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 Parasitology 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 parasitology 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

3 PROCESS INSTRUCTIONS

3.1 INTRODUCTION

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

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

Name of the Laboratory Director----------

Qualification of the Laboratory Director----------

Name of the Quality Manager ----------

Qualification of the Quality Manager ----------

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----------

- Laboratory technologists/technicians----------
- Laboratory assistants----------
- 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	**Work Load 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: ----------

3.2 LABORATORY SPACE

3.2.1The laboratory shall have overall space adequate for this section

a) Administrative and clerical functions
b) Technical functions (benches)
c) Incubators (adequate number available)
d) Instruments
e) Storage (including adequate number of refrigerators)

3.2.2 Work areas shall be shaded from direct sunlight

3.2.3 Biological Safety Cabinets – (Adequate Number Present-Adequate Number Present)

3.2.4 Media Preparation area sufficient

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

3.3 CHECKING AND VERIFICATION OF REAGENTS

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 Outdated reagents shall be discarded

3.3.7 Reagents shall be stored according to specifications

3.3.8 Reagents shall be checked immediately upon receipt for damage (e.g. freezing)

3.3.9 Reagents requiring desiccants shall contain active desiccants

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.

3.3.10 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 **PROFICIENCY TESTING**

3.4.1 The laboratory shall enroll in an external Proficiency Test (PT) program or in the case where PT does not exist, there shall be procedures in place to validate performance semiannually, and the PT menu 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 does not exist, i.e. the range must cover all procedures conducted on patient specimens.

3.4.2 The 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 performs testing on corresponding patient specimens in order to ensure that staff are competent in all aspects of testing and verification of testing and accuracy of patient results.

3.4.3 The survey activity shall be reviewed by the laboratory director or designate.

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

3.4.4 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 chances of recurrence. There must be evaluation and if indicated, corrective action in response to each “unacceptable” result, and actions taken to reduce the likelihood of recurrence.

3.4.5 There shall be documentation of receipt of parasites imported for control purposes.

3.4.6 There shall be records to indicate where the parasites were stored and the date of disposal

3.5 SPECIMEN COLLECTION MANUAL SHALL INCLUDE:

3.5.1 This information shall be readily available in nursing stations and other collection sites. Written instructions shall include:

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

The manual shall be consistent throughout the hospital clinics/laboratory

Standard: 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 must be consistent with good laboratory practice and must be provided throughout hospital/clinics/laboratory.

3.5.2 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.

3.5.3 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.

3.5.4 Specimens received 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

3.5.5 **Procedure manual and reporting of results**

3.5.5.1 There shall be a complete procedure manual reflecting current procedures (Manufacturers package insert should NOT supplement, not replace the procedure manual).

3.5.5.2. The procedure manual shall be written as per the standard guidelines (ISO 15189).

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.

3.5.5.3. 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 three years with documentation of initial date of use and retirement date initialed.*

3.5.5.4. 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.*

3.8 Reporting of Results

3.8.1 Preliminary reports shall provide whenever necessary.

Standard: Results shall 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)

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

3.8.3 There shall be mechanisms in place to check results issued on weekends or out-of-hours.

3.8.4 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 parasitology 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.

3.8.5 There shall be documentation for prompt notification of the physician (or other clinical personnel responsible for patient care) on 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.

3.9 EXTENT OF SERVICES

3.9.1 There shall be full services with definitive Identification of parasites to the extent required for diagnosis and selection of therapy

3.9.2 Definitive identification of parasites excluding when fixed, stained and permanently mounted preparations can be prepared and sent to a reference laboratory for identification

3.9.3 Ability to determine presence of parasites in specimens with referral to reference laboratory for final identification

3.9.4 No parasitology procedures performed on site. All specimens referred to a reference laboratory

3.9.5 Referral laboratory shall be identified on final report

3.9.6 Name of referral laboratory:

Standard: all permanent parasitology stains must be checked for intended staining characteristics at least monthly (or with each test if performed less frequently than every month) with controls or reference materials.

3.9.7 Specimen collection and handling:

- If specimens are not examined in the fresh state, proper steps shall be taken to preserve them (e.g. SAF preservative)

3.9.8 The examination of unformed stool shall include;

- A Direct wet mount of a fresh specimen
- A Concentration procedure
- Permanent stained preparations.

Standard: The examination of all stools should include a concentration procedure and where necessary permanent stain. When a stool specimen is submitted fresh, the usual approach would be to perform a direct wet preparation (looking for motile amoeba), a concentration helminth eggs/larvae/protozoan cysts), and the permanent stained smear (identification of protozoa missed by concentration and confirmation of suspect organisms). As a minimum (and certainly if the stool is submitted in preservatives), the standard O&C examination would include the concentration procedure and where necessary, permanent stained smear. The main point is to ensure that the *permanent* stained smear is performed on all stool specimens, regardless of what was or was not seen in the concentration wet preparation. Often, intestinal protozoa will be seen in the permanent stained smear, but may be missed in the concentration examination.

3.9.9 Glassware and slides used in stool examination shall be clean, dry and free of detergents.

3.9.10 If the procedure uses Formalin, there shall be a record of formaldehyde vapor monitoring

Standard: The use of concentration techniques other than those requiring the use of ether and formalin is recommended. Formaldehyde vapor concentrations must be monitored and maintained at concentrations below the following maxima: 8 hour Time-Weighted Average (TWA): 0.75 parts per million 15 minute Short-Term Exposure Limit (STEL): 2.0 parts per million

Initial monitoring must be repeated any time there is a change in production, equipment, process, personnel, or control measures which may result in new or additional exposure to formaldehyde. Periodic monitoring is

mandated only if the initial monitoring is at or exceeds TWA or STEL. The laboratory may discontinue periodic formaldehyde monitoring if results from two consecutive sampling periods taken at least 7 days apart show that employee exposure is below the action level and the short-term exposure limit, and no change in equipment, process or personnel or control measures that may result in new or additional exposure to formaldehyde, and no reports of conditions that may be associated with formaldehyde exposure.

3.9.11 If the procedure uses Ether, the diethyl ether shall be stored on open shelves in a well-ventilated room using the smallest can manufactured

Standard: Diethyl ether must be stored on open shelves in a well-ventilated room using the smallest can (as shipped by the manufacturer).

3.10 MICROMETRY

3.10.1 An ocular micrometer shall be available for determining the size of eggs, larvae, cysts or trophozoites.

Standard: An ocular micrometer is required in the parasitology section.

3.10.2 The ocular micrometer shall be calibrated for the microscope in which it is used and recalibrated whenever eyepieces or objective lenses are changed

Standard: Ocular micrometers must be calibrated for the microscope(s) in which they are used. Recalibration is needed any time eyepieces or objectives are changed. If there are no changes to a particular microscope's optical components, there is no need for checking calibration on some fixed calendar schedule.

3.11 PROCEDURE MANUAL

3.11.1The procedure manual shall include:

a) Proper collection of specimens
b) Preparation of reagents
c) Criteria for identification of ova and parasites

Standard: Reference materials, such as permanent mounts, photomicrographs, NCCLS documents M15-T or M28-A or printed atlases must be available at the work bench for reference.

3.12 REAGENT QUALITY CONTROL

3.12.1. If zinc sulfate is used is the solution checked for specific gravity by an accurate method?

Standard: If zinc sulfate is used, the solution must be checked periodically for specific gravity (1.18 for fresh specimens and 1.20 for formalin-fixed specimens) with a hydrometer whose scale is large enough to differentiate the two values.

3.12.2The zinc sulfate flotation solution shall be stored in tightly stoppered bottles

Standard: Zinc sulfate solution should be stored in a tightly-stoppered bottle.

3.12.3 Permanent stains shall be checked with control specimens routinely.

3.12.3 Stains that are used to detect specific parasites must be checked with appropriate control organisms each time that stain is used.

3.13 BLOOD TESTS FOR MALARIA

3.13.1 Both thick and thin blood films shall be examined for malarial parasites

Standard: Both thick and thin films should be used in examination for malarial parasites.

3.13.2 Stained blood films shall be washed with a buffer of known pH

Standard: Stained films should be washed with a buffer of known pH (6.8-7.2).

3.13.3 At least 300 oil immersion fields of thick blood films shall be examined for malarial parasites

Standard: Routine examination of a thick film should include examination of at least 300 fields under oil immersion.

3.13.4 The results of positive malaria films shall be reported in accordance with laboratory policy for alert values

Standard: When a patient's blood film is positive for malaria, results must be reported immediately to the physician or nursing unit in accordance with laboratory's policy for critical values.

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 these 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