QAI CLA 005

Quality and Accreditation Institute

Centre for Laboratory Accreditation

POLICY FOR PARTICIPATION IN PROFICIENCY TESTING ACTIVITIES

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1. Objective:

Proficiency Testing (PT) is one of the important tools to determine the technical competence of the Testing and Medical laboratories.

Both the accreditation standards (ISO/IEC 17025 and ISO 15189) require a mechanism to be in place to ensure quality of test results.

This document of QAI is based on the requirements of ILAC-P9- 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

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

A. 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.

B. 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.

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.

Alternative approaches
Whenever an interlaboratory comparison is not available, the laboratory shall develop other approaches and provide objective evidence for determining the acceptability of examination results.
Whenever possible, this mechanism shall utilize appropriate materials.
NOTE Examples of such materials may include:
— certified reference materials;
— samples previously examined;
— material from cell or tissue repositories;
— exchange of samples with other laboratories;
— control materials that are tested daily in interlaboratory comparison programmes.

2. Scope:

This document stipulates the QAI CLA policy for PT Participation in Proficiency Testing Activities for Testing and Medical laboratories.

References

- ILAC-P9:06- 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

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. CLA 101: Information brochure for medical laboratories

b. CLA 201: Information brochure for 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 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 will be considered as satisfactory participation.*
Participation in PT program with Z score ≥2 (questionable/ outliers results) will also be acceptable, if the laboratory has taken necessary corrective actions based on root cause analysis.

PT provider should preferably be accredited by an Accreditation Body covered by the APAC/ ILAC Arrangement whose service is suitable for the intended need (i.e. the scope of accreditation specifically covers the appropriate PT items/ parameters). Laboratory shall participate in APAC PT program when requested.

However, where above formal PT Programs are not available/ scheduled or not appropriate, alternatively Testing/ Medical Testing laboratory shall participate in suitable interlaboratory comparisons with sufficient number of accredited laboratories and use alternative approaches mentioned above under 'Objective'.

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 may lead to appropriate action including the scope reduction.

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