surveillance) beyond two months of the intimation from NABL.
- d) When laboratory has not taken adequate corrective action against NCs observed during on-site assessment (surveillance) within the stipulated time period of 30 days.
- e) When laboratory has not paid the fee within three months.
- f) Any violation of terms and conditions
- g) When the laboratory relinquishes/withdraws recognition by giving notice in writing to NABL after decision on recognition by surrendering the recognition certificate and scope. Outstanding is to be cleared before making request for withdrawal of recognition.

Annexure A

1. HIV-1 antibodies

2. Clinical Biochemistry

Sodium	Chloride	Potassium	Magnesium	Glucose	Amylase	Lipase	Calcium
D. Bilirubin		Glycated Hb (HbA1C)		Inorganic Phosphorus		Lactic Acid Dehydrogenase (LDH)	
Creatine Phosphokinase (CPK/CK)		Lipid Profile Cholesterol, Triglyceride		High Density Lipoprotein Cholesterol (HDL)		Gamma Glutamyl Transferase (GGT)	
Low Density Lipoprotein Cholesterol (LDL)		Renal Function Tests (Urea/Blood Urea Nitrogen, Creatinine, Uric acid)		Liver Function Tests (Total Bilirubin, Alanine Aminotransferase (ALT/SGPT), Aspartate Aminotransferase (AST/SGOT), Alkaline Phosphatase (ALP), Albumin, Total Protein)			

3. Haematology

Haemogram/ CBC (Haemoglobin, Total Leucocyte Count (TLC), Differential Leucocyte Count (DLC – Lymphocyte, Monocyte, Basophils, Eosinophils, Neutrophils), Platelet count, Red Blood Cell Count (RBC) Count, Packed Cell Volume (PCV)/ Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Haemoglobin Concentration (MCHC)

4. Clinical Pathology (Urine Routine Examination)

Protein	Glucose	pH	Leukocytes	Specific Gravity
Ketones	Bilirubin	Nitrite	Blood (Haemoglobin)	Urobilinogen

5. Infectious Serology/Immunology (Rapid tests)

Rheumatoid (RA)Factor	C-Reactive Protein (CRP)	Anti HCV/ HCV Ab	Typhoid (IgG / IgM)	WIDAL for Typhoid	Antistreptolysin O (ASO)
Hepatitis B Surface Antigen (HBsAg)		HIV Antigen + HIV Ab		Syphilis Serology (Rapid Plasma Reagin), VDRL, Treponema pallidum hemagglutination assay (TPHA)	

National Accreditation Board for Testing and Calibration Laboratories (NABL)

NABL House

Plot No. 45, Sector- 44,
Gurugram – 122003, Haryana

Tel.: +91-124 4679700

Fax: +91-124 4679799

Website: www.nabl-india.org