

## ORIGINAL ARTICLE - PUBLIC HEALTH

# NABL CERTIFICATION FOR THE LABORATORIES IN PRIMARY HEALTH CENTRES UNDER MELT PROGRAM: PROCESS AND PERFORMANCE TO ENSURE QUALITY ASSURANCE

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## Abstract

**INTRODUCTION :** NABL provides certification under MELT Program for the peripheral labs based on the quality standards adopted to ensure Quality Assurance (QA). The laboratories in PHCs in Tamil Nadu have been consistently involved in the QA Program and are eligible to apply for NABL Certification. By taking part in this program, laboratories can improve their performance and ensure that they meet the highest standards of quality. This, in turn, helps to improve the quality of healthcare services provided to the community.

**AIM :** To obtain NABL certification under the MELT Program to ensure the laboratory's commitment to deliver reliable and reproducible diagnostic test results ensuring appropriate treatment in a primary health care setting.

**OBJECTIVE :** To obtain NABL Certification under MELT Program for the Laboratories in PHCs in Tamil Nadu

**METHODOLOGY :** NABL certification process involves a series of assessments and evaluations to determine the laboratory's compliance with the NABL standards. State Public Health Laboratory (SPHL) of DPH&PM has facilitated this process by conducting online training to District Microbiologists and Laboratory Technicians of PHCs to understand the essential component required for NABL Certification. All the 2127 PHC laboratories in Tamil Nadu were registered under Medical Entry Level Testing (MELT) during Sep 2023 and uploaded all the vital documents. NABL assessors evaluated the laboratory's infrastructure, equipment, personnel, procedures, and performance in EQAS and proceed further for issue or denial of certification process.

**RESULTS :** Out of 2127 PHCs in Tamil Nadu, a total of 1622 Laboratories in Primary Health Centre (76%) have received the NABL certification under MELT program in Oct 2023. Five districts have also achieved 100% of their PHC labs obtaining NABL Certification.

**CONCLUSION :** Quality of laboratory investigations are paramount importance to deliver reliable and reproducible test results in the primary health care centres to serve the community. Participation in NABL certification program ensures credibility of the laboratory system in PHCs and also contributes to the overall development and improvement of primary healthcare systems in Tamil Nadu.

**KEYWORDS :** NABL, MELT, PHC Lab, EQAS, Certification

## INTRODUCTION

Primary Health Care Centers (PHC) play a crucial role in providing essential healthcare services to the community. Laboratory services is an integral part of the primary health care services covering both communicable and non-communicable diseases. Accurate testing is necessary to diagnose, treat and prevent illnesses effectively. It is essential to maintain the highest standards of accuracy in laboratory testing to ensure that the patients receive the best possible care.

PHC laboratories are responsible for conducting a wide range of tests including hematology, biochemistry, clinical pathology and serological investigations. Integrated Essential Laboratory System (IELS) being implemented in Tamil Nadu has assured Test Menu to cover 29 tests in Addl. PHCs and 35 tests in Block PHCs. In addition, 62 tests

can be referred out from primary health care institutions to the higher centers like Govt. Hospitals and Medical College Hospitals through an effective Hub and Spoke Model of sample transportation. Laboratory Information Management System (LIMS) provides barcoding of each and every sample registered in a PHC laboratory. These test facilities provide valuable information to healthcare providers, enabling them to diagnose and treat health conditions.

National Accreditation Board for Testing and Calibrating Laboratories (NABL), being the apex institution in the



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country is implementing the ISO 15189:2021 standards for the Medical Laboratories fulfilling the requirements for quality and competence. NABL has recently launched a voluntary program namely "Medical Entry Level Testing (MELT) Labs Program" for the medical testing laboratories functioning in villages and small towns, performing basic testing. In order to encourage these labs for their quality practices, NABL provide Certifications under MELT Program. This program is based on the satisfactory External Quality Assurance Scheme (EQAS) or Proficiency Testing (PT) performance participated by the lab from an NABL accredited PT provider.

The NABL certification program is designed to evaluate the quality of laboratory services provided by primary healthcare laboratories and ensure that they meet the required standards.

The certification process involves a series of assessments and evaluations to determine the laboratory's compliance with the NABL standards. The process begins with an online application submitted by the laboratory seeking certification along with uploading of necessary documents including the recent EQAS performance. Upon receiving the application, the NABL team conducts an initial review of the laboratory's documents and procedures to determine if they meet the requirements.

If the laboratory meets the stipulated requirements, the reviewer recommends for certification for a period of three years. During this period, an assessor is assigned to conduct an on-site assessment who evaluates the laboratory facilities, equipment, personnel, procedures, and implementation of quality management system. The assessors also conduct sample testing to ensure that the laboratory's testing methods meet the NABL standards.

### About NABL Medical Entry Level Testing (MELT) Labs Program :

The program is offered by the National Accreditation Board for Testing and Calibration Laboratories (NABL), which is an autonomous body under the Department of Science and Technology, Government of India. NABL is responsible for providing accreditation to testing and calibration laboratories in India as per ISO standards.

The NABL MELT Labs Program is designed to help laboratories to establish a quality management system that meets international standards. The program covers all aspects of laboratory testing, including pre-analytical, analytical, and post-analytical phases. It also provides guidance on the selection and use of equipment, as well as the calibration and maintenance of instruments.

It is a comprehensive program that includes both on-site and off-site assessments. On-site assessments are conducted by a team of assessors who visit the laboratory and evaluate its facilities, equipment, personnel, and procedures. Off-site assessments are conducted through a review of the laboratory's documentation and quality management system.

It is a valuable resource for laboratories with limited experience in medical testing. It provides a framework for quality management system implementation and offers guidance on testing procedures, equipment, and personnel training. The program also provides a level of credibility and recognition for laboratories that have successfully completed the certification process.

The program provides a comprehensive initiative designed to help labs establish their proficiency in conducting medical tests. It is an investment in a lab's future and provides them with a competitive edge.

### OBJECTIVES

- To register all the 2127 PHC laboratories under NABL certification under MELT
- To sensitize the District Microbiologists and Laboratory Technicians about the MELT Program and submit the documents for verification.
- To follow-up each and every PHC laboratory to submit necessary documents and comply the requirements.
- To ensure completion of application process to obtain NABL certification.

### METHODOLOGY

The NABL accreditation procedure is a rigorous process that ensures that laboratories meet the highest standards of quality and accuracy. The first step in the process is to submit an application to NABL through online. This application should include a detailed description of the laboratory, including its scope of work, equipment, and staff qualifications. Once the application is received, NABL will conduct a preliminary assessment to determine if the laboratory is eligible for accreditation. If the laboratory meets the stipulated requirements, certificate will be issued.

For NABL accreditation, Proficiency Testing (PT) plays a vital role. In Tamil Nadu, all the 2127 PHC laboratories were registered with CMC-Clinical Biochemistry EQAS Program for the year 2021,2022 and 2023. A total of 9 biochemistry analytes have been included under the Chemistry III program, Glucose, one of the basic investigations done in a PHC was taken for the performance assessment. The program is based on satisfactory proficiency testing (PT) performance and

valid for one cycle of three years.

The Laboratory application will be reviewed by NABL and decision on recognition will be taken based on performance in proficiency testing (PT). During the recognition period (within three years), on-site assessment (surveillance) will be conducted.

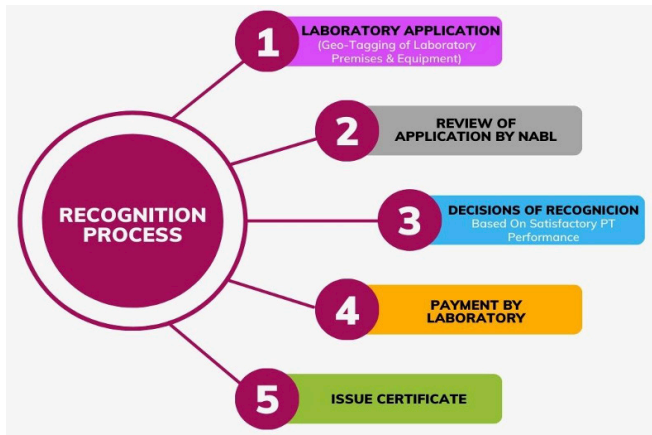


Figure 1 : Flow Diagram for NABL Accreditation Process

**The Assessment was based on the following parameters.**

- Legal Identity Certificate issued by the PHC Medical Officer.
- EQAS or Proficiency Testing (PT) by a third-party service provider accredited by NABL-Minimum 6 months participation and satisfactory performance in all 6 months.
- Calibration of essential equipments like Semiautoanalyzer, Centrifuge and Micropipettes.
- Availability of facilities like patient waiting area, sample collection area, testing area, washing area and segregation of BMW.
- BMW Authorization issued by Tamil Nadu Pollution Control Board.

The investment and participation in EQAS/IQC and the NABL Certification will ensure the credibility of the PHC labs to deliver quality laboratory investigations for the poor and needy rural community.

**RESULTS :**

A total of 2127 PHC laboratories were registered with NABL Medical Entry Level Testing (MELT) Labs Program during Sep 2023. A total of 1622 PHC Labs under the Directorate of Public Health and Preventive Medicine have obtained the NABL Certification under the MELT Program (Fig-2).

**NABL Accreditation in PHC Labs - 2023**  
n=2127

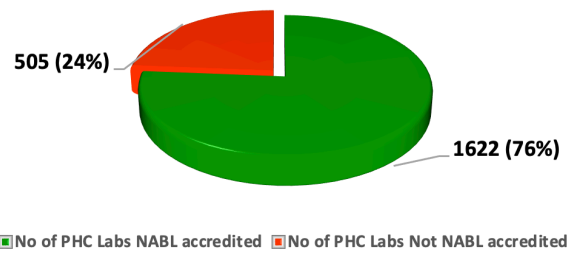


Figure 2 : Percentage NABL Registration and certification in 2023

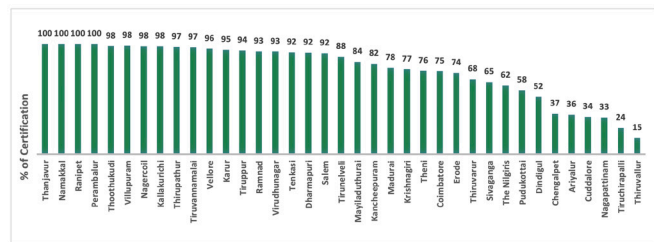


Figure 3 : Overall District wise status-Percentage of NABL Certification

Due to the sustained efforts and constant follow-up, Thanjavur, Namakkal, Ranipet and Perambalur districts have obtained NABL Certification for all their PHC laboratories (Fig-3).

NABL charges a certification fee of Rs 17,718 per laboratory and out of 1622 PHCs in Tamil Nadu 45 PHCs have obtained the certificate by paying the recommended fee from NHM funds. In commemoration of the Silver Jubilee Celebration of Quality Council of India (QCI) in 2023, certification fee for the remaining 1577 PHC laboratories were paid from QCI funds to a sum of Rs 2,79,41,286 (Rs 2.79 crores) which is a saving to Govt.of Tamil Nadu.

**DISCUSSION :**

Laboratory services in PHCs are very essential for the prevention and control of communicable and non-communicable diseases and also to provide better Maternal and Child Care services. Laboratory strengthening required a sustained efforts to improve infrastructure, necessary human resources, provide essential and quality equipment and consumables and implementation of quality assurance.

Introduction of Semiautoanalyzers in 2006 in PHC laboratories has changed the perception of basic Microscopic Centers into a clinical laboratory. Human resources being one of the critical components of laboratory strengthening, the qualification criteria changed by the Government, allowed recruitment of qualified laboratory technicians in PHCs with CMLT qualification. During the Dengue outbreak in

2017, hematology analyzers were supplied to all Block PHCs and Upgraded PHCs, which has further strengthened and redefined the role and importance of laboratory support in PHCs to the community.

In order to deliver reliable and reproducible test results in PHCs, all the 2127 PHC labs have been registered under CMC-Biochemistry EQAS Program since 2021 onwards and Tamil Nadu is the only state in the country in which all the PHC laboratories are taking part in the QA program organized by a NABL accredited 3rd party.

There was a vision to get NABL certification in all the 2127 PHC labs in a Phased manner covering all block PHCs and UG-PHCs first to obtain the NABL Certification followed by the remaining Additional PHCs. In continuation of the quality initiatives in PHC laboratories, five PHC laboratories representing 5 Districts in Tamil Nadu have obtained the NABL Certification under MELT program viz., Thalavaipattinam PHC in Tiruppur, Venkitankuruchi PHC in Ramanathapuram, Mapillaiurani PHC in Thoothukudi and Thovalai PHC in Kanyakumari and Patchur in Tirupattur. All these 5 PHCs have fulfilled the requirements without any Non-Conformities (NC) and got the NABL Certificates at the National Conclave in Bangalore in Aug 2022.

NABL certification drive in PHC laboratories was initiated in Sep 2023 with financial support from QCI funds. This was the first time in the country that 1622 PHC labs have obtained the NABL certification.

The NABL certification under MELT Program is an essential resource for medical laboratories that are just starting out or have limited experience in medical testing. The program provides a framework for quality management system

implementation and offers guidance on testing procedures, equipment, and personnel training. By participating in the program, laboratories can establish their credibility and ensure the accuracy and reliability of their test results. Accreditation provides formal recognition of competency, thus providing a ready means for the beneficiaries to find a reliable testing laboratory services to meet their needs.

## CONCLUSION :

NABL Certification gives quality recognition to the institution at the Primary Health Care level so that it encourages more and more patients from the community to reach and avail health services. It is very important that the out of the pocket expenditure for the laboratory investigations spent by the poor and needy community is very high and a quality certification in PHC labs will drastically reduce the individual expenditure on laboratory investigations in the community.

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