Ministry of Health

Standard Operating Procedures for HIV Viral Load Monitoring




September 2020

Version 1

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Foreword

The Department of HIV & AIDS (DHA) in the Ministry of Health (MOH), in conjunction with its stakeholders that included implementing partners, other units within the MOH and Civil Society Organizations (CSOs), under the umbrella of the "Civil Society Forum on HIV and Other Opportunistic Infections" embarked on a journey aimed at harmonizing different practices in HIV viral load monitoring among healthcare service providers in Malawi.

The goal of producing these Standard Operating Procedures (SOPs) was therefore targeted at fostering standardization across all levels of care to ensure HIV viral load monitoring remains a basic right offered to all people living with HIV (PLHIV) on lifelong antiretroviral therapy (ART) regardless of their location and place where they are accessing care.

These SOPs are designed to provide practical information to healthcare providers. They must be considered as supplementary and secondary to all guidelines issued by the MOH, including the Malawi Clinical Management of HIV in Children and Adults Guidelines and the Malawi HIV Testing Services (HTS) Guidelines.

These SOPs will be made available to all health facilities offering ART. All healthcare providers offering ART must utilize this manual to improve patient care by offering better and proven methods of patient education on viral load monitoring, screening, identification, testing, sample handling & transport and, most importantly, utilization of results.

The manual has eleven (11) SOPs in total. It also has all the materials used in the viral load program captured in the appendices for easy reference.

The Department wishes to acknowledge all persons and organizations that supported the development of these SOPs. In a special way, we wish to thank the Clinton Health Access Initiative (CHAI) for the technical and material support which made the production of this manual possible.

Sincerely,

Rose Nyirenda (Mrs)

Director, Department of HIV & AIDS, Malawi Ministry of Health

Acronyms

ART	Antiretroviral Therapy
ARVs	Antiretroviral Drugs
CSO	Civil Society Organization
DBS	Dried Blood Spot
DSD	Differentiated Service Delivery
DTG	Dolutegravir
EDS/EMR	Electronic Data System/Electronic Medical Records
HCW	Healthcare Worker
HDA	HIV Diagnostic Assistant
HIV	Human Immunodeficiency Virus
HSA	Health Surveillance Assistant
HTS	HIV Testing Services
HVL	High Viral Load
IAC/EAC	Intensive Adherence Counseling/Enhanced Adherence Counseling
LDL	Lower than the Detection Limit
LLV	Low-Level Viremia
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor
NRTI	Nucleoside Reverse Transcriptase Inhibitor
PI	Protease Inhibitor
PLHIV	People Living with HIV
POC	Point-of-Care
SOP	Standard Operating Procedure
TND	Threshold Not Detected
VL	Viral Load
VLFP	Viral Load Focal Person
VLT	Viral Load Testing

Definition of Terms

A. General

Adherence: This refers to a client's ability and motivation to follow a treatment plan.

Dose Adherence: Taking the correct amount of medication at the right time of day and at the right intervals. The average dose adherence is estimated from the client's verbal report of doses missed. Pill counts are used to emphasize the importance of adherence and to encourage an open discussion about adherence challenges and solutions. The ART adherence target is taking at least 95% of doses continuously. Adherence % is estimated and documented at each ART clinic visit.

Appointment Adherence: Returning to the ART clinic within +/- 2 days of the appointment date. The target is to ensure uninterrupted supply of ARVs and to follow the treatment monitoring schedule.

Antiretroviral therapy (ART): ART consists of the combination of 3 or more antiretroviral (ARV) drugs with complementing action to suppress HIV replication and stop disease progression. ART also prevents onward transmission of HIV.

Certified 2nd Line Provider: A nurse or clinician accredited by the Ministry of Health to prescribe 2nd line ART regimens in Malawi.

Dried Blood Spot (DBS) Sample: A defined small amount of blood is transferred via glass capillary from a finger prick (or toe/heel prick for infants) onto a special type of filter paper card. DBS do not require venipuncture which makes them safe and easy to conduct for HTS providers. After air drying in a rack, filter paper cards are cleanly wrapped and transported at normal temperature in envelopes to a central laboratory or point-of-care machine for testing. VL results from DBS samples cannot be used to accurately measure Low Level Viremia (usually below 839 copies/mL) due to the small amount of blood contained in the sample.

Intensive Adherence Counseling (IAC): This is a counseling approach offered to ART clients with detectable viral load results or (suspected) poor drug adherence. The aim of IAC is to conduct a structured exploration of adherence barriers and agree on specific strategies for improvement. This is also known as Enhanced Adherence Counseling (EAC).

Plasma Sample: This is a procedure used to collect blood plasma for testing. Plasma is produced when whole blood is collected in tubes that are treated with an anticoagulant. The blood does not clot in the plasma tube. The cells are removed by centrifugation. The supernatant, designated plasma, is carefully removed from the cell pellet using a Pasteur pipette. In this circumstance, blood plasma is collected for viral load testing.

Point-of-Care (POC): This generally refers to when a diagnostic test is done at or near the site of patient contact. Point-of-care testing offers reduced turn-around times, allowing for faster clinical decision-making and delivery of services.

Viral Load Test: A test to measures the number of HIV viral particles per milliliter of blood. The number of viral particles measured in the VL result indicates the efficacy of HIV treatment.

B. Viral Load Testing Types

Catch-Up Viral Load Testing: This is VL testing for clients who have previously missed a testing milestone.

Follow-Up Viral Load Testing: This is VL testing for clients with an initial detectable VL who have undergone at least one Intensive Adherence Counseling (IAC) session and are believed to have achieved good adherence to ART in the past 3 months.

Repeat Viral Load Testing: This is VL testing done after an initial sample was rejected by the testing laboratory or the result was declared as lost or missing

Routine Viral Load Testing: This is VL testing for routine monitoring of clients' ART success, with scheduling independent of adherence measures and based on ART duration milestones and time to previous sampling date.

Targeted Viral Load Testing: This is VL testing which is conducted when requested by a clinician to confirm suspected ART failure (clinical).

C. Viral Load Results

Detectable: A VL result greater than 200 copies/mL. This is inclusive of Low-Level Viremia (LLV) results (200-999 copies/mL) and Viremia 1000+ results (1000+ copies/mL).

Low Level Viremia (LLV): A VL result that is Detectable, but below a threshold of 1000 copies/mL (i.e. in the range between 200-999 copies/mL).

Suppressed: A VL result that is Undetectable or falls within the range of 0-199 copies/mL. Viral load suppression is defined as, literally, suppressing or reducing the function and replication of a virus. When discussing ART for HIV, a regimen is considered to be highly successful if it reduces a person's viral load to undetectable levels.

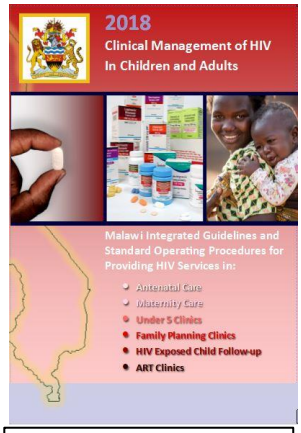
Undetectable: The number of viral copies is so low that it cannot be detected by the method/platform of VL testing used. Undetectable results are expressed as <LDL because they fall below the detection limit. For most modern platforms using plasma samples, the level of detection is 20-50 copies/mL. An undetectable viral load does not indicate elimination of the virus, but rather suppression of the virus below levels that can be quantified on the testing platform.

Viremia 1000+: Viral load results that are detectable and high (i.e. above a threshold of 1000 copies/mL).

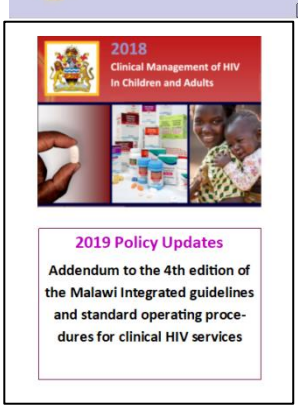
Overview of Key Viral Load Documents

National Policies

- **2018 Clinical Management of HIV in Children and Adults (4th edition, July 2018):** This is the most recent version of the national HIV treatment guidelines. This is the central document for clinical management of children and adults with HIV.



- **2019 Policy Updates to the 2018 Clinical Management of HIV in Children and Adults (April 2019):** This is a supplementary addendum which must be used side-by-side with the 2018 HIV treatment guidelines. This document introduced the new annual Viral Load policy.



Facility Registers

- **HIV Viral Load Sample Log**: This is the key national register used at the facility to record EVERY viral load sample that is collected (regardless of sample collection method or result).

- **High HIV Viral Load Register**: This register is used at the facility to record detectable (200+) viral load results. Detectable viral load results will be recorded in BOTH the HIV Viral Load Sample Log AND the High HIV Viral Load Register.
    - **<u>The High HIV Viral Load Register (Green cover) will be replaced with the forthcoming Detectable HIV Viral Load Register</u>**

DETECTABLE HIV Viral load Register

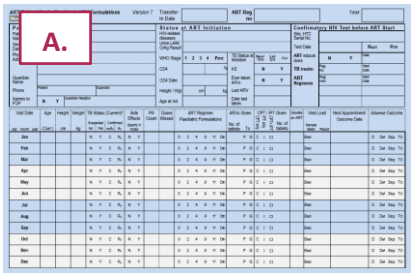
Client Forms

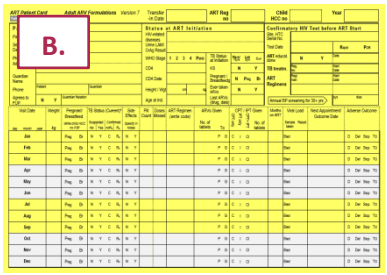
- **ART Mastercard:** The ART Mastercard (also known as the ART Patient Card) is the national document used to track a client's HIV status and visit history to the ART clinic. Each client on ART has a corresponding ART Mastercard. There are three different types of Mastercard, which are distinguished by their color:

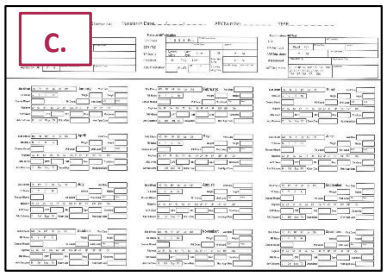
    A. **YELLOW ART Mastercard**: This is the standard ART Mastercard for clients on ***Adult*** formulations.

    B. **BLUE ART Mastercard**: This is the standard ART Mastercard for clients on ***Pediatric*** formulations.

    C. **WHITE ART Mastercard**: This is the standard ART Mastercard for sites with point-of-care (POC) machines. It is used for all clients at the site, regardless of whether they are on Adult or Pediatric formulations.







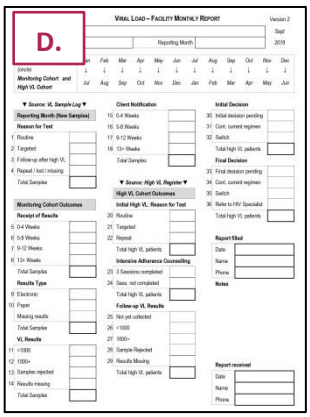
VL Forms

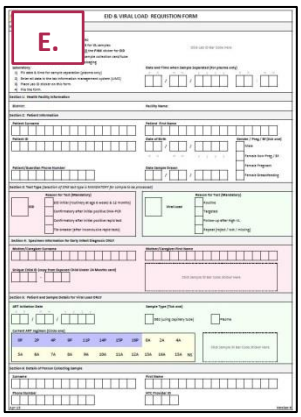
- There are also several important forms for reporting, monitoring and tracking Viral Load:

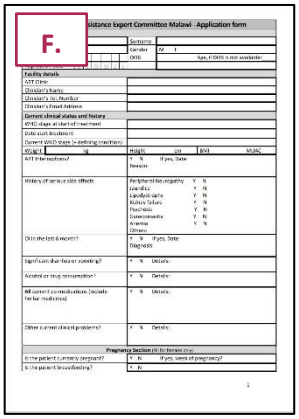
    D. **Viral Load Monthly Reporting Form**: At the end of each month, each facility completes this report to summarize data on the VL cohort.

    E. **VL/EID Laboratory Requisition Form**: This is filled out for every viral load sample sent for testing at the laboratory.

    F. **HIV Drug Resistance Application Form**: This is filled out and sent to the HIV Drug Resistance Expert Committee for every application for genotype testing.







Background and Introduction

Viral load testing (VLT) is the "gold standard" for monitoring the response to antiretroviral therapy (ART).

Malawi introduced VLT in 2011. Since then, Malawi has made strides in making the test accessible for all clients on ART, at all of the ART sites in the country. The number of molecular laboratory platforms with capacity to test VL has increased from 4 laboratories in 2011 to 10 laboratories housing 22 molecular testing platforms and 43 point-of-care (POC) sites in 2020.

As of the end of 2019, Malawi had over 830,000 people on ART. For these people, a suppressed VL is both lifesaving and stops the potential to transmit HIV, contributing to epidemic control. In order to extend accessibility of VLT, and align with World Health Organization (WHO) guidance, **Malawi now recommends annual VLT as the preferred monitoring tool for the confirmation of treatment success.**

Previously, Malawi had recommended VLT to be conducted once every two years. Therefore, the shift to annual VLT has doubled the number of VL tests done in the country. In 2018, 413,211 VL tests were done, which was a record high. However, this only represents 52% of the current national VLT need. This indicates that further concentrated stakeholder efforts, demand generation activities and implementation support are needed to facilitate a successful national scale-up.

As VLT scales up, it is also critically important that results utilization is supported and improved. In 2019, only 59% of clients with a detectable viral load result had completed their necessary Intensive Adherence Counseling (IAC) sessions. Further, only 38% of clients with an initial high VL result (1000+) had received a clinical decision at the end of a 6-month follow-up period (Department of HIV & AIDS, Ministry of Health, 2019).

Overall, there are persistent gaps that are still present across the viral load cascade. Key challenges include: long turn-around times of VL results from laboratories, poor patient literacy on VL monitoring, poor documentation in VL registers, low utilization of VL results to improve patient management and long delays in clinical decision-making from VL results.

With the development of these Standard Operating Procedures (SOPs) for HIV VL monitoring, the Ministry aims to provide a guiding tool and a handy reference to standardize ART providers' practices on VLT and result utilization in alignment with the existing HIV Clinical Management Guidelines in all the ART points in Malawi.

Document Structure

This document provides Standard Operating Procedures (SOPs) for each step associated with the provision of viral load services in Malawi:

This document does NOT provide information on diagnosing HIV disease, providing rapid HIV antibody testing, or treatment for HIV. Please refer to the appropriate guidelines for information concerning those topics.

Each SOP is structured according to:

A. The purpose of the section

B. The healthcare provider responsible for conducting the service

C. The healthcare provider responsible for providing oversight for the service

D. The supplies required to complete the service

E. The procedure for conducting each service

F. References to any Ministry of Health (MOH) guidelines that may provide specific guidance for the provision of that service

Overview of the Timeline for Viral Load Service Provision

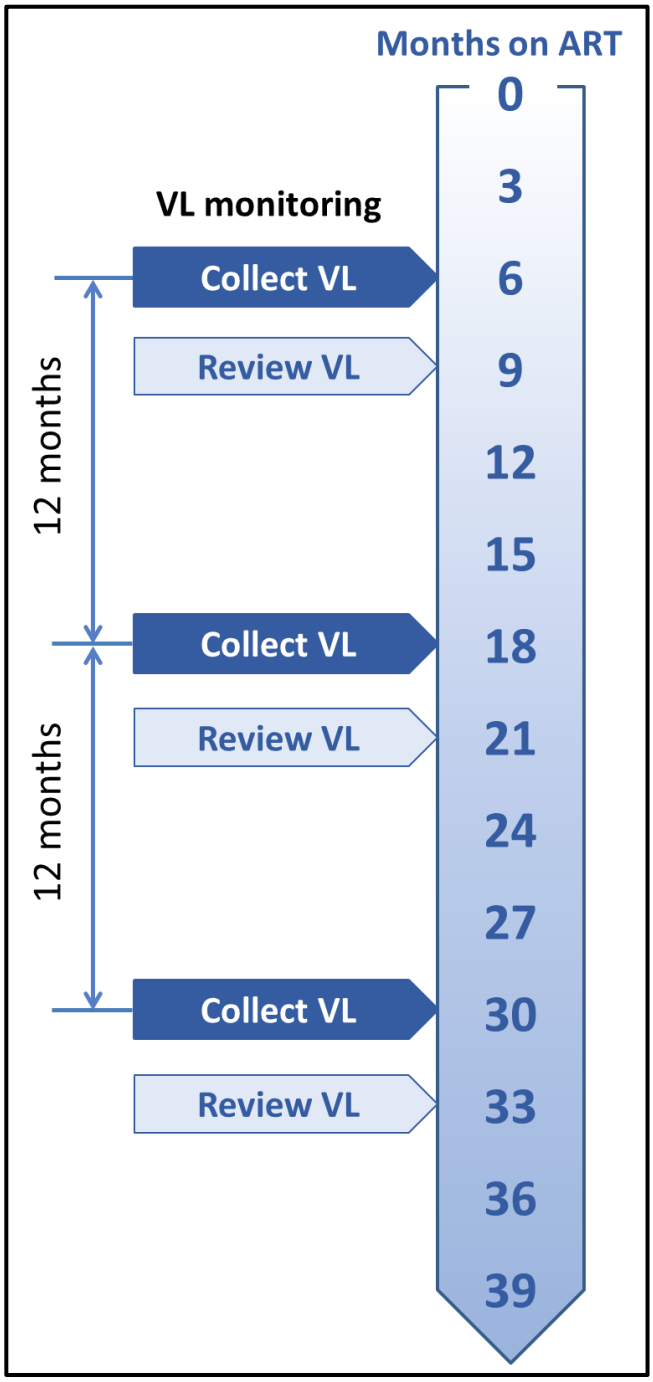
The provision of thorough and effective viral load services begins at the time of initial patient interaction. VL must be considered as an integral piece of the continuum of treatment and care. The VL monitoring schedule is shown in **Figure 1**. The schedule is designed to detect ART failure early while avoiding unnecessary testing.

As instructed in **Figure 1**, the first VL sample is collected **after a client has been on ART for 6 months**. If the client is adherent and the treatment is effective, the VL is expected to be undetectable at this time. Clients with an undetectable VL have a low risk of ART failure. Therefore, routine VL monitoring for these clients takes place **every 12 months** after the initial VL sample. Routine VL samples must be routinely collected when 11 months or more have elapsed since the last VL sample was collected.

If VL tests are missed, **catch-up** testing must be conducted at the next regular visit. Additional **targeted** VL tests outside of this schedule must be conducted if ART failure is suspected on clinical grounds.

Every time a VL test is conducted, the provider must explain the VL monitoring schedule to the client. Providers must emphasize the importance of routinely monitoring one's VL and ask the client to help remember when their next VL test is due.

Figure 1: Routine Viral Load Monitoring Schedule



Policy

This section provides an overview of the policies that shape and inform Malawi's viral load program.

Identification of Clients Eligible for Viral Load Testing

- All clients attending ART clinic must be screened for eligibility for viral load testing before any clinical consultations or receiving drug refills
- Identification for eligibility for viral load testing can be task shifted to other lay cadres
- Screening can be done using the following methods:
    - Pre-screening and flagging of the ART Mastercards before clinic day

    AND

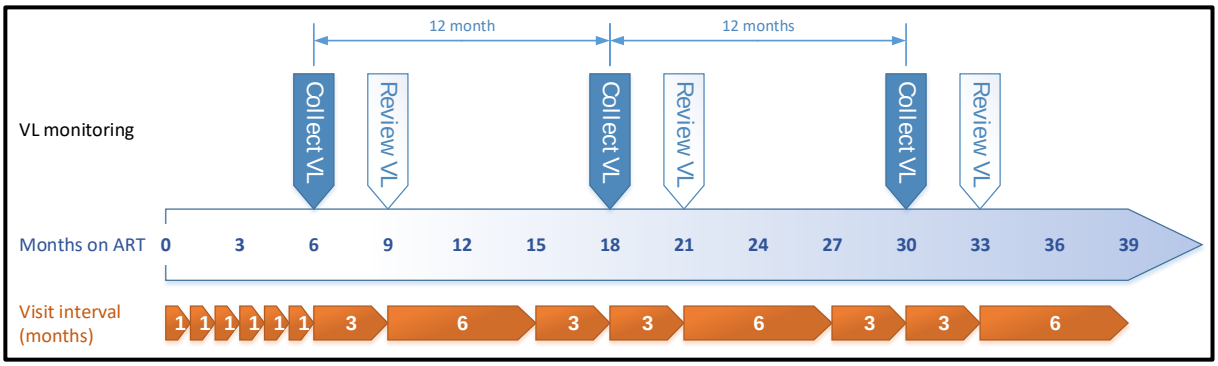
    - Screening of patient's file during clinic day in the waiting areas
        - ART providers can also check in the EMR system as they update the clinic visit, to determine the date the client is due for VL

Viral Load Testing Schedule

- The VL schedule is designed to detect ART failure early while avoiding unnecessary testing
- The first VL sample is collected after a client has been on ART for 6 months. If the client is adherent and the treatment is effective, the VL is expected to be undetectable at this time. Clients with an undetectable VL have a low risk of ART failure. Therefore, routine VL monitoring for these clients takes place every 12 months after the initial VL sample. Routine VL samples must be routinely collected when 11 months or more have elapsed since the last VL sample was collected.
- Routinely collect the next VL sample when 11 months or more have elapsed since the last VL sample was collected.
- Don't delay a scheduled/routine or targeted viral load sample collection because of (suspected) poor adherence.
- Ascertain good adherence in the last 3 months before taking the follow-up sample ("2nd VL") after a detectable VL.
- Delay collection of follow-up sample after IAC ONLY if poor adherence is confirmed and if the patient is still clinically stable. If the patient is not clinically stable, full clinical review and VL testing is indicated.
    - Poor adherence is indicated when fewer than 95% of dosages have been taken as prescribed

- A client's viral load testing schedule must be aligned with their ART drug dispensing schedule. See **Figure 2**, below, for the alignment of the VL monitoring schedule and 6 month dispensing.

Figure 2: Routine Viral Load Monitoring Schedule against 6-Month Dispensing Schedule



Acting on Viral Load Results

- The dissemination of HIV VL test results to clients or caregivers is an essential function of ART providers and/or any viral load trained providers (e.g. HDAs, HSAs or ART clerks)
- Dissemination and interpretation of detectable viral load results to clients is an essential responsibility of a certified ART provider
- Other supporting lay cadres (ART clerks, psychosocial counselors and patient support officers) that have received training on viral load services in the ART clinic may help sorting out the viral load results when they return from the laboratory

Overview of Responsibility at a Health Facility

The provision of VL testing services is now largely the responsibility of Clinicians, Nurses, HIV Testing Services Counselors, HIV Diagnostic Assistants (HDAs) and Health Surveillance Assistants (HSAs) in public health facilities. However, all healthcare providers present in a health facility are expected to contribute to the effective provision of VL testing services. Clinicians and/or Nurses in particular should assume a role of leadership.

Leadership Responsibilities

- At every facility, a designated individual must be assigned to lead the establishment and supervision of VL testing services. He or she will be known as the **Viral Load Focal Person (VLFP)**. Any staff member who is actively involved in VL service provision can be appointment as the VLFP.
- The VLFP will be responsible for the following tasks, among others:
    - Ensuring that quality assurance measures related to VL testing are conducted according to national guidelines.
    - Maintaining a roster that always ensures the presence of at least one trained VL provider in the facility, to ensure that DBS and plasma samples can be collected at any time.
    - Assessing the completeness of the HIV VL Sample Log, Detectable HIV VL Register, VL Requisition Forms and other VL related documentation on a weekly basis.
    - Ensuring that all samples are sent to the laboratory in a timely manner and that the test results are returned from the laboratory, correctly documented in the appropriate registers and client's ART Mastercard, and transmitted to the client.
    - Identifying performance gaps in the viral load cascade and intervening to resolve them.
    - Coordinating the provision of ongoing mentorship for current VL providers and building capacity of HSAs and HDAs who would like to gain the skills necessary to collect DBS samples.
    - Overseeing that follow-up efforts are completed by providers, with a special focus on ensuring that detectable VL results are returned to clients and caregivers as soon as the results are received at the facility.
    - Ensuring that those clients with detectable VL undergo Intensive Adherence Counseling (IAC) and that follow-up VL samples are collected after the sessions as indicated.
    - Ensuring the quality and integrity of VL data and assisting in the monthly collection of this data from the health facility.

Counseling Responsibilities

- Intensive adherence counseling (IAC) must only be conducted by healthcare providers who have received in-service or on-the-job training. These may include VL trained HSAs, HDAs and HTS Counselors.
    - Lay health workers like expert clients, psychosocial counsellors and other community health workers may also be assigned to provide IAC sessions if they have received the training.

Testing Responsibilities

- Viral load testing (VLT) must only be conducted by healthcare providers who have received the relevant training. These may include VL trained HSAs, HDAs and HTS Counselors.
- All VL testing procedures must be supervised by an experienced healthcare manager at the site.
- Healthcare providers who conduct any type of VL testing must be provided with regular on-site clinical mentoring to ensure the continued quality of these services.
- The completion of all logbooks and other paperwork associated with VL is an essential part of the provision of VL services.
    - **Qualifications for DBS Sample Collection**
        - The collection of DBS samples is generally the responsibility of VL-trained HSAs, HDAs and HTC counselors, although nurses or clinicians may be required to collect samples if another healthcare provider is not available.
        - HSAs and HDAs who have not received formal training in the collection of DBS samples may collect samples after receiving on-the-job training from a VL-trained HSA; this on-the-job training must be overseen by the VLFP.
    - **Qualifications for Plasma Sample Collection**
        - The collection of whole blood/plasma samples for VL is the responsibility of a healthcare provider trained to do venipuncture or phlebotomy.

SOP 1: Client Education and Demand Creation for Viral Load Testing

Purpose

To provide guidance to healthcare providers on how to deliver educational messages to clients or their guardians/caregivers so that they understand the meaning and importance of VL testing and are empowered to request their VL test

Responsibility

- All healthcare providers working in ART clinics, especially those involved in conducting health talks
- Trained lay cadres supporting ART clinics

Oversight

- Viral Load Focal Person (VLFP)

Supplies

- Job aide on key VL education messages (included in **Appendix II: Viral Load Key Messages**)

Procedure

- Support patients to be empowered to request for a VL test and understand the result.
- Aim to provide VL education messages at every opportunity within the clinic setting. Such opportunities include, but are not limited to:
    a. Routine health talks
        - This can apply to either individual health talks or group health talks
        - This is especially emphasized on ART clinic days
    b. During routine pre-ART counseling at initiation
    c. Before collection of blood sample for routine VL testing
    d. At IAC sessions for unsuppressed clients
    e. During psychosocial support group meetings

- Use the following educative materials to draw patient's attention (All of these materials should be translated into local languages):
    a. Leaflets
    b. Posters in waiting areas, consultation rooms and laboratories with simple messages encouraging the patient to request a VL test
    c. Other promotional materials
- Conduct patient education at community-level utilizing the following recommendations:
    - People living with HIV (PLHIV) and Civil Society Organizations (CSOs) have long been recognized for their positive role in the HIV response through their activities in mobilization, raising awareness and advocacy
    - Community awareness activities can be done together with partner institutions including CSOs working with/for PLHIV groupings such as:
        - Support groups
        - PLHIV network organizations
    - Explain to every patient the VL schedule as part of the routine counseling when enrolling clients on ART treatment, during health education sessions, and at every other opportunity:
        - Ask clients to keep track of their routine VL testing schedule (milestone and intervals)
        - Encourage clients to demand/request for a VL test when they have reached the routine testing milestones
            - Explain (example): "You had your viral load drawn in November. Therefore, every November ASK your provider for your viral load test to be done."

Further Information

1. VL Key Messages, included in **Appendix II: Viral Load Key Messages** on **page 53**

SOP 2: Identification of Clients Eligible for Routine, Catch-Up, Targeted, Repeat and Follow-Up Viral Load Testing

Purpose

- To provide guidance to healthcare providers on how to identify clients eligible for viral load testing

Responsibility

- Healthcare providers working in ART clinics
- Trained lay cadres supporting ART clinics

Oversight

- Viral Load Focal Person (VLFP)

Supplies

- Client's Health Passport Book
- Client's ART Mastercard
- Electronic Medical Records (EMR) e.g. eMastercard

Procedure

- Identify clients eligible for VL before clinical consultation through the following methods:

1. **Pre-Screening Prior to Client Visit**

    a. **Pre-Screening of Paper-Based Patient Files**

        - ART clinic staff must pre-screen the ART Mastercard for VL sample collection eligibility by flagging those that need a viral load test so that the next time the patient comes for ART refill they are already flagged.
        - Pre-screening of eligible clients for VL testing can be task-shifted to other lay cadres like HDAs, Expert Clients, and data clerks with on-the-job training.
        - Based on the screening, flag all eligible ART Mastercards with "VL Due."
        - Pre-screened eligible clients must be advised to remind the clinical provider that they were screened eligible by the lay cadres.
        - Remove the "VL Due" flag after the VL sample has been collected.

2. **Screening within ART Clinic Patient Waiting Areas**

   a. **Screening of Paper-Based Patient Files**

   - Within ART clinic patient waiting areas, ART providers or trained lay cadres must review Client Health Passport Books and Client ART Mastercards to identify those due for viral load testing.
   - Check with the patient if they have not recently had a VL test. If they report they have had one, but do not have documentation, crosscheck with the VL sample log. If documentation is not available, send the client for a new sample collection.
   - Review the date of the last VL sample recorded in the 'viral load column' of the client ART Mastercard. **If the VL test result is not returned within 3 months (sample lost, rejected or declared missing), then the client must be sent for a new sample**.

   b. **Screening of Electronic-Based Patient Files**

   - For sites using Electronic Medical Records (EMR), a pop-up message may appear for every client due for VL testing, as shown in **Figure 3**.
   - Always double-check the date of last VL test for clients in EMR in case of an error with the pop-up reminder!
   - Determine eligibility based on the schedule.

Figure 3: Examples of an EMR Reminder for a Client's Viral Load Test

- A schedule for when to do viral load testing is shown below, for each viral load test type:

    a. **ROUTINE**

        - VL is done for all clients at 6 months after initiation and every 1-year interval from the date the last VL test sample was drawn.

    b. **CATCH-UP**

        - For clients who have missed a VL testing milestone, a catch-up VL sample must be collected at the next regular appointment.

        - Thereafter, revert to the regular 1-year interval-based testing schedule.

    c. **REPEAT**

        - For clients whose first VL test was declared as rejected/missing/lost. **TARGETED**

        - VL testing done outside of the routine schedule is conducted when a provider/clinician suspects ART treatment failure.

        - Patients with clinically suspected treatment failure AND good adherence in the last 3 months must have a targeted VL test drawn.

    d. **FOLLOW-UP**

        - A client is eligible for follow-up testing if the client's last routine VL result was detectable

            - AND the client has received at least one IAC session

            - AND adherence is good as reported by the patient and as indicated by pill counts (>95% of dosages taken)

            - AND 3 months have elapsed since the client's first IAC session (**This requirement is waived if the patient becomes clinically unstable before the end of 3 months. If this happens, the patient must receive full clinical review and immediate follow-up VL testing**).

        - While clients can be offered monthly IAC sessions, clients are eligible for a follow-up VL test if at least one IAC session is completed. **Failure to complete more than one IAC session must NOT prevent a patient from receiving a follow-up VL test.**

        - Refer all clients who meet the above criteria on the clinic day for VL sample collection to the designated VL provider.

Further Information

1. 2018 Malawi Clinical Management of HIV in Children and Adults

2. 2019 Guideline Addendum to 2018 Clinical Guidelines

SOP 3: Viral Load Testing Documentation

Purpose

- To support monitoring of uptake and coverage of viral load (VL) services in Malawi
- To encourage proper documentation of viral load testing in order to track and monitor appropriate and timely testing and results delivery to the client, as well as to inform clinical decision-making

Responsibility

- Clinicians, nurses, midwives, HTS Counselors, HDAs, HSAs and lay cadres in all facilities providing VLT services

Oversight

- Viral Load Focal Person (VLFP)

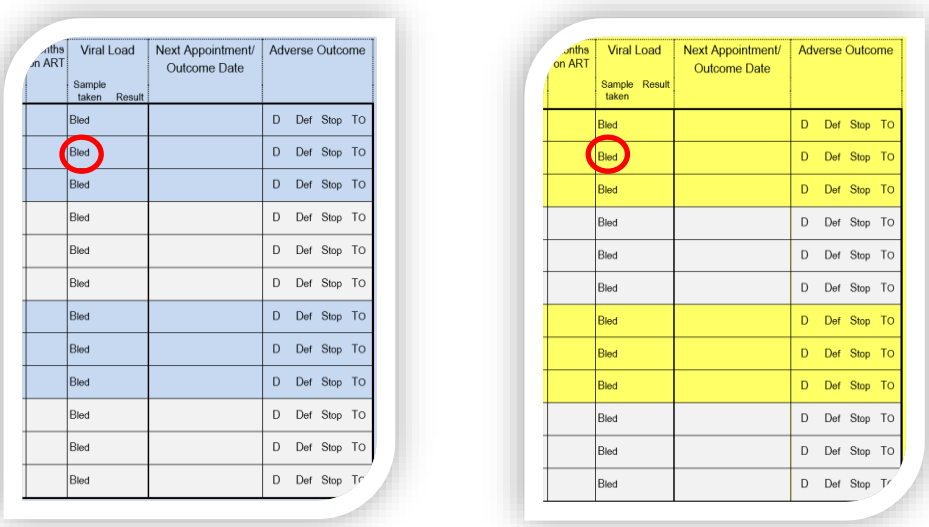
Supplies

- Client's Health Passport Book
- Client's ART Mastercard
- HIV Viral Load Sample Log
- EID/VL Laboratory Requisition Form

Procedure

- Ensure that clients are aware of the privacy rights of their personal and medical information
    - Access to client's records will only be available to healthcare providers who are directly involved in the client's care and only relevant medical information will be shared.
    - All documents related to VL testing should be located within the HIV care clinic. Keep the documents in a locked room/ cabinet when not in use to prevent unauthorized access.
- When a new VL sample is taken, enter the information in the following places:
    1. **Client's Health Passport Book**: In the next available page of the health passport, record the date of the VL sample collection.
    2. **Client's ART Mastercard**: Circle "Bled" at the corresponding date on the Mastercard, as shown in **Figure 4** below, and record the date of the client's next appointment.
    3. **HIV Viral Load Sample Log**: Fill in the client's VL information in the sample log
    4. **EID/VL Laboratory Requisition Form**: Fill in the client's sample details on the form

Figure 4: ART Mastercard Reporting of New Viral Load Samples



...nths on ART	Viral Load Sample taken	Viral Load Result	Next Appointment/ Outcome Date	Adverse Outcome
	Bled			D Def Stop TO
	Bled			D Def Stop TO
	Bled			D Def Stop TO
	Bled			D Def Stop TO
	Bled			D Def Stop TO
	Bled			D Def Stop TO
	Bled			D Def Stop TO
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...nths on ART	Viral Load Sample taken	Viral Load Result	Next Appointment/ Outcome Date	Adverse Outcome
	Bled			D Def Stop TO
	Bled			D Def Stop TO
	Bled			D Def Stop TO
	Bled			D Def Stop TO
	Bled			D Def Stop TO
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	Bled			D Def Stop Tr

Further Information

1. 2018 Malawi Clinical Management of HIV in Children and Adults
2. 2019 Guideline Addendum to 2018 Clinical Guidelines

SOP 4: Preparation and Collection of Dry Blood Spot (DBS) Samples for Viral Load Testing

Purpose

- To provide guidance to healthcare providers on how to collect and prepare DBS specimens suitable for viral load testing

Responsibility

- Trained HDAs, HTS Counselors and Nurses/Clinicians

Oversight

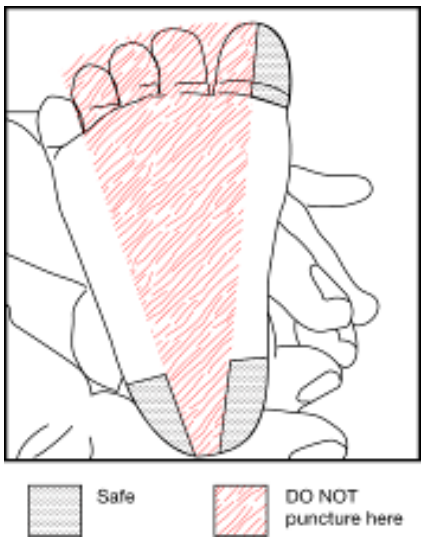
- The Viral Load Focal Person (VLFP) is not required to be present at the time of sample collection, but is responsible for ensuring that HDAs, HTS Counselors and nurses/clinicians are confident in collecting DBS samples.

Supplies

- Client's ART Mastercard
- HIV Viral Load Sample Log
- EID/VL Laboratory Requisition Form
- DBS bundle, which includes:
    - DBS card (Filter paper) x 1
    - Capillary Tube x 1
    - Gauze x 1
    - Zip-lock bags x 2
    - Desiccant packs x 3
    - Drying Racks x 1
    - Alcohol swab x 1
    - Lancet x 1
    - Powder-free gloves (pair) x 1
- 70 uL EDTA Capillary tube x 1
- Permanent marker to label the bag
- Large envelope
- Infectious and non-infectious waste bins
- Sharps container

Procedure

1. **Prepare for the Heel, Toe or Finger-Prick Procedure**



   a. Ensure that the procedure is conducted at a separate place from EID sample collection to avoid cross-contamination of samples.

   b. Fill in the client and sample details in the ART Mastercard, HIV Viral Load Sample Log, Laboratory Requisition Form, and specimen labels as required according to specific test procedure.

   c. Clearly label each card with ID number and date

2. **Chose the Puncture Site (According to Age)**

   a. **Infants 5 to 9 months**: Prick the heel or the lateral aspect of the big toe. Fingers and small toes should still be avoided because of the risk of hitting bone.

   b. **Adults, Infants and children over 10 months**: Prick the finger. The best finger is the ring (fourth) finger of the left hand as this finger is typically the least used by the patient. Select the lateral side of the fingertip. Do not stick the very end of the finger where the bone is close to the skin. The thumb is not recommended because it is the most painful.

3. **Prepare the Patient (According to Age)**

   a. **For Children, show the caregiver how to hold the child for the procedure**

      - **Children less than 2 years of age**: Ask the caregiver to sit holding the baby in an upright position against his/her chest. Position the infant with his foot hanging downward to increase venous pressure and thereby help the blood flow more easily.

      - **Children 2 years old or greater**: The child may sit on his /her own or on the caregiver's lap. Have the child rest her hand on a horizontal surface such as a counter, table or desk.

   b. **For Adults, ask them to sit and be comfortable**

4. **Prepare the Puncture Site**

    a. Assure puncture site is clean; it can be washed with soap and clean water.

    b. Warm the site to increase blood supply. For children, the caregiver can do this by holding the child's hand or foot and rubbing gently.

    c. Wash hands and put on powder-free gloves.

    d. Clean the puncture site (fingertip or foot) with alcohol. Start in the middle and work outward to prevent contaminating the area. Allow the area to dry without fanning.

Figure 5: Sample Collection Using the Toe-Prick Method

5. **Collect the Specimen**

    a. Hold the client's finger (or foot for infants)

    b. Firmly puncture the site off center with a new sterile 2 mm lancet. The puncture should be one continuous, deliberate motion at an angle slightly less than 90 degrees.

    c. Allow a first large blood drop to form and wipe it away with a dry, sterile gauze pad.

    d. Allow a second, large blood drop to form. Blood may flow best if the finger is held lower than the elbow or, if collecting from the heel or toe, the child must be held upright with the foot hanging down.

        - If blood flow diminishes, wipe away the congealed blood with a sterile gauze pad and gently massage or apply pressure to the whole arm and hand for both children and adults (or lower leg and foot for infants).

        - It is important to avoid squeezing or milking the area directly around the puncture site. Milking the site may contaminate the blood specimen resulting in an invalid specimen.

        - If the puncture is still not bleeding after applying pressure, a second puncture is required. The second puncture can be taken from the other hand or from a different, safe part of the same hand (or foot for infants).

e. Allow the drop of blood to lightly touch the circle on the DBS card, allowing the blood to completely fill the pre-printed circle by natural flow. The blood should be drawn onto the filter paper card.

   - Apply blood to 1 side of the filter paper card only.
   - Repeat this procedure to fill the remaining circles with blood.
   - Please ensure that all circles are completed. Failure to complete all circles will result in the sample being rejected from the laboratory.

f. When all 5 of the circles have been filled, wipe excess blood from the client's hand or infant's foot and apply gentle pressure to the wound with gauze pad, discarding gauze in a bin after use.

g. Place the filter paper card in a drying rack or place it flat on a clean dry surface and allow to dry for at least 4 hours or overnight.

6. **Method for DBS Creation Using Capillary Tube**

a. Wipe out the first drop of blood from the puncture site before collecting the specimen.

b. Allow a large drop of blood to collect.

c. Using the 70µL EDTA capillary tube supplied, touch the longer section to the drop of blood that formed on the patient. The blood will naturally draw into the tube. Fill with blood up to the mark.

d. Lightly touch the end of the capillary tube to the circle on the DBS card to fill the entire circle with blood, allowing the blood to soak through and completely fill the pre-printed circle by natural flow. The blood is drawn onto the filter paper card by capillary action.

e. Apply blood to 1 side of the filter paper card only.

f. Repeat this procedure to fill the remaining circles with blood.

g. Use the same capillary tube to collect the remaining 4 drops of blood, filling the capillary tube to the line each time.

h. Please ensure that all circles are completed. Failure to complete all circles will result in the sample being rejected from the laboratory.

i. When all 5 of the circles have been filled, wipe excess blood from the client's hand or infant's foot and apply gentle pressure to the wound with gauze pad, discarding gauze in a bin after use.

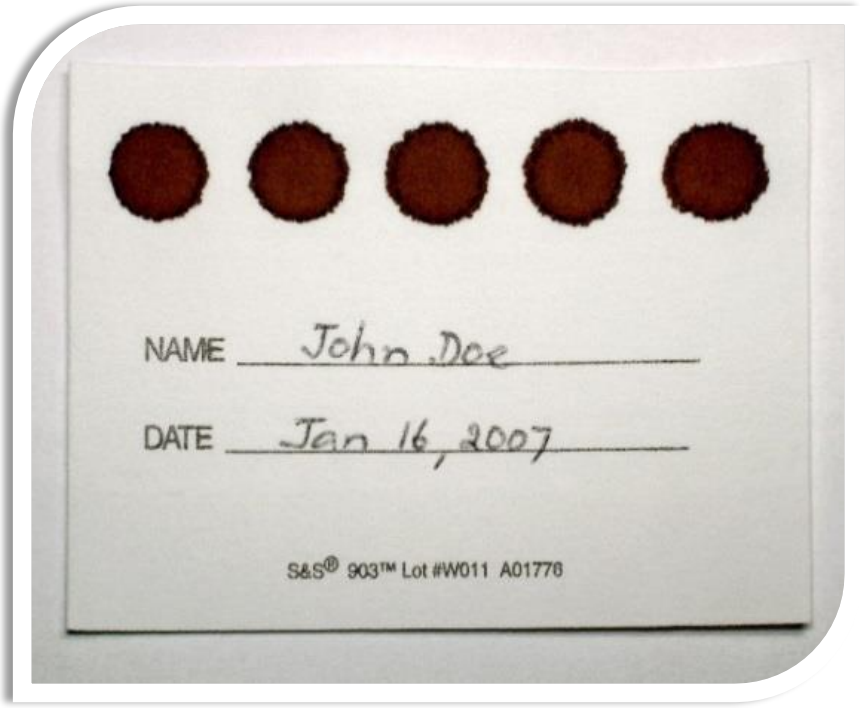
j. Place the filter paper card in a drying rack or place it flat on a clean dry surface and allow to dry for at least 4 hours or overnight.

Figure 6: Procedure for Toe-Prick Sample Collection Using Capillary Tube

- Features of acceptable DBS samples include:
    - Five circles completely filled with blood.
    - The DBS card is completely and accurately labeled.
    - The laboratory requisition form is complete and ready to accompany the sample to the laboratory.

ACCEPTABLE: The laboratory can process these DBS cards and repeat samples will not be required to obtain a VL result. See **Figure 7**, below, for an example of an acceptable DBS card.

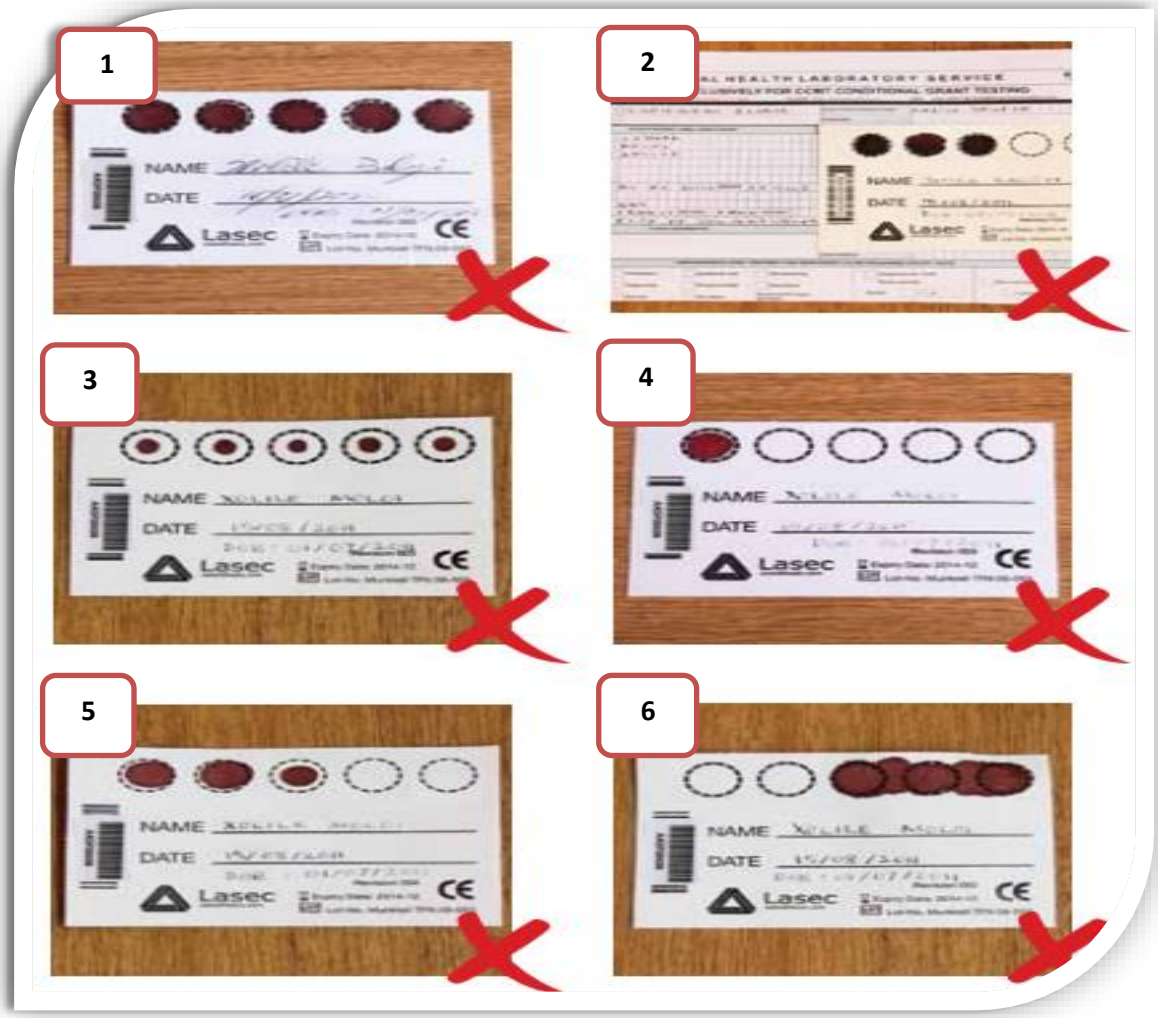
Figure 7: Example of an ACCEPTABLE DBS Card



- Features of unacceptable DBS samples include:
    - Filling fewer than 5 circles with blood
    - Not filling each circle completely with blood
    - Incomplete, inaccurate or ineligible completion of the DBS card
    - Incomplete or unavailable laboratory requisition form

UNACCEPTABLE: The laboratory cannot process these DBS cards. Repeat samples will be required to obtain a VL result. See **Figure 8**, below, for examples of unacceptable DBS cards:

Figure 8: Examples of UNACCEPTABLE DBS Cards



- **Picture 1**: Patient details on DBS card are not legible
- **Picture 2**: Patient details on DBS card and request form do not match
- **Picture 3**: Insufficient sample for processing
- **Picture 4**: Blood filled only on 1 circle
- **Picture 5**: 1 circle is filled with insufficient sample and 2 circles are empty
- **Picture 6**: Card only has 3 circles filled and they are outside the pre-printed circle

7. **Completion of documentation at the time of DBS collection**

    a. After specimen collection is completed, record the test and the date of the test in the following places:

        - Client's ART Mastercard
        - Client's Health Passport Book
        - HIV VL Sample Log
        - DBS Card
        - EID/VL Laboratory Requisition Form

    b. Check that the filter paper card and the laboratory requisition form are accurately completed.

    c. Add the specimen information to the courier's sample logbook. The courier's logbook allows tracking of specimens transported to the laboratory and results returned from the laboratory.

    d. Provide a follow-up appointment for the client and/or caregiver to return for the rest results. Collect up-to-date contact information (Phone number, address) so that you can contact the family if needed. Counsel the clients and/or caregiver to promptly return/bring the child for evaluation if there are any signs of illness.

Further Information

1. 2018 Malawi Clinical Management of HIV in Children and Adults
2. 2019 Guideline Addendum to 2018 Clinical Guidelines

SOP 5: Preparation and Collection of Whole Blood/Plasma Samples for Viral Load Testing

Purpose

- To provide guidance to healthcare providers on how to collect blood plasma for VL testing

Responsibility

- Healthcare providers trained in venipuncture for blood collection

Oversight

- The Viral Load Focal Person (VLFP) is not required to be present at the time of sample collection but is responsible for ensuring that healthcare providers are confident in collecting plasma samples.

Supplies

- EDTA tube x 1
- Gauze x 1
- Alcohol swab x 1
- Powder-free gloves (pair) x 1
- Vacutainer needle x 1
- Vacutainer holder
- Permanent marker to label bag
- Requisition form
- VL stickers
- Barcode stickers

Procedure

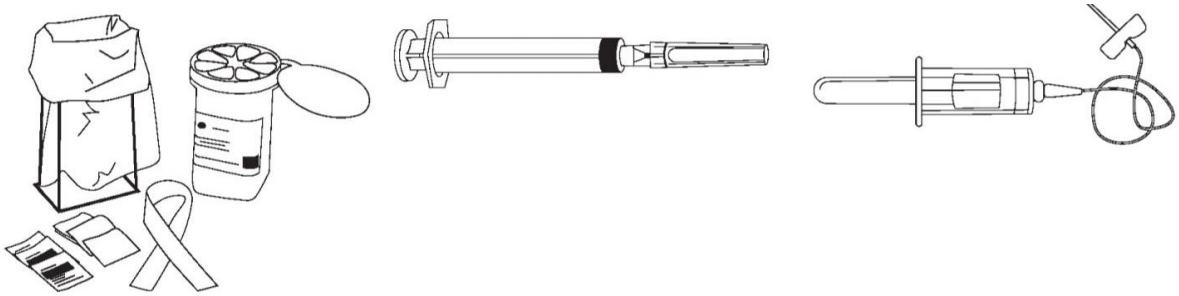
- Whole blood/Plasma sample collection is usually only done at sites where the molecular laboratory and/or point-of-care device is located within or nearby the facility. This is because of the complexity of the sample storage and transportation.

- Targeted viral testing using whole blood/plasma sample will be processed at a point-of-care (POC) machine if available. **All routine VL testing samples must be sent to the conventional laboratory and only targeted VL samples are eligible for testing on POC machines.**

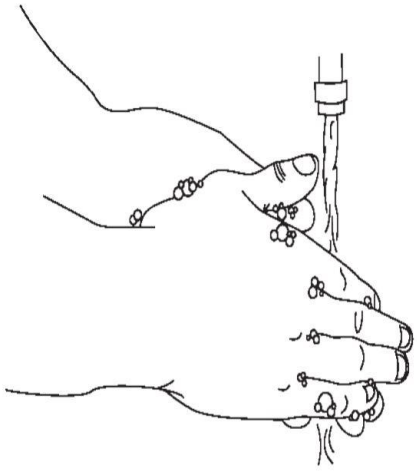
- Whole blood/plasma samples need to be processed within 24 hours from the sample collection.

- Whole blood/plasma specimen is collected by doing venipuncture, following the steps detailed in **Figure 9**.

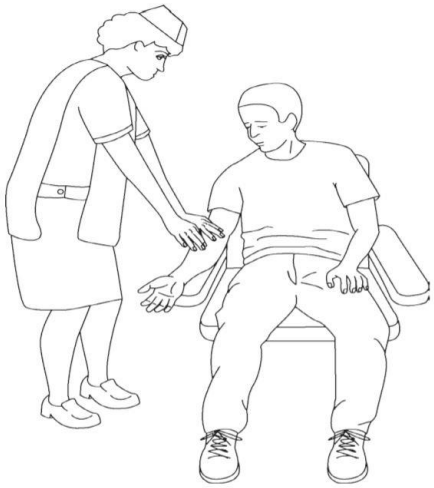
Figure 9: Venipuncture in Adults*



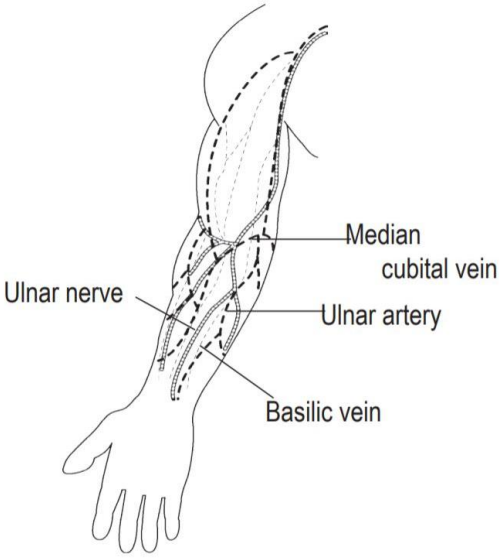
1. Assemble equipment and include needle and syringe or vacuum tube, depending on which is to be used.



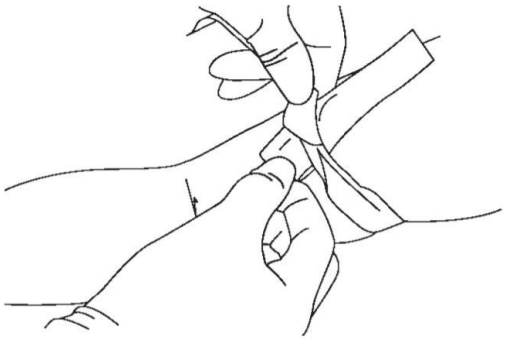
2. Perform hand hygiene (if using soap and water, dry hands with single-use towels).



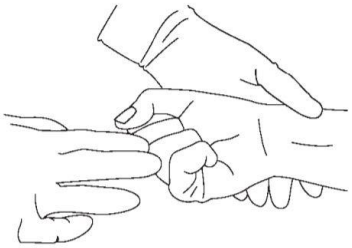
3. Identify and prepare the patient



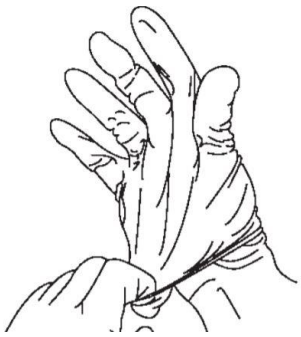
4. Select the site, preferably at the antecubital area (i.e. the bend of the elbow). Warming the arm with a hot pack, or hanging the hand down may make it easier to see the veins. Palpate the area to locate the anatomic landmarks. DO NOT touch the site once alcohol or other antiseptic has been applied.



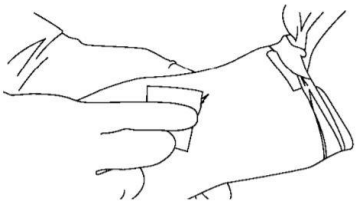
5. Apply a tourniquet, about 4—5 finger widths above the selected venipuncture site.



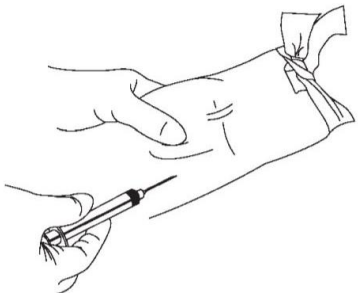
6. Ask the patient to form a fist so that the veins are more prominent.



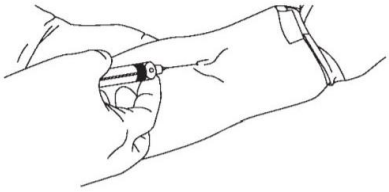
7. Put on well-fitting, non-sterile gloves.



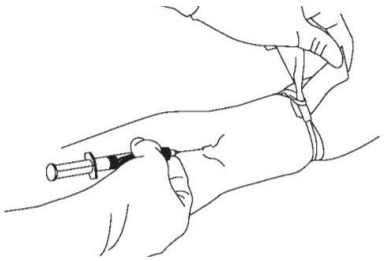
8. Disinfect the site using 70% isopropyl alcohol for 30 seconds and allow to dry completely (30 seconds).



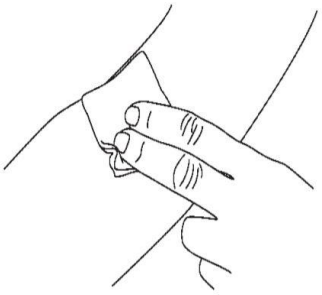
9. Anchor the vein by holding the patient's arm and placing a thumb BELOW the venipuncture site.



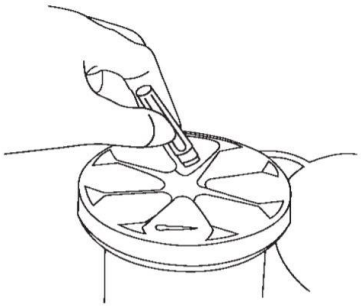
10. Enter the vein swiftly at a 30 degree angle.



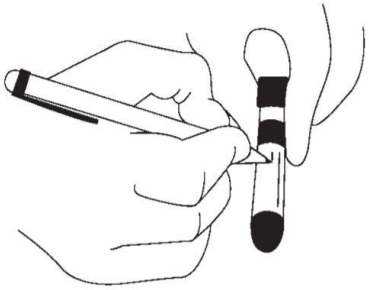
11. Once sufficient blood has been collected, release the tourniquet BEFORE withdrawing the needle.



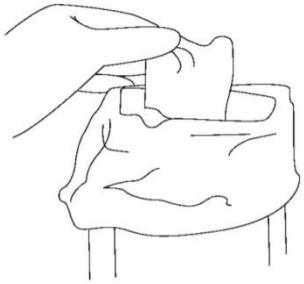
12. Withdraw the needle gently and then give the patient a clean gauze or dry cotton-wool ball to apply to the site with gentle pressure.



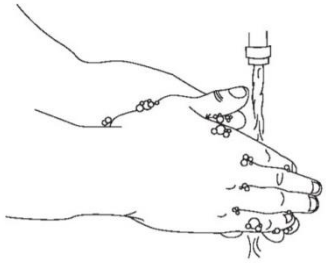
13. Discard the used needle and syringe or blood-sampling device into a puncture-resistant container.



14. Check the label and forms for accuracy.

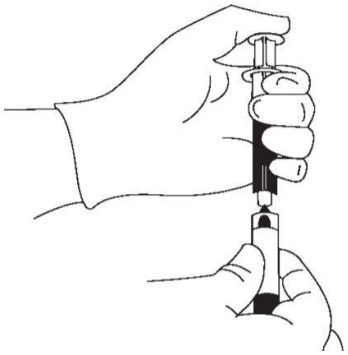


15. Discard sharps and broken glass into the sharps container. Place items that can drip blood or body fluids into the infectious waste.

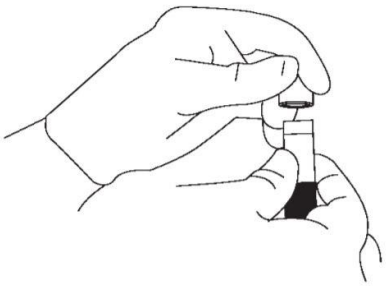


16. Remove gloves and place them in the general waste. Perform hand hygiene. If using soap and water, dry hands with single-use towels.

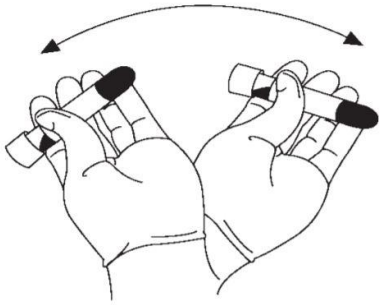
Figure 10: Filling Tubes*



1. If the tube does not have a rubber stopper, press the plunger in slowly to reduce haemolysis (this is safer than removing the needle).



2. Place the stopper in the tube.



3. Following laboratory instructions, invert the sample gently to mix the additives with the blood before dispatch.

These figures were adapted from the 2010 WHO Guidelines on Drawing Blood: Best Practices in Phlebotomy

- When a whole blood/plasma sample is collected, the following documentation must be completed:
    - After specimen collection is completed, record the test and the date of the test in the VL sample log, on the client's ART Mastercard by circling 'Bled' and on the client's health passport.
    - Check that the EDTA tube and the laboratory requisition form are accurately labelled.
    - Provide a follow-up appointment for the client to return for the test results. Record the next appointment date in the ART Mastercard and client's health passport. Collect up-to-date contact information (phone number, address) so that you can contact the family or guardian if needed.
- In order for a whole blood/plasma sample to be accepted, it must be collected, stored and labelled correctly.
    - Features of **ACCEPTED** whole blood plasma sample for VL testing:
        - Well labelled form and sample tube
        - No leaking or blood-stained tubes
        - Sufficient sample (>5mL)

- Features of **REJECTED** whole blood/plasma sample for VL testing:
    - Specimen collected in heparin or plain tubes
        - Heparin-containing tubes must not be used when collecting specimens for VLT because **heparin has been shown to inhibit PCR**
    - Clotted sample
    - Hemolysed sample
    - Insufficient sample (<5mL)
    - Sample and form mismatch
    - Lack of sufficient information on the sample or form.
    - Long stay at room temperature
    - Leaking sample due to broken tubes or unscrewed vials
    - Improperly labelled specimens

Further Information

1. 2018 Malawi Clinical Management of HIV in Children and Adults
2. Malawi EID SOPs version 1

SOP 6: Handling of Viral Load Samples (Drying, Packing, Storing)

Purpose

- To provide guidance to healthcare providers on how to dry, pack and store DBS specimens for viral load testing
- To provide guidance to healthcare providers on how to handle samples for POC & conventional lab testing

Responsibility

- Healthcare provider collecting and creating DBS specimen

Oversight

- The Viral Load Focal Person (VLFP) is not required to be present at the time of sample collection but is responsible for ensuring that healthcare providers are trained and confident in drying and storing DBS samples.

Supplies

- For DBS
    - DBS card (Filter paper) x1
    - Ziploc bags x2
    - Desiccant packs x3
    - Drying racks
    - Permanent marker to label bag
- For Plasma
    - EDTA Tubes
    - Cooler boxes
    - Refrigerator

Procedure

1. **Drying DBS Samples**
   - DBS cards for EID and VL must be arranged on separate racks/areas to avoid contamination.
   - Filter paper cards with DBS specimens must be put in a drying rack or placed flat on a clean, dry, non-absorbent surface and allowed to air dry for overnight or at least 4 hours at room temperature in special circumstances. They must be placed away from direct heat and sunlight.

   - Keep the laboratory form with the drying filter paper card.
   - The filter paper card must not be dried near an open window because they need to be kept away from dust, insects and animals (e.g. mice), as well as direct sunlight, while drying.
   - The filter paper cards must not be heated or allowed to touch one another or other surfaces during the drying process.
   - Dry the filter paper completely before packing (overnight or at least 4 hours at room temperature in special circumstances).

2. **Packing DBS Samples**
   - Filter cards must be carefully packed for storage and shipment. Packages used to store filter paper cards must keep the specimens as dry as possible, particularly since humid conditions will accelerate degradation of the specimen. Once filter paper cards are completely dry, they must be stored according to the following steps:

      a. Remove each dry DBS card from the drying rack, one at a time
      b. Add Desiccants in each Ziploc bag containing a card to absorb moisture

c. Fold the ends of the glassine paper over each of the cards

d. Place cards into sealable plastic bags. The bags used for storage must be made of heavy-duty plastic and sealable to prevent moisture from entering

e. The number of filter paper cards that can fit into a bag will depend on the size of the bag used. Up to 5 filter paper cards can be put into 1 of the standard bags. Wrap each card individually and then batch multiple wrapped cards in a single card. The bag used must be just the right size to hold the cards. Bags that are too big allow the cards to move around inside risking cross-contamination

f. Remove air from the bag and seal

3. **Storing DBS Samples**

- Packaged filter paper cards must be kept cool and dry until they can be sent to the district laboratory. It is not necessary to refrigerate specimens.
- Place the plastic bag of filter paper cards, the laboratory requisition forms related to each specimen into a large, strong envelope. The outside of the envelope must be clearly labeled with the facility name and the date sent to the laboratory. Mark the bag "specimens for viral load testing."
- Now the VL testing sample is ready for transportation. Verify the following before transportation:

  a. Verify that each specimen has a laboratory requisition form.

  b. Check that each specimen is listed on the laboratory delivery checklist

4. **Handling Whole blood/Plasma Samples**

- Blood is put into a sterile 4ml EDTA tube (Heparin containing tubes must not be used when collecting specimens for VLT because heparin has been shown to inhibit PCR).
- Whole blood specimens collected in EDTA tubes can be kept between 2°C and 25°C for up to 24 hours before testing. If testing cannot be done within 24 hours of collection, the whole blood must be centrifuged at 800-1600 RPM for 20 minutes at room temperature to extract and separate the plasma.
- It is recommended that plasma be stored in 1.1 - 1.2 mL aliquots in sterile, 2.0 mL polypropylene screw-cap tubes. Plasma specimens may be stored at room temperature (25°C to 30°C) for up to 1 day, at 2°C to 8° C for 6 days, or frozen at -20°C to -80°C for up to 6 weeks.

Further Information

1. 2018 Malawi Clinical Management of HIV in Children and Adults
2. Malawi EID SOPs version 1

SOP 7: Transportation of Viral Load Samples for Testing

Purpose

- To outline expectations around the dispatch and transportation of VL samples for viral load testing

Responsibility

- Courier (e.g. Riders for Health)
- Healthcare providers
- Molecular laboratories
- DHOs/District Hospitals

Oversight

- The Viral Load Focal Person (VLFP) is responsible for coordinating the preparation of samples ready for transportation to molecular lab

Supplies

- DBS Samples
- Plasma Samples
    - Cooler boxes
    - Ice packs
- Laboratory requisition form

Procedure

- The Viral Load Focal Person (VLFP) must liaise with special courier regarding the schedule of sample transportation from the facility (e.g. Riders for Health)
- Health facilities must keep samples in a standardized location. This is to allow uninterrupted access to samples by courier.
- Transportation guidance for different sample types is detailed below:

1. **DBS Sample Transportation**

    - Specimens must be packed according to the agreed schedule with courier with all appropriate lab forms completed
    - DBS samples must be transported from the health facility to the assigned district hospital (hub) within 3 days of sample collection

- The district laboratory personnel must check all the samples from the health facilities for quality before being sent to the molecular laboratory
- Within 1-2 days, the district must log the samples in all appropriate registers (manual and electronic)
- Samples must be transported from the district hospital to the central laboratory at least once per week –coinciding with the collection of blood from blood bank –as well as via additional transport as available.
- It is the responsibility of the district lab personnel to ensure transportation of VL samples to the laboratory
- Central laboratory must log results the same day they are tested

2. **Whole blood/Plasma Sample Transportation**

- During transport, specimen tubes must be protected from mechanical damage, thermal shock and tampering. Blood specimens in transit must never be left unattended.
- Plasma may be transported at 2—8°C, however, once it has been frozen it is preferable to ship it frozen (the temperature it was frozen at should be maintained) as multiple freeze-thaw cycles can compromise specimen quality. If it is not feasible to transport frozen samples, the specimens must ALWAYS be packaged in cooler boxes with ice packs to maintain their integrity.
- Sites that have the capacity to collect venous blood through phlebotomy must transport the samples within four hours to the molecular laboratory for centrifugation and storage of the isolated plasma in -20 degrees Celsius freezers.
- In the event of an accidental spill, the sample transporter must manage the spill using standard protocols for biohazard management. For spills and any transportation delay, an incident report must be completed on the Specimen Tracking Form for quality assurance purposes.
- Results must be picked up from the assigned central laboratory by the district health office (preferably through the courier) at least once per week.
- Results must be collected by courier from the district hub to the health facility on the same day that subsequent samples are collected.

Further Information

1. Malawi National Sample Transport Guidelines

SOP 8: Methods of Viral Load Testing on Point-of-Care (POC) Platforms

Purpose

- To provide guidance to healthcare providers on how to conduct a VL test on point-of-care platform

Responsibility

- Trained HDAs, HTS Counselors and Nurses/Clinicians

Oversight

- Clinician in-charge
- Laboratory assistant/technician (if available)

Supplies

- EDTA tube x 1
- Gauze x 1
- Alcohol swab x 1
- Powder-free gloves (pair) x 1
- Vacutainer needle x 1
- Vacutainer holder
- Requisition form
- Cartridges

Procedure

- Point-of-care testing requires collection of a whole blood/Plasma sample.
- Only targeted viral testing using whole blood/plasma sample is currently recommended for testing on a point-of-care (POC) machine if available. **All routine & follow-up VL testing samples must be sent to the conventional laboratory.**
- Whole blood/plasma samples need to be processed within 24 hours from time of sample collection.
- Whole blood/plasma specimen is collected by doing venipuncture, following the steps detailed in **Figure 9**.
- When a whole blood/plasma sample is collected, the following documentation must be completed:

- After specimen collection is completed, record the test and the date of the test in the VL sample log, on the client's ART Mastercard by circling 'Bled' and on the client's health passport.
- Check that the EDTA tube and the laboratory requisition form are accurately labelled.

- For a whole blood/plasma sample to be accepted, it must be collected, stored and labelled correctly.
    - Refer to **SOP 5 (Page 29)** for features of an acceptable whole blood/plasma specimen

- **Actual running of a test on POC platform must only be conducted by trained personnel and following the manufacturer's instructions.**

SOP 9: Viral Load Test Result Delivery

Purpose

- To outline the process for delivering VL test results from the laboratory or point-of-care (POC) platform to the health facility
- To outline the process for documenting VL test results when they are received at the facility

Responsibility

- VL-trained HSA, HDA, Nurses who participate in VL
- Clinicians who provide test results to clients

Oversight

- Viral Load Focal Person (VLFP)

Supplies

- Client's Health Passport Book
- Client's ART Mastercard
- HIV Viral Load Sample Log
- Detectable HIV Viral Load Register

Procedure

- HIV viral load testing can be done either through conventional testing at molecular laboratory or on point-of-care (POC) platforms and VL results can be delivered either through paper-based systems or electronic-based systems

1. **Paper-based results delivery**

    a. **From molecular laboratories:** The majority of VL results will be delivered as paper-based results from the molecular laboratory. These results are delivered via courier (e.g. Riders for Health).

        - Results will be individual patient-based and are delivered to the facility as soon as the results are approved and ready at the laboratory
        - In addition to the individual VL paper-results, every first week of the month the laboratory will produce a **list of viral load summary results** of clients for each facility processed in the previous month. These are called **Monthly Viral Load Summary Sheets**. These summary sheets will be delivered to the facility by the same couriers as the individual VL

paper-results. These summary sheets do NOT replace the individual paper-results! They are meant to summarize the VL results to promote accountability in case any individual results were lost, misplaced or mis-documented.

b. **From point-of-care (POC) platforms**: VL results tested via POC will also be delivered as paper-based results from the POC location. These results will either be available on-site or delivered via courier (e.g. Riders for Health). Unlike the molecular laboratories which have longer processing times, POC results are printed immediately from the testing machines and delivered to the clinic for **same-day result delivery**.

2. **Electronic results delivery**

   a. **From molecular laboratories OR point-of-care platforms**: There are ongoing initiatives to deliver VL results electronically –either via **SMS** or via access to the **Laboratory Information Management System (LIMS)**. These efforts are starting to scale-up in selected districts and will be utilized where available.

- When ANY result is received at the facility (regardless of whether it was testing via molecular lab or POC or delivered via paper or electronic), it must be recorded immediately in the relevant registers and client forms:
  - **For all VL Results**
    - In the client ART Mastercard, in the "viral load result" column
    - In the HIV Viral Load Sample Log against the same sample ID as the ART Mastercard
    - In the Client's Health Passport book
  - **For High VL Results (>1000 copies/mL) <u>ONLY</u>**
    - Also document the result in the Detectable HIV Viral Load Register (*OR the High HIV Viral Load Sample Register if the Detectable HIV Viral Load Register is not available*)
  - **For Detectable Results (200 –1000 copies/mL) <u>ONLY</u>**
    - Also document the result in the Detectable HIV Viral Load Register (*OR the High HIV Viral Load Sample Register if the Detectable HIV Viral Load Register is not available*)

- **For sites that have EMR <u>ONLY</u>**
  - Also enter the result in the EMR system.
    - In the EMR, if the result is "<839 copies/mL," enter it as "839" if the system does not provide qualifiers (<, >, =)
    - In the EMR, if the result is "<40 copies/mL," enter it as "40" if the system does not provide qualifiers (<, >, =)

Further Information

1. 2018 Malawi Clinical Management of HIV in Children and Adults
2. 2019 Guideline Addendum to 2018 Clinical Guidelines

SOP 10: Interpretation and Acting on Viral Load Results

Purpose

- To outline the process of interpreting the viral load results
- To guide the healthcare providers in the management of clients with both suppressed & High Viral load results Low Level Viremia and Viremia 1000+, together also named as High Viral Load (HVL)
- To outline the process of disseminating HIV viral load results to clients and caregivers
- To outline expected follow-up of clients with Low Level Viremia and Viremia 1000+

Responsibility

- All ART providers
- Other lay cadres supporting (ART clerks, psychosocial counselors and patient support officers)

Oversight

- Clinician in-charge

Supplies

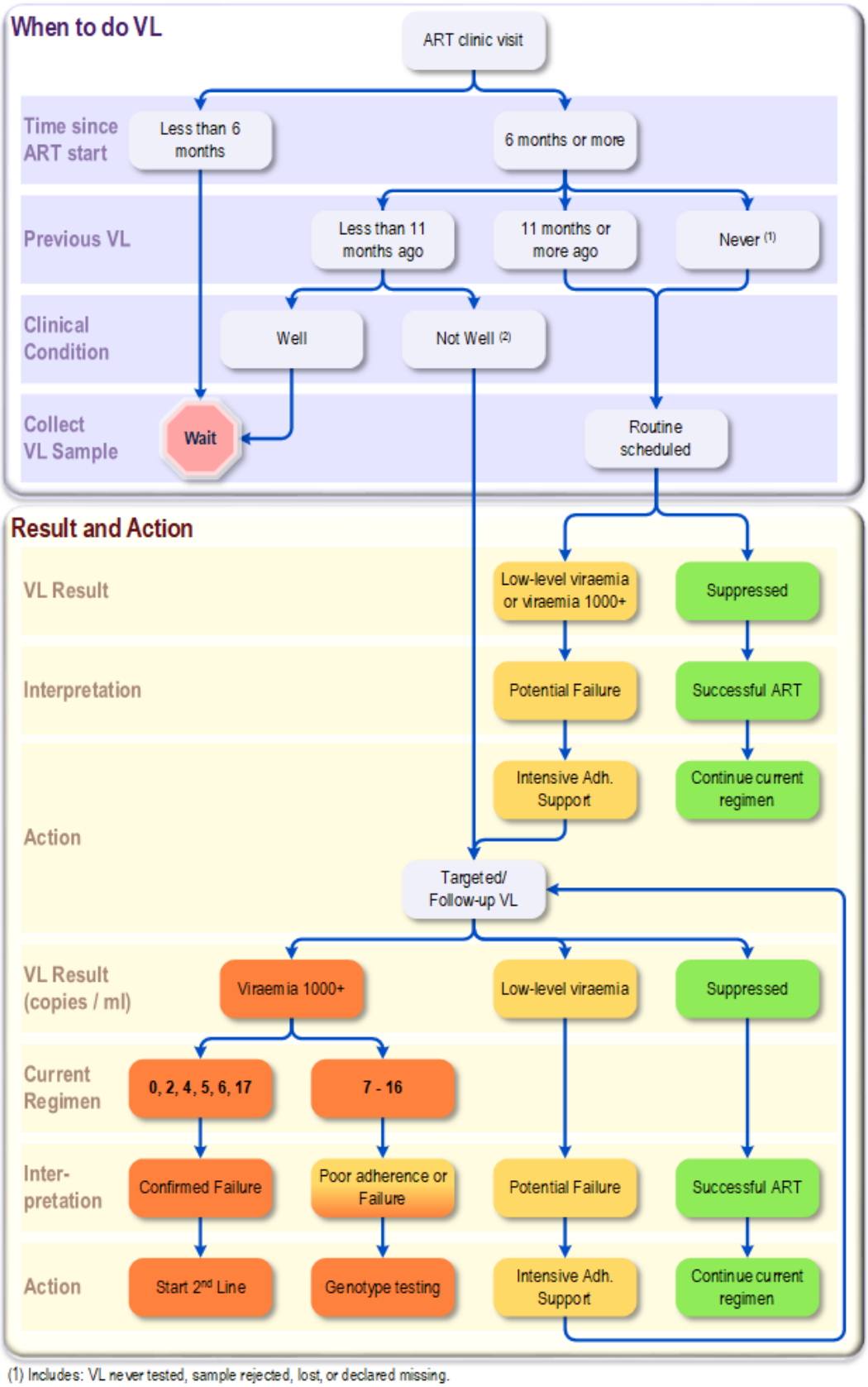
- Client's Health Passport Book [1]
- ART Mastercard
- HIV Viral Load Sample Log
- HIV High Viral Load Register
- Viral Load Test Results

Procedure

- The quick dissemination of HIV VL test results to clients or caregivers is an essential responsibility of ART providers and/or any viral load trained providers e.g. HDAs, HSAs or ART clerks
- Dissemination and interpretation of HVL results to clients is an essential responsibility of a certified ART provider
- Supporting lay cadres (ART clerks, psychosocial counselors and patient support officers) who have received training on viral load services in the ART clinic may help sorting out the viral load results when these return form the laboratory
- Use national guidelines (See Further Information below) and study **Figure 11** below

[1] All Viral load results and ARV treatment switches must be captured in the client's health passport always.

Figure 11: Indication, Interpretation and Action for Routine Scheduled and Targeted VL Testing



(1) Includes: VL never tested, sample rejected, lost, or declared missing.
(2) Any of the following: Significant unintended weight loss, failure to thrive, new / worsening HIV-related disease (suspected or confirmed)

- It is essential that all providers involved in VL monitoring know the categories of VL test results: Suppressed VL, Low Level Viremia and Viremia 1000+ (see page **5**)
- First determine which type of VL test was done:

    1. First routine VL
    2. Follow-up VL
    3. Targeted VL

Table 1: Interpreting and acting on VL results

	Result	Interpretation	Action	Next VL appointment
STEP 1: FIRST VL RESULT FROM ROUTINE VL MONITORING	**(Suppressed VL)** Plasma result of: • <LDL/<20/<40/<150 • any value 20-199 DBS result of: • <LDL	***Successful ART***	• Praise the patient, explain the meaning of suppressed viral load and emphasize the importance of continued good adherence • Ensure that the patient has no misconceptions: this result does not mean that the patient is cured from HIV • Continue the same ART regimen • Offer Multi-Month Dispensing if otherwise eligible	• 12 months after the most recent sampling date
	(Low Level Viremia) Plasma result of: • any value 200-999 DBS result of: • <400/<550/<839 • any value 400-999	***Potential ART failure***	• Potential treatment failure (drug resistance or poor adherence) • Actively communicate (Phone/Home visit) the result to the patient as soon as the result is received at the site. Call for an early appointment • Enter the result in the "Detectable Viral Load" register • Deliver one quality session of intensive adherence counseling (IAC) at the same visit when returning the result to the patient. Provide additional IAC sessions at 1-month intervals for patients with specific adherence problems. • Continue the same ART regimen/ **Give a regular 3-month appointment**.	• Collect a follow-up VL sample after 3 months of good adherence.
	(Viremia 1000+) Plasma or DBS result of: • >1000 copies/mL	***Potential treatment failure or poor adherence***	• Actively communicate (Phone/Home visit) the result to the patient as soon as the result is received at the site. Call for an early appointment • Enter the result in the "Detectable Viral Load" register • Deliver one quality session of intensive adherence counseling (IAC) at the same visit when returning the result to the patient. Provide additional IAC sessions at 1-month intervals for patients with specific adherence problems • Continue the same ART regimen/ Give a regular 3-month appointment	• Collect a follow-up VL sample after 3 months of good adherence

	Result	Interpretation	Action	Next VL appointment
STEP 2: FOLLOW-UP VL TEST RESULTS FROM ROUTINE MONITORING AND TARGETED VL RESULTS (INTERPRETATION IS SIMILAR)	**(Suppressed VL)** Plasma result of: • <LDL/<20/<40/<150 • any value 20-199 DBS result of: • <LDL	***Successful ART***[2] *(This patient has achieved re-suppression due to improved adherence!)*	• Praise the patient, explain the meaning of suppressed viral load and re-emphasize the importance of continued good adherence • Make sure that the patient has no misconceptions: this result does not mean that the patient is cured from HIV • Continue the patient on the same regimen • Offer 3-Month Dispensing if otherwise eligible	• Schedule the next routine VL after 12 months from the date of most recent sample collection
	(Low Level Viremia) Plasma result of: • any value 200-999 DBS result of: • <400/<550/<839 • any value 400-999	***Potential ART failure*** *(drug resistance or poor adherence or a drug interaction)*	• Actively communicate (Phone/Home visit) the result to the patient as soon as the result is received at the site. Call for an early appointment • Enter the result in the "Detectable Viral Load" register • Deliver one quality session of intensive adherence counseling (IAC) at the same visit when returning the result to the patient. Provide additional IAC sessions at 1-month intervals for patients with specific adherence problems. • Check if the patient uses other drugs that can reduce ARV drug levels (especially important for DTG and PIs). Consult expert if this is the case. • Continue same ART regimen/ **Give a regular 3-month appointment.**	• Collect a follow-up VL sample after 3 months of good adherence.

[2] For a targeted VL result this means that the clinical condition or low CD4 count that triggered the VL test does not appear to be related to Virological failure. Look for other causes of the clinical condition or low CD4 count and consider consultation by an experienced clinician

	(Viremia 1000+)
	Plasma or DBS result of:
	• >1000 copies/mL
		Potential or confirmed ART treatment failure *(BUT; it depends on which regimen the patient is taking)*	• Actively communicate (Phone/Home visit) the result to the patient as soon as the result is received at the site. Call for an early appointment
			• Enter the result in the "Detectable Viral Load" register
			• Check if the patient uses other medicines that can reduce ARV drug levels (especially important for DTG and PIs). Examples include anti-TB medicines; Rifampicin & Rifapentine, anti-psychotics/epileptics; Carbamazepine, Phenobarbitone & phenytoin.
			  ○ Consult expert if this is the case before going to the next steps for switching treatment or HIVDR testing.
			• **For clients on an NNRTI based regimen (nevirapine or efavirenz)**
			  ○ Confirmed treatment failure
			  ○ Consult certified 2nd Line Prescriber for initiation of 2nd line ART without delay.
			• **For clients on DTG or PI-based regimens [7, 8, 9,10, 11, 12, 13, 14, 15 and 16]**
			  ○ Potential treatment failure (persistent adherence problems or treatment failure due to drug-resistant virus)
			  ○ Do HIV drug resistance testing ("genotype testing" or "genotyping") is needed to confirm drug resistance[3]
			  ○ Continue current regimen until genotyping results and advice from the HIVDR expert committee are available.
			  ○ Give a regular 3-month appointment.
			• If the patient switches to a 2nd or 3rd line ART regimen:
			  ○ Make an appointment for 1 month after the switch
				• 'Reset the clock' for routine VL monitoring: 6 months after switch to 2nd or 3rd line and every 12 months thereafter.

[3] Consult certified 2nd Line Prescriber, and/or call the HIV Dept. hotline to organize resistance testing. A standardized form needs to be filled**.** Collect DBS or plasma sample for genotyping. A national HIVDR expert committee will approve the indication for HIVDR testing, and provide interpretation of the results, with a recommendation for switching or not.

SOP 11: Viral Load Reporting

Purpose

- To outline expected reporting practices for viral load testing

Responsibility

- ART providers and/or any provider trained in viral load testing
- Data clerk

Oversight

- Facility-in-charge

Supplies

- HIV Viral Load Sample Log
- High or Detectable HIV Viral Load Register
- Viral Load Monthly Reporting Form

Procedure

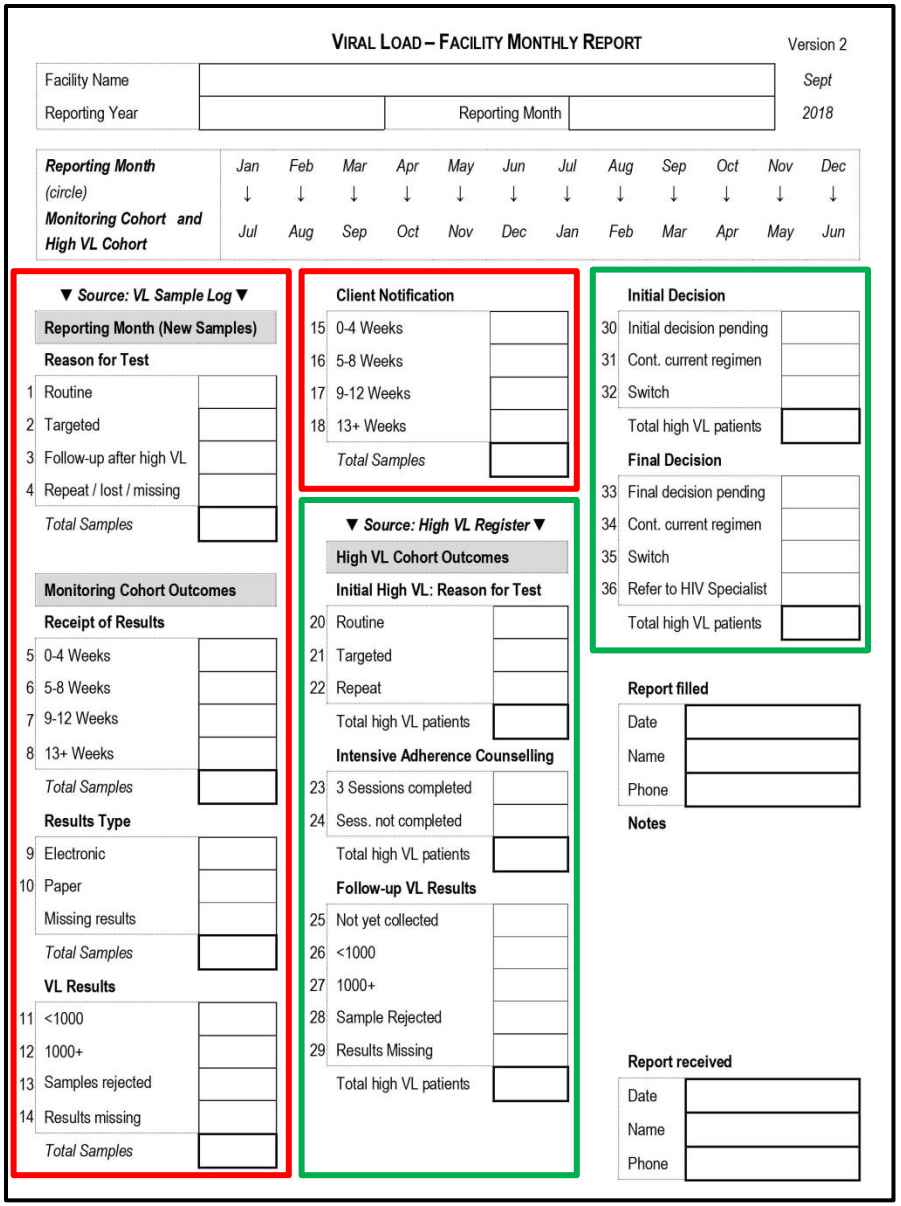
- At the end of every month, the facility must complete the viral load monthly reporting form
- One member of staff will be responsible for completing this form, overseen by the clinician and nurse and verified by the Viral Load Focal Person (VLFP)
    - Begin by identifying the appropriate cohort for completion by using the guide at the top of the form. An example of **reporting for the month of May** is shown below:

VIRAL LOAD – FACILITY MONTHLY REPORT Version 2

Facility Name											Sept	
Reporting Year				Reporting Month							2018	
Reporting Month	*Jan*	*Feb*	*Mar*	*Apr*	*May*	*Jun*	*Jul*	*Aug*	*Sep*	*Oct*	*Nov*	*Dec*
(circle)	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
Monitoring Cohort and High VL Cohort	*Jul*	*Aug*	*Sep*	*Oct*	*Nov*	*Dec*	*Jan*	*Feb*	*Mar*	*Apr*	*May*	*Jun*

        - **Reporting Month**: All the new samples collected in the particular month
        - **Monitoring Cohort**: Results of all new samples collected 6 months ago
        - **High Viral Load Cohort**: Outcome of initial High Viral Load from 6 months ago
    - Then, fill out the rest of the reporting form using the facility registers, as shown in **Figure 12**.

Figure 12: Viral Load Facility Monthly Report



VIRAL LOAD – FACILITY MONTHLY REPORT Version 2

Facility Name			Sept
Reporting Year		Reporting Month	2018

Reporting Month (circle) Monitoring Cohort and High VL Cohort	Jan ↓ Jul	Feb ↓ Aug	Mar ↓ Sep	Apr ↓ Oct	May ↓ Nov	Jun ↓ Dec	Jul ↓ Jan	Aug ↓ Feb	Sep ↓ Mar	Oct ↓ Apr	Nov ↓ May	Dec ↓ Jun

▼ *Source: VL Sample Log* ▼

Reporting Month (New Samples)

Reason for Test

1	Routine	
2	Targeted	
3	Follow-up after high VL	
4	Repeat / lost / missing	
	Total Samples	

Monitoring Cohort Outcomes

Receipt of Results

5	0-4 Weeks	
6	5-8 Weeks	
7	9-12 Weeks	
8	13+ Weeks	
	Total Samples	

Results Type

9	Electronic	
10	Paper	
	Missing results	
	Total Samples	

VL Results

11	<1000	
12	1000+	
13	Samples rejected	
14	Results missing	
	Total Samples	

Client Notification

15	0-4 Weeks	
16	5-8 Weeks	
17	9-12 Weeks	
18	13+ Weeks	
	Total Samples	

▼ *Source: High VL Register* ▼

High VL Cohort Outcomes

Initial High VL: Reason for Test

20	Routine	
21	Targeted	
22	Repeat	
	Total high VL patients	

Intensive Adherence Counselling

23	3 Sessions completed	
24	Sess. not completed	
	Total high VL patients	

Follow-up VL Results

25	Not yet collected	
26	<1000	
27	1000+	
28	Sample Rejected	
29	Results Missing	
	Total high VL patients	

Initial Decision

30	Initial decision pending	
31	Cont. current regimen	
32	Switch	
	Total high VL patients	

Final Decision

33	Final decision pending	
34	Cont. current regimen	
35	Switch	
36	Refer to HIV Specialist	
	Total high VL patients	

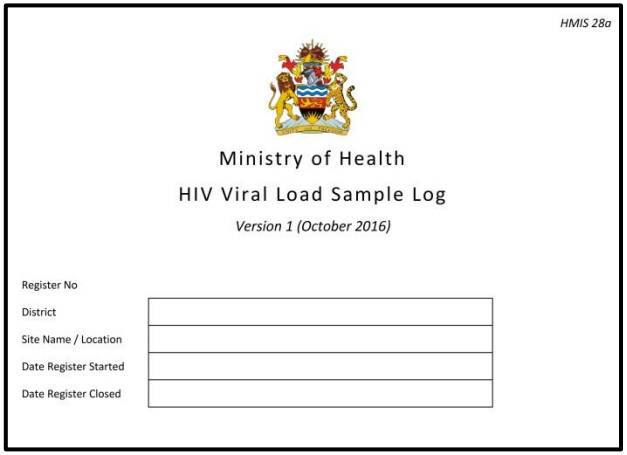
Report filled

Date	
Name	
Phone	

Notes

Report received

Date	
Name	
Phone	



HMIS 28a

Ministry of Health

HIV Viral Load Sample Log

Version 1 (October 2016)

Register No	
District	
Site Name / Location	
Date Register Started	
Date Register Closed	

HMIS 28b

Ministry of Health

High HIV Viral Load Register

Version 1 (October 2016)

Register No	
District	
Site Name / Location	
Date Register Started	
Date Register Closed	

At the end of the month, the facility must complete the viral load monthly report based on the cohorts as follows:

For the areas marked in **RED**, the information comes from the HIV Viral Load Sample Log

For the areas marked in **GREEN**, the information comes from the High HIV Viral Load Register

In all areas, the data is inputted by aggregating totals in the particular cohort.

Appendix I: ART Codes Job Aide

This job aide explains the drugs contained in each ART regimen for easy reference while filling out the EID/VL Laboratory Requisition Form.

Number	Line	Drugs
4P	1st	AZT/3TC + EFV
9P	1st or 2nd	ABC/3TC + LPV/r
11P	2nd	AZT/3TC + LPV/r
14P	1st or 2nd	AZT /3TC + DTG
15P	1st or 2nd	ABC/3TC + DTG
16P	1st	ABC/3TC + RAL
17P	1st	ABC/3TC + EFV
4A	1st	AZT/3TC + EFV
5A	1st	TDF/3TC + EFV
7A	2nd	TDF/3TC + ATV/r
8A	2nd	AZT/ 3TC + ATV/r
9A	1st or 2nd	ABC/3TC + LPV/r
10A	2nd	TDF/3TC + LPV/r
11A	2nd	AZT/3TC + LPV/r
12A	3rd	DRV+ r + DTG (± NRTIs)
13A	1st or 2nd	TDF/3TC/DTG
14A	1st or 2nd	AZT/3TC + DTG
15A	1st or 2nd	ABC / 3TC + DTG
16A	1st	ABC/3TC + RAL
17A	1st	ABC/3TC + EFV

Key

	Pediatric Formulation
	Adult Formulation

Acronyms:

- **3TC**: Lamivudine
- **ABC**: Abacavir
- **ATV**: Atazanavir
- **AZT**: Zidovudine
- **DTG**: Dolutegravir
- **DRV**: Darunavir
- **EFV**: Efavirenz
- **LPV**: Lopinavir
- **NVP**: Nevirapine
- **r**: ritonavir
- **RAL**: Raltegravir
- **TDF**: Tenofovir disoproxil fumarate

Appendix II: Viral Load Key Messages

Objective	Key Messages for the Recipient of Care
1. The goal of ARV Therapy	• You are taking ARVs on a daily basis to fight HIV in your body. Due to ARVs the number of HIV will decrease while your soldiers (CD4 cells) will increase and protect you from diseases
2. What is Viral Load and Viral Load Testing	• Viral load is the amount of HIV in the blood • A viral load test measures how much HIV is in the blood • The test is done by taking a sample for the lab by a finger prick or by drawing blood • High viral load (> 1000 copies/mL) means that there is a lot of HIV in the blood and your treatment is not working well. This is most probably due to an adherence problem • Undetectable viral load means that you have so little HIV in your blood that it can hardly be detected. It means your treatment is working well for you, because the ARVs are fighting HIV and thus reducing the amount of HIV in your blood. It does not mean you no longer have HIV but that it is too low to be measured by the test • The aim of your treatment is to reach and maintain an undetectable viral load
3. When You Have a Viral Load Test	• All those on ARV treatment will be offered a viral load test as part of the routine follow up at Month 6 after starting any ARVs and every 12 months afterwards. Depending on your health condition, the health worker may request you to have additional VL tests • Your health worker will tell you when to come for the next viral load test, according to your last test results • It is important not to miss your next appointment date for viral load test and to come for the results on time • If you are already on ART more than 6 months and have not been tested yet, remind your health worker to collect the sample and ask for your result. It is your right to know your viral load and know if you are doing well on treatment
4. Importance of Having a Viral Load Test	• It determines if you have high or low number of HIV in your blood • If the viral load is high it means that the ART is not working well either because it is not getting into your body enough (adherence challenges) or because the virus no longer works against your virus (resistance problem) • It helps you and the healthcare provider to know if ARVs are working well.
5. Advantages of Undetectable/ Very Low Viral Load	• Immune system stays strong and you have lower risk of becoming ill from opportunistic infections • Pregnant women reduce the risk of transmitting HIV to their babies • All people reduce the risk of transmitting HIV to sexual partners
6. Motivation to ART Adherence	• Adhere to ARV treatment in order to maintain undetectable viral load, a strong immune system and a long life • Good adherence on ARVs that works well against your virus will make your virus undetectable, prevent you from developing resistance to the ARVs, and help prevent you from getting other HIV-related illnesses.

Appendix III: List of M&E Tools for Capturing Viral Load Monitoring Data in Malawi

1. Client ART Mastercard (Pediatric & Adult Formulations)
2. HIV Viral Load Sample Log
3. High HIV Viral Load Register
4. EID & Viral Load Laboratory Requisition Form
5. Viral Load Monthly Reporting Form
6. Monthly VL Summary Sheet