

PPHRL-R&D /ILC/L2-015		<b>Procedure for Inter laboratory comparisons (ILC)</b>	 Primary & Secondary Healthcare Department
Issue on	DD-MM-YYYY		
Revision	00		
Curator	PPHRL, P&SHD		
Approved By	IRB, P&SHD		

## Purpose

This procedure defines the mechanism for PPHRL lab to arrange Inter Lab Comparison / Proficiency Testing (PT).

## Application

The procedure covers the requirements of Inter Lab Comparison and is applicable in all the section of PPHRL lab under the international standard ISO 15189:2012 clause 5.6.

## Procedure

Lab has developed annual program to participate in Proficiency Testing (PT) or in case PT is not available the lab will arrange Inter Lab Comparison with any other accredited laboratory nationally/internationally having same scope of test.

## Participation in PT Program

### Register in a PT Program

PPHRL aims to participate in the Inter Laboratory Comparison (ILC) i.e. Proficiency Testing one test per annum. Initially it will participate in the tests which are in the scope of ISO 15189:2012.

To find out the PT providers, QM is responsible to made contact with organizations or labs who are initiating PT Programs.

QM will confirm registration for PT test after the initial communication (via e-media / courier etc) has been finalized. He will manage the communication record in form of hard copies in the PT / ILC record folder.

The QM ensures availability of resources & finances and confirms to MR who shall register the lab and perform future correspondence.

## Conducting PT

After getting confirmation by the PT provider, the PT program/schedule will be received to the lab. The PT program/schedule will be distributed to all concerned section.

After receiving the PT samples, the sample will be retained according the given sample retention conditions.

QM will finalize a date for examination performance over PT samples after getting approval by the laboratory Director. This program will be distributed to all concerned sections.

The lab will perform the examination over PT samples and results will be submitted to the PT provider.

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The result of PT will be discussed in the Management Review. In case the results are outlier the whole process for quality assurance will be repeated and Lab will participate again in the PT program.

Inter Lab Comparison: In case the PT provider are not available; then lab will plan to arrange ILC with any other accredited laboratory in the country. For this purpose the blind coded will be shared by accredited lab whose results are known to the accredited lab.

The labs will perform the testing activity and the result will be compare through Z-Score method.

The most appropriate way of calculating / determining the comparison between the labs is to use Z-Score formula as recommended in Guide-43-1 by ISO which is based on inter laboratory exercise.

$$Z = \frac{x - X}{s}$$

Where,

- Z= Z- Score (required result)
- x = Result from a Lab
- X= True Value / Average / Median / Mode
- s = Standard Deviation

Following criteria is used to judge a lab's level of performance based on Z-Score calculated;

**$|z| \leq 2 = \text{Satisfactory}$**   
(Z-Score is less than equal to 2)

**$2 < |z| < 3 = \text{Questionable}$**   
(Z-Score is greater than 2 but less than 3)

**$|z| \geq 3 = \text{Unsatisfactory}$**   
(Z-Score is greater than equal to 3)

It must be noted here that it does not matter while calculating Z-Score, whether the final result is in Negative (-ve) or Positive (+ve). These characteristics are ignored.

Lab may want to use any other equivalent methodology to calculate level of performance of each lab, but it must be ensured that it is incorporated in this procedure and has a traceability to international methodology or standard, just like Z-Score (*Reference*; Guide 43-1: Proficiency Testing by Inter laboratory Comparison – Part 1: Development and operation of Proficiency Testing Scheme).

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### Developing ILC Report

The final stage to ensure proper closing of ILC is to develop an ILC report, which contains complete details about the samples, the tests involved and data in tabular form expressing the results from each lab. It is also recommended to display the results in the form of graphs as they provide the same results in a quick and more visually appealing manner. It depends on the number of results received, whether ILC Originator wants to place their Z-Score and Uncertainties separately or wants to express all of them in a single table, but it should follow a theme that is easily understood by all labs involved.

### Corrective Action and Its Follow up (Wherever Applicable)

Any highlighted problems / non-conformities are to be eradicated following the procedure of corrective action. In case of repeated errors, it is recommended to investigate the problem before taking any corrective action, to ensure that it won't happen again.

After corrective action has been taken, it is the responsibility of MR to check its effectiveness. In case its not, re-investigation is performed so that proper / better corrective action can be taken.

### Replicating the Sample and Distribution Control

Personnel performing the tests are recommended to follow same test method and same type of equipment and accessory (it is recommended to use same model). He shall ensure that everything remained same at all levels of the testing activity, the only thing changing is the performer and any differences can be traced easily

Same procedure will be followed in case of replicate testing mentioned in section 5.3 to record this activity

## **1. Related Documents**

- PT Plan
- ILC Plan
- Procedure for corrective action