

NABL opening for Small & Medium Labs



- The laboratory accreditation program in India was initially setup by Department of Science & Technology, Government of India in 1982 with its name as "National Coordination of Testing & Calibration Facilities (NCTCF)" for providing accreditation services to testing & calibration laboratories. NCTCF, with the cooperation of India's National Metrology Institute (NMI), National Physical Laboratory (NPL),
- Subsequently in 1993, NCTCF was renamed as "National Accreditation Board for Testing and Calibration Laboratories (NABL)".
- In the year 1996, Govt of India has approved NABL to be set up as a society under the Societies Registration Act and It will be fully answerable to the QCI and at the appropriate stage be brought within the fold of the society under which the QCI is set up".
- In the year 2016, in pursuance of cabinet decision (February 1996), NABL was transferred to the Department of Industrial Policy and Promotion (DIPP), Ministry of Commerce and Industry and subsequently transferred to QCI (Quality Council of India) as one of its Board.







National Accreditation Board for testing and Calibration Laboratories

National Accreditation Board for Testing and Calibration Laboratories (NABL) is a Constituent Board of Quality Council of India, an autonomous body under Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industries, Government of India. NABL is an accreditation body, with its accreditation system established in accordance with ISO/ IEC 17011. 'Conformity Assessment – Requirements for Accreditation bodies accrediting conformity assessment bodies.

Testing and Calibration laboratories in accordance with ISO/IEC 17025: 2017

Medical Testing
Laboratories in
accordance with
ISO 15189: 2012

Proficiency
Testing Provider in accordance with ISO/IEC 17043: 2010

Reference Material Producers (RMP) in accordance with ISO 17034: 2016







National Accreditation Board for testing and Calibration Laboratories

- Accreditation is the third-party attestation related to a conformity assessment body conveying the formal demonstration of its competence to carry out specific conformity assessment task.
- Accreditation Body (NABL) Authoritative body that performs accreditation
- Conformity Assessment Body (CAB) is a body which includes Testing including Medical Laboratory, Calibration Laboratory, Proficiency Testing Provider and Reference Material Producers.









National Accreditation Board for testing and Calibration Laboratories

- NABL is signatory to ILAC and APAC Mutual Recognition Arrangements (MRA) since year 2000 which is based on mutual evaluation and acceptance of other MRA Partner accreditation systems.
- Such MRA reduces technical barrier to trade and facilitates acceptance of test/ calibration results between countries which MRA partners represent

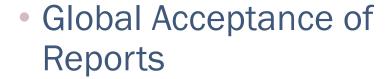
TESTED ONCE AND ACCEPTED EVERYWHERE











 Test reports issued by an NABL accredited laboratory is considered equivalent to those issued by ILAC/APAC MRA partners.

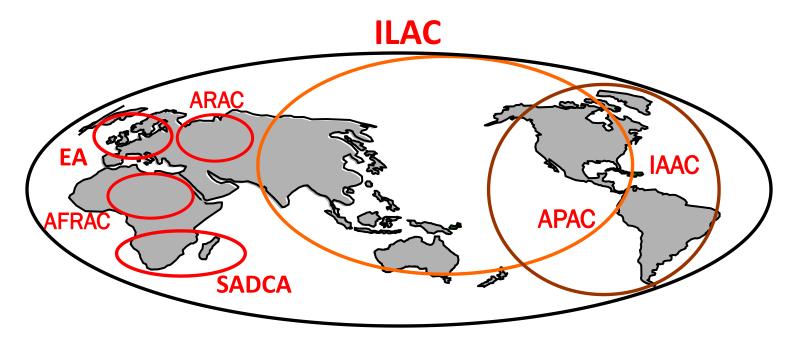








Global Structure of Conformity Assessment



ILAC International Laboratory Accreditation Cooperation

APAC Asia Pacific Accreditation Cooperation

EA European co-operation for Accreditation

IAAC Inter-American Accreditation Cooperation

AFRAC African Accreditation Cooperation

ARAC Arab Accreditation Council

SADCA Southern African Development Cooperation for Accreditation







NABL Accreditation Benefits

- Increased confidence in Testing/ Calibration Reports issued by the laboratory.
- Better control of laboratory operations and feedback to laboratories as to whether they have sound Quality Assurance System and are technically competent.
- Potential increase in business due to enhanced customer confidence and satisfaction.
- Customers can search and identify the laboratories accredited by NABL for their specific requirements from the NABL Web-site or Directory of Accredited Laboratories.
- Users of accredited laboratories enjoy greater access for their products, in both domestic and international markets.
- Savings in terms of time and money due to reduction or elimination of the need for retesting of products.









Acceptance by Government & Regulators



Ministry of Jal Shakti



Food Safety and Standards Authority of India



Agricultural and Processed Food Products Export Development Authority



Export Inspection Council



Ministry of Health and Family Welfare



Atomic Energy Regulatory Board







Acceptance by Government & Regulators



Ministry of Environment, Forest & Climate Change



Bureau of Indian Standards



Bureau of Energy Efficiency



Telecommunication Engineering Center



Ministry of Defence



Ministry of Railways



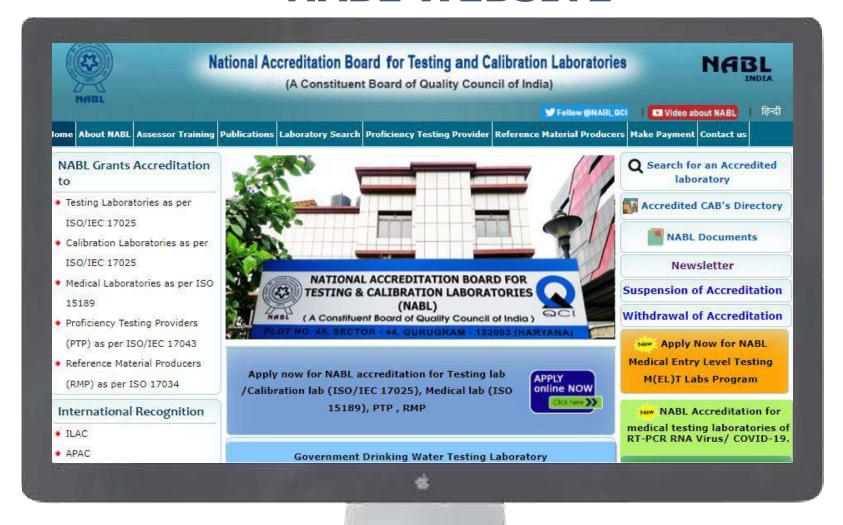
Government e Marketplace







NABL WEBSITE











	Home		
Accredited Laboratories Search			
	Laboratory Name		
	Country *	Please Select 🗸	
Please Select	City	Please Select	
□ CENTRAL	Nature of Lab	☐ In-House	
□ EAST		Open to Others	
☐ Eastern		Partly Open to Others	
□ NORTH			
SOUTH			
☐ Southern			
□ WEST			
□ Western			
Calibration	Facility	☐ Mobile Facility	
☐ Medical		Permanent Facility	
		Site Facility	
☐ Reference Material Producer		Chicago and Chicago	
☐ Testing			
- Serving			
	CENTRAL EAST Eastern NORTH SOUTH Southern WEST Western Calibration Medical Proficiency Testing Provider Reference Material Producer	Please Select City CENTRAL Nature of Lab EAST Eastern NORTH SOUTH SOUTH Southern WEST Western Calibration Medical Proficiency Testing Provider Reference Material Producer	





Search for accredited Laboratories



Search by Name of Laboratory Search by accreditation certificate number

Search by standard

Search by parameter

Search by category





NABL Symbol in Test Reports and Calibration Certificates



Check for NABL Symbol which is mandatory in test reports containing accredited parameters

Valid results traceable to SI units





Enquire status or report violation at info@nabl.qcin.org

Verify the validity and authenticity in NABL website

TC- XXXX CC- XXXX

QR Code and ULR number on test reports and calibration certificates

Demand scope of accreditation from lab

Ask reason if NABL symbol not used in test reports









PREPARING FOR ACCREDITATION

- 1. Conscious decision by Top Management
 - Why accreditation
 - Resource requirements
- 2. Communication within the laboratory
 - What is ISO 15189
 - Why go for accreditation
 - Role of scientific personnel in quality system







PREPARING FOR ACCREDITATION

Know NABL 100 "General Information Brochure"



Download all relevant documents from NABL website (www.nabl-india.org)



Nominate a responsible person to co-ordinate all activities of QMS and Internal Audit as per ISO 15189

Prepare Management system document as per ISO 15189, Procedures (wherever applicable)

Ensure training of personnel, environment conditions, Internal Quality checks etc.



Ensure calibration of all equipment and traceability



Participate in PT Programme



Conduct Internal Audit and Management Review

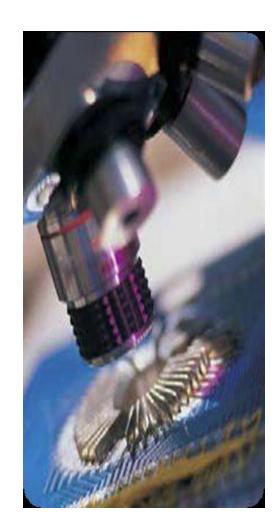


Apply to NABL on NABL Web Portal along with System Document



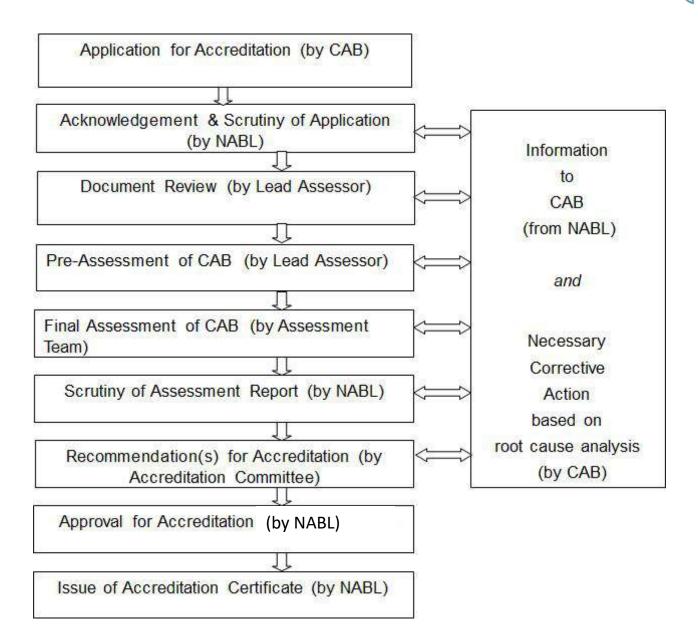
Evaluation of testing laboratory by NABL Tools & Technique

- On the spot assessment of the laboratory by the experts for its technical competence and its adherence to management system practices.
- By analyzing the test data of a particular test/measurement as a result of its participation in a proficiency testing program.





Accreditation n Process (by NABL)







General Documents





NABL-100: General Information Brochure



NABL-112: Specific Criteria for Accreditation of Medical Laboratories.



NABL -131: Terms & Conditions for Obtaining & maintaining NABL accreditation



NABL-141: Guidelines for Estimation and Expression of Uncertainty in Measurement



NABL-153 Application form for Medical Laboratories



NABL-160: Guide for Preparing Management System Document / Quality Manual



NABL-161: Guide for Internal Audit and Management Review for Conformity Assessment Bodies (Laboratories / PTP / RMP)







Policy Document

 NABL- 142: Policy on Traceability of Measurement Results

Key Point

 For achieving Metrological Traceability to the International System of Units (SI), measuring equipment (including standards and reference materials) shall be calibrated by either NMI (NPL-India) or Accredited Laboratory.





Policy Document

 NABL- 163: Policy for Participation in Proficiency Testing Activities

Key Point

- Clearly defined PT Policy (Minimum participation, Frequency, PT plan)
- Specified meaning of satisfactorily participation
- Two year PT Plan



Post accreditation evaluation of laboratory by NABL: onsite/desktop surveillance

- Accreditation valid for the period of 2 years.
- Annual onsite/desktop surveillance after 10 months of the accreditation
- Lab to apply for renewal of accreditation at least 6 months before the expiry of validity of accreditation.
- Re-assessment similar to the final Assessment is conducted before the expiry of Accreditation.





NABL Medical (Entry Level) Testing Labs {NABL M(EL)T Labs} Program



About M(EL)T Program

• NABL has launched voluntary scheme namely "NABL Medical Entry Level Testing M(EL)T Labs Program" for sensitizing the medical testing laboratories performing basic testing to quality practices and to provide access to quality health care for the majority of Indian citizens.

 This program is an independent quality assurance program, which is not covered under APAC & ILAC MRA



Documents

- NABL 128 Criteria and Procedure Document
- NABL 155 Application Form and Checklist Document

Both Documents are available on NABL website under Publications.



Criteria for Submitting application

- PT Participation
- Legal Identity
- Calibration of Equipment with Valid Traceabilit



PT Participation

- The applicant laboratory shall have satisfactorily participated in Proficiency Testing (PT) program conducted by NABL accredited PT provider as per ISO/IEC 17043 before submission of application.
- 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.
- Date of issue of PT result / report shall be considered as date for PT participation.
- The laboratory shall continue participation for its scope in PT programs during recognition period atleast once in a year.



Process of Submitting Application

User friendly online portal and mobile app to submit the application. Application can be submitted through this link: http://nablmelt.qci.org.in/Laboratory/login.php



Process Flow

Recognition is valid for one cycle of three years only.

- No initial assessment involved.
- Only one on-site assessment (surveillance) in three years cycle.
- Minimal application processing time if information submitted in the application is adequate, recognition can be granted in two to three working days.
- Fees to be paid only after getting the decision from NABL.

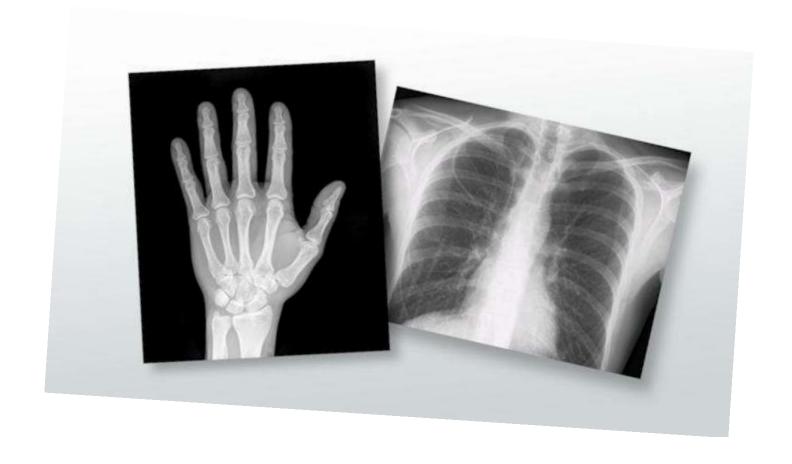


Privilege given to M(EL)T Labs

- Recognized laboratory may use NABL M(EL)T symbol on the test reports, which will enhance the confidence of general public as well as that of the laboratory.
- Publicity through NABL website, recognized laboratory details will be updated in NABL 900 which is available on NABL website under Publications.
- Gateway to ISO 15189. At any stage lab may switch over to NABL accreditation ISO 15189.



Medical Imaging Accreditation





Medical Imaging

- All MI-CABs can apply for NABL accreditation regardless of the level at which they function e.g. attached to a clinical Medical Imaging facility / stand-alone / Hospital based facility.
- The classification of medical imaging is based on following categories:
- a) Category A: MI-CAB using Ionized radiation
- b) Category B: MI-CAB using Sonography
- c) Category C: MI-CAB using Magnetic Resonance
- d) Category D: MI-CAB using Nuclear Medicine
- e) Category E: MI-CAB using Interventional Radiology
- f) Category F: MI-CAB having any combination of above categories.



Scope of Medical Imaging

- Projectional Radiography & Fluoroscopy
- a. X Rays, Bone Densitometry (DEXA), Dental X Ray-OPG, Mammography etc
- b. Fluoroscopy
- II. Computed Tomography (CT)
- III. Magnetic Resonance Imaging (MRI)
- IV. Ultrasound and Colour Doppler
- V. Nuclear medicine
- a. SPECT
- b. PET CT
- c. PET MRI
- VI. *Basic Diagnostic Interventional Radiology Procedures (Image guided Core Biopsy and/or Needle Aspiration e.g. Fine Needle Aspiration Cytology)
- *For only such IR procedures that will be carried out by Radiologists



Documents for Medical Imaging

- NABL 135- Specific Criteria for Accreditation of Medical Imaging – Conformity Assessment Bodies
- NABL 153 Application form for Medical Imaging

Contact us at:

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Any Questions ???