



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 15189:2022/ ISO 15189:2012* Medical Laboratories – Requirements for Quality and Competence

1.2.2 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 Policy on Proficiency Testing:

FDAS requires its laboratories to comply with FDAS 135, FDAS Policy on Proficiency Testing.

4.0 Policy on Metrological Traceability:

Laboratory to establish metrological traceability of measurement results by practicing FDAS 136, FDAS Policy on Metrological Traceability.

5.0 Policy on Shifting of CAB's Location:

In case laboratory wants to shift to new location after grant of accreditation, it should comply with FDAS 137, FDAS Policy on Shifting of the CABs location.

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

*Please note, if laboratory wants Accreditation as per ISO 15189:2012, Accreditation will be valid only until December 2025 & required to be reassessed as per ISO 15189:2022 before October 2025 to ensure continuity in Accreditation.