



KEMRI LABORATORY FOR MOLECULAR BIOLOGY

SAMPLE COLLECTION MANUAL

KEMRI/HIV/MAN/002



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Document Approval

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ABBREVIATION/TERMS

- I. **CCC**- Comprehensive Care Center
- II. **CP/ML**-Copies per millitre
- III. **DBS**- Dry Blood Spots
- IV. **DNA**- Deoxyribonucleic Acids
- V. **EDTA**-Ethylene Diamine TetraAcetic Acid
- VI. **EID**- Early Infant Diagnosis
- VII. **HIV**- Human Immunodeficiency Virus
- VIII. **ID**- Identity
- IX. **ISO**- International Organization Standardisation
- X. **KEMRI**- Kenya Medical Research Institute
- XI. **LDL**- Low Detectable Limit
- XII. **LSM**- Laboratory Safety Manual
- XIII. **MFL**- Master Facility List
- XIV. **MOH**- Ministry Of Health
- XV. **PCR**- Polymerase Chain Reaction
- XVI. **QMS**- Quality Management System
- XVII. **RT**- Room Temperature
- XVIII. **SCM**- Sample Collection Manual
- XIX. **SOP**- Standard Operating Procedure
- XX. **TAT**- Turn Around Time
- XXI. **VL**- Viral Load



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1. INTRODUCTION

This manual is designed to give an overall view of the services available in the KEMRI Laboratory for Molecular Biology as well as to give a detailed explanation of how samples are collected from patients and transported to KEMRI Laboratory for Molecular Biology which is a referral Laboratory. It is intended as a quick reference guide for all users for use in the collection of referral samples.

2. SCOPE

This manual applies to all sample collection points where samples are forwarded to the KEMRI Laboratory for Molecular Biology for referral testing. This manual shall be reviewed from time to time and is a controlled document for KEMRI Laboratory for Molecular Biology and therefore all users are requested to check with KEMRI Laboratory for Molecular Biology for the latest copy of the Primary Sample Collection Manual.

3. GENERAL INFORMATION

3.1 KEMRI Laboratory for Molecular Biology Location

The KEMRI Laboratory for Molecular Biology is located within the Kenya Medical Research Institute's hub for infectious diseases research, Nairobi County along Mbagathi way, Nairobi, Kenya.

3.2 KEMRI Laboratory for Molecular Biology Opening Hours

The KEMRI Laboratory for Molecular Biology is open Monday- Friday from 8 a.m to 5 p.m

3.3 Services offered by KEMRI Nairobi HIV Laboratory

Name of Test	Procedure Used	Normal Ranges	Critical values	Units	TAT	Urgent TAT	Time limit for additional requests

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Name of Test	Procedure Used	Normal Ranges	Critical values	Units	TAT	Urgent TAT	Time limit for additional requests
Molecular							
HIV Viral Load							
DBS	PCR using Abbott m2000 systems	Abbott LDL 550 - 10,000,000 cp/ml. Less than 550 cp/ml is considered undetectable	Above 10,000,000 cp/ml	cp/ml	10 days	3 days	None
PLASMA	PCR using Abbott m2000 systems and CAP/CTM	Abbott LDL 40-10,000,000 cp/ml. Less than 40cp/ml is considered undetectable CAP/CTM LDL 20-10,000,000 cp/ml. Less than 20cp/ml is considered undetectable.	Above 10,000,000 cp/ml	cp/ml	10 days	3 days	None
EID TEST							



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Name of Test	Procedure Used	Normal Ranges	Critical values	Units	TAT	Urgent TAT	Time limit for additional requests
DBS	PCR using Abbott m2000 systems	The results are either DBS detected and DBS not detected	All DBS detected samples	None	10 days	3 days	None

Turnaround Time (TAT): This is defined as the time when the samples are received in the laboratory until the time results are authorized or verified and are ready for dispatch.

NOTE:1 TAT does not include weekend. For samples received during the weekend TAT starts to be calculated from Monday at 0800 hours.

NOTE: 2 The lab uses following consideration to determine urgent samples;

- I. Viralload samples from infant below 1 years.
- II. Viralload samples from expectant mothers.
- III. Viralload samples collected from hospitalized patients in the wards.
- IV. Samples collected incase of an emergency.
- V. Any other justifiable consideration from the clinicians.

4. LABORATORY REQUEST FORMS, SAMPLE CONTAINERS

4.1 General Information

This section deals with the information that is required to be documented on the laboratory request form and the sample container, upon sample collection.

4.2 Completing the Request Form

The following essential information must be documented in a legible manner on the request form

- I. Patient's facility name

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- II. Patient's facility MFL code
- III. Patient's facility Number
- IV. Patient's Age
- V. Patient's gender
- VI. The name of the requesting Clinician and signature
- VII. Sample type and anatomical site where appropriate
- VIII. Collection date, time and name of the person who collected the specimen
- IX. Examination(s) required
- X. Date and time of sample collection
- XI. Relevant clinical information appropriate to the test(s) requested must be supplied e.g. history of administration of drugs, antenatal history, blood transfusion history etc. The minimum clinical information supplied relevant to the patient may include gender and date of birth for interpretative purposes. A clear indication as to whether the tests requested are urgent or routine.

4.3 Determination of the identity of the patient

Before collecting any sample from the patient, the member of staff collecting the sample should first confirm the identity of the person from whom the sample(s) are to be collected. This will be done by confirming the details on the identity card. If the patient does not have an identity card, it can be done by asking the patient his/ her name. For unconscious patients, determination of the patient identity can be done by asking their relatives or next of kin.

4.4 Verification that the patients meet the pre examination requirements

Before collecting patient sample(s), confirm from the patient about pre examination requirements;

- Fasting status
- Medical status (time of last dose, cessation)
- Sample collection at pre determined time or time intervals

4.5 Labelling the Sample Container

The following **essential** information should be documented in a **legible** manner on the sample container before collecting samples:-

1. Patient Unique identifier
2. Date of sample collection where need be.



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4.6 Quality of Blood Samples

KEMRI Laboratory for Molecular Biology personnel shall inspect each blood sample received for testing for:-

- I. Evidence of Haemolysis
- II. Gross Lipemia
- III. Presence of clots in whole blood VL samples
- IV. Within an acceptable time frame for the test concerned,
- V. Within acceptable condition (broken, haemolysed etc)
- VI. Within temperatures acceptable for test performance;
- VII. Transport and packaged in a safe manner, to protect the carrier, the public and the laboratory personnel.

In such instances, a second sample may be requested or the issued report will have an appended comment noting the presence of haemolysis, lipemia or clots as appropriate.

4.7 Advice on ordering of examination and on interpretation of results

KEMRI Laboratory for Molecular Biology Technical staffs are always available to offer Laboratory clients with any information regarding correct collection of patient samples to ensure that Laboratory results are produced by the Laboratory. Advice is also offered in terms of proper interpretation on of patient results. Clients in need of advice should contact KEMRI Laboratory for molecular Biology through the contact details provided above.

4.8 Protection of personnel information

KEMRI Laboratory for Molecular Biology members of staff have signed Confidentiality and conduct undertaking form and are bound not to release any patient information. Member of staff are also required to follow KEMRI-LMB-MGT-021 Confidentiality and conduct undertaking. Any breach of this will results in disciplinary action.

4.9 Laboratory complaints procedure

- 4.9.1 Any customers who are not happy with the service received from the KEMRI Laboratory for Molecular Biology are free to complain to the KEMRI Laboratory for Molecular Biology .
- 4.9.2 The Complainant is required to complete the complaints form (QMS/MF/016) attached at the end of this manual and forward it to KEMRI Laboratory for Molecular Biology Quality Officer.



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- 4.9.3 Complainants can communicate directly with KEMRI Laboratory for Molecular Biology Quality Officer or any member of staff through contact details provided at the beginning of this document.
- 4.9.4 KEMRI Laboratory for Molecular Biology will acknowledge the receipt of complaint to the complainant upon receipt and will follow KEMRI/HIV/MGT/05 Resolution of complaints procedure to handle complaints.
- 4.9.5 After successful resolution of complaints, KEMRI Laboratory for Molecular Biology will contact complainants and inform him/her about the results achieved.

5. SAMPLE COLLECTION, TRANSPORT AND STORAGE REQUIREMENTS

5.1 Samples

Name of Test	Sample type	Sample Collection Guidelines	Transport and/or amount of primary samples	device	Transport Time and Temp before delivery	Storage and Temp	time	Special instructions	considerations/
Viral Load Test	DBS		Whatman paper 5 spots	filter	Room temperature		6 months		
Plasma			Cryovial tubes Plasma preparation tubes	-80°C -30°C		6 months 6 months			
EID TEST	DBS		Whatman paper 5 spots	filter	Room temperature		6 months		



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5.2 Phlebotomy Procedures

The venipuncture system should be used for blood collection. These are the guidelines to use when collecting samples.

5.3 Vacutainer Blood Collection System

The Vacutainer system consists of a double-pointed needle, a plastic holder or adapter, and a series of vacuum tubes with rubber stoppers of various colours. The stopper colours indicate the type of additive present. The blood goes from the patient directly into the appropriate test tube.

5.4 Vacutainer Colour System

Vacutainer® Tubes with Hemogard™ Closure	Vacutainer® Tubes with Conventional Stopper	Additive	Minimum Volume	Mix Number of Times	Laboratory Use
Lavender	Lavender	<ul style="list-style-type: none"> Liquid K3EDTA (glass) Spray-coated K2EDTA (plastic) 	4ML	8	<p>K2EDTA and K3EDTA for whole blood hematology determinations. K2EDTA may be used for routine immunohematology testing, and blood donor screening.</p> <p>Tube inversions ensure mixing of anticoagulant (EDTA) with blood to prevent clotting</p>



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	White	<ul style="list-style-type: none">K2EDTA and gel for plasma separation	4ML	8	For use in molecular diagnostic test methods (such as, but not limited to, polymerase chain reaction [PCR] and/or branched DNA [bDNA] amplification techniques). Tube inversions ensure mixing of anticoagulant (EDTA) with blood to prevent clotting.
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5.5 Principle

The patient's vein is punctured with a sterile needle attached to an aspirating device. This allows the drawing of venous blood with the least amount of patient discomfort and trauma.

5.6 Safety and Infection Control

It is important to follow safety and infection control procedures.

PROTECT YOURSELF.

a. Practice universal precautions:

- I. Wear gloves when handling blood/body fluids.
- II. Change gloves after each patient or when contaminated.
- III. Wash hands frequently.
- IV. Dispose of items in appropriate containers.
- V. Dispose of needles immediately upon removal from the patient's.
- VI. Clean up any blood spills with a freshly made 1:10 bleach disinfectant.

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b. Protect the patient:

- I. Place blood collection equipment away from patients, especially children.

5.7 Equipment

5.7.1 The following are needed for routine venipuncture:

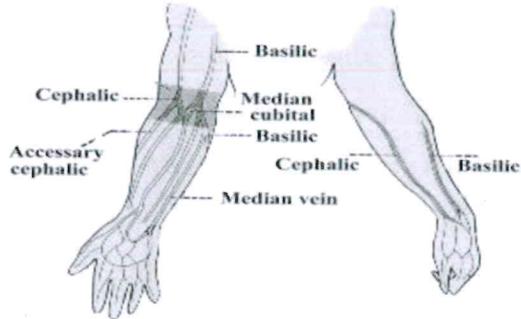
- I. Evacuated collection tubes – the tubes are designed to fill a predetermined volume of blood by vacuum. The rubber stoppers are colour coded according to the additive the tube contains. Blood should NEVER be poured from one tube to another since the tube can have different additives or coatings.
- II. Needles – The gauge number indicates the bore size: the larger the gauge number, the smaller the needle bore.
- III. Holder – use with the evacuated system.
- IV. Tourniquet – wipe off with alcohol and replace frequently.
- V. Alcohol wipes – 70% isopropyl alcohol.
- VI. Adhesive bandages / tape – protects the venipuncture site after collection.
- VII. Needle disposal unit – needles should NEVER be broken, bent, or recapped. Needles should be placed in disposal unit IMMEDIATELY after their use.
- VIII. Gloves – can be made of latex, rubber, or vinyl, and are worn to protect the patient and the phlebotomist.
- IX. Syringes – may be used in place of the evacuated collection tube for special circumstances

5.8 Procedure for Vein Selection

5.8.1 The median cubital and cephalic veins of the arm are used most frequently. See diagram below:



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- 5.8.2 Palpate and trace the path of veins with the index finger. Arteries pulsate, are most elastic, and have a thick wall. Thrombosed veins lack resilience, feel cord like, and roll easily.
- 5.8.3 If superficial veins are not readily apparent, you can force blood into the vein by massaging the arm from wrist to elbow, tap the site with the index and second finger, apply warm, damp wash cloths to the site for 5 minutes, or lower the extremity to allow the veins to fill.

5.9 Venipuncture Procedure

- 5.9.1 Position the patient so he or she is comfortable and safe in case the patient becomes faint and falls.
- 5.9.2 Recommended needle size: 20G, 21G or 22G.
- 5.9.3 Closed vacutainer system is recommended.
- 5.9.4 Select tube or tubes appropriate for type of samples desired.
- 5.9.5 Select site for venipuncture.
- 5.9.6 Put on gloves.
- 5.9.7 Prepare venipuncture site with alcohol prep. Cleanse in a circular fashion, beginning at the site and working outward. See diagram below.



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- 5.9.8** DO NOT PALPATE VENIPUNCTURE AREA AFTER CLEANSING. Allow site to dry.
- 5.9.9** Apply the tourniquet 3-4 inches above the selected puncture site. Do not place too tightly or leave on more than 2 minutes.
- 5.9.10** Remove needle shield. Perform venipuncture WITH PATIENT'S ARM IN A DOWNWARD POSITION AND TUBE STOPPER UPPER MOST. This reduces the risk of backflow of any anticoagulant into the patient's circulation.



- 5.9.11** Push the tube onto the needle, puncturing the stopper.
- 5.9.12** REMOVE TOUNIQUET AS SOON AS BLOOD APPEARS IN TUBE, within 2 minutes of venipuncture. DO NOT ALLOW CONTENTS OF TUBE TO CONTACT THE STOPPER DURING THE PROCEDURE.



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- 5.9.13** When first tube has filled to its stated volume, remove it from the holder.
- 5.9.14** Place succeeding tube in holder puncturing stopper to initiate flow.
- 5.9.15** While each successive tube is filling invert previous tube GENTLY 5 times. DO NOT SHAKE. Vigorous mixing can cause haemolysis.
- 5.9.16** When all tubes of blood have been collected, remove the last tube from the vacutainer holder, place a cotton ball or gauze over the site and withdraw the needle in a smooth and cautious manner so as not to bruise the vein.
- 5.9.17** After withdrawing the needle fully, apply pressure to the cotton ball over the puncture site and hold pressure. If patient is able, ask them to apply pressure for 3 to 5 minutes until the bleeding stops.
- 5.9.18** Discard the needle of the vacutainer into the biohazard container WITHOUT RECAPPING the needle.
- 5.9.19** Immediately invert the last tube GENTLY 5 times.

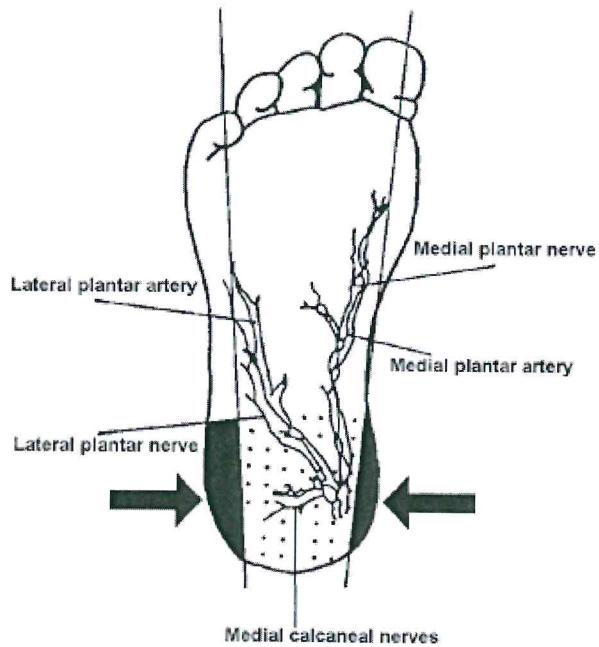
5.10 Neonate Capillary Blood Collection (Heel Stab)

5.10.1 Choosing a site for the heel prick

- 5.10.1.1 Use the most medial or lateral portions of the planter surface of the heel (in diagram below areas indicated by arrows). Limit the depth of the puncture wound by using an automated lancet.
- 5.10.1.2 Only consider using the whole plantar surface of the foot (using automated lancets of 2.2mm in length or less) for neonates over 33 weeks' gestation if they are having multiple/frequent heel pricks



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5.10.2 Preparation of the neonate

5.10.2.1 Methods to reduce pain for the neonate

- Skin-to-skin contact with the mother
- Swaddling/containment
- Breastfeeding
- Administration of oral Sucrose

5.10.2.2 Position the neonate: ensure the foot is lower than the body.

5.10.3 Taking the blood sample

5.10.3.1 Choose a puncture site – do not use a previous puncture site.

5.10.3.2 Clean the heel site (i.e. gauze and water) if the foot appears unclean (e.g. faecal material)

5.10.3.3 Encircle the foot with the palm of the hand and the index finger.

5.10.3.4 Make a quick puncture with the automated lancet device

5.10.3.5 Wipe off the first drop of blood with a gauze swab



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5.10.3.6 Allow enough time for capillary refill of the heel and only gently “pump” the heel if necessary to continue the blood flow.

5.10.3.7 Apply gentle digital pressure with a gauze swab to puncture site if bleeding continues after procedure.

5.10.3.8 Wipe the heel and apply gauze over the puncture site holding until the bleeding stops.

5.10.3.9 Document as required.

5.11 Preparation of Plasma from whole blood

5.11.1 Materials and equipments

- A refrigerated centrifuge capable of generating 1,300g
- -30°C Freezer
- Human blood sample in vacutainer tubes containing anticoagulant
- Cryovials

5.11.2 Procedure

- I. Place the blood collection tubes in a centrifuge and spin at 1000 RPM for 10 minutes at 4°C.
- II. Using a sterile pipette , collect 1.5-2.0 Ml plasma being sure to avoid collection of cells or gel. Distribute the plasma among the labeled corresponding cryovials.
- III. Transfer tubes to a -30°C freezer for storage.

5.12 Preparation of Dried blood spot

5.12.1 Materials and Equipments

- I. 100ul filtered tips
- II. Whole blood sample
- III. Sterile pipettes
- IV. Whatman filter paper
- V. DBS rack

5.12.2 Procedure

- I. Label the DBS card using the unique patient identifier.
- II. Gently invert the blood collection tube 2 to 4 times and then open the stopper carefully.
- III. Draw 70 µl whole venous blood on a transfer pipette, avoiding air bubbles.
- IV. Transfer 1-2 drops of blood to the center of each of the 5 circles without touching the filter paper directly. Fully saturate the circles.
- V. Store DBS card on drying rack with blood spots facing up and dry the DBS card at room temperature overnight.



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- VI. Insert the dried card into the sealable plastic bag with the desiccant and humidifier indicator.

5.13 Rejection Criteria for Samples

5.13.1 Causes for Rejection of Sample

The quality of laboratory results are directly affected by the quality of the blood sample obtained from the patient. Samples may need to be rejected as unacceptable for the following reasons:

- I. Haemolysis - this is usually caused by a procedural error such as using too small of a needle, or pulling back too hard on the plunger of a syringe used for collecting the sample.
- II. Clotted - failure to mix or inadequate mixing of samples collected into an additive tube.
- III. Insufficient sample. When many tests are ordered on the same tube, be sure to know the amount of sample needed for each test.
- IV. Wrong tube collected for test ordered.
- V. Samples not processed before shipping to lab.
- VI. Samples held too long in facility before shipping.
- VII. Submitting specimens in expired collection tubes. It is the responsibility of the submitter to ensure that specimens are collected in tubes that have not expired.
- VIII. Missing or inadequate identification of the sample.
- IX. And any other.

5.13.2 DBS Sample rejection criteria

5.13.2.1 Procedure steps

- I. Check the quality of the envelope received; look for any damage in the envelope
- II. Open the envelope; check the specimen delivery form. Ensure that the form corresponds to the number of the samples received.

5.13.2.2 Reject DBS if:

- I. Insufficient blood has been submitted



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- II. Blood did not completely soak through the filter paper
- III. DBS card scratched
- IV. Specimen is contaminated or discoloured
- V. Specimen is caked, clotted or layered on the filter paper
- VI. Missing or invalid patient demographic information
- VII. Form serial number does not match that of the blood circles
- VIII. Specimen is too old upon receipt (received 14days or more following collection)
- IX. No blood on filter paper
- X. Specimen submitted on improper collection form
- XI. Serum separation due to improper drying or collection
- XII. Specimen torn or damaged on transit
- XIII. Finger prints seen on filter paper circles
- XIV. Haemolysed DBS
- XV. Insufficiently dried DBS (humidity greater than 60)

Note: The collection devices must be within expiry date through the whole testing process.

5.14 Non-Conforming Specimen Containers, Forms or Specimen Quality Issues

Where the requirements with respect to labelling the request form and specimen container or specimen quality issues are not met the following will apply.

SPECIMEN ISSUES	ACTION	DOCUMENTATION
5.15 No specimen received I. Specimen site not identified II. Specimen collected at incorrect time or date and time of collection not	<ul style="list-style-type: none">• A second specimen must be collected <i>or</i> the originator accepts responsibility for same in emergency cases or	<ul style="list-style-type: none">• Originator or nominee signs for the correction of the error on a Specimen Reception form.



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<p>indicated</p> <p>5.16 Specimens unlabelled</p> <p>III. No unique identifiers present on the specimen (MFL code, Lab I.D/CCC.No)</p> <p>IV. Miscellaneous specimen issues</p>	<p>where the specimen cannot be replaced.</p> <ul style="list-style-type: none"> If tested the report will show the non-conforming event. 	
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FORM ISSUES	ACTION	DOCUMENTATION
<p>I. No request form provided with</p> <ul style="list-style-type: none"> a. Specimen <p>II. Inadequate or incorrect patient details:-</p> <ul style="list-style-type: none"> a. Unique identifier b. Name c. Age d. gender e. clinic information <p>III. Incorrect test requested</p> <p>IV. No patient details on form</p> <p>V. Ordering Physician not identified</p>	<ul style="list-style-type: none"> A second specimen is requested if the originator does not correct the error. If tested or appropriate the report will show the non-conforming event 	<ul style="list-style-type: none"> Originator or nominee signs for the correction of the error on a Specimen Reception form.



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VI. Specimen collected at incorrect time or date and time of collection not indicated (For CD4 tests, Viral tests involving whole blood/plasma) VII. Miscellaneous form issues		
SPECIMEN APPEARANCE/ QUALITY ISSUES <ul style="list-style-type: none"> • Evidence of Haemolysis • Gross Lipemia • Age of specimen • If DBS delivered fits DBS sample rejection criteria • Miscellaneous quality issues 	ACTION <ul style="list-style-type: none"> • The KEMRI Laboratory for Molecular Biology will make a decision on whether or not the specimen is suitable for testing and a second specimen is requested as appropriate. • The KEMRI Laboratory for Molecular Biology may report results within a multi test profile on analytes unaffected by the specimen quality, while not reporting affected analytes in the profile. • If tested or appropriate the report will show the non- 	DOCUMENTATION Not applicable



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	conforming event	
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5.17 Further Additional Testing

If on sending a specimen for testing and further additional testing is required, please contact the appropriate section of the KEMRI Laboratory for Molecular Biology to investigate the feasibility of using the initial specimen for analysis as age of specimen may impact on the validity of test results. Ideally, a request form should accompany such a request but the lack of the request form should not impede the processing of an urgent request.

6 DELIVERY, PACKING, AND TRANSPORTATION OF SAMPLES

It is the policy of the KEMRI Laboratory for Molecular Biology to treat all specimens and samples as potentially infectious or high risk. Therefore, we advise you to take universal precautions in the collection, packaging and the delivery of specimens being sent to the KEMRI Laboratory for analysis.

6.1 Specimen Delivery to KEMRI Laboratory for Molecular Biology

The requirements stated below apply to all specimens or samples directed to the KEMRI Laboratory for Molecular Biology. These will be required to be packed and transported in accordance with the WHO and IATA requirements for the transportation of infectious goods.

It is the policy of the KEMRI Laboratory for Molecular Biology to provide our clients with specimen transport packaging instructions. Please do not hesitate to contact KEMRI Laboratory for Molecular Biology for more information regarding the packaging of samples.

6.1.1 Packing Procedure for the Transport of Diagnostic Specimens

6.1.1.1 Specimen to be sent should be stored in a secure (preferably plastic) primary container.

6.1.1.2 Wrap the container in tissue or cotton wool which will act as absorbent material in event of any spillages.



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- 6.1.1.3 This will be placed in a biohazard bag.
- 6.1.1.4 Place the biohazard bag with the sample in a padded (jiffy bag) envelope.
- 6.1.1.5 Label the envelope with a hazard warning label, “Diagnostic Specimen”.
- 6.1.1.6 Place the name, address and contact number of the destination laboratory (KEMRI LABORATORY FOR MOLECULAR BIOLOGY) on the outside of the envelope.
- 6.1.1.7 Place the name, address and contact number of the originator on the outside of the envelope.
- 6.1.1.8 The specimen can be transported or posted as appropriate.

6.1.2 Procedure for the Transport of Infectious or Suspected Infectious Specimens

Specimens or samples suspected or known to contain risk group 3 or 4 Pathogens are classified as infectious and are packaged and transported accordingly as outlined below.

- 6.1.2.1 Specimens or samples to be sent should be stored in a secure (preferably plastic) primary container.
- 6.1.2.2 Wrap the container in tissue or cotton wool which will act as absorbent material in event of any spillages.
- 6.1.2.3 Place the wrapped primary specimen or sample container inside of the plastic container of the UN-approved Class 6.2 package type.
- 6.1.2.4 Place the container inside the cardboard box.
- 6.1.2.5 The box should contain a label “Infectious Substance”. Write the name of the suspected microbe being transported in brackets.
- 6.1.2.6 Place the name, address and contact number of the destination laboratory on the outside of the box.
- 6.1.2.7 Place the name, address and contact number of the originator on the outside of the box.
- 6.1.2.8 Complete a transport document and provide a copy to the licensed courier.

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6.2 Safe Disposal of Waste Material Used in Specimen Collection

All materials used in specimen collection should be treated as potentially hazardous and discarded using sharps containers and other appropriate colour coded bags. Please refer to the National IPC guidelines for Healthcare Services in Kenya.

6.3 Repeat Examination due to Analytical Failure

It is the policy of the KEMRI Laboratory for Molecular Biology in the event of an analytical failure to:-

- I. Repeat the test using a back-up instrument or
- II. Store the specimens in appropriate conditions until the cause of the analytical failure is identified and corrected and then repeat the test.

6.4 Further Examination of the Primary Specimen

Where further testing is relevant to the investigation or diagnosis of the condition or symptoms which gave rise to the original test request then it is the policy of the KEMRI Laboratory for Molecular Biology to pursue a diagnosis by performance of additional tests using the primary specimen.

6.5 Referral Laboratory Testing

It is the policy of KEMRI Laboratory for Molecular Biology to refer all samples for testing to referral laboratories for the tests not conducted within KEMRI Laboratory for Molecular Biology or whereby the tests are not conducted but due to any reason the test is not being offered. In such circumstances, KEMRI Laboratory for Molecular Biology has the responsibility to refer the test to the laboratory of its choice chosen following the KEMRI/HIV/MGT/03 Examination by Referral laboratory procedure.

6.6 Emergency Service

Generally the KEMRI Laboratory for Molecular Biology does not operate a standby service or on call service for emergency cases. However in case of national outbreaks or whenever the need arises, the management can organise to arrange members of staff to test samples after



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normal hours. In case of an emergency, clients are requested to contact the Director or laboratory manager on the telephones numbers available.

7 REPORTING OF TEST RESULTS

7.1 Reporting of Results

All results, once released, shall be sent to the MOH site requesting the test within the same day the results are released. If the results are within the critical limits, the laboratory shall contact the clinician requesting the test on telephone following the KEMRI/HIV/MGT/19 Results Management Procedure.

7.2 Reference Ranges (Biological Reference Intervals)

Reference ranges for quantitative tests are described in section 3.3 above.

7.3 Verbal Test Request Procedure

- 7.3.1 The clinician phones the laboratory and verbally requests addition, or change of tests to the samples already received in the laboratory.
- 7.3.2 The Laboratory staff receiving the telephone will write the information in laboratory communication book.
- 7.3.3 The laboratory staff will read back the recorded details to the person requesting a verbal request of tests.
- 7.3.4 The laboratory staff will request the clinician to send in the completed sample request for with the new tests ordered.
- 7.3.5 The completed form is forwarded to the relevant section
- 7.3.6 The relevant section will look for the original sample and check for appropriateness of the additional test request and verify proper sample type and adequate volume. If necessary, check for additional samples that may have been collected and are located in other areas of the laboratory.
- 7.3.7 If additional testing can be performed, the test is added to the original sample number or new number is generated.



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7.3.8 If additional test(s) cannot be performed, notify the requesting clinicians and at the bottom of the Verbal Request Form.

7.3.9 Time limits for additional tests are indicated in the sample collection manual.

8 REFERENCE DOCUMENTS/ RECORDS

- 8.1.1 Complaint management form (QMS/MF/16)
- 8.1.2 Procedure for complain management (KEMRI/LMB/MGT/05)
- 8.1.3 Viral load requisition form (QMS/EXT/19)
- 8.1.4 EID Requisition Form (QMS/EXT/18)

8 REFERENCES

- ISO 15189: Medical laboratories — Particular requirements for quality and competence (2012) International Organization for Standardisation.



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Amendment Sheet

Proposed by	Unit/Section	Summary of changes	Date of amendments
Quality manager	Molecular	Updated according to ISO 15189:2012	8/10/2015
Quality manager	Molecular	Amended the documents unique identifiers, Table of contents and formats	20 June 2018
Quality Manager	Quality Office	Amended lab name, document unique identifier, version number, added considerations for urgent samples, plasma and DBS preparation	Februrary 2019