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1 OVERVIEW CONTENT

1.1 Process Overview

This document describes the managerial and technical accreditation requirements of Haematology 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 Haematology 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	Blood	
2	CSF	
3	Fluid (Other than CSF)	
4	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)

3.2.2 Work areas shall be shaded from direct sunlight
3.2.3 Biological Safety Cabinets – (Adequate Number Present) Fume Hoods – (Adequate Number Present)

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

3.3 CHECKING AND VERIFICATION OF REAGENTS

This applies to all reagent, consumables and kit;

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 Examination Procedures

3.4.1 Hematocrit / packed-cell volume determinations:
3.4.2 The method used shall be traceable to the available reference measurement procedures.
3.4.3 The centrifuge shall be calibrated, and capable of reaching at least 10000xg at the rotor periphery for 5mins without heating the tubes to more than 45^{o}C.
3.4.5 The constant packing time (minimum spin time to reach maximum packing of cells) shall be determined and recorded for each instrument method

3.5 Erythrocyte Sedimentation Rate (ESR)

3.5.1 The ESR method shall be traceable to the available reference measurement procedure. The following more essential points shall be considered:
3.5.2 Sedimentation tubes must be specified or proven valid for ESR determinations. (Some plastics cause aberrant values)
3.5.3 Repeatability controls shall be tested during a day's batch to control for test variability. Controls can be randomly selected patient samples.
3.5.4 If the method in routine use differs from the Westergren method, randomly selected samples shall be repeated at reasonable intervals (at least weekly) against a carefully performed Westergren method or the working method must have been tested against the Westergren method and found to have an acceptable correlation. The laboratory shall set up its own control limits to determine acceptable differences. (See the CLSI Guideline)
3.5.6 ESR's shall be performed out of direct sunlight in an air-conditioned area away from drafts.
3.5.7 Pipette diameter shall be more than 2.55 mm if undiluted blood is tested.
3.5.8 Blood samples shall be stored maximally 4 hours at room temperature or 24 hrs at 4^{o}C
3.5.9 Specimen for ESR shall be checked for presence of clots.

3.6 Manual Platelet and White Cell Counts;

3.6.1 The following shall apply for both cell counts:

i. The blood cell counting chambers shall be examined regularly to ensure that the lines are bright and free from scratch marks and dust particles.
ii. The correct standard thickness cover slips shall be used.
iii. The diluting fluid shall be filtered before use and checked periodically for background count. The fluid should be changed when required.
iv. For cells counted in a Neubauer counter, the calculations shall be carried out according to the following dilutions:
- 0.4 mm^3 for white cell counts
- 0.1 mm^3 for platelet counts

3.6.2 Blood Film Examinations

3.6.2.1 Blood films shall exhibit satisfactory quality for the following:
i. Staining (White cell differentials must be possible)
ii. Little or no debris
iii. Morphology and distribution of cells

3.6.2.2 The cell morphology shall be evaluated and reported.

3.6.2.3 Where appropriate an estimation of the platelet count should be made from the blood film.

3.6.2.4 If significantly abnormal platelet counts are reported, they shall be correlated with an estimate from the blood film.

3.6.2.5 Blood film examinations should be done if any abnormality in the automated full blood count is found.

3.6.2.6 Where appropriate an estimation of cell counts shall be made from the blood film and correlated with abnormal counts reported

3.6.3 Where haemoglobin is quantified manually, at least four concentrations shall be used to construct a calibration curve. Patient sample dilutions shall be checked for turbidity.

3.6.4 Abnormal hemoglobin detection; where relevant, abnormal bands or peaks detected during screening shall be verified by another method.

3.6.5 Cerebrospinal fluid (CSF); CSF preparations with suspected malignant cells shall be reviewed by a haematologist or cytopathologist.

3.6.6 Reticulocyte Counts (Manual or Automated)

3.6.6.1 The blood film shall be stained and examined within 24 hours of collection.

3.6.6.2 The reticulocyte stain shall be filtered before use.

3.6.6.3 The reticulocyte percentage should be based on the count of at least 1000 red blood cells.

3.6.6.4 The accuracy, sensitivity and specificity of the method should be determined according to CLSI recommendations.

3.6.7 Coagulation Screening Tests

3.6.7.1 Coagulation samples shall NOT be the first sample drawn.

3.6.7.2 Samples shall always be visually checked for clots and haemolysis.

3.6.7.3 Blood for heparin therapy shall only be drawn by venipuncture.

3.6.7.4 Controls shall be tested on a daily basis with either a pool of frozen plasma for which method-specific laboratory limits have been determined, or a commercial, traceable control with known value limits.

3.6.7.5 All reagents and test samples shall be incubated at 37^{o}C immediately prior to testing to ensure proper reaction temperatures.

3.6.7.6 Care shall be taken not to use reagents or controls that have not been properly validated (preferably manufacturer-recommended) for use on the specific instrument in use.

3.6.7.7 Transport and storage requirements for samples must be closely followed.

3.6.7.8 If testing cannot be completed within 24 hours for Prothrompin Time (PT) specimens and 4 hours for APTT (Activated Prothrombin Thromboplastin Time) and other assay specimens, plasma must be removed from the cells and frozen at –20^{o}C for up to two weeks or at -70° for up to six months. Frost-free freezers should not be used. If it not possible to comply with this section, the laboratory must show that the test results are not affected.

3.6.7.9 Coagulation samples shall only be centrifuged in a temperature-controlled centrifuge or 15 minutes at room temperature to prevent heating above 30^{o}C during high-speed centrifugation.

3.6.7.10 Water baths, where needed, must be temperature-controlled to 37^{o}C + 0.5^{o}C.

3.6.7.11 All temperature-controlled incubation wells on coagulometers shall be calibrated or verified against a certified thermometric device annually or as specified by the manufacturer.

3.6.7.12 Timers shall be checked for accuracy at least annually.

3.6.8 Detection of Malarial Parasites

3.6.8.1 The British Committee for Standards in Haematology (BCSH) is the preferred method for the detection and identification of malarial parasites. The CLSI guidelines or standards are also acceptable for use. If the laboratory does not follow a specific guideline or standard, the following must be used as a minimum standard:

3.6.8.2 Where rapid antigen tests or other methods used for malaria screening produces doubtful or negative results, specimens shall be re-checked using the recommended BCSH method.

3.6.8.3 The 'Quantitative Buffy Coat'' (QBC), used as screening test, must be followed up by thin film microscopy to identify the species.

3.6.8.4 Slides from all positive cases determined by microscopy at a peripheral site must be sent to an experienced main or reference centre for verification.

3.6.8.5 Both thick and thin blood films shall be examined if there are no facilities for secondary follow-up / confirmatory tests.

3.6.8.6 Positive P. falciparum infections should be quantified. Quantification must be based on at least 1000 red cells. A P. falciparum parasitaemia must be reported immediately.

3.6.8.7 For thick films, at least 100 fields shall be examined under 100X oil immersion or a 5 minute examination before a negative report is made.

3.6.8.8 Microscopy detection methods require that an experienced staff member double-check any negative results. Where the initial screen is performed by an experienced staff member, negative microscopy results shall be double checked when a thrombocytopaenia or positive malaria antigen are present.

3.6.8.9 The following appropriate staining techniques shall be used with the appropriate buffers:

1. Fields, Giemsa or QBC stain for thick films
2. Wright and Giemsa stains for thin films. (Leishman's stain also acceptable)
3. Ensure that the pH of Giemsa or Wrights-Giemsa stain is between 7.0 and 7.2

3.6.9 Bone Marrow Preparations

3.6.9.1 Bone marrow slide handling & staining shall be done at a special desk.

3.6.9.2 The bone marrow films shall be satisfactory in respect of:

- Staining
- Debris

- Morphology and distribution of cells

3.6.9.3 Where possible, histological section of marrow specimens should be routinely prepared (trephine).

3.6.9.4 The laboratory shall have a policy stating whether iron stains are done routinely for evaluation of iron stores.

3.6.9.5 A pathologist or medical specialist in Haematology shall report all bone marrow slides.

3.6.10 Immunohaematology

3.6.10.1 All blood typing and compatibility procedures shall be followed in accordance with national or international guidelines/procedures e.g. National Transfusion Practice Guideline produced by Ministry of Health, , Kenya.

3.6.10.2 Transfusion services provided by the laboratory shall follow authorized procedures with particular emphasis on patient identification and blood component handling procedures.

3.6.10.3 Blood and blood component shall have traceability, from source to final disposition.

3.6.10.4 The laboratory shall have a system to review the previous blood group and transfusion record for every request for blood and blood products.

3.6.10.5 The laboratory shall have a system in place to:

i. Identify and manage laboratory errors.

ii. investigate notified adverse clinical events

3.7 Reporting of Results

3.7.2 All routine reports should be available within 24 hours.

3.7.3 Prothrombin time results for patients on oral anticoagulants shall be reported as INR (International Normalised Ratio).

3.7.4 Where appropriate, different reference ranges shall be reported for automated and manual methods used by the laboratory for tests used for evaluation of haemostasis.

3.7.5 Specimens for thrombophilia screening shall be done on fresh samples.

3.7.6 All EDTA specimens shall be on a rotator until analyzed.

3.7.7 All specimens for special tests shall be carefully checked before analysis.

3.7.8 Blood film examinations: The blood film shall exhibit satisfactory quality for staining properties, minimal debris and distribution plus morphology of cells.

3.8 Transfusion Services

3.8.1 The goal of the transfusion service shall be safe transfusion of effective blood products to the patient. There should be a comprehensive and coordinated quality assurance programme in place which should include

i. Measures to significantly decrease errors,
ii. Ensure credibility of test results,
iii. Implement process and system controls and
iv. Ensure continued product safety and quality.

3.8.2 There shall be written procedure manuals on handling of specimens, preparation, reagents and controls, maintenance of instruments, and verification and documentation of reagent performance.

3.8.3 All blood typing and compatibility procedures shall be followed in accordance with the procedures authorized by the procedure manual of the laboratory.

3.8.4 Transfusion and aphaeresis services provided by the laboratory shall follow authorized procedures with the particular emphasis on patient identification and blood component administration procedures.

3.8.5 Blood and blood component records shall be documented and traceable from source to final disposition. It shall have identification and traceability for every unit, including quarantine, ultimate disposition, wastage, incineration and other records. For transfusion services, it shall record and retain the identity the patient receiving a given unit.

3.8.6 Records of regular maintenance and monitoring of equipment including blood storage refrigerators shall be documented and monitored. Storage facilities for blood and blood components shall have a system to monitor the temperature continuously; this shall include an alarm system.

3.8.7 If donors are drawn and/or units are processed at the facility then there shall be written polices and procedures to be followed for

i. The donor interview and selection,
ii. The phlebotomy procedure
iii. Storage,
iv. Release and quarantine procedures.

3.8.8 Blood and blood components shall be managed appropriately including handling, storage and transport conditions as detailed by the procedure manual of the laboratory. If blood components are prepared, a system must be in place to ensure that blood component specifications are met. There shall be adequate and appropriate documentation of procedures if infectious disease testing is done in the premises, regardless of where in the facility this is performed. Results not satisfying specified acceptance criteria shall be clearly identified to ensure that blood components are held from release.

3.8.9 There shall be a system of quarantine for blood components to ensure that they cannot be released for issue until all the specifications for collection, processing, handling and testing have been met.

3.9 Histocompatibility

3.9.1 The emphasis on this section is on proper procedure in specimen handling, and preparation of reagents and controls with verification and documentation of reagent performance.

3.9.2 Quality control requirements are similar to those in chemistry and diagnostic immunology in regard to procedure manuals and instrument maintenance.

3.10 Assuring Quality of Examination Procedures

3.10.1 The laboratory shall design and implement internal quality control systems that verify the attainment of the intended quality of results.

3.10.2 The Laboratory shall participate in interlaboratory comparisons provided through external quality assessment schemes.

3.10.3 Whenever formal interlaboratory comparison programmes are not available, the laboratory shall adopt mechanisms to determine the acceptability of procedures not otherwise evaluated.

3.10.4 The effectiveness of the quality control programmes shall be measured and be included in the management review of the laboratory.

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. • Addition of transfusion services and histocompatibility • Incorporate references in the guideline