Approval and Authorization

Completion of the following signature blocks signifies the review and approval of this Document.

Name	Job Title / Role	Signature	Date
Authored by	**CO-HEALTH & SAFETY**	Approved	14/03/2017
Checked by	**ASSISTANT DIRECTOR HEALTH AND SAFETY**	Approved	14/03/2017
Approved by	**ASSISTANT DIRECTOR HEALTH AND SAFETY**	Approved	14/03/2017

Periodic Review Approval and Authorization

Completion of the following signature blocks signifies the review and approval of this Document.

Required by: *(03/2020)*

Name	Job Title / Role	Signature	Date
Checked by			
Approved by			

Required by: *(03/2023)*

Name	Job Title / Role	Signature	Date
Checked by			
Approved by			

1 OVERVIEW CONTENT

1.1 Process Overview

This document describes the managerial and technical accreditation requirements of medical mycology 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 mycology 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:

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

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).

iii. 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	----------	----------

3.1.3 TYPES OF SPECIMENS PROCESSED

No.	Type of specimen	Number of specimen 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: ----------

3.1.4 **LABORATORY SPACE**

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 shaded from direct sunlight
g) There shall be Adequate Number Present
h) Biological Safety Cabinets
i) 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.

3.2 CHECKING AND VERIFICATION OF REAGENTS

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

3.2.1 Shall be Labeled as content: date of receipt, or preparation, and date of opening and expiration

3.2.2 Stored according to specifications

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

3.2.4 Reagents requiring desiccants shall contain active desiccants

3.2.5 Reagents shall have lids secured tightly

3.2.6 All outdated reagents shall be discarded

3.2.7 Reagents shall be stored according to specifications

3.2.8 Regents shall be checked immediately upon receipt for damage (e.g. freezing)

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.

3.2.9 All 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

3.3 REFERENCE CULTURES

3.3.1 ATCC reference cultures shall be maintained

3.3.2 Method for storage of (reference strains) ATCC cultures shall be specified

3.3.3 Appropriate or required reference cultures shall be used to check media, stains, reagents, identification kits

3.3.4 If above (5.3) is not in place, specify:

3.4 MEDIA CHECKS

All media shall be checked for:

3.4.1 Sterility

3.4.2 Ability to support growth of appropriate organisms

3.4.3 Selectivity

3.4.4 Biochemical reactivity

3.4.5 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

3.4.6 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.

3.4.7 The laboratory shall 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. 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.

3.4.8 Shelf life or outdate times shall be defined and observed

3.4.9 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.

3.5 PROFICIENCY TESTING

3.5.1 The laboratory shall be 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 does not exist, i.e. the range must cover all procedures conducted on patient specimens.

3.5.2 Testing of proficiency test samples shall be performed by staff that routinely process, analyze and report the patient/environmental samples

Standard: Proficiency Test samples must be integrated with routine workloads and tested by staff that 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.

3.5.3 The survey of the PT shall be reviewed by the director or designate and documentation of corrective action taken.

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

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

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

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

3.6 SPECIMEN COLLECTION MANUAL

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

3.6.2 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) 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?
j) Is the manual consistent throughout the hospital/clinics/laboratory?

3.6.3 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.

3.6.4 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 must 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.

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

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

3.7 PROCEDURE MANUAL AND REPORTING OF RESULTS

3.7.1 There shall be a complete procedure manual reflecting current procedures (manufacturer's package insert should supplement, not replace the procedure manual)

***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.
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

3.7.2 There shall be a file on manufacturers' inserts

Standard:

i. 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.

ii. 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.

3.7.3 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.

3.7.4 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.

3.7.5 The receipt of specimens recorded shall be in an accession book, work sheet or computer

3.7.6 Procedures shall be reviewed yearly, signed and dated

3.7.7 All changes in methodology 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.

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

3.7.9 If electronic manuals are used, are they 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 (ie. only authorized persons may make changes, changes are dated/signed (manual or electronic), and there is documentation of periodic review.)

3.7.8 Procedure manual shall be available in the work area

3.7.8.1 The following shall be included for each procedure:

i. Specimen Required
ii. Preparation of reagents, standards, controls etc.
iii. Procedure (including step by step instructions)
iv. Directions for calibration
v. Derivation of results (ea. Mathematical calculations, dilutions)
vi. Linearity limits
vii. Quality Control (including numbers, types and location in runs)
viii. Interpretation (reference ranges, sources of interference, other limitations)
ix. Critical values
x. Safety
xi. References
xii. Are criteria for evaluation and interpretation of results of each type of culture, and identification of major organisms included

Standard: There shall 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.

3.7.9 Copies of discontinued policies and procedures shall be maintained for at least two years, with the initial date of use and retirement date recorded

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.

3.7.10 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 reviews.

3.7.11 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)

3.7.12 final reports shall be provided in a timely manner

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

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

3.7.15 There shall 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 mycology 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.

3.7. 16 There 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.

3.8 EXTENT OF SERVICES

3.8.1 Full service with definitive Identification of mycoses to the extent required for diagnosis and selection of therapy

3.8.2 Isolation and limited identification only with definitive identification by a reference laboratory

3.8.3 Direct examination of specimens and isolation of fungi by culture with identification by a reference laboratory

3.8.4 No mycological procedures performed. All specimens referred to a reference laboratory Is referral laboratory identified on final report

Name of referral laboratory: _____

3.9 SPECIMEN COLLECTION

3.9.1 There shall be written instructions for collection, handling and transport of specimens for mycology studies

3.9.2 PROCEDURE MANUAL SHALL INCLUDE:

3.9.2.1 Proper collection of specimens for fungal culture from different sites

3.9.2.2 Preliminary processing of specimens from different sites

3.9.2.3. Inoculation and incubation procedures

3.9.2.4 Differential tests

3.10 SAFETY

3.10.1 If a specimen is suspected of harboring an infectious dimorphic fungus, initial inoculation of media shall be performed in a biological safety cabinet

Standard: A biologic safety cabinet must be provided for handling cultures containing organisms considered to be highly contagious by air borne routes.

3.10.2 The hood shall be validated/verified annually to assure that filters are functioning properly and that air flow rates meet specifications

Standard: The hood must be certified annually to assure that filters are functioning properly and that flow rates meet specifications.

3.10.3 If culture media for mycology is used in petri dishes, appropriate safety precautions shall be taken to prevent accidental opening of plates

Standard: Appropriate safety precautions must be taken if culture media for mycology are used in petri plates. Taping the lids of plate media on both sides reduces the chance of accidental opening and exposure of the laboratory personnel to infectious spores.

3.10.4 When working with a colony exhibiting mycelial growth, transfers shall be performed within a biological safety cabinet

Standard: Upon observing growth of aerial mycelia on culture media, it must always be handled in a functional biological safety cabinet.

3.10.5 The use of slide cultures shall be prohibited in working with highly infectious dimorphic fungi

3.10.6 When preparing tease preparations or scotch tape preparations armycelia always submerged in a liquid medium such as Lactophenol cotton blue

Standard: When dealing with teased or scotch tape preparations, mycelia must always be submerged in some liquid medium such as Lactophenol cotton blue

3.11 QUALITY CONTROL

3.11.1 There shall be evidence of active review of records of controls for routine procedures, instrument function tests, and temperature records

Standard: Controls must be reviewed before reporting patient results. It is implicit in quality control that patient test results will not be reported when controls are unacceptable

3.11.2 All reagents (e.g. dry media, stains, chemicals) shall be properly labeled as to contents, concentration, dated in service and expiration.

3.11.3 Stains (e.g. acid fast, PAS, Giemsa, Gomori's methenamine silver, Calcofluor white, India ink) shall be checked with positive and negative controls on each day of patient sample testing. This will also apply to histological specimen

Standard: All staining procedures should be checked and results recorded for each new batch of preparation, and at least daily against known positive and negative control organisms.

3.11.4 There shall be proper records of Quality Control and procedures for corrective action

3.12 ISOLATION AND IDENTIFICATION

3.12.1 Preliminary screening procedures such as direct preparations and stains shall be performed when indicated

Standard: Isolation and identification procedures should include preliminary screening with direct or stained preparations, use of selective media for dermatophytes and systemic fungi and use of media with antimicrobial agents.

3.12.1 Suitable selective media shall be used for the growth and isolation of dermatophytes and/or systemic fungi

Standard: Additional or different media must be used for culture of dermatophytes and/or systemic fungi.

3.12.2 Media with antimicrobial agents used to suppress the growth of contaminants

Standard: Media with antimicrobial agents must be available and used, when indicated, to suppress overgrowth of bacteria. Antimicrobial agents may inhibit some yeasts and the yeast phase of dimorphic organisms. Both types of media (with and without antimicrobials) must be available and used when indicated.

3.12.3 Incubation temperatures for the growth and isolation of dermatophytes and systemic fungi shall be defined and followed under culture conditions.

Standard: Incubation temperatures for the growth and isolation of dermatophytes and

3.12.4 Systemic fungi must be defined and adhered to under culture conditions. If cultures are incubated at room temperature, the actual temperature shall be checked daily to determine if proper growth conditions are being maintained

3.12.5 If cultures are left at room temperature, the ambient temperature (22-26°C) must be checked and recorded daily.

3.13 DIFFERENTIAL TESTS

3.13.1 Procedures for the differentiation and identification of fungi shall be adequate for the laboratory's extent of services

Standard: If the laboratory is providing full identification services, adequate procedures for differentiation and identification of fungi must be provided. Individual judgement will be required. Laboratories offering full identification must have sufficient procedures to do so. Smaller laboratories with limited services must have an arrangement with an approved reference laboratory for back-up and complete identification of mycology specimens.

IF DIFFERENTIAL PROCEDURES ARE PERFORMED, THEY SHALL INCLUDE:

3.13.2 Chlamydospore formation on corn meal, or rice agar

3.13.3 Biochemical tests such as urease and carbohydrate assimilation or fermentation

3.13.4 Slide cultures where appropriate

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 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