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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 virology 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 virology 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

HIV	Human Immunodeficiency Virus

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

3.2.1 The overall space adequate for this section shall be adequate for its function

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 which shall be shaded from direct sunlight
g) Biological Safety Cabinets – (Adequate Number Present) - Which shall be adequately serviced
h) Media Preparation area sufficient

Standard: The laboratory shall have space allocated for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel patients and visitors (ISO 15189:2012 Clause 5.2)

3.3 SPECIMEN COLLECTION MANUAL

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

3.3.2 The specimen collection manual 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) The manual shall be consistent throughout the hospital/clinics/laboratory

3.3.3 The laboratory shall have a written procedure describing methods for;

1) Unique 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.

***Standard*:** Such protocols/ procedures must be consistent with good laboratory practice and must be provided throughout hospital/clinics/laboratory. (ISO 15189 Clauses 5.4, GLP)

3.3.4 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

3.3.5 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.

3.3.6 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.

3.4 PROCEDURE MANUAL AND REPORTING OF RESULTS

3.4.1 There shall be a complete procedure manual reflecting current procedures

(Manufacturer's package insert should supplement, not replace the procedure manual)

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

3.4.2 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. (Clause 5.3 GLP)

3.4.2 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. (Clause 5.3).

3.4.3. 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.

3.4.4 Procedures shall be reviewed yearly, signed and dated

3.4.5 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.

3.4.6. There shall be a procedure manual available in the work area.

3.4.7. 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) 5Directions for calibration
e) Derivation of results (ea. 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

3.5 Current references

3.5.1 There shall be criteria for evaluation and interpretation of results of each type of culture, and identification of major organisms included.

Standard: Reactive and nonreactive controls must be tested in all serologic procedures.

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.

3.5.2 There shall be copies of discontinued policies and procedures 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 (clause 4.3).

3.5.3 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 that performing annual procedure review.

3.5.4 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)

3.5.5 Final reports shall be provided in a timely manner

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

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

3.5.8 Documented criteria shall be 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 virology 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 (GLP, GLCP)

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

3.6 EXTENT OF SERVICES

3.6.1 Full viral identification services……

3.6.2 Cell culture and viral isolation only……

3.6.3 All specimens for virology analysis referred to a reference Laboratory……

3.6.4 Referral laboratory identified on final report……

3.6.5 Name of referral lab ……

3.7. SPECIMEN COLLECTION

3.7.1 There shall be written instructions for collection, handling and transport of specimens for viral studies (If applicable)

3.7.2 Request for viral isolation shall include:

a) Patient clinical history

b) Provisional diagnosis

c) Source of specimen

3.8 TECHNICAL PROCEDURE MANUAL

3.8.1 Isolation systems shall be specified for types of viruses suspected and/or source of specimens

3.8.2 The procedure manual shall include:

a) Type and collection of specimens

b) Reagents and preparations

3.9 FREEZER

3.9.1 There shall be a -70^{O}C or colder freezer available for the preservation of viral antisera and stock virus cultures, or nitrogen tanks

3.10. CELL CULTURES

3.10.1 Continuous cell lines shall be checked for mycoplasma infection, or other contaminants.

3.10.2 Animal sera shall be used for growth media checked for absence of toxicity to cells and cell cultures.

3.11. QUALITY CONTROL

3.11.1. Records shall be kept of cell types, passage number, source and the media used for their growth and maintenance

Standard: Records must be maintained of cell types, passages, sources and media used for growth and maintenance.

3.11.2 Two or more host systems shall be used for diagnostic isolation where applicable.

3.11.3 Inoculated cultures shall be checked at least every other day for cytopathic effects

Standard: If tube cultures are the only means for detection of virus, primary cultures must be checked at least every other working day for cytopathic effect during the first 2 weeks of incubation. If additional diagnostic methods are used (erg. shell vials, antisera) the observation schedule may be modified as appropriate.

3.11.4 Media and diluents shall be checked for sterility and pH and recorded

***Standard*:** Media and diluents must be checked for sterility and pH.

3.11.5 Red cell suspensions shall be standardized

***Standard*:** Red cell suspensions used for quantitative serologic procedures should be standardized and checked by photometric or some other equivalent procedure.

3.11.6 Work sheets and/or records shall indicate the actual results of titres of complement hemolytic serum and antigen control sera

Standard: Worksheets and/or records must indicate results of titers, when known, of reagents and control sera.

3.11.7 Positive and negative controls shall be run in serologic reactions

Standard: Reactive and nonreactive controls must be tested in all serologic procedures.

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