



Medical Laboratories Accreditation Scheme (MLAS)

Background

The SADCAS Medical Laboratories Accreditation Scheme (MLAS) was established in June 2010. The MLAS is multi-disciplinary accreditation scheme operated in accordance with ISO/IEC 17011: Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.

The Need for Accreditation

Over the years and with challenges such as HIV/AIDS, TB, malaria, etc. there has been global rapid growth in the various branches of health care services. As part of this growth, laboratory diagnosis has gained tremendous importance in today's practices. The main purpose of a medical laboratory is to provide diagnosis and management system for the physician to use in the care of patients. Therefore the competence and efficient operation of a medical laboratory and timeous delivery of medical laboratory services to the physician is critical in any health care delivery system. Accreditation is the strategy for a medical laboratory to achieve this. Medical testing is also pivotal in epidemiological surveillance, outbreak investigations, initiation and monitoring of treatment, as well as research and development. The International Standard ISO 15189 specifies the requirements for quality and competence particular to medical laboratories.

Accreditation of a medical laboratory in accordance with ISO 15189 provides a number of benefits:

- It is a means of demonstrating competence to clients both internal and external;
- It is a guarantee for accurate and reliable test results;
- It improves patient care;
- It strengthens community confidence in test results;
- It provides continuous staff education and attracts professional reference due to accuracy and competence.

Fields of Testing

The current fields of testing offered on the SADCAS MLAS are:

- Biochemistry;
- Cytology;
- Haematology;
- Histopathology;
- Immunology;
- Microbiology;
- Pathology;
- Virology;
- Serology;
- Andrology.

The fields of testing are listed in SADCAS TG 03: Area of accreditation.

Accreditation Criteria

Medical laboratories seeking to be accredited on the SADCAS MLAS need to comply with the International Standard ISO 15189: General requirements for the competence of medical laboratories.

The Accreditation Process

A medical laboratory wishing to be accredited:

- Submits directly to SADCAS duly completed SADCAS F 43 (c): Application for accreditation of medical laboratory together with the laboratory quality manual, and duly completed SADCAS F 43 (f): Application for approval of personnel, i.e. nominated representatives in the case of medical laboratories and SADCAS F 44: SADCAS accreditation agreement.
- Upon receipt, SADCAS undertakes a **completeness check** of the application documents.
- SADCAS provides the applicant with a detailed quotation based on the scope of application. If acceptable, the applicant signs and returns duly signed quotation to SADCAS.





- SADCAS undertakes a **documentation review** of the applicant's quality manual and provides feedback to the applicant who, if there are non conformities institutes corrective action. If the quality manual addresses all the requirements of the standard then the application proceeds to the assessment stage.
- **Pre-assessments** are optional but may be compulsory depending on the regulator's condition for acceptance where required. Pre-assessment is an on- site visit to check the readiness of applicant for accreditation.
- An **initial assessment** of the organization's competence is undertaken on-site and involves an opening meeting, assessment, witnessing of select technical activities and a closing meeting. Findings from the assessment are recorded as non conformities where the laboratory needs to institute corrective action.

Assessors

Assessors are experts drawn from a pool of medical scientists and technologists and pathologists from the public and private sectors as well as from technical institutions/associations in the SADC region who have been trained, qualified and registered as assessors by SADCAS. Assessors trained and qualified by other accreditation bodies and evaluated for competence can also undertake assessments on behalf of SADCAS. An assessment is undertaken by an assessment team consisting of a Team Leader and at least one Technical Assessor/Technical Expert with expertise in the scope of assessment. The assessment team makes **recommendations for accreditation**.

Accreditation Certificate

Accreditation decision is made by the Accreditation Approvals Committee based mainly on the information gathered during an assessment. The accreditation certificate is valid for 5 years and renewed subject to terms and conditions of the MLAS.

Periodic On-site Assessment and Re-assessment

In order to maintain accreditation **periodic assessments** are conducted on- site. The first periodic on-site assessment is undertaken not more than 12 months after accreditation thereafter annually throughout the accreditation cycle of 5 years. The intervals between periodic on-site visits can be extended depending on the risks associated but must not exceed two years.

Re-assessments are conducted at least 6 months prior to the end of the accreditation cycle of 5 years.

Appeals

Appeals from laboratories on an accreditation decision shall be in writing and shall be forwarded to the Chief Executive Officer within 3 months of the cause of appeal. Appeals are handled in accordance with SADCAS AP 08: Customer feedback handling procedure which maintains independency and impartiality.

Complaints

Complaints concerning SADCAS services, personnel and assessors/experts can be received by any member of staff who shall complete SADCAS F 85 and direct the complaint to the Quality Manager.

Accreditation Fees

SADCAS accreditation fees are contained in SADCAS AP 02: SADCAS service fees. The fees contained therein are estimates. Individual quotations are provided based on the fee estimates contained therein. SADCAS accreditation fees are reviewed annually.

Accreditation Documents

SADCAS accreditation documents are available from the SADCAS website: www.sadcas.org



For further information, please contact:

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