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ACCREDITATION CRITERIA FOR MEDICAL LABORATORIES

AC780

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PREFACE

The attached accreditation criteria have been issued to provide all interested parties with guidelines on implementing performance features of the applicable standards referenced herein. The criteria were developed and adopted following public hearings conducted by the International Accreditation Service, Inc. (IAS), Accreditation Committee and are effective on the date shown above. All accreditations issued or reissued on or after the effective date must comply with these criteria. If the criteria are an updated version from a previous edition, solid vertical lines (|) in the outer margin within the criteria indicate a technical change or addition from the previous edition. Deletion indicators (→) are provided in the outer margins where a paragraph or item has been deleted if the deletion resulted from a technical change. These criteria may be further revised as the need dictates.

IAS may consider alternate criteria provided the proponent submits substantiating data demonstrating that the alternate criteria are at least equivalent to the attached criteria and otherwise meet applicable accreditation requirements.

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ACCREDITATION CRITERIA FOR MEDICAL LABORATORIES

1. INTRODUCTION

- 1.1 **Scope:** These criteria set forth the requirements for obtaining and maintaining International Accreditation Service, Inc. (IAS), Medical Laboratory accreditation. Medical Laboratories seeking accreditation shall comply with the requirements specified in ISO 15189, *Medical Laboratories – Requirements for quality and competence*; and supplemented by this IAS Accreditation Criteria, IAS Rules of Procedure for Medical Laboratories, and International Laboratory Accreditation Cooperation (ILAC) guidance documents on application of ISO 15189.
- 1.2 **Normative and Reference Documents:** Publications listed below refer to current editions (unless otherwise stated).
- 1.2.1 ISO 15189, Medical laboratories -- Requirements for quality and competence.
 - 1.2.2 ISO 22870 Point-of-care Testing (POCT) – Requirements for quality and competence.
 - 1.2.3 IAS Rules of Procedure for Medical Laboratory Accreditation.
 - 1.2.4 ILAC-G26, Guidance for the Implementation of a Medical Laboratory Accreditation System.
 - 1.2.5 ILAC-P9, ILAC Policy for Participation in Proficiency Testing Activities.
 - 1.2.6 ISO/IEC Guide 2, Standardization and related activities – General Vocabulary.
 - 1.2.7 ISO/IEC Guide 99, International Vocabulary of Metrology – Basic and general concepts and associated terms.
 - 1.2.8 ISO/IEC 17000, Conformity assessment – Vocabulary and general principles.

2 DEFINITIONS

Applicable definitions of ISO Standard 15189 and ISO/IEC 17000 series apply.

3 ELIGIBILITY

- 3.1 All applicants seeking accreditation must demonstrate their competence and establish conformance with the requirements of ISO 15189.
- 3.2 Medical laboratories must always demonstrate competence to perform specific tests or type of tests on samples in the scope for which they wish to become accredited.
- 3.3 IAS accreditation services are available to medical laboratories that meet the requirements of ISO 15189 and who operate in the following disciplines:
- 3.3.1 Clinical Biochemistry
 - Toxicology

- 3.3.2 Clinical Microbiology
- 3.3.3 Clinical Pathology
- 3.3.4 Genetics
 - Cytogenetics
- 3.3.5 Haematology
- 3.3.6 Histopathology
 - 3.3.6.1 Cytopathology (Cytology)
 - 3.3.6.2 Hospital Autopsy
- 3.3.7 Immunology
- 3.3.8 Medical Imaging
- 3.3.9 Molecular Pathology
- 3.3.10 Nuclear Medicine
- 3.3.11 Point-of-care Testing (POCT)
- 3.3.12 Pharmacology

Note: In general, for diagnostic medical laboratories, scopes may include aspects regarding the discipline of practice, sample type and techniques employed. ILAC G18: *Guideline for the Formulation of Scopes of Accreditation for Laboratories* is taken into consideration when formulating the scope of accreditation for medical laboratories.

4 REQUIRED BASIC INFORMATION

Medical Laboratories must demonstrate compliance with the following requirements:

- 4.1 ISO Standard 15189, Medical laboratories -- Requirements for quality and competence.
- 4.2 IAS Rules of Procedure for Medical Laboratory Accreditation.

5 ADDITIONAL INFORMATION (AS APPLICABLE)

Specific national and/or international regulatory requirements.

6 LINKS TO ADDITIONAL REFERENCES

- 6.1 International Laboratory Accreditation Cooperation – www.ilac.org
- 6.2 Asia Pacific Laboratory Accreditation Cooperation – www.aplac.org
- 6.3 IAS – www.iasonline.org