NABL 155

National Accreditation Board for Testing and Calibration Laboratories (NABL)

Application Form and Checklist
for
NABL Medical (Entry Level) Testing labs {NABL M(EL)T Labs} Program

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AMENDMENT SHEET

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1. Information for Laboratory

a. This scheme is based on performance in proficiency testing and applicable for medical testing laboratories which are based in India and for one recognition cycle only.

b. Laboratory is required not to request for any changes in scope of recognition during the recognition process and recognition cycle.

c. The application must be filled up by the authorized representative of the laboratory.

d. Laboratory is required to pay due attention while providing information to NABL in application form. After submission of application, the laboratory will not be able to make changes in the application form.

e. Incomplete application will be rejected by NABL.

f. Applicable fee and other necessary charges related to the recognition process is given in NABL document NABL 100 'General Information Brochure' under NABL Finance and Fee Structure'. NABL 100 is available on NABL website.

g. The application will be kept confidential (unless required by law) by NABL and information obtained during the processing of application, grant of recognition and on-site assessment (surveillance) will be safeguarded and confidentiality and impartiality will be maintained. The procedure for processing of application for accreditation is given in NABL 100.

2. Requirements to be fulfilled and Instructions to be followed by the laboratory, while applying for NABL recognition

a. On-line application (http://nablmelt.qci.org.in) is to be submitted by the laboratory in the format prescribed in NABL 155.

b. The laboratory is required to satisfactorily participate in Proficiency Testing (PT) program/ EQAS conducted by NABL accredited PT provider as per ISO/IEC 17043 before submission of application (within six months prior to the date of application).

3. Application Form

We apply for NABL Medical Entry Level Testing Laboratories Program for our laboratory as per details given below:

Laboratory Details	
Details	**Data Submitted by Laboratory**
Name of the Laboratory	
Country	
State/Province	
District	
Address	
Pincode	
Mobile No.	
Email Id	
Are you NACO ICTC Laboratory?	
Type	
Technical Head/ Lab Manager	
Accredited PT Program?	

Scope Applied					
S. No.	**Name of PTP**	**Discipline**	**Type of Sample**	**Specific Tests**	**Test method/technique**

Note: This scheme is applicable only for following **Basic Routine Tests** (for more details, please refer NABL 128):

a. HIV-1 antibodies

b. 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)			

c. 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)

d. Clinical Pathology (Urine Routine Examination)

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

e. 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)	

List of major test equipment available for use				
S. No.	**Discipline**	**Name of equipment**	**Calibration certificate of equipment**	**Image of the equipment via Mobile App**

Note: *Laboratory equipment shall be geotagged through mobile app.*

Participation in PT / /EQAS/ any other Inter Laboratory Comparison					
S. No.	**Organizing body**	**Discipline**	**Date of issue of PT report**	**Is result satisfactory**	**Upload report**

Note: *PT report shall be submitted by the laboratory.*

4. Checklist

Checklist Section (to be filled in App)	
Infrastructure	
Signage: A signage within or outside the facility should be made available containing the following information:	
1.	Laboratory Display Board (Outside or on laboratory entrance)
2.	Name of the person-in-charge with qualification
3.	Fee structure: To be displayed separately including type of investigation and charges for all routine tests.
Hygiene and Safety (wherever applicable)	
1.	General cleanliness • Dust free • Good house keeping
2.	Universal standard safety precautions
Space requirement	
1.	Registration, waiting space ~~room~~, public utilities, safe drinking water etc.
2.	Sample collection ~~room/~~area
3.	Washing area
4.	Preservation of the specimen and slides
5.	Temperature control for specialized equipment etc.
6.	Counselling room for HIV (If HIV test is done)
7.	Basins
Legal or Statutory requirements as applicable	
1.	Valid Registration Certificate for under the provisions of Biomedical Waste Management
2.	Valid Pollution Control Board registration certificate
Record maintenance and reporting	
1.	Reports of all patient's date wise as per regulatory requirement or till next audit, whichever is later.
2.	Medico legal records, if applicable (as per relevant law).
3.	Duration of preservation of record (as applicable from time to time)
Standards on basic processes	
1.	Infection Control practices - as per Bio Medical Waste Management Rules, 2016
2.	Patient Information
3.	Kit inserts used as SOPs)
4.	Complaints redressal mechanism

Quality Checks	
1.	Performing internal quality control
2.	Participating in proficiency testing programs in every six months

5. Declaration by the laboratory

I/ We declare that

a) We agree to comply with procedure of this scheme, pay charges for assessment irrespective of the result.

b) We agree to co-operate with the assessment team appointed by NABL for examination of all relevant documents by them and their visits to those parts of the laboratory that are part of the applied scope.

c) We satisfy all national, regional and local regulatory requirements for operating a laboratory.

d) We agree to comply with the terms & conditions mentioned in Procedure for NABL M(EL)T Labs Program.

e) All information provided in this application is true.

Signature of Head of the organization_____

Name of Head of the organization_____

Date_____

Place _____

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