



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

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			

National Accreditation Board for Testing and Calibration Laboratories

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Issue No.: 03	Issue Date: 30-Jul-2020	Amend. No.: 01	Amend. Date: 11-Jan-2021
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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),

NABL recognizes calibration of equipment from NABL accredited calibration laboratory. When the same is not possible for a particular calibration, calibration laboratory whose service is suitable for the intended need is also accepted.

- viii. Scope once recognized cannot be changed during recognition period. There is no provision for extension in scope in this scheme.

3. RECOGNITION PROCESS

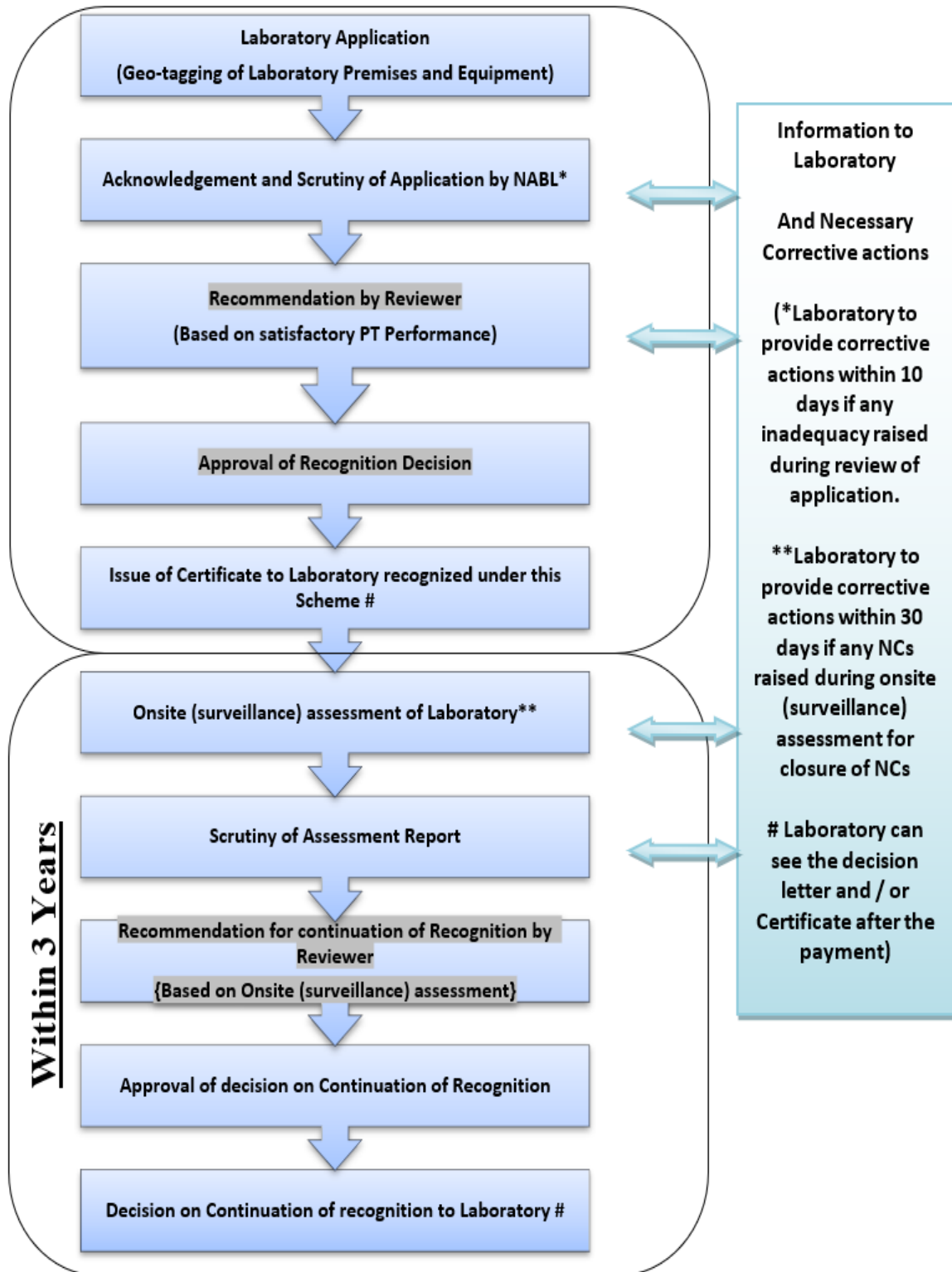
- i. Laboratory shall apply through web-portal only (<http://nablmelt.gci.org.in>).
- ii. Laboratory location and its equipment shall be geo-tagged with the help of mobile app.
- iii. Laboratory application shall be reviewed along with PT results.
- iv. Decision on recognition shall be taken on the basis 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.

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
 - 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 laboratories.

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. 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.

Actions by NABL

- a) The application will be closed.
- b) The decision will be formally communicated to the laboratory by NABL.

Procedure for re-enrollment

The laboratory can apply afresh with relevant application form and fees applicable at that time along with outstanding charges (if any). The application will be treated as new application.

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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.

Actions by NABL

- a) The recognition will be denied.
- b) The decision will be formally communicated to the laboratory by NABL.

Procedure for re-enrollment

The laboratory can apply afresh with valid responses for the reason(s) on earlier denial, using relevant application form and pay applicable fees at that time along with outstanding charges (if any). The application will be treated as new application.

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.

Actions by NABL

- a) The recognition will be derecognized.
- b) The decision will be formally communicated to the laboratory by NABL.

Note: Laboratory once derecognized, cannot be re-enrolled for the scheme.

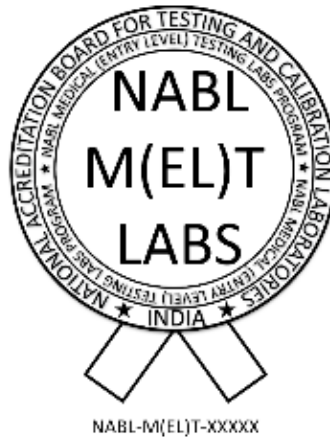
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9. PRIVILEGES EXTENDED TO THE LABORATORY UPON APPROVAL

Certificate of Compliance shall be issued to the laboratories upon approval by NABL. The same will carry Certificate No. along with validity period.

Below is the representation of NABL claim to be made by the approved laboratory on its test reports.



9.1 Instructions to claim recognition:

- a) Recognized laboratory should claim recognition for the recognized test parameters by using above image in test reports.
- b) The image shall be legible and displayed only in the appropriate form and proportion.
- c) Electronic reproduction of above image is permitted provided that the requirements of this document are met, integrity of above image is maintained and distortion of graphic is avoided.
- d) Recognition under NABL M(EL)T Labs Program is location specific. The recognition claim shall be related only to the specific laboratory location that is covered under the recognized scope, and not with any other non-recognized locations.
- e) Recognized laboratory shall not authorize the claim of recognition by their customers, sub-contractors or any other third party. It is the responsibility of each recognized laboratory to describe their recognition status in a manner that does not imply recognition in areas that are outside their actual recognized scope and facilities not covered under NABL M(EL)T Labs Program and to minimize the risk of a customer / general public being misled.
- f) The claim of recognition shall only be used by recognized laboratory during the period when it holds valid recognition.
- g) If recognized laboratory wishes to claim recognition then they may write following statement:

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“Recognized for NABL M(EL)T Labs Program vide NABL-M(EL)T- XXXXX”

Note: Certificate of compliance shall be provided by NABL.

- h) Where results of both recognized and non- recognized parameters are included on test report, non-recognized results shall be clearly and unambiguously identified. Each non-recognized parameter shall be identified at a prominent place on each page of the report by an asterisk (*) along with a footnote in bold stating: **“The parameter marked with an * are not- recognized by NABL”**.
- i) There shall be nothing in report or in any attachment or other material, which implies or may lead any user of the results or any interested party to believe/ made to believe, that the work is recognized by NABL when in fact it is not.

9.2 Situations for not to claim recognition

- a) Applicant laboratories shall neither claim recognition nor use any image related to NABL and/or NABL M(EL)T Labs Program.
- b) When the laboratory is derecognized by NABL, then laboratory shall neither claim recognition nor use any image related to NABL and/or NABL M(EL)T Labs Program.

Note: Once derecognized, the laboratory shall immediately cease to issue test report displaying the recognition to NABL M(EL)T Labs Program in any form; and shall cease publishing and/or distribution of documents (including promotional & advertisement, website, letter head etc.) containing the recognition status to NABL M(EL)T Labs Program.

9.3 Actions for Misuse of claim recognition

- a) Any false claim of recognition under NABL M(EL)T Labs Program in any form shall be treated as misuse of recognition claim and derecognition process shall initiated against the laboratory.

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)	

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