FEDERATION FOR DEVELOPMENT OF ACCREDITATION SERVICES
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FDAS SUPPLEMENTARY CRITERIA FOR MEDICAL LABORATORIES

1.0 Introduction

1.1. Scope: These criteria are for Medical Laboratories

1.2. Normative and other Reference

1.2.1 ISO 15189:2012, General Requirements for the Competence of Medical Testing Laboratories.

1.2.2 ISO/IEC 17000:2020 Conformity Assessment – Vocabulary and General Principles

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

1.2.4. ILAC P10:07/2020 ILAC Policy on the Traceability of Measurement Results

1.2.5. ILAC G17:01/2021 ILAC Guidelines for Measurement Uncertainty in Testing

2.0 Definitions

Applicable definitions of ISO/IEC Standard 17000 series apply.

3.0 Proficiency Testing Activity:

The minimum amount of appropriate proficiency testing required per laboratory is given below:

- One PT/ILC activity from each applied field prior to gaining accreditation.
- One PT/ILC activity relating to each group of laboratory's scope of accreditation at least every four years.

4.0 Traceability of measurement results

All measuring devices including subsidiary measuring devices which can impact the results should have the Traceability of Measurement to SI units, directly from National Physical Laboratory (NPL) New Delhi/ any other National Metrological Laboratory or from a laboratory from India or abroad accredited by a laboratory accreditation body which is signatory to MRA with APAC/ILAC.

5.0 Uncertainty in Measurement

Medical Laboratories shall estimate uncertainties as per:

ILAC G17:01/2021 ILAC Guidelines for Measurement Uncertainty in Testing, Para 3 "Guidance on Evaluation of Measurement Uncertainty in Testing".

6.0 Links to Additional References

6.1 Asia Pacific Accreditation Cooperation-www.apac-accreditation.org

6.2 International Laboratory Accreditation Cooperation – www.ilac.org

6.3 International Organization for Standardization – www.iso.org

6.4 International Electro technical Commission – www.iec.ch