



## 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 Links to Additional References

**4.1** Asia Pacific Accreditation Cooperation-[www.apac-accreditation.org](http://www.apac-accreditation.org)

**4.2** International Laboratory Accreditation Cooperation –[www.ilac.org](http://www.ilac.org)

**4.3** International Organization for Standardization – [www.iso.org](http://www.iso.org)

**4.4** International Electro technical Commission –[www.iec.ch](http://www.iec.ch)