

NABL 163



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Policy for Participation in Proficiency Testing Activities

ISSUE NO.: 09
ISSUE DATE: 29-Oct-2020

AMENDMENT NO.: --
AMENDMENT DATE: --

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.	Scope	5
3.	Policy	6
4.	Annexure A – Proficiency Testing Plan (Form 18)	10

1. INTRODUCTION

Proficiency Testing is one of the important tools to determine the technical competence of the Testing, Calibration and Medical Testing laboratories.

According to ISO/IEC 17025 a laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. This monitoring may include the participation in interlaboratory comparisons or proficiency testing programs. Other means may include the regular use of reference materials, or replicate tests or calibrations using the same or different methods. By these mechanisms a laboratory can provide evidence of its competence to its clients, interested parties and the accreditation body.

ISO 15189 also requires that medical laboratories seek confirmation for confidence in their results through participation in suitable interlaboratory comparisons.

This document derives NABL policy on participation in Proficiency testing activities to conform to the requirements of ILAC-P9:06/2014- ILAC Policy for Participation in Proficiency Testing activities.

The minimum PT activity according to a laboratory's scope is:

- evidence of satisfactory participation prior to gaining accreditation where PT is available and appropriate;
- further and ongoing activity that is appropriate to the scope of accreditation and consistent with the PT participation plan

Satisfactory participation in National / International PT programs enhances the confidence in the competence of laboratory.

It is recognized that there are areas of Testing, Calibration and Medical Testing for which suitable PT does not exist or is not practical. In such cases, the laboratory should follow this document.

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 163	Policy for Participation in Proficiency Testing Activities			
Issue No.: 09	Issue Date: 29-Oct-2020	Amend No: --	Amend Date: --	Page No.: 3 of 10

According to ISO/IEC 17025:2017, The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:

- a) use of reference materials or quality control materials;
- b) use of alternative instrumentation that has been calibrated to provide traceable results;
- c) functional check(s) of measuring and testing equipment;
- d) use of check or working standards with control charts, where applicable;
- e) intermediate checks on measuring equipment;
- f) replicate tests or calibrations using the same or different methods;
- g) retesting or recalibration of retained items;
- h) correlation of results for different characteristics of an item;
- i) review of reported results;
- j) intralaboratory comparisons;
- k) testing of blind sample(s)

The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:

- a) participation in proficiency testing;
Note: ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.
- b) participation in interlaboratory comparisons other than proficiency testing.

According to ISO 15189: 2012, The laboratory shall participate in an interlaboratory comparison programme(s) (such as an external quality assessment programme or proficiency testing programme) appropriate to the examination and interpretations of examination results. The laboratory shall monitor the results of the interlaboratory comparison programme(s) and participate in the implementation of corrective actions when predetermined performance criteria are not fulfilled.

Note: The laboratory should participate in interlaboratory comparison programmes that substantially fulfil the relevant requirements of ISO/IEC 17043.

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 163	Policy for Participation in Proficiency Testing Activities			
Issue No.: 09	Issue Date: 29-Oct-2020	Amend No: --	Amend Date: --	Page No.: 4 of 10

The laboratory shall establish a documented procedure for interlaboratory comparison participation that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the interlaboratory comparison programme.

Interlaboratory comparison programme(s) chosen by the laboratory shall, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-examination procedures, and post-examination procedures, where possible.

2. SCOPE

This document stipulates the NABL policy on PT Participation (minimum PT participation requirements and frequency of PT participation) during accreditation process of Testing, Calibration and Medical Testing Laboratory.

Note: This document is also applicable to laboratories of Proficiency Testing Provider (PTP) and Reference Material Producers (RMP).

This document also describes the requirements of reviewing PT participation and performance (in particular consistent poor performance) according to PT Plan submitted by the laboratory.

Interlaboratory Comparison is *organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.*

Proficiency testing means *evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.*

Outlier is *observation in a set of data that appears to be inconsistent with the remainder of that set.*

References

- ILAC-P9:06/2014- ILAC Policy for Participation in Proficiency Testing activities.
- ISO/IEC 17025: 2017- General requirements for the competence of testing and calibration laboratories
- ISO 15189: 2012- Medical laboratories — Requirements for quality and competence
- ISO/IEC 17043: 2010- Conformity assessment — General requirements for proficiency testing

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 163	Policy for Participation in Proficiency Testing Activities			
Issue No.: 09	Issue Date: 29-Oct-2020	Amend No: --	Amend Date: --	Page No.: 5 of 10

3. POLICY

- 3.1. Applicant laboratory shall satisfactorily participate in at least one PT program/ EQA prior to gaining accreditation in each discipline applied.

Note 1: Refer to following documents for more details about disciplines:

- a. NABL 120: Guidance for Classification of Product Groups in Testing & Calibration Field
- b. NABL 153: Application Form for Medical Testing Laboratories

Note 2: *It is expected from the laboratory that at least all major analytes/ parameters of the applied scope are covered/ planned under PT participation.*

(Analytes/ parameters whose testing/ calibration significantly demonstrates the capability and competence of the laboratory and involves the application of critical instrumentation/ equipment may be considered as major analyte/ parameter).

Note 3: *Participation in PT program with Z score less than 2 or En value less than 1 will be considered as satisfactory participation.*

Participation in PT program with Z score ≥ 2 or En value ≥ 1 (questionable/ outliers results) will also be acceptable, if the laboratory has taken necessary corrective actions based on root cause analysis.

- 3.2. For applicable tests and calibrations in the laboratory's scope of accreditation, the laboratory is required to participate in one or more of the following PT activity options. They are listed in descending order of preference, with the most desirable at the top of the list:

- I. PT program/ EQA delivered by an Accredited PT provider
Note: PT provider should be accredited by an Accreditation Body (e.g. NABL) covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC e.g. by APAC, IAAC & EA whose service is suitable for the intended need (i.e. the scope of accreditation specifically covers the appropriate PT items/ parameters)
- II. PT program/ EQA delivered by reputed institute (e.g. ASTM, AIIMS)
- III. PT program delivered by an Applicant PT provider
- IV. PT Program delivered by PTP which is accepted by NABL by other means like approval, funded, policies or guidance document;

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 163	Policy for Participation in Proficiency Testing Activities			
Issue No.: 09	Issue Date: 29-Oct-2020	Amend No: --	Amend Date: --	Page No.: 6 of 10

However, where above formal PT Programs are not available/ scheduled or not appropriate, alternatively:

- a. The Testing/ Medical Testing laboratory shall participate in suitable interlaboratory comparisons with sufficient number of accredited laboratories.
- b. The Calibration laboratory shall participate in inter laboratory comparisons either with National Metrological Institutes (such as NPL-India) or another accredited laboratory having better CMC than the participating laboratory in that particular parameter.

Note: *There are areas of testing and calibration for which suitable PT/ ILC is not practical. In such cases, the laboratory is encouraged to*

- a. Participate in another similar product/ parameter related to the scope of accreditation
- b. Participate in other QC measures as mentioned in relevant standard (ISO/IEC 17025/ ISO 15189)
The above are acceptable as alternative means by which performance can be assessed and monitored. This would need to be considered as part of the planned PT and/or related activities.

- 3.3. Accredited laboratory shall have 2-year plan for Proficiency Testing participation which shall cover all the accredited groups as practicable under each discipline of accreditation. In Medical testing, accredited laboratories shall participate in at least one Proficiency Testing/ EQA in a year per discipline, as appropriate. This plan shall be applicable strictly considering the above options for PT given under section 3.2 of this document.

Note 1: *The laboratories are encouraged to participate in PT program up to subgroup level.*

Note 2: *Frequency of PT Participation shall be sufficient to ensure that major sub-groups, analyte and materials/matrices in the scope of accreditation are covered over a two-year period (irrespective of the size of the scope of accreditation).*

Note 3: *The assessment team may not be deputed for areas (groups and/or sub groups) where laboratories have satisfactorily participated in sufficient number of PT Programs.*

Note 4: *The laboratory should participate in PT programs on sampling as well as testing for the particular parameter, where available, in the areas that involve sampling as an integral part of testing in the relevant test method e.g. Ambient air, stack emissions and/ or in the areas where sampling is made mandatory by the regulators.*

- 3.4. Satisfactory participation in PT is necessary for significant enhancement of scope such as addition of discipline (including groups).

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 163	Policy for Participation in Proficiency Testing Activities			
Issue No.: 09	Issue Date: 29-Oct-2020	Amend No: --	Amend Date: --	Page No.: 7 of 10

3.5. Apart from the above defined minimum requirements, laboratory shall also abide by the PT participation required by the respective Regulators, NABL & regional bodies like APAC.

3.6. The laboratory shall take appropriate corrective actions based on root cause analysis in case of poor performance in PT programs within one-month period. In two consecutive events of poor performance in PT participation/ unsatisfactory corrective actions leads to the scope reduction as per NABL 216.

3.7. PT Plan

a) Accredited laboratory shall submit 2-year PT plan as per Form 18 (Annexure A) which will be reviewed by NABL for its suitability in relation to the scope of accreditation.

NABL provides the information of proficiency testing programs through its website, by giving the list of NABL accredited PT Providers with their accredited PT scheme details. Laboratories may visit the NABL website (www.nabl-india.org) for a full listing of available NABL accredited PT programs.

b) Continued compliance to PT plan submitted by the laboratory will be verified during the assessment. Appropriateness of root cause analysis and corrective actions undertaken by the laboratory for poor performance will also be verified during the assessment.

3.8. Instances for additional PT activity

NABL shall seek more frequent PT participation when the laboratory-developed plan is not considered suitable in relation to the scope(s) of accreditation or otherwise. Examples of instances in which NABL may require additional PT activity including but not limited to the following:

- a) The number and nature of technical deficiencies identified during an assessment;
- b) Due to the number and nature of laboratory documented nonconforming work;
- c) Due to receipt of complaints by Laboratories which are of technical nature/ directly affecting the results;
- d) Due to poor performance in previous proficiency testing participation;
- e) Due to changes in laboratories technical personnel / management.

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 163	Policy for Participation in Proficiency Testing Activities			
Issue No.: 09	Issue Date: 29-Oct-2020	Amend No: --	Amend Date: --	Page No.: 8 of 10

3.9. **Criteria for nomination in International PT Programs**

NABL can nominate its accredited/ applicant laboratories for participation in APAC and other international Proficiency Testing program, as and when they are available. Following preference are generally considered while selecting the laboratory for participation:

- a) Accredited laboratory not having participated in any other APAC and other international PT program.
- b) Laboratory having unsatisfactory performance in a past PT program.
- c) Laboratory with long period of accreditation
- d) Applicant laboratory

NABL will co-ordinate all activities related to PT program with APAC and other international organization and the participating laboratory.

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 163	Policy for Participation in Proficiency Testing Activities			
Issue No.: 09	Issue Date: 29-Oct-2020	Amend No: --	Amend Date: --	Page No.: 9 of 10

Annexure A

Form 18

Proficiency Testing Plan						
Laboratory ID (CAB ID)						
Laboratory Name						
Field of Accreditation	Testing / Calibration / Medical					
Period of Participation	(Date of accreditation cycle to be mentioned)					
Accredited Discipline(s)	Group(s) / Sub groups under Discipline	Proficiency Testing Activities Plan (Year wise)		Status and Result of Proficiency Testing Activities (Year wise)		Remarks (for NABL use only)
		1 st Year	2 nd Year	1 st Year	2 nd Year	
(Discipline name to be mentioned)	(Group and/or subgroup name to be mentioned)	(Name of the parameters to be mentioned)	(Name of the parameters to be mentioned)	(Activity: PT/ EQA/ ILC Status: Completed/ Not completed Results: Name of parameter (Z score/ En Value etc.)	(Activity: PT/ EQA/ ILC Status: Completed/ Not completed Results: Name of parameter (Z score/ En Value etc.)	
<p>Note: Laboratory should ensure that PT plan covers the groups/ sub-groups, analyte/ parameter and materials/ matrices under each discipline</p>						
<p>For NABL use only</p> <p>Reviewed and Approved by:</p>						

National Accreditation Board for Testing and Calibration Laboratories (NABL)
NABL House

Plot No. 45, Sector 44,
Gurugram - 122003, Haryana
Tel. no.: 91-124-4679700 (30 lines)
Fax: 91-124-4679799
Website: www.nabl-india.org