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Periodic Review Approval and Authorization

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1 OVERVIEW CONTENT

1.1 Process Overview

This document describes the managerial and technical accreditation requirements of Medical Bacteriology laboratory. The requirements for accreditation are laid down in ISO 15189, medical laboratories- requirements for quality and competence. These requirements apply to all types of medical testing but in certain instances, additional guidance is necessary to take to account the type of testing and technologies involved

1.2 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

1.3 Scope

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

1.4 Role(s) and Responsibility

Role	Responsibility
Health and Safety Team	• Development of draft for Technical Committee Review. • Administration and Periodic review
Medical Lab and Point of Care Testing Technical Committee	• Technical Draft Review and approval
Medical Labs	• Compliance
Assessors	• Utilization during assessments

2 DEFINITIONS / ABBREVIATIONS

The table below defines new or changed terms that are included in or associated with this process.

Term	Definition
KENAS	Kenya Accreditation Service
POCT	Point of Care Testing
GLP	Good Laboratory Practice

3. PROCESS INSTRUCTIONS

3.1 INTRODUCTION

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. (5.1.2)

Standard: the Head of medical bacteriology laboratory must have relevant qualifications experience in microbiology/bacteriology as described in the institutional job description

Standard: 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)

3.1.1 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)----------

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)

Laboratory consultants:

Name of consulting pathologist----------

Name of consulting scientist----------

Work load	**workload units**	**tests**
Inpatients	----------	----------
Out patients	----------	----------
Referred in patients	----------	----------
Others	----------	----------
Total	----------	----------

3.2 TYPES OF SPECIMENS PROCESSED

No.	Type of specimen	Number per month
1	Eye	
2	Genital	
3	Blood	
4	CSF	
5	Fluid (other than CSF):	
6	Stool	
7	Wound	
8	Ear	
9	Urine	
10	Others (specify):	
11	Referred	

REFERENCE LABORATORY:

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

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

3.3 LABORATORY SPACE

Adequate space shall be allocated to:

1. Administrative and clerical functions
2. Technical functions (benches)
3. Incubators (adequate number available)
4. Instruments (equipment)
5. Storage (including adequate number of refrigerators)
6. Work areas shall be shaded from direct sunlight

7. The laboratory shall have adequate number of Biological Safety Cabinets –(Adequate Number Present) Fume Hoods –(Adequate number Present)
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.

3.4 CHECKING AND VERIFICATION OF REAGENTS

This applies to all reagents: including media, susceptibility disc, E strips, typing sera, PCR kit, PFGE kit etc.

1. Labeled as content: date of receipt, or preparation, and date of opening and expiration
2. Stored according to specifications
3. Checked immediately upon receipt for damage (e.g. freezing)
4. Reagents requiring desiccants contain active desiccants
    a) Reagents shall have lids secured tightly
    b) outdated reagents shall be discarded
    c) Stored according to specifications
    d) Checked immediately upon receipt for damage (e.g. freezing)
    e) reagents requiring desiccants shall contain active desiccants
    f) Reagents shall have lids secured tightly
    g) Outdated reagents shall be discarded.

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.

3.5 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.

3.6 REFERENCE CULTURES

3.6.1. ATCC reference cultures shall be maintained

3.6.2 If yes, specify method of storage of reference strains:

3.6. 3 *Appropriate or required reference cultures shall be used to check media, stains, reagents, identification kits e.g. API strips, etc. and susceptibility testing? If no, specify:*

3.7 MEDIA CHECKS

3.7.1 All media checked for:

a. Sterility

b. Ability to support growth of appropriate organisms

c. Selectivity

d. Biochemical reactivity

3.7.2 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

3.7.3 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.

The user laboratory must continue to test each lot of chocolate Agar Thayer Martin, Martin Lewis, Campylobacter, and other media not listed specifically in the NCCLS document M22-A2 as being exempt from such testing. Quality control methods that are used for media manufactured in-house must be used .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.

3.7.4 Shelf life or outdate times shall be defined and observed

3.7. 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.

3.8 PROFICIENCY TESTING

3.8.1 The laboratory shall enrolled in an external proficiency test (PT) program) or in the case where PT does not exist, are procedures in place to validate performance semiannually, and is the PT menu 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.

3.8.2 Testing of proficiency test samples shall be performed by staff who routinely process, analyze and report the 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.

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

3.8.3 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.

3.8.4 There shall be documentation of receipt of pathogens imported for control purposes

3.8.5 Records shall indicate where the pathogen was used/stored and the date of disposal

3.9 SPECIMEN COLLECTION MANUAL

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

3.9.2 There shall be 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. Specimen preservation
f. Conditions for transportation and storage
g. Instructions for proper completion of requisition
h. Need for prompt delivery of specimens to ensure minimum delay in processing of spinal fluid, wound cultures, anaerobes, etc.

i. Procedures for the safe handling of specimens

3.9.3 The laboratory must have a written procedure describing methods for;

1) Patient identification

2) Patient preparation prior to specimen collection

3) Specimen collection

4) Proper labeling of the specimen

5) Specimen preservation

6) Conditions for transportation and storage before testing

7) Completion of the requisition with all necessary information.

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

3.9.4 There shall be criteria for rejection of specimens that are unacceptable due to gross external contamination, drying, lack of transport media where required, etc.

Standard: Criteria shall be established for acceptance of specimens, such as absence of gross external contamination, adequate or properly preserved specimens, and correct use of transport media when required.

3.9.5 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.

3.9.6 The receipt of specimens 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.

3.10 PROCEDURE MANUAL AND REPORTING OF RESULTS

3.10.1 There shall be a complete procedure manual reflecting current procedures

(Manufacturers package insert should supplement, not replace the procedure manual)

Standard: A procedure manual reflecting current procedures must be developed in standardized format. Manufacturer inserts may supplement the procedure manual but will not replace the procedure.

Standard: 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. 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.

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.

3.10.2 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

3.10.3 Procedures shall be reviewed yearly, signed and dated

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

Standard: There must 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.

3.10.5 If a card file is used, it shall agree with the manual

3.10.6 If electronic manuals are used, are 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 inspection, or rapidly generated at the request of the inspectors.

3.10.11 There shall be a procedure manual available in the work area

3.10.12 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. Derivation of results (eg. Mathematical calculations, dilutions)
e. Directions for calibration
f. Linearity limits
g. Quality Control (including numbers, types and location in runs)
h. Interpretation (reference ranges, sources of
i. interference, other limitations)
j. Critical values
k. Safety
l. Reference

3.10.13 Criteria for evaluation and interpretation of results of each type of culture, and identification of major organisms 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.

3.10.14 Copies of discontinued policies and procedures shall be maintained for at least two years, with the initial date of use and retirement date recorded according to national/regional regulations

***Standard*:** All retired policies and procedures will be maintained for at least two years with documentation of initial date of use and retirement date initialed.

3.10.15 There shall be adequate and up to date reference text books in the laboratory

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.

3.10.16 Preliminary reports shall be provided whenever necessary

Standard: Results of cultures should be reported promptly to provide clinically useful information. The quality of service should include submitting preliminary reports based on the initial examination. (E.g. reading plates on a timely basis, wet mounts, stained preparations)

3.10.17 Final reports provided shall be in a timely manner

3.10.18 Reports shall be reviewed to detect clerical errors, significant analytical errors and unusual laboratory results.

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

3.10.20 There shall be a 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 bacteriology laboratory must 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.

3.10.21There shall be documentation of prompt notification of the physician (or other clinical personnel responsible for patient care) of results of all critical values

Standard: Records must be maintained indicating the notification of the appropriate clinical individual promptly after observing results in the critical range

4 REFERENCE AND RELATED 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
5.	GLP	Good Laboratory Practice

5 TRAINING

None required except for notification and awareness by Medical Laboratories. Assessors need to be aware of this criteria for utilization during assessments.

6 REVISION HISTORY

Date	Ver	Revised By	Reason For Revision
03/08/2013	01	ADHS	• Initial
14/03/2017	02	CO H&S	• Align guideline to the right template. • Incorporate references in the guideline • Amend technical committee name to include POCT