



FDAS Policy on Proficiency Testing

What is Proficiency Testing & its use?

Proficiency Testing (PT) is a means of independently assessing the performance of laboratories in specific tests/calibrations. It is an important part of quality assurance systems in that it provides laboratories with an objective and independent means of assessing and demonstrating the reliability of the data they are producing. Laboratories producing poor quality results may seek advice from the organizers of the scheme, so that their performance may be improved. Laboratories which are already competent also have a need for proficiency testing as a means of demonstrating the accuracy of their data. It is important to recognize this dual role of PT schemes. Information on laboratory performance obtained from these schemes is therefore of interest to a broad range of parties including QA Managers, customers, regulatory authorities, and accreditation bodies alike.

Essentially a proficiency testing scheme checks the competence of a group of participating laboratories by a statistical evaluation of the data they obtain on analyzing distributed items. Each laboratory is then provided with a numerical indicator of its performance, together with information on the performance of the group, enabling its proficiency relative to the group to be compared and evaluated. Participation of proficiency testing scheme also reinforces an interest in quality control and provides those laboratories whose data does not meet the required level of acceptability with an indication that they have a problem.

The use of a consensus value produced by a group of expert laboratories using best possible methods is the mean of the test results to determine any outliers.

There are number of PT providers for various fields across the globe.

FDAS PT Policy:

FDAS PT Policy requires its laboratories to comply with the following.

- i. Prior to grant of accreditation:**
Applicant laboratory is required to have successfully participated in PT/ILC* in at least one parameter for the test or calibration, prior to getting the accreditation from each applied field.
- ii. After the grant of accreditation:**
Accredited laboratory is required to have participated in one round of PT/ILC* for each accredited parameter during a cycle of four years.
- iii. When desired PT scheme is not available:**
FDAS accepts Inter Laboratory Comparisons (ILC*) subject to approval of FDAS.
- iv. In addition to above policy:**
FDAS may ask applicant laboratory/accredited laboratory, to test or calibrate an item to be provided by FDAS for which the results are known to it, including for surveillance activities.



Laboratory's Assessment and follow-ups:

- i. Includes verification of the PT/ILC participation and PT/ILC plan and its suitability to determine compliance against above requirements.
- ii. When results of PT/ILC participation are not satisfactory, laboratory's cause analysis and corrective action are examined.
- iii. If laboratory fails to take any corrective action & without any justification, FDAS may reduce the scope of accreditation for the test(s)/calibration(s) in question.
- iv. When laboratory repeatedly ignores cause analysis & corrective action, clarification is sought and for non-satisfactory response, the accreditation could be withdrawn.
- v. In case of interlaboratory comparisons between the laboratories, statistical analysis of results is done using technique of Z-score for testing laboratories & En value for Calibration laboratories.
- vi. FDAS considers laboratory's PT/ILC Participation findings from Assessment team for appropriate decision.

***ILC:** When the laboratory (Applicant/Accredited) intends to opt for ILC (Inter- Laboratory Comparison) the following norms to be followed.

- i. Calibration Laboratories are advised to identify a calibration laboratory with better CMC than its own.
- ii. Testing Laboratories are advised to identify a testing laboratory for ILC, where referral laboratories' scope of testing is not covered for the desired parameter. FDAS maintains a list of referral laboratory.
- iii. Laboratory to send its results (test/calibration) to FDAS along with the name of laboratory it intends to have ILC to seek clearance of FDAS.
- iv. The results of ILC (Z Score or En Value) must be communicated to FDAS at the earliest.

Note:

Laboratories are advised to refer ISO/IEC 17043, Annex – C for selection of proficiency testing scheme.

Reference:

ILAC P9:06/2014 – ILAC Policy for Participation in Proficiency Testing Activities