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KENYA
ACCREDITATION
SERVICE

ACC-CD-20-01

Criteria for Accreditation of Immunology Laboratories

Table of Contents

1 Background Information 2
1.1 Purpose 2
1.2 Scope 2
1.3 Role(s) and Responsibility 2
2 Terms and Definitions 2
2.1 Acronyms and Abbreviations 2
2.2 Definition of Terms 3
3 Criteria 3
3.1 Introduction 3
3.2 Laboratory Space 4
3.3 Examination Procedures and Quality Control and Quality Assurance 5
4 Associated Documents 8
5 Revision/ Amendment Records 9

1 Background Information

1.1 Purpose

This document has been prepared by the Technical Committee on Medical laboratory and Point of Care Testing (POCT) and authorized for adoption by KENAS. It supplements ISO 15189 standard and provided specific guidance on the accreditation for Immunology laboratories for use by assessors and by laboratories preparing for accreditation.

1.2 Scope

This document covers the application of ISO 15189 for accreditation of immunology laboratories, and should be read in conjunction with KENAS rules and procedures as well ISO 15190 and Good Clinical Laboratory Practices.

1.3 Role(s) and Responsibility

Role	Responsibility
All KENAS Technical Staff	Process owner
MEDO	Reviewer
CMLA	Recommender
CEO	Approval
Accreditation Committee	Compliance

2 Terms and Definitions

For the purpose of this manual, the following terms and definitions shall apply in addition to those given in ISO/IEC 17000 and the Kenya Accreditation Service Act 2019.

2.1 Acronyms and Abbreviations

CEO	Chief Executive Officer
CMLA	Chief Manager, Laboratories
KENAS	Kenya Accreditation Service
GLP	Good Laboratory Practice
POCT	Point of Care Testing

2.2 Definition of Terms

2.2.1 Accreditation

A third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

2.2.2 Committee

A group of people appointed for a specific function by a larger group or organization.

3 Criteria

3.1 Introduction

3.1.1 Laboratory Particulars

Name of laboratory----------

Address of the medical/clinical laboratory----------

Name of the laboratory head----------

Qualification of the laboratory head----------

Name of the technical supervisor----------

Qualification of the technical supervisor----------

Standard: *the laboratory management shall maintain records of the relevant educational and professional qualifications, training and experience, and competence of all personnel. (Clause 5.1.2)*

Standard: *there shall be staff resources adequate to the undertaking of the work required (clause 5.1.5).*

Standard: *there shall be continuing education programme available to* ***all staff level*** *(clause 5.1.9)*

3.1.2 Staffing:

List the number of full time:

- Laboratory clinicians (physicians)----------
- Laboratory scientist ----------
- Supervisor technologist----------
- Other technologists other than supervisors----------
- Certified combined technicians----------
- Laboratory assistance----------
- Clerical staff----------

- Support staff----------
- Other staff (specify)----------
- Name of consulting pathologist----------
- Name of consulting scientist----------
- IT----------

Standard:

i. *The laboratory management shall maintain records of the relevant educational and professional qualifications, training and experience, and competence of all personnel. (ISO 15189)*
ii. *There shall be staff resources adequate to the undertaking of the work required (ISO 15189).*
iii. *there shall be continuing education programme available to all staff level (ISO 15189)*

Work Load	Workload Units	Tests
Inpatients	----------	----------
Out patients	----------	----------
Referred in patients	----------	----------
Others	----------	----------
Total	----------	----------

TYPES OF SPECIMENS PROCESSED

Number per month----------

Gastric washings----------

Others----------

REFERENCE LABORATORY:

Name: ----------

Address:----------
-

3.2 Laboratory Space

3.2.1 Adequate space shall be allocated to:

a) Administrative and clerical functions
b) Technical functions (benches)
c) Incubators (adequate number available)
d) Instruments

e) Storage (including adequate number of refrigerators)
f) Work areas shall be shielded from direct sunlight
g) Biological Safety Cabinets – (Adequate Number Present)Fume Hoods –(Adequate Number Present)- (BSC-2 or 3) and shall be adequately serviced
h) Media Preparation area shall be sufficient

Standard: *Space and equipment must be adequate for the (clause 5.2) extend of services offered by the laboratory.*

3.3 Examination Procedures and Quality Control and Quality Assurance

3.3.1 Rheumatoid Factor

3.3.1.1 The following shall apply where testing for rheumatoid factors is carried out using latex test kits:

a) The laboratory shall state whether the test is used as a screening procedure or whether this is the only test method used.
b) The test should be performed in parallel with a sheep red blood cell agglutination test.
c) The kit shall be standardized against a WHO reference material.
d) The detection level for a positive result should be clearly defined.

3.3.1.2 For laboratories using SRBC agglutination (Rose Waaler) the following shall apply:

a) All sera shall be treated in a water bath at 56 °C for 30 minutes to inactivate complement before use.
b) Each new batch of anti-sheep red cell antiserum shall be titrated.
c) If a fixed incubation time required this shall be clearly stated in the procedure.
d) At least one reactive serum, of known titre near the level of significance, shall be included in each batch
e) Measures shall be taken to ensure that the sensitivity level of a batch of sensitized SRBC is maintained over a defined period.

3.3.1.3 Laboratories using quantitative nephelometric or other immunoprecipitin methods for Rheumatoid Factor measurements should refer to CLSI guideline “DI2-A2 Immunoprecipitin Analysis: Procedures for Evaluating the Performance of Materials – Second Edition; Approved Guideline”. The following minimum guidelines for nephelometry shall be followed:

a) Nephelometer performance shall be regularly validated (i.e.: to control for laser deterioration).
b) Calibrations shall be carried out with calibrators traceable to IFCC or WHO reference materials.

c) High, normal and low controls shall be measured frequently, at least once with every batch of patient samples.
d) Controls shall have similar properties to fresh serum (No or little “matrix” effects).

3.3.1.4 ELISA methods may also be used. The laboratory shall ensure that:

a) Calibration standards used are traceable to IFCC or WHO reference materials.
b) That ELISA reader wavelength and absorption is calibrated or checked periodically according to manufacturer’s specifications.

3.3.2 Tissue antibody testing using two-stage immunofluorescence

3.3.2.1 The magnifications of the fluorescence microscopes used for screening and endpoint determination shall be clearly stated.

3.3.2.2 The working dilution of the Fluorescein isothiocyanate (FITC) reagent shall be determined by checkerboard titration.

3.3.2.3 The heavy chain specificity of the FITC reagent shall be stated.

3.3.2.4 All reagents shall be filtered prior to use.

3.3.2.5 All sections shall be examined for fluorescence within four hours of preparation.

3.3.2.6 The sections shall be stored in the dark until they are examined.

3.3.2.7 Each slide shall be screened by more than one person.

3.3.2.8 Specimens of particular interest shall be stored for future reference.

3.3.2.9 Follow up testing shall be performed on all positive Antinuclear Antibody (ANA) sera.

3.3.3 Haemagglutination tests (e.g. Thyroid Auto-antibodies)

3.3.3.1 Appropriate precautions shall be taken to avoid interference from heterophile antibodies, such as pre-absorption of test sera or control cells shall be included and if heterophile antibodies are present the test sera then absorbed.

3.3.3.2 Reactive and non-reactive controls shall be used with each batch.

3.3.3.3 The titre of the reactive control shall be at the level of significance for the assay.

3.3.4 Lymphocyte enumeration

3.3.4.1 The methods used by the laboratory for cell preparation shall be clearly stated (e.g. haemolysis of whole blood, using Ficoll-Paque method, other).

3.3.4.2 Cells shall be tested for viability.

3.3.4.3 For analysis by flow cytometry:

a) Blood collection, transport and storage procedures shall be designed to ensure maximum stability of the blood cells.
b) Lot specific factors in different batches of monoclonal reagents shall be controlled.
c) The flow cytometer shall be monitored for optimum performance.
d) Where applicable, the haemopoietic and non-haemopoietic cells, within the gated structure, shall be distinguishable.
e) Lymphosum determinations (CD3 + CD16 + CD19) shall be used as internal quality control for all tests. Lymphosum shall be between 90 and 110%.
f) T-sum shall also be calculated as internal controls: Sum of CD3+, CD4+ and CD3+CD8+ cells shall equal the total % CD3 within 10%.
g) Appropriate isotype controls shall be used as part of the internal quality control.
h) A positive reagent control if a new batch of any reagent for cell preparation or staining is initiated.
i) Each sample count shall be based on at least 2000 cells.

3.3.4.4 For analysis by microscopy:

a) The adequacy of the fluorescent illumination shall be checked.
b) The dead cells shall be identified.
c) More than 200 living cells should be counted.
d) Monocytes shall be discriminated from lymphocytes.

3.3.5 Lymphocyte proliferative studies

3.3.5.1 The blood shall be collected into a preservative-free, sterile anticoagulant.

3.3.5.2 The lymphocytes shall be separated from blood using sterile, endotoxin-free Ficoll-Paque.

3.3.5.3 Proliferation shall be expressed as a stimulation index.

3.3.5.4 A minimum of 2 normal donor controls shall d be used in each assay.

3.3.5.5 Where Phytohemaglutinin (PHA), Concanavalin A (Con A) and (pokeweed Mitogen) PWM are used as stimulants:

a) They shall be of immunological grade.
b) They shall be stored below 4 °C.
c) Dose-response curves and time courses should be performed with each run.

3.3.5.6 In mixed leukocyte cultures, the stimulator population shall be treated to prevent its proliferation in the lymphocyte culture.

3.3.5.7 Cultures shall be checked for bacterial or mycoplasma contamination.

3.3.5.8 The serum used in the proliferation medium:

a) Shall be assessed for optimum performance.
b) The batch-to-batch quality of the proliferation serum shall be
c) monitored.

3.3.6 In vivo assays of immuno function

3.3.6.1 If the laboratory performs delayed hyper-sensitivity skin testing the laboratory shall indicate if the material used is obtained commercially.

3.3.6.2 Delayed hypersensitivity skin tests and skin prick tests shall be performed and read by trained personnel, and where possible preferably by a clinical allergist.

3.3.7 Immunoblotting

If the laboratory runs its own gels and does its own blotting the following shall apply:

a) The molecular weights and purities of the antigens shall be checked.
b) Western blots shall be performed.
c) Diffusion blots shall be performed.
d) Antigen transfer shall be confirmed.
e) The method (s) of detection shall be clearly stated in the procedure.

4 Associated Documents

Ref	Document Identifier	Document Title
1.	ISO/IEC 17011	Conformity Assessment-General requirements for accreditation bodies accrediting conformity assessment bodies
2.	ISO 15189	Medical Laboratories – Requirements for Quality and Competence
3.	ISO 15190	Medical Laboratories – Requirements for Safety
4.	GLP	Good Laboratory Practice
5.	D12-A2	Immunoprecipitin Analysis: Procedure for evaluating the performance of materials 2nd Edition
6.	QMM-01	KENAS Quality Manual

5 Revision/ Amendment Records

Date	Ver	Revised By	Reason for Revision
10/10/2022	01	RSQ	Newly developed/formatted document