MINISTRY OF HEALTH

SOP Title: **National HIV Viral Load Sample Chain of Custody SOP**	SOP No: **MOH VL 000**
	Version 01
Effective Date: 01 AUGUST 2019	Page 1 of 9

Signatures and Dates:

Author: _**National HIV Viral Load Technical Working Group (NVLTWG)**_ _____
Date

QA Review: _____
Date

Approving Authority: _____
Laboratory In charge/ Designee Date

Review/Approval for unchanged documents

DATE	Author	QA Review	Approving Authority

1. Purpose/Applicability/Principle:

1.1. Purpose:

This document provides technical and programmatic recommendations on the appropriate specimen collection, storage transportation and HIV VL testing. Along with the national guidelines for specimen collection, storage and transportation. These standards should provide guidance on the creation or improvement of specimen referral networks and specimen transport systems. In addition, standard operating procedures (SOPs) targeting drivers and persons responsible for packing of specimens and results return are included in this document.

1.2. Applicability:

This SOP applies to Phlebotomists, Laboratory Technicians, Technologists, Nurses, Clinicians, Laboratory data clerks, Research Assistants, and Laboratory Manager/Director but not limited to the courier services.

1.3. Principle:

All referred samples and results must be traceable from the point of requisition to the receipt of results at facility. Integrity of samples must be maintained during transportation to provide accurate and reliable results. During sample handling universal safety precautions must be adhered to, to avoid unnecessary incidents and accidents.

2. Precautions

2.1. All specimens should be treated as potentially infectious, and handled with care to avoid infection.
2.2. Triple packaging of samples must be observed.
2.3. Applicable PPE must be worn when handling the specimen.
2.4. Do not use expired tubes or (DBS bundles for designated facilities)
2.5. Handle all samples aseptically or in the Class II Biosafety Cabinet where applicable.

3. Abbreviations and Terms:

3.1. SOP – Standard Operating Procedure
3.2. RNA- Ribonucleic acid
3.3. PCR- Polymerase Chain Reaction
3.4. EDTA – Ethylene diamine tetra acetic acid
3.5. ACD- Acid Citrate Dextrose
3.6. °C – Degree Centigrade
3.7. HIV – Human Immuno Deficiency Virus
3.8. ML – Milliliter
3.9. µl – Microliter
3.10. PPE- Personal protective equipment
3.11. DBS- Dried blood spot
3.12. PPT- Plasma Preparation tube

4. Equipment and Materials

4.1. Ethanol 70%
4.2. Bleach 10%
4.3. Plasma aliquot labels
4.4. Permanent marker pens
4.5. Disposable powder-free latex gloves
4.6. Elastoplast or band aids
4.7. Biohazard waste container
4.8. Refrigerator (with -20°C compartment), or freezer -20°C- to -80°C
4.9. Cool box, and ice packs, thermometers, and sample rack
4.10. Glycine envelop, humidity indicators, desiccants, 5x6 zip lock bags, padded envelops

5. PROCEDURE:

5.1. Sample collection

5.1.1. Refer to Sample collection SOP_#

5.2. Specimen Transportation

5.2.1. Ensure and countercheck adequate labeling on specimens and the corresponding request forms are accurately completed.

5.2.2. Verify the specimen requisition forms against the samples and send them to the lab at the required temperature.

5.1.1. Log samples in the facility log book prior to sending.

5.1.2. All samples including DBS must be triple packaged, accompanied by proper sample request forms/manifest.

5.2.

5.3. Samples collected in PPT tubes must be centrifuged and aliquoted before shipping to the testing Lab within 24 hours from time of collection. **For sites that can separate plasma**: Plasma should be separated from whole blood within 6 hours of collection, and transported frozen with ice packs or dry ice, and accompanied thermometer to testing labs. Refer to viral load sample collection, processing, transport and result feedback job aid on instructions regarding centrifugation.

5.4. DBS must be packaged with Glycine envelop, humidity indicators, desiccants, 5x6 zip lock bags, padded envelops. (**Designated sites only**)

5.5. Call the testing lab in advance for samples that will arrive after hours.

5.6. Ensure the samples are received and verified in the central lab.

5.7. Or refer to each lab Specific SOP on Transportation

6. Rejection Criteria for the Specimens

6.1. Sample missing
6.2. Specimen collected in heparin tubes and/or plain tubes.
6.3. Clotted sample.
6.4. Leaking samples due to broken tubes or properly unscrewed vials.
6.5. Unlabeled or mislabeled specimen.
6.6. Hemolysed blood.
6.7. Insufficient sample
6.8. Request form and sample mismatch

6.9. Poor storage and transportation of the sample as per the specific SOPs
6.10. Incomplete request form or form not matching the corresponding tube
6.11. Inadequate size and number of spots on DBS filter
6.12. Multilayered spots DBS
6.13. Insufficiently dried DBS with serum halo
6.14. Soiled request forms
6.15. Samples without request forms
6.16. ETC

7. Specimen receiving and accessioning

7.1. Ensure that each sample or batch of samples sent to the testing labs is accompanied with a MOH- HIV viral load Lab requisition form that is completely filled out with the correct patient and matching sample demographics.
7.2. Samples should be accessioned and registered using the NASCOP LIMS system (NASCOP.org) as applicable. Refer to remote logging Job aid. The variables to be captured include ref to the viral load request forms.
7.3. Clearly provide details as to where the samples are originating from, where the results will be sent to and to whom including the sites email address.
7.4. Samples should be sent to the testing lab based on the networking refer back up SOP

NOTE: Ensure that packaging for the samples are clearly labeled, if shipment has to be done through a courier system. Include how to access G4S (account, phone number, e-mail), and to report complaint.

7. Testing

7.4. Refer to specific Technical SOPs for each Laboratory

8. Results interpretation

8.4.1. LDL (≤400cp/ml)
8.4.2. LLV (401 to 999 cp/ml)
8.4.3. ≥1000 cp/ml suspected treatment failure
8.4.4. NB refer key messaging on viral Load result interpretation (Job aid)

9. Specimen Storage

8.1. Plasma specimens may be stored at -20 ºC for up to 5 days or frozen at -80ºC until when ready to process or pending results.
8.2. PPT specimens can be stored at 2º-8ºC for up to 7 days and whole blood can be stored for up to 6 hours before shipment.
8.3. DBS can be stored at room temperature, well inventoried, protected from rodents and insects, spilling.

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9. Results Dispatch and Receipt

9.1. Results shall be up loaded on the NASCOP web based system by individual staff, who will also do first review. Second review will be done by a second staff before being dispatched online to the various sites.

9.2. For lab using LIMS/any other lab information system, individual staff, will also do first review. Second review will be done by a second staff before being dispatched online to the various sites. The LIMS will automatically upload to the NASCOP using the specified API

9.3. For sites that cannot access results on the NASCOP web based system, clearly address the hard copy results with the right facility contacts information and agreed destination before dispatch.

9.4. For sites that can access results via SMS send SMS (RMFLCODE-/ CCC No.) to 20027 (Safaricom line only) or refer Result query via SMS

9.5. If a facility does not receive its results after two weeks, they are advised to call or email the testing lab to check on the results status.

9.6. Hard copies results should be sent to the sites without internet or SMS printer.

9.7. All samples with viral load copies of ≥1000cp/ml would be considered CRITICAL and such results MUST be communicated immediately through mail and or notify by message.

9.8. Contact information for the testing laboratories are as indicated below;

KEMRI P3 LABORATORY **KEMRI: Headquarters, Mbagathi RD Nairobi** **Tel: 0725793260/ 0725796842** **Email: eid-nairobi@googlegroups.com**	**KEMRI HIV-Reference Laboratory,** **Off Busia Road, Opposite Kisian Primary School,** **Tel: 0572053017/8** **EXT: 605 or 477** **Email: kisianhivrlab@kemricdc.org**	**MPATH Care Laboratory, Nandi Road,** **Nairobi-Uganda RD, Eldoret** **el: 0720824338** **e-mail:carelab@ampatthplus.or.ke**	**COAST General Hospital. P.O.Box 90231-80100 .Mombassa** **Land Line Tel: 304 204/5** **Mobile: 0722-207 868** **e-mail:**
National HIV Reference Laboratory **KNH Grounds off Ngong Road, Nairobi** **NHPLS Complex** **Tel: 0202610963/0202011660** **e-mail:nhrl@nphl.or.ke**	**Walter Reed CRC Laboratory , Kericho,** **Hospital Road** **P.O Box 1357,** **Kericho.** **Tel:05250686**	**KEMRI Alupe- Busia. Malaba Road, Busia** **Tel: 0726156679** **Email: eid-alupe@googlegroups.com**	**KNH CCC** **KNH ground, Upper hill hospital rd** **P.O. BOX 20723-00202, Nairobi** **Phone:** **Email:knhccclab@gmail.com**
NYUMBANI Nyumbani House **P.O. Box 24970 Dagoretti Rd, Nairobi** **Phone: 0722 201163** **Email-diagnosis@nyumbani.org**	**EDARP** **P.O. BOX 47351 - 00100** **GPO Nairobi** **Phone;0722699211,** **0731334461/67/55** **Email:info@edarp.org**		

NOTE: All samples marked URGENT will be fast tracked both at testing and results dispatch.

10. Specimen Archiving and Destruction after testing

10.1. Samples for viral load assays should be disposed of after testing and results dispatch or held for not more than 1 week after testing or refer Lab specific SOP

10.2. Samples should be discarded through autoclaving and or incineration.

10.3. Destruction of samples should be done after confirming that the results of the viral load have been generated and relayed to the requesting facility.

11. Quality Control

11.1. All viral load testing laboratories MUST ensure that they place orders for kits supply in good time to avoid stock outs and backlog of samples.

11.2. All testing batches for viral load MUST include three levels of control Negative Control, Low Positive Control and High Positive Control.

11.3. The turnaround time between sample receipt in the lab and dispatch of results should be 10 working days.

11.4. All control invalid run batches MUST be repeated

11.5. A maximum of three freeze thaws during testing of repeat samples should be adhered otherwise a new sample should be requested.

11.6. Plasma separating labs and HIV Viral load testing labs must be following a program of QMS including documentation control, and review, temperatures and equipment calibration and daily maintenance charts reviews, Levy-Jennings chart review, Method validation, verification of Precision and Accuracy (when applicable), and staff yearly proficiency assessment. refer to Lab Specific QMS

11.7. Testing labs must be enrolled in the EQA for HIV Viral Load coordinated by MOH, and EQA with the ILB CDC Atlanta, and with VQA.

References:

Reference Number or Authors	Document Title
6.1	MOH National Policy for HIV Viral Load Testing Scale-Up In Kenya

Forms and Appendices:

Form or Appendix Number	Title
7.1	SOP Copy Control and Updating Log
7.2	Training Documentation Log for SOP Files
7.3	Virology Quality Assurance Program Quantitative testing for HIV testing guidelines
7.4	Remote login job aid
7.5	Sample collection SOP #
7.6	key messaging on viral Load result interpretation (Job aid)

Version Table:

Original: Title: **National HIV Viral Load Sample Chain of Custody SOP**	Dated:	SOP No.: **MOH VL 002**	No. Pages: 7
Version 1: Title: **National HIV Viral Load Sample Chain of Custody SOP**	Dated:	SOP No.: **MOH VL 002**	No. Pages:9
Version 2: Title:	Dated: June 09	SOP No.: **MOHVL 002**	No. Pages:
Version 3: Title:	Dated:	SOP No.:	No. Pages:
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Version 6: Title:	Dated:	SOP No.:	No. Pages:

Appendix

SOP Copy Control and Updating Log

DOCUMENT COPY CONTROL

DATE PRINTED: August 2019 No of copies: 11	
SOP DISTRIBUTION GUIDE	
COPY 1 of 10 **LAB QA OFFICE**	COPY 11 of 11 **NASCOP OFFICE**

By Initialing and dating below I understand and approve of the changes to the attached SOP.

SOP CHANGES		Changes Approval Initials/Date	
Date/Initials	Nature of Change	QA	Approving Authority
4/7/2019	Updated result interpretation Added 'missing sample' as a rejection criteria Changed the sample type preferred to plasma/whole blood **DBS is only allowed to designated facilities**		

Appendix

Training Documentation Log for SOP Files

Ministry of Health Viral Load Standard Operating Procedure	**COPY 1 OF 11**	SOP No: **MOH VL 003** Supersedes: Effective Date:01/08/2019
Title: **National HIV Viral Load Sample Chain of Custody SOP**		

This SOP has been read and understood by:

Date: DD-MM-YY	Printed Name OR Initials	Signature	Date: DD-MM-YY	Printed Name OR Initials	Signature