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# ACC-CD-31-01

# Criteria for the Accreditation of Medical Molecular Biology 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 molecular biology 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 |
| All KENAS Technical Staff | 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 |
| KEBS | Kenya Bureau of Standards |
| KENAS | Kenya Accreditation Service |
| NMI | National Metrology Institute |
| NSB | National Standards Body |
| POCT | Point of Care Testing |

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| | |
|---|---|
| GLP | Good Laboratory Practice |

## 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.

*2.2.2 Committee*

A group of people appointed for a specific function by a larger group or organization.

# 3 Criteria

## 3.1 Introduction

3.1.1 Laboratory Particulars

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 have an adequate plan, personnel policies and job descriptions that define qualifications and duties for all personnel. (5.1.1)

***Standard:*** the director/head of medical Molecular biology laboratory must have relevant qualifications experience in microbiology immunology/molecular biology as described in the institutional job description

***Standard***: the laboratory shall be directed by a person (s) having executive responsibilities and competence to assume responsibility for the services provided: (clause 5.1.3)

3.1.2 Staffing

List the number of full time:

- Laboratory clinicians (physicians)----------
- Laboratory scientist----------
- Supervisor technologist----------

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- Laboratory technologists/technicians----------
- Laboratory assistants----------
- Clerical staff----------
- Support staff----------
- Other staff (specify)----------
  All staff shall sign confidentiality agreements before commencing work.

Staff shall undergo competency testing at least once annually.

***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)

Consultants:

Name of consulting Pathologist ……

Name of consulting scientist ……

| **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) | |

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| No. | Type of specimen | Number of specimen per month |
|---|---|---|
| 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

3.2.2 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) (Adequate Number Present) - which shall be adequately serviced

***Standard:*** Space and equipment must be adequate for the (ISO 15189:2012 Clause 5.2) extend of services offered by the laboratory.

## 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

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g) Instructions for proper completion of requisition
h) Need for prompt delivery of specimens to ensure minimum delay in processing sample
i) Procedures for the safe handling of specimens

***Standard:*** The laboratory must have a written procedure describing methods for

a. Unique 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.

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

3.3.3 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.

3.3.4 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.

3.3.5 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 Extent Of Service

3.4.1 The laboratory should indicate under the scope of activities whether the laboratory services provided cover any one of the following or combination of services.

a) Forensic analysis
b) Genetic disorders
c) Infectious diseases

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d) Paternity testing

3.4.2 There shall be a documented procedure for sample preparation. If stored samples are removed this shall be clearly indicated by an empty tube.)

3.4.3 A novel (research based) in-house method shall be validated appropriately by comparison with published data and by DNA sequencing for a novel mutation.

3.4.4 The appropriate current method in use shall be accessible for reference as required.

3.4.5 Adequate measures shall be taken to prevent cross contamination of material between samples. Filter tips shall be used for;

a) Template preparation
b) Reagent and PCR set-up

3.4.6 The following procedures shall be followed when the template for the second or nested PCR is added:

3.4.7 A dedicated pipette shall be used.

3.4.8 Filter tips shall be used.

3.4.9 The procedure shall be carried rest of the working area.

## 3.5 Quality Control and Quality Assurance

3.5.1 A reagent blank control (water / buffer instead of template) shall be used with every batch of tests.

3.5.2 Negative and positive controls shall be used in each batch.

3.5.3 Where appropriate, the positive control should be of "low amplification".

3.5.4 Controls shall be set up last, at the end of each batch. The blank control shall always be set up last.

3.5.5 When applicable, an internal amplification control shall be used in every sample.

3.5.6 Random duplicate tubes for amplification shall be used in every batch.

3.5.7 The fragment sizes of PCR products on each gel shall be determined by:

3.5.8 Comparison with a positive and negative control sample.

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3.5.9 The use of a DNA / size marker, where appropriate.

3.5.10 The use of an allelic ladder, where appropriate.

3.5.11 If the diagnosis depends on the presence of a PCR product all results shall only be accepted when the positive / internal / negative controls have worked.

3.5.12 If the diagnosis depends on a size difference in the PCR products generated and the positive control fails, all positive results shall only be accepted after size verification of PCR products.

3.5.13 When detecting mutations using restriction enzymes the following procedure shall be followed for mutations that abolish the restriction site:

a) All positive samples shall be repeated if the positive control fails and the negative control works.
b) All samples shall be repeated if the negative control fails.
c) where a mutation creates a restriction site:
d) All negative samples shall be repeated if the positive sample fails
e) All positive results shall only be accepted if the size of the products can be verified.
f) For quantitative (e.g. viral load) assays, if the positive control is out of range all positive samples shall be repeated.
g) For viral load assays the procedure shall state clearly, whether all negative results are accepted and or positive results repeated if the negative control is out of range.

## 3.6 Reporting of Results

3.6.1 Where necessary, the report should contain comments relating to the quality and quantity of sample submitted for examination.

3.6.2 Where appropriate, an interpretation of the laboratory findings shall be available on the report.

## 3.7 Laboratory Safety, Environment & Accommodation

3.7.1 When working with infectious organisms, biohazard P2 cabinets shall be used.

3.7.2 The cabinets shall be inspected by an accredited testing authority biannually.

3.7.3 The following manual procedures shall be carried out in separate areas of the laboratory;

a) DNA / RNA isolation and preparation.
b) Reagent set-up and PCR reaction preparation.
c) Amplification and detection.
d) The thermocycler shall be separated from the set-up area.

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3.7.4 The laboratory environment shall be such that;

a) The flow of traffic between the above separate areas is unidirectional.
b) Separate benches are used in low throughput areas and in cases of high throughput, separate rooms are used.
c) There are appropriate facilities for changing of protective clothing when moving between the different areas.

3.7.5 Laboratory coats and gloves shall be changed as deemed appropriate while moving between the different areas.

3.7.6 Dedicated equipment and reagents are provided for each of the separate areas.

3.7.7 When any items (e.g. tube racks) are moved between the areas they shall be decontaminated.

## 3.8 Paternity Testing

3.8.1 Sample Collection and Requisition Form

a) Either the following original documents shall be accepted for purposes of identification: ID card, driving license and Passport
b) If the legal guardian of the child is unable to attend with the child for testing, written permission shall be obtained from the guardian before testing can proceed.
c) The parents / legal guardians shall be required to sign the labels attached to all samples taken from them and the child.
d) The requisition form shall have the following information:
e) Date of sampling.
f) Name and signature of the person taking the sample.
g) Name and signature of an independent witness.

3.8.2 Sample Transport, Sample Reception, Sample Identification

a) The laboratory shall have a documented procedure that details the steps to be taken from sample collection to its final disposal such that the chain of custody is maintained and traceable at all times.
b) The integrity of the sample shall be maintained at all times. The laboratory shall implement procedures to minimize deleterious changes, loss and contamination of samples.
c) Samples and DNA preparations shall be stored in a separate secure area.
d) A portion of the original DNA extract shall be retained by the laboratory for at least five years under appropriate conditions.

3.8.3 Examination Procedures

a) The laboratory shall use population data which include the allele frequency distributions for the loci used from the relevant population groups.

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b) The probability of paternity shall be greater than 99.8% before issuing a report stating that the alleged father is not excluded as being the biological father.
c) The laboratory shall have a documented procedure for dealing with paternity cases where the calculated probability of paternity is less than 99.8 %.
d) For STR systems a minimum of nine individual DNA loci and the amelogenin locus shall be tested for each sample.
e) All DNA profiles shall be checked for adequate amplification and for the presence of additional / contaminating peaks before further analysis.
f) Visual matches shall be supported by numerical data or traceable standards.
g) There shall be a written procedure for the scoring of off-ladder / rare alleles.
h) The laboratory shall have a documented policy for repeating profile determinations in cases where the analyzed data do not give a complete result.
i) In cases where an apparent single locus exclusion is found:
j) Appropriate additional tests shall be performed.
k) The exclusion of a putative father shall be based on mismatch of two or more loci.
l) The above two points shall be reflected in the final reports where appropriate.

3.8.4 Reporting of Results

a) Each report shall state the names and apparent relationship, of the individuals concerned, exactly as stated on the requisition form at the time of sample collection.
b) When discrepancies in reporting are discovered, the final report shall reflect this fact.
c) The DNA profile of each individual shall be stated in the report.
d) The report shall state the calculated probability of paternity and the combined paternity index.
e) The report shall state whether the putative father can or cannot be excluded as being the biological father of the child in question.

## 3.9. Forensics - Reporting of Results

3.8.5 The forensic report shall contain the following information:

3.8.6 The case identifier.

3.8.7 A description of the evidence examined.

3.8.8 A brief description of the methodology used.

3.8.9 The typed loci.

3.8.10 The results and conclusions reached.

3.8.11 An interprétative statements (qualitative, or quantitative).

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3.8.12 The date of issue of the report.

3.8.13 A signature and title, or equivalent identification, of the person(s) accepting responsibility for the contents of the report.

# 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 |
| 5. | GLP | Good Laboratory Practice |

# 5 Revision/ Amendment Records

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

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