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KENYA ACCREDITATION SERVICE

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Criteria for the Accreditation of Medical Mycobacteriology Laboratories

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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 mycobacteriology 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
MEDO	Medical Officer
POCT	Point of Care Testing
GLP	Good Laboratory Practice
IST	International Standard for Tuberculosis care

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.

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 document personnel qualifications for each position. The qualification shall reflect the appropriate education, training, experience and demonstrated skills need, and be appropriate to the tasks performed. (ISO 15189 5.1.2)

The Head of Microbiology/ Mycobacteriology laboratory must have relevant qualifications experience in Microbiology/Mycobacteriologists as described in the institutional job description.

The laboratory shall be directed by a person or persons with the competence and delegated responsibility for the service provided (ISO 15189 4.1.1.4)

3.1.2 Staffing

3.1.3 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 15189:2012 Clause 5.1.9)

ii. There shall be staff resources adequate to the undertaking of the work required (ISO 15189:2012 clause 4.1.2.1 -i).

There shall be continuing education programme available to ***all staff level*** (ISO 15189:2012 clause 5.1.8)

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

3.1.4 Types of Specimens Processed

(Number per month) ----------

Sputum ----------

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

Others----------

REFERENCE LABORATORY:

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

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

3.2 Laboratory Space

Adequate space shall be allocated to;

3.2.1 Administrative and clerical functions

3.2.2 Technical functions (benches)

3.2.3 Incubators (adequate number available)

3.2.4 Instruments

3.2.5 Storage (including adequate number of refrigerators)

3.2.6 Work areas shall be shielded from direct sunlight

3.2.7 Biological Safety Cabinets – (Adequate Number Present- Adequate Number Present) - (BSC-2 or 3) and shall be adequately serviced

3.2.8 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 Checking and Verification Of Reagents

This applies to all reagent: including media (Lowestein –jensen, Ogawa etc.) susceptibility disc, E strips, typing sera, PCR kits, BACTEC, MGIT system, Nucleic Acid Amplification Tests.

3.3.1 Labeled as content: date of receipt, or preparation, and date of opening and expiration.

3.3.2 Stored according to specifications.

3.3.3 Checked immediately upon receipt for damage (e.g. freezing)

3.3.4 Reagents requiring desiccants shall contain active desiccants

3.3.5 Reagents shall have lids secured tightly

3.3.6 Expired reagents shall be discarded

3.3.7 Stored according to specifications

Standard: Reagents must be stored as recommended by the manufacturer in order to prevent environmentally induced alterations that could affect test performance. If ambient temperature is indicated, there must be documentation that the defined ambient temperature is maintained and corrective action is taken when tolerance limits are exceeded.

3.3.8 New reagent lots shall be checked against old reagent lots or with suitable reference material before or concurrently with being placed in service

Standard: New reagents must be tested in parallel or validated with old reagents or checked against other reference material to ensure appropriate reactivity before or concurrently with being placed in service.

3.4 Reference Cultures

3.4.1 ATCC reference cultures shall be maintained.

3.4.2 Method of storage of reference strains shall be specified

3.4.3 Appropriate or required reference cultures shall be used to check media, stains, reagents, identification kits e.g. susceptibility testing.

3.5 Media Checks

3.5.1 All media shall be checked for;

a) Sterility
b) Ability to support growth of appropriate organisms
c) Selectivity
d) Biochemical reactivity

3.5.2 All batches of media shall be labelled as to type, date of preparation, expiration date and Lot number for in house prepared media and purchased media.

3.5.3 There shall be documentation that all media both purchased and prepared are checked for drying, visible contamination and for cracked plates/tubes in satisfactory condition prior to being put into use.

***Standard*:** The laboratory has the responsibility for assuring that all media used, whether purchased or prepared by the laboratory, are sterile, able to support growth appropriately and are appropriately reactive biochemically. This will ordinarily require that the laboratory maintain a stock of reference organisms and test the media before or concurrent with use. Explicit documentation of such testing is essential. The laboratory should have documentation that each shipment of purchased media is examined for breakage, contamination, appearance, and evidence of freezing or overheating, and that media observed to be unsatisfactory for use have been discarded with documentation of follow up activities e.g. notification of company.

For prepared, purchased media, the laboratory must have explicit documentation that each lot of purchased medium has been tested by the manufacturer.

In addition, each shipment or lot, if more than one lot number is received per shipment of a commercial identification system must be tested for appropriate performance.

3.5.4 Shelf life or outdate times shall be defined and observed.

3.5.5 There shall be written instructions to indicate the number and types of media, and method of inoculation required

Standard: The laboratory must have documented procedures to be followed which include instructions for number of media required and inoculation procedures.

3.6 Proficiency Testing

3.6.1 The laboratory shall be enrolled in proficiency test (PT) program or in the case where PT does not exist, procedures shall be put in place to validate performance. The PT menus shall be appropriate for the range of procedures performed by the laboratory.

Standard: The laboratory must participate in an approved program of graded inter-laboratory comparison testing and perform semiannual validation of procedures for which PT do not exist, i.e. the range must cover all procedures conducted on patient specimens

3.6.2 Testing of proficiency test samples shall be performed by staff who routinely process, analyze and report patient/environmental samples.

Standard: Proficiency Test samples must be integrated with routine workloads and tested by staff who perform testing on corresponding patient specimens in order to ensure staff are proficient in all aspects of testing and verification of testing and accuracy of patient results.

3.6.3 The PT survey activity reviewed by the director or designate

Standard: There must be evidence of active review of survey results by the laboratory director or designee.

3.6.4 There shall be documentation of corrective action

Standard: .Each result designated as “unacceptable” must be evaluated in order to determine the cause of the error. Where appropriate, corrective action must be instituted in order to reduce the chance of recurrence of the error. There must be evaluation and if indicated, corrective action in response to each “unacceptable” result, and actions taken to reduce the likelihood of recurrence

3.6.5 There shall be documentation of receipt of pathogens imported for control purposes.

3.6.6 The laboratory shall ensure that it has decontaminated the pathogens materials before disposal. The laboratory shall maintain records that indicate where the pathogen was used/ stored and the date of Disposal.

3.7 Specimen Collection Manual

3.7.1 This information shall be readily available on nursing stations and other collection sites

3.7.2 The Information Shall Include Written Instructions For;

a) Patient identification
b) Patient preparation prior to specimen collection
c) Methods of proper collection of culture specimens from different sources
d) Proper labeling of the specimen
e) Conditions for transportation and storage
f) Instructions for proper completion of requisition

g) Need for prompt delivery of specimens to ensure minimum delay in processing of spinal fluid, wound cultures, anaerobes, etc.
h) Procedures for the safe handling of specimens
i) Sample rejection/acceptance criteria

3.7.3 The manual shall be consistent throughout the hospital/clinics/laboratory

3.7.4 The laboratory shall have a written procedure describing methods for

a) Patient identification
b) Patient preparation prior to specimen collection
c) Specimen collection
d) Proper labeling of the specimen
e) Specimen preservation
f) Conditions for transportation and storage before testing
g) Completion of the requisition with all necessary information.

3.7.5 Such protocols/ procedures must be consistent with good laboratory practice and must be provided throughout hospital/clinics/laboratory.

3.7.6 The laboratory shall establish criteria for rejection of specimens that are unacceptable due to gross external contamination, drying, lack of transport media where required, etc.

3.7.7 Only specimens collected, identified and transported as described in the Specimen Collection Manual shall be accepted for processing

Standard: Only specimens properly collected, identified and transported as described in the Specimen Collection Manual will be accepted for processing to ensure the reporting of accurate and valid results.

3.7.8 Receipt of specimen shall be recorded in an accession book, work sheet or computer

Standard: All samples received by the laboratory will be recorded in an accession book, daybook, computer, or other comparable record.

3.8 Procedure Manual And Reporting Of Results

3.8.1 The laboratory shall have a complete procedure manual reflecting current procedures (Manufacturers package insert should supplement, not replace the procedure manual)

3.8.2 There shall be a file on manufacturers' inserts.

Standard:

1. The use of inserts provided by manufacturers is not acceptable in place of a procedure manual; however, such inserts may be used as part of a procedure description if the insert accurately and precisely describes the procedure as performed in the laboratory. Any variation from this printed procedure must be detailed in the procedure manual. In all cases, appropriate reviews must occur.

2. A manufacturer's procedure manual for an instrument/reagent system may be acceptable as a component of the overall departmental procedures. Any modification to, or deviation from, the procedure manual must be clearly documented.

3.8.2 The file on manufacturers' inserts shall be up to date

Standard: A file on manufacturers' most current inserts will be maintained, and evidence of review of such inserts will be present documenting the laboratory staff are aware of most current product requirement, product use and limitations, etc.

3.8.4 The laboratory shall have a system documenting that all personnel are knowledgeable about the Contents of procedure manuals (including changes) relevant to the scope of their testing activities

Standard: The laboratory must have a system documenting that all personnel are knowledgeable about the contents of procedure manuals (including changes) relevant to the scope of their testing activities.

3.8.3 Procedures shall be reviewed yearly, signed and dated.

3.8.4 All changes in methodology shall be signed and dated by authorized staff

Standard: There shall be documentation of at least annual review of all policies and procedures in the laboratory by the current laboratory director or designee. The director is responsible for ensuring that the technical protocols are complete, current, and have been thoroughly reviewed by a knowledgeable person. Technical approaches must be scientifically valid and clinically relevant. To minimize the burden on the laboratory and reviewer(s), it is suggested that a schedule be developed whereby roughly 1/12 of all procedures are reviewed monthly.

3.8.5 If the laboratory uses a card file, it shall agree with the manual

3.8.6 If electronic manuals are used, they shall be available to all personnel, annually reviewed and subjected to document control.

Standard: Electronic manuals are fully acceptable. There is no requirement for paper copies, so long as the electronic versions are readily available to all personnel. Such electronic versions must be subjected to proper document control (i.e. only authorized persons may make changes, changes are dated/signed (manual or electronic), and there is documentation of periodic review.) Current paper copies of electronically stored procedures should be available at the time of the assessment, or rapidly generated at the request of the assessment.

3.8.7 A procedure manual /SOP shall be available in the work area

The following shall be included for each procedure;

a) Specimen Required
b) Preparation of reagents, standards, controls etc.
c) Procedure (including step by step instructions)
d) Directions for calibration
e) Derivation of results (i.e. Mathematical calculations, dilutions)
f) Linearity limits
g) Quality Control (including numbers, types and location in runs)
h) Interpretation (reference ranges, sources of interference, other limitations)

i) Critical values/ reference ranges.
j) Safety
k) References

3.9 Reporting of results

3.9.1 Criteria for evaluation and interpretation of results of each type of culture, and identification of the mycobacterium shall be included.

Standard: There must be a complete and current Procedure Manual available at the workbench, and any card files used must correspond to the procedures described in the Procedure Manual. Each procedure must include: principle, specimen type (including container and preservatives), required reagents, calibration, quality control, procedure, interpretation, calculations, and reference ranges.

3.9.2 Copies of discontinued policies and procedures shall be maintained as per the set regulations, with the initial date of use and retirement date recorded.

Standard: All retired policies and procedures will be maintained as per set regulations or policies with documentation of initial date of use and retirement date initialed.

3.9.3 Preliminary reports shall be provided whenever necessary

Standard: Adequate and up to date reference text books will be obtained and made readily available for use by those performing the testing and to those performing annual procedure review

3.9.4 Final reports shall be provided in a timely manner

3.9.5 Reports shall reviewed to detect clerical errors, significant analytical errors and unusual laboratory results

3.9.6 There shall be a mechanism in place to check results issued on weekends or out-of-hours

3.9.7 Documented criteria established for immediate notification of a physician or other clinical personnel responsible for patient care, when results of certain tests exceed critical limits

Standard: The mycobacteriology /Microbiology laboratory shall have documented criteria for the immediate notification of a physician or other clinical personnel, when results of certain tests exceed critical limits. This is important for prompt patient management decisions.

3.9.8 There shall be documentation of prompt notification of the physician (or other clinical personnel responsible for patient care) of results of all critical values

3.10 Extent Of Services

3.10.1 Full service with definitive identification of mycobacteria, to the extent required for diagnosis and selection of therapy.

3.10.2 Isolation and limited identification only with definitive identification by a reference laboratory.

3.10.3 Direct examination of specimens only, and culture for mycobacteria done by a reference laboratory.

3.10.4 No mycobacteriology procedures performed. All specimens referred to a reference laboratory.

3.10.5 Referral laboratories shall be identified on final report where applicable.

Name of referral laboratory: _____

3.11 Specimen Preparation

3.11.1 Specimens for mycobacteriology shall be collected appropriately and transported to the testing laboratory without delay

***Standard**:*

i. All the patients (adults, adolescents, children who are capable of producing sputum) suspected of having pulmonary tuberculosis should have at least two, preferably three, sputum specimens obtained for microscopic examination. When possible, at least one early morning specimen should be obtained.

ii. The diagnosis of sputum smear-negative pulmonary tuberculosis should be based on the following criteria: at least three negative sputum smears (including atleast one early morning specimen); chest radiography findings consistent with tuberculosis: lack of response to a trial of broad spectrum antimicrobial agents. For such patients, if facilities for culture are available, sputum should be obtained.

iii. NB/: Distinguish between sputum and saliva

3.11.2 Specimens such as sputum shall be concentrated before AFB smear examination and culture.

Standard:

i. The laboratory shall have pretreatment of the specimen before sedimentation or centrifugation.

ii. Certain specimens (e.g. sputum) submitted for culture of mycobacteria must routinely be concentrated and AFB smears / cultures prepared from concentrate sensitivity of microscopy is higher with concentration by centrifugation and or sedimentation as compared to direct microscopy .

iii. The specimen should be pretreated with chemicals such as bleach, NaOH, NaCl to avoid infection to the laboratory personnel.

3.12 Reporting of Results

3.12.1 Results of acid-fast stains shall be reported within a timely manner of specimen receipt by the testing laboratory.

3.12.2 Susceptibility test results for *M. Tuberculosis* shall be available in a timely manner.

***Standard**:* The rapid recognition of drug resistant organisms is essential to the control of multi-drug resistant tuberculosis.

3.13 Quality Control

3.13.1 Control specimens shall be handled/ tested in the same manner as patient specimens

Standard: It is implicit that control specimens be tested by personnel who routinely perform testing and in the same manner as patient specimens.

3.13.2 The results of controls shall be reviewed for acceptability, before reporting patient results

Standard: Controls must be reviewed for acceptability before reporting patient results.

3.13.3 Fluorochrome staining shall be performed on mycobacterial smears prepared from primary specimens, either in the laboratory or by the reference laboratory

Standard: Such smears are easier to read than those stained with a conventional carbo-fuchsin based stain. Fluorescing organisms stand out prominently against the background of the smear, and the smears can be examined at a lower power than conventionally-stained smears, so that a larger amount of material can be examined in a given period of time. As with the interpretation of Ziehl-Neelsen and Kinyoun stained smears, expertise is needed for interpretation of smears stained with a fluorescent stain; not everything that fluoresces in such a stain is necessarily a mycobacterium. Particularly when only a few organism-like structures are seen, it is important to pay careful attention to their morphology before interpreting them as Mycobacteria.

3.13.4 AFB and fluorescent stains shall be checked with positive and negative controls each day of use and results documented.

Standard: Positive and negative controls must be performed and documented, with each staining procedure each day of use

3.13.5 If nucleic acid probes are used for identification of mycobacteria grown in culture, appropriate positive and negative controls shall be tested on each day of use

3.13.6 All biochemical tests employed shall be checked each day of use with appropriate positive and negative controls and results recorded.

Standard: Appropriate positive and / or negative controls must be performed and documented, with all biochemical test procedures each day of use.

4 Associated Documents

Ref	Document Identifier	Document Title
1.	ISO/IEC 17011	Conformity Assessment-General requirements for accreditation bodies accrediting conformity assessment bodies
2.	KENAS-QM-MAN-001	KENAS Quality Manual
3.	ISO 15189	Medical Laboratories – Requirements for Quality and Competence
4.	ISO 15190	Medical Laboratories – Requirements for Safety

Ref	Document Identifier	Document Title
5.	GLP	Good Laboratory Practice
6.	IST	International Standards for Tuberculosis Care

5 Revision/ Amendment Records

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