



**UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE
NATIONAL AIDS CONTROL PROGRAMME**



**NATIONAL HIV VIRAL LOAD TESTING GUIDELINE TO
SUPPORT HIV AND AIDS PREVENTION, CARE AND
TREATMENT**

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NATIONAL HIV VIRAL LOAD TESTING GUIDELINE TO SUPPORT HIV AND AIDS PREVENTION, CARE AND TREATMENT

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Any part of this National HIV Viral Load Testing Guideline to Support HIV and AIDS Prevention, Care and Treatment can be used provided that the source, which is the Ministry of Health and Social Welfare, National AIDS Control Programme is acknowledged.

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Abbreviations and Acronyms

AC	-	Air conditioning
ADDS	-	Assistant Director Diagnostic Services
Amref Health Africa	-	formerly African Medical and Research Foundation (AMREF)
ART	-	Antiretroviral therapy
BMC	-	Bugando Medical Centre
CAP/CTM	-	CobasAmpliPrep/CobasTaqMan
CCHPs	-	Comprehensive Council Health Plans
CD4	-	Cluster of differentiation 4
CDC	-	Centers for Disease Control and Prevention
CHAI	-	Clinton Health Access Initiative
CHMT	-	Council Health Management Team
CM	-	Curative maintenance
CME	-	Continuous Medical Education
Cp/ml	-	Copies per milliliter
CSSC	-	Christian Social Services Commission
CT	-	Care and treatment
CTC	-	Care and Treatment Centre
DBS	-	Dried blood spot
DHLS	-	District Head of Laboratory Service
DMO	-	District Medical Officer
DNA	-	Deoxyribose Nucleic Acid
DOD	-	Department of Defense
DSS	-	Diagnostic Services Section
EAC	-	East African Community
EDTA	-	Ethylenediamine tetra-acetic acid
EGPAF	-	Elizabeth Glaser Pediatric AIDS Foundation
EQA	-	External quality assessment
HCTS	-	Health Care Technical Services
HDRT	-	HIV drug resistance testing
HEID	-	HIV Early Infant Diagnosis
HLIS	-	Health Laboratory Information System
HF	-	Health Facility

HIV	-	Human immunodeficiency virus
HJFMRI	-	Henry Jackson Foundation Medical Research Institute
HLPC	-	Health Laboratory Practitioners' Council
HSHP	-	Health Sector HIV Strategic Plan
HVL	-	HIV Viral Load
ICAP-CU		International Center for AIDS Care and Treatment Programs- Columbia University
JICA	-	Japan International Cooperation Agency
JSI	-	John Snow Inc.
KCMC	-	Kilimanjaro Christian Medical Centre
KCRI	-	Kilimanjaro Christian Research Institute
LIS	-	Laboratory Information System
M&E	-	Monitoring and Evaluation
MDH	-	Management Development for Health
ml	-	milliliter
MNH	-	Muhimbili National Hospital
MOHSW	-	Ministry of Health and Social Welfare
MRH	-	Mbeya Referral Hospital
MSD	-	Medical Stores Department
NACP	-	National AIDS Control Program
NHIF	-	National Health Insurance Fund
NHLQATC		National Health Laboratory Quality Assurance and Training Centre
°C	-	Degrees Celsius
PCR	-	Polymerase Chain Reaction
PHLB	-	Private Health Laboratory Board
PMTCT	-	Prevention of Mother to Child Transmission
POC	-	Point of care
PPE	-	Personal preventive equipment
PPM	-	Planned preventive maintenance
PPRA	-	Public Procurement Regulatory Authority
PPT	-	Plasma precipitating tube
PT	-	Proficiency Testing
QA	-	Quality assurance

QC	-	Quality control
RHMT	-	Regional Health Management Team
RNA	-	Ribose Nucleic Acid
RRP	-	Reagent Rental Placement
SLA	-	Service Level Agreement
SLIPTA		Stepwise Laboratory Improvement Process towards accreditation
SLMTA	-	Strengthening laboratory management toward accreditation
SMS	-	Short messages
SOPs	-	Standard operating procedures
TAT	-	Turnaround time
THPS	-	Tanzania Health Promotion Support
UNICEF	-	United Nations Children’s Fund
URC	-	University Research Co.
USAID	-	United States Agency for International Development
VL	-	Viral load
WHO	-	World Health Organization

Acknowledgement

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Last but not least the NACP would like to convey sincere thanks to all MOHSW staff from Departments, Sections, Programs and Professional Councils (appendix 1) for their valuable contributions towards developments of the guidelines. Specifically, NACP commends the tireless efforts of the secretariat team for coordination process and finalization of the document.



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Program Manager
National AIDS Control Program

Foreword

Since the first case HIV that was reported in 1983, HIV has spread to all regions of the country and remains a leading cause of death in Tanzania. There are about 1,411,829 people living with HIV (TACAIDS, National HIV/AIDS Response Report, 2014) and the prevalence has reduced from 7.1% (THMIS 2003-04) to 5.1% (THMIS 2011-12).

The prevalence has concentrated in the different groups and geographical locations. Generally, HIV is higher in women (6.2%) than men (3.8%) (THMIS2011-12) and higher in urban than rural areas. Beginning 2004, The National AIDS control Program (NACP) has been collaborating with implementing partners to support care and treatment programs in the country, which has brought a significant impact on people living with HIV and AIDS.

The HIV care and treatment program has been scaled up to over 1, 500 health facilities in order to increase access to the services. The recent WHO recommendation (July 2014) on management of HIV treatment has led to the development of guideline in monitoring patients on treatment through HIV Viral Load (HVL) testing. The HVL testing is a good indicator to monitor patients on treatment as well as identify treatment failure as the exact number of HIV viral particles is measured immediately after patients start treatment.

The MOHSW through the NACP has developed the HIV Viral Load Guideline and Scale up Plan, which will give direction on HVL monitoring and the plan to scale up HVL testing in Tanzania. This document has been developed for use at the primary to tertiary health facilities; and will assist to provide high quality, effective and standardized HVL testing to monitor patients on ART. It is our hope that this document will contribute to quality health care service delivery in the country.



Dr. Neema Rusibamayila
Director of Preventive Service

Definition of Terms

The following definitions apply to the terms used in this document:

Examination: This includes all procedures in the actual testing analysis

Collection point: This is a space used to collect specimen for HVL testing

Curative maintenance: Is servicing the machine following breakdown in accordance to the manufacturers' instructions

DBS: Is blood sample collected on a special filter paper card, dried and tested

Equipment downtime: Is the total number of hours for which the HVL testing equipment is not functional

Occurrence: Is any incidence that occurs in the HVL testing laboratory

Plasma: Is the clear fluid separated from whole blood collected in EDTA tube

Post-examination: This covers the steps that follow after the results are ready for documentation and release

Pre-examination: This includes procedures, which are performed at the HVL sample collection point and prior to actual HVL sample analysis.

Service interruption: Is any hindrance in the delivery of HVL testing services

Service level agreement: Is the service contract between the supplier and the end user

Treatment failure: Is defined by persistent HVL test result exceeding 1,000 cp/ml after at least 6 months of using ART.

Viral load testing: Is the estimation of the number of HIV copies in the blood of an HIV infected individual

CHAPTER ONE: NATIONAL GUIDELINES FOR VIRAL LOAD TESTING

INTRODUCTION AND BACKGROUND

For more than three decades, Tanzania has made concerted response to the HIV and AIDS epidemic, which nevertheless continues to claim the lives of thousands of her people, and threaten national, social, and economic development. With a generalized epidemic, HIV prevalence averaging at 5.1% (THMIS 2011-12) on the Mainland, but with noticeable regional variations (range Pemba region with 0.3% to Njombe region with 14.8%), (THMIS 2011-12), still more people continue to get infected.

The commitment from the government is still sustained and enhanced throughout the implementation of NMSFIII to achieve the goals of Zero New HIV Infections, Zero AIDS-related Deaths, and Zero Stigma and Discrimination. Moreover, supporting programs with sustained financial resources required to achieve the overarching results, the Government of Tanzania is also in the process of exploring feasible financing mechanisms that will support the country's long-term response to the HIV and AIDS epidemic through formation of the AIDS Trust Fund.

In December 2012, from the 6,342 health facilities, a total of 1,078,018 PLHIV were enrolled in care and treatment clinics all over the country and 660,723 PLHIV initiated on ART (NACP data 2012) Of those who are on first line ARVs, some 2% of the cases are shifting to the second line treatment regimens based on the immunological and clinical evaluation despite the sensitivity and specificity of these algorithms are less compared to determination of plasma viral load determination (NACP data 2013).

According to the ART guideline of the country, successful antiretroviral therapy results in decrease of HVL, immune recovery and therefore increases in number of CD4 cells. Based on this principle, every six months the CD4 count is used to monitor the immunologic response to antiretroviral therapy. However, due to limited capacity and availability of HVL testing, it is considered as an addition to clinical and immunologic measurements to diagnose treatment failures earlier, or to access discordant clinical and immunologic findings in patients with suspected ART failure.

It is well known plasma viral load (VL) measurement is not required before the initiation of ART. However, expanded access to HIV viral load (HVL) testing is necessary to improve the accuracy of diagnosing treatment failure; HVL measurement is considered a more sensitive indicator of treatment failure as compared to clinical or immunologic indicators. HVL may be used in a targeted or routine strategy. The objective of the targeted strategy is to confirm suspected clinical or immunologic failure, maximizing the clinical benefits of first-line therapy and reducing unnecessary switching to second-line therapy. Earlier detection of virological failure allows for targeted adherence interventions and better preservation of the efficacy of second-line regimens.

However, routine viral load monitoring is now strongly recommended as the monitoring strategy of choice. In 2013, WHO recommended HVL as the preferred monitoring approach to diagnose and confirm ART failure and using the reduced threshold of viral failure of 1000 copies/ml based on two consecutive HVL measurements using plasma specimens within 12 months, with adherence support between measurements.

RATIONALE

In Tanzania, ART program started in 2004, clinical and immunological assessments (using CD4 T cell count or percentage) are used to determine ART eligibility and monitor response to treatment. However, clinical and immunological criteria are associated with limitations in monitoring ART, follow-up and detection of treatment failures. Also, assessing treatment failure by clinical monitoring is insufficient, when depending only on clinicians due to observer variation or error and subjectivity in the assessment. Though sensitivity of immunological monitoring is higher than clinical monitoring, it is still lower than HVL monitoring and may not be proportion to the HVL

Published data from Tanzania and other countries show that HVL is more specific and sensitive to monitor ART program compared to immunological and clinical monitoring. In Tanzania, HVL monitoring has so far been done to clients with suspected treatment failure in research settings.

HVL testing would be useful for early detection of treatment failure and shifting the client to second line treatment regimen, ART response monitoring will increase. When HVL is suppressed to less than 1,000 copies/milliliter (cp/ml), it implies a good response to ART.

HVL TESTING FOR ART MONITORING

The importance of HVL testing guideline and the current status of testing

- The HVL test will be performed six month after initiation of ART (CD4 will be used to initiate ART)
- A repeat HVL test will be performed six months later if the initial HVL test result was less than 1000cp/ml
- A repeat HVL test will be performed after 3 months of intensive adherence counseling if the preceding HVL test result was more than 1000cp/ml
- An HVL test will be performed annually if two preceding HVL test results were less than 1000cp/ml
- For clients, who have been on ART and immunological monitoring for more than 6 months an HVL test will be performed at any time in the next scheduled visit.

IMPORTANT THINGS TO NOTE:

- Adherence to TAT is important to avoid delays in switching clients to second line treatment regimen.
- For clients who have been on ART for longer periods (more than six (6) months prior to the use of this guideline), HVL test shall be done at any time and be regarded as the initial test and thereafter the HVL testing algorithm shall be followed.
- Use of HVL testing will gradually replace CD4 T cell absolute count or percentage testing for monitoring response to ART.
- It is important to create a mechanism of tracking HVL testing specimen and results, and regularly monitor and evaluate the efficiency of specimen transportation, processing, testing and timely delivery of HVL test results.

HIV DRUG RESISTANCE TESTING SURVEILLANCE

HDRT is recommended for the following purposes:

- Provide information on ARV drug efficacy.
- Provide indication on patient adherence to treatment regimen
- Determine trends on ART failure
- Determine the magnitude of drug resistance

Special populations

- HVL testing for HIV infected children and pregnant women shall follow the National HVL testing algorithm

Decision Tree

- Clinician shall make a decision to request for HDRT based on the National HVL testing algorithm.

Clinical Tools

- **Clinical HVL Testing Form**
 - There shall be clinical HVL testing form at collecting and testing sites.
- **HDRT Clinical Forms**
 - There shall be HDRT clinical form at collecting and testing sites
- **HDRT Surveillance Form**
 - There shall be HDRT surveillance form at collecting and testing sites
- **Registers**
 - Registers for recording HVL test and HDRT information shall be available at collecting and testing sites
- **SOPs**
 - SOPs will be available to guide sample collection, packaging, transportation, referral and testing

CAPACITY BUILDING

HR availability of trained human resource on VL monitoring and testing

- On job training for sustainability of the program and improving its quality

Facilities, Instruments and supplies

- Availability of required instruments and supplies
- Owning the program by RHMT/CHMT

Financial

- Trainings on effective sample collection, transportation and referral linkage
- Train and recruit qualified and competent health laboratory practitioners for HVL testing
- Train health service providers on HVL specimen collection, handling and transportation procedures.
- Conduct on-job-training to health service providers focusing on reduction of sample rejection rate.
- Conduct on job training to health laboratory practitioners focusing on improving quality of HVL test results as well as their competency.
- Conduct competency assessment to HVL service providers based on the training needs before authorizing them to perform HVL testing.
- Include Quality Management System into HVL testing

THIRD LINE TREATMENT REGIMEN

- Currently, there is no third line treatment regimen for clients developing resistance to second line treatment regimen. Should there be a need; the National HVL testing algorithm will be followed.
- No third line treatment regimen will be initiated without HDRT results
- Clinical HDRT forms will be used for HDRT request for clients suspected to have resistance to second line treatment regimen

CHAPTER TWO: CLINICAL LABORATORY PROCEDURE FOR HVL TESTING

HVL testing should follow the standard phases of clinical laboratory testing procedures, which include: pre-examination, examination and post-examination phases. All phases should adhere to a defined quality management system.

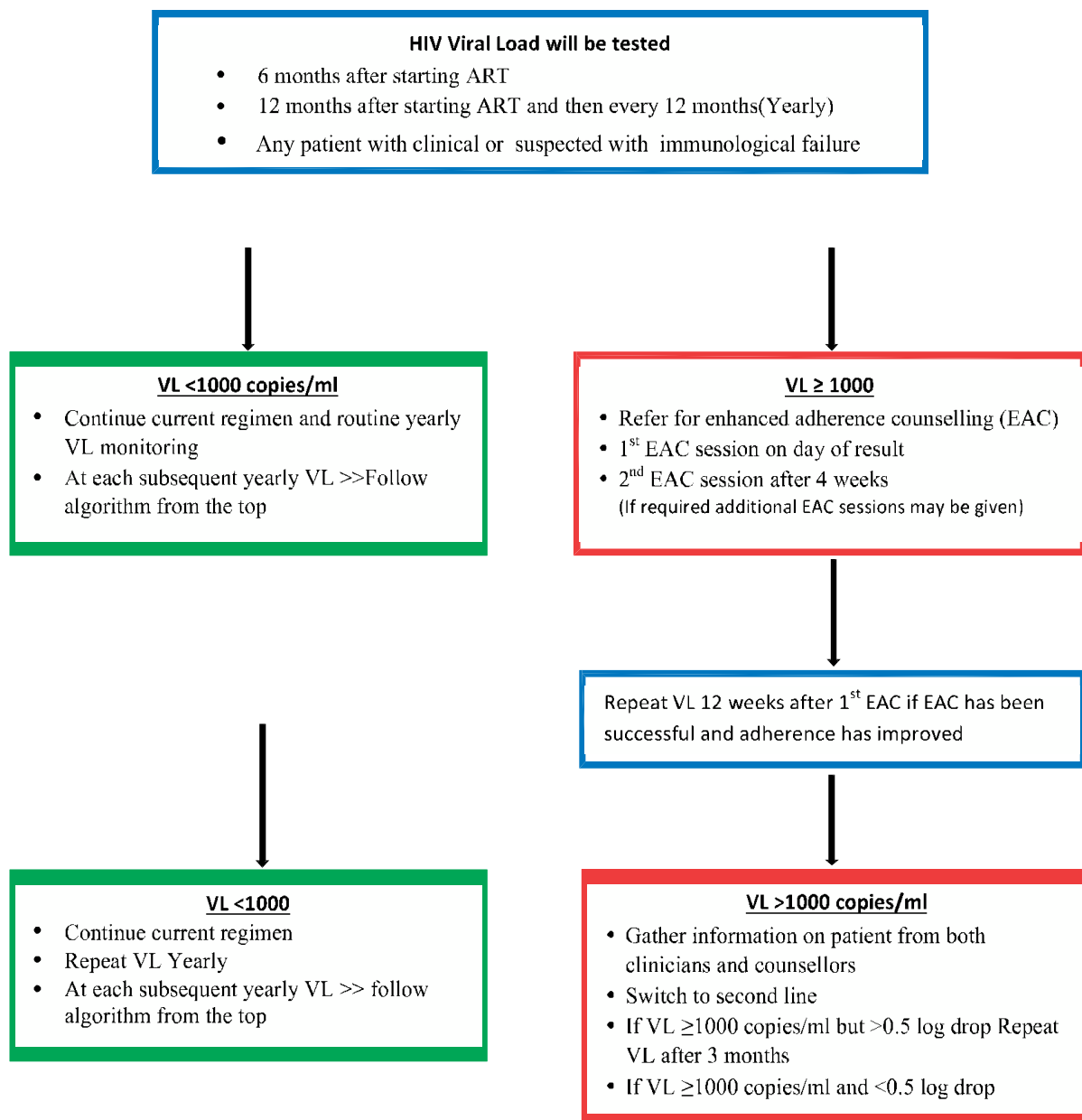


Figure 1: National HIV Viral Load Testing and Clinical Algorithm

Source: Adapted from WHO Consolidated Guideline July 2014

PRE-EXAMINATION PHASE AT THE SAMPLE COLLECTION POINT

Sample Requisition

- HVL testing should be requested on a standard HVL request form, which clearly states the indication for HVL testing, sample types
- HVL testing can be conducted on 3 sample types, namely: Whole blood, Plasma and Dried Blood Spot (DBS)

Sample Collection, Preparation and Material Requirements

Plasma:

- SOPs for sample collection and preparation should be in place
- A minimum of two tubes of 4ml each of whole blood sample should be collected in EDTA or PPT container
- Plasma separation **MUST** be done within 6 hours of whole blood collection
- At least two (2) aliquots of plasma of 1ml each (preferable three aliquots) should be prepared (primary aliquot for testing, the secondary aliquot as back up and the third for sample archive if required)

Dried Blood Spots

- SOPs for sample collection and DBS preparation should be in place including all necessary materials
- DBS should be prepared from venous whole blood or capillary blood by finger prick using measured micro capillary tube.
- Standard DBS collection kit for HVL consists of: EDTA/PPT vacuum collection tubes and corresponding needles, alcohol swab, pre-punched filter papers, weighing/glassine paper, zip lock bags, racks for drying DBS card, humidity indicators, desiccants and Pasteur pipettes
- Sample volume for whole blood should not be less than 100 microliters per spot
- The number of spots per DBS card should not be less than three (3)

Sample Handling and Storage

- SOP for sample handling and temporary storage after preparation should be in place

- Plasma should be kept under room temperature for not more than 24 hours, or in a refrigerator at 2°-8°C for not more than five (5) days or frozen at -20°C or lower temperature for longer storage
- DBS should be dried overnight and kept at room temperature away from sunlight, dust and insects.
- Each DBS card should be wrapped individually in glassine paper, prior to packaging in an appropriate zip lock bag with desiccants, and is kept at ambient temperature until time for transportation
- DBS samples should be stored at -20°C or below for long term storage

Table 1: Performance characteristics for commercially available molecular HVL assays using Plasma and DBS samples at 1000copies/ml cut-off

Assay assessed	Sensitivity (mean %)	Specificity (mean %)	n
Abbott Molecular: Abbott RealTime HIV-1 (manual, m24sp and m2000sp) assays with m2000rt platform	95.24 ^a	91.67 ^a	1529
Biocentric: Generic HIV Charge Virale	94.86 ^a	55.16 ^a	531
bioMérieux: NucliSENS EasyQ® HIV-1 v2.0	84.37 ^a	94.52 ^a	1062
Roche Molecular Systems: COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, version 2.0 [free virus elution protocol]	81.02 ^b	96.74 ^b	229
HIV-1 RNA 1.0 Assay (kPCR)	90.97 ^a	87.76 ^a	144

Source: WHO Technical and Operational Consideration for Implementing HVL testing, July 2014

Sample Transportation

- Whole blood samples should be transported from the collection point to the testing site at an ambient temperature within six (6) hours of collection.

Note: Avoid vigorous movement to prevent haemolysis.

- When transporting whole blood samples by motorbikes, one should carry the samples in a backpack in a secured manner using standard packaging materials to avoid rupturing of red blood cells due to vibration of the motorbike engine.
- Plasma should be transported in cold chain (4°C) within five (5) days of collection

- Frozen plasma should be transported on ice packs (-21°C)/dry ice (-78.5°C)/liquid nitrogen (-196°C)
- DBS should be transported in a rip resistant and waterproof envelope in humidity controlled conditions within one week after collection.
- Plasma/whole blood samples for HVL testing should be packed in a triple packaging container and labeled with BIOHAZARD signage

Table 2: Summary of studies and manufacturer recommendations for time of transport and storage at various conditions for plasma, whole blood and dried blood spot specimens for HVL testing

Temperature (in °C)	37°C (humid condition)	15-30°C (room temp)	4°C	-20°C	-70°C
Time	Whole Blood (Venous EDTA)				
	6 hrs.	6 hrs.	N/A	N/A	N/A
	Plasma				
	24 hrs.	24 hrs.	5 days	1 year	5 years
	Dried Blood Spot				
	1-2 weeks	1-2 weeks	2-52 weeks	3-36 months	1 year

Source: WHO Technical and Operational Consideration for Implementing VL testing, July 2014

Documentation and Sample Tracking

- There should be MOHSW approved standard sample tracking forms and registers in place
- The forms and registers should capture the following information: site name, unique client identifier number, age, sex, HVL testing laboratory name, date and time of specimen collection, temperature indicator information, type of specimen, officer requesting and collecting specimen, reason for test and any other clinical information deemed necessary by the requesting officer.
- The form should also capture specimen acceptance or rejection as feedback to the site
- The specimen should be labeled with the Unique Client Identification number, date and time of collection, site name and other identifiers.

PRE-EXAMINATION PHASE AT THE HVL TESTING LABORATORY

Sample Reception and Acquisition

- Sample should be received and registered into the standard register or log book

Sample Accession/Rejection

- Samples should be inspected for compliance; and be accepted or rejected according to criteria in the sample collection manual
- Rejected samples should be registered into the sample rejection log book
- Sites from where the rejected samples came from should be informed immediately on sample rejection and the reasons for rejection
- Rejected samples should be disposed according to the waste management guidelines

Sample Holding/Transition to Testing

- Accepted samples should be stored at -20 to -80°C until they are ready for testing.
- Documentation should be done for ease of accessibility and tracking of the samples.

EXAMINATION PHASE

At the testing bench receiving of the samples at the working station

- Primary identification of samples should be done prior to processing
- Worksheets should be prepared prior to testing
- Sample should be processed according to the SOP in place

Quality Control (QC) Process

- Internal QC should be performed according to the HVL testing platform in place
- HVL testing laboratory should participate in Proficiency Testing (PT) or inter laboratory comparison schemes
- HVL testing laboratory should participate in PT at least twice (2) per year
- Internal QC and External Quality Assessment (EQA) performance should be documented and reviewed regularly

Result Verification and Interpretation

- Results should be verified according to the SOP of the HVL testing platform
- Results should be interpreted according to the SOP in place

Documentation

- In the testing laboratory the following should be observed:
 - Client test result should be documented into the result register or log book
 - Nonconformities related to the testing process should be documented into the log book.
 - Plasma samples should be archived at the HVL testing laboratory
 - Samples should be retained and disposed according to the National guideline

POST-EXAMINATION PHASE AT THE HVL TESTING LABORATORY

Report Feedback Process

- Client report should be verified and authorized by a designated health laboratory practitioner before dispatching to the requesting site or sender

Sorting and Packaging

- Clients' reports should be sorted and linked with the request forms and packaged
- Clients' reports should be delivered or communicated by courier, SMS printer, online or any other appropriate means to the requesting sites.
- Report archiving

All copies of HVL testing reports should be archived according to National guideline for easy retrieval.

Report Disposal

- Archived HVL test reports should be disposed according to National Guideline
- Disposal records of HVL test reports should be maintained.

ISSUES AFFECTING HVL TESTING

Human Resource

- For conventional methods, qualified and competent health laboratory practitioners in number and skills should be available
 - Minimum number of health laboratory practitioners per HVL testing laboratory should be three (3)
 - For health laboratory technologists minimum qualification should be Diploma in Medical Laboratory Sciences
 - All laboratory staff must be properly trained and deemed competent to perform their duties from specimen handling, processing, testing, transporting, data and technical support.
- For point of care methods, specific national guidelines for required personnel and training should be followed
- Continual medical education (CME) and professional development
 - Planned and regular relevant continual professional development should be in place
 - Continuous assessments should be performed on regular basis
 - There should be easy access to reference and resource materials

Facility and Safety

Testing Space

- Should be adequate and ensure safety for the health laboratory practitioner, client and the environment.
- Dedicated laboratory space with not less than two (2) rooms for sample preparation, sample processing and reagent and consumables storage
- A power backup system is recommended
- The following laboratory safety measures need to be considered in addition to others:
 - Biosafety Cabinet Class II
 - Eye wash station, emergency shower, firefighting equipment, first aid kit, spill kit
 - Air Conditioning to support cooling system in testing and storage areas
 - Regular cleaning and decontamination plan

- Uni-directional air flow to control contamination (for new construction and/or renovation)

Personal Protective Equipment (PPE)

- Minimum PPE to be provided include: goggles, nitrile or powder free gloves, long sleeved laboratory gown with cuffs, facemask, shoe covers or clogs

Waste Management Plan

- Waste segregation bins should be provided at all HVL testing sites
- Waste disposal should be according to National Guideline

Sample storage space

- Sample repository space should be available at the HVL testing laboratory
- A -80°C chest freezer (with racks, cryovial boxes and temperature monitor) should be available for sample repository purposes and a -20°C freezer in the testing area for temporary storage

Equipment

- To establish and scale up HVL testing, a decision on the type of technology i.e. robust, upgradable and suitable for the country should be done at the national level.
- Key considerations should be made when selecting a technology for HVL testing include but not limited to:
 - Detection limit (sensitivity)
 - Precision/reproducibility
 - Dynamic ranges (low to high range detection)
 - Fixed and recurrent costs

Acquisition of HVL Testing Equipment

- Prior to acquisition, a comprehensive costing analysis should be performed.
- Reliable vendor and technical support should be available and the equipment should be registered with Private Health Laboratory Board (PHLB)
- Instrument installation with complete training, commissioning and follow up should be clearly defined in the warrant period

Equipment Service Contract and Reagent Rental Option

- The option for leasing HVL testing equipment should be explored with manufactures. Often schemes exist to enable country o lease equipment and purchase reagents hence saving on a capital investment and increasing the economic feasibility of introducing HVL testing

Maintenance

- Planned preventive maintenance (PPM) should be done according to manufacturer's recommendations
- Corrective maintenance should be conducted as per service contract agreement
- Documentation on maintenance should be done and reviewed on regular basis

Backup Plan

- Each HVL testing laboratory should have two different HVL testing platforms.
- It is recommended that different HVL testing laboratories should act as backup testing sites for one another.

Commodities and Logistics

- Forecasting and quantification should be planned at the National level by NACP
- Ordering, receiving and distribution should be conducted through MSD
- Requesting should be done at the HVL testing facility based on consumption data
- Documentation and consumption reports should inform the National quantification and forecasting
- Budget allocation should be according to the quantification

Laboratory Information System

- To minimize clerical and transcription errors and ease the workflow, it is recommended that:
 - HVL testing laboratory should have an electronic laboratory information system in place
 - Central HVL test result data repository is in place at the National level
 - National networking of the HVL testing laboratories and sites is in place.

MONITORING AND EVALUATION OF HVL TESTING

Laboratory Indicators

Sample Rejection Rate

- Proportion of samples (plasma or DBS) rejected should not be more than 2%
- Numerator: Number of rejected samples
- Denominator: Number of collected samples from the sites
- If the rejection rate is greater than 2% the laboratory management should take corrective action

Equipment Downtime

- All HVL testing facilities should strive to attain no service interruptions due to equipment break down and unavailability of reagents and supplies. The laboratory should have an equipment service contract that specifies the response time in case of a break down.
- Standing orders for reagents and testing supplies required for the continuous provision of services should be in place.

Turn Around Time (TAT)

- Turnaround time from sample collection to results feedback should not be more than fourteen (14) days
- The turnaround time at the laboratory should not exceed three (3) days

EQA Performance

- Participation in EQA is mandatory for all HVL testing laboratories
- EQA performance pass rate should be 100% for all HVL testing laboratories
- If the pass rate is below 100%, corrective action should be taken

Reagent Stock out

- All HVL testing laboratories should ensure reagents and supplies for HVL testing are available at all times

Program Indicators

Human Resource

- Number of HVL testing laboratories with a minimum of three (3) competent health laboratory practitioners

Meeting National Care and Treatment Targets

- Percentage of clients who are currently on ART who had HVL test and received results
- Proportion of clients' current on ART who have been correctly identified as treatment failure using HVL testing.

Turnaround time

- Proportion of clients who received their HVL test results within the defined TAT

Service Interruption

- Proportion of days of service interruption per annum due to stock out of reagents and supplies
- Proportion of days of service interruption per annum due to equipment breakdown

POINT OF CARE (POC) TECHNOLOGY FOR HVL TESTING

- The infrastructure required for HVL POC will depend on the type of technology and should follow the National POC guideline.
- Criteria for acquisition of HVL POC equipment (this has been stipulated more in the POC guideline)

Minimum Training

- Registered and competent health laboratory practitioner by Health Laboratory Practitioners' Council
- Trained and certified non-laboratory health service providers according to the Health Laboratory Practitioners' Council regulation as stipulated in (The Health Laboratory Practitioners' Act (Cap 48))

- The HVL POC technology should be easy to use with four to five procedural steps
- Reagents should be stable at ambient temperature for both transportation and storage for 100% shelf life

Quality Assurance and Internal Quality Control

- Site providing HVL testing using POC technology shall be enrolled EQA scheme either in country or outside the country at least twice a year
- HVL POC technology should have an in-built internal quality control system

Use of Alternative Power Source

- HVL POC devices shall be able to operate on alternative power source e.g. solar power

Waste Disposal of POC Reagents and Supplies

- HVL POC reagents and supplies waste should be environmental friendly
- HVL POC reagents and supplies should be easily disposed by incineration

Maintenance and Supplies

- For sustainability and maintenance of supplies for HVL POC, vendors who have been evaluated and registered by PHLB are recommended.

CHAPTER THREE: NATIONAL HVL TESTING SCALE UP PLAN

INFRASTRUCTURE:

In Tanzania, there are six (6) public health facilities with the capacity to perform HVL testing. These are: BMC, KCMC, Mbeya Referral Hospital, Muhimbili National Hospital, Temeke Regional Referral Hospital and NHLQATC. There are other five (5) sites, which are providing HVL to targeted groups; these are Hindu Mandal Hospital, Dream Centre Arusha, Dream Center Iringa, Ifakara Health Institute Morogoro and Village of Hope Dodoma

Create more adequate HVL testing facilities that meet standards with the necessary physical (such as warehouses, meeting rooms, consultation space, laboratories, pharmacies, administration areas and equipment) and transport infrastructure (such as vehicles, motorcycles, courier services) needed to support implementation.

In addition, communication infrastructure between health facilities, health service providers, laboratories and clients is needed.

Point Of Care

- There should be a strategy to use both conventional and POC HVL testing platforms
- HVL POC placement should focus on technology, equipment capacity, facility location, costs and human resource.
- The selection criteria of viral load technologies should not rely solely on the technical specifications and characteristics of a viral load platform but also specimen type specificities and operational considerations, such as efficiency of specimen transport system, expected testing volumes, human resources and technical support.
- Describe performance characteristics of POC as per the guidelines

HVL Laboratory Scale Up

- Testing platforms and other supporting equipment should be provided adequately in each HVL testing laboratory. Currently, there are five (5) CAP/CTM 48 testing platforms.
- The plan is to evaluate the capacity of the testing laboratory to see if there is a need to increase number of HVL testing laboratory or if there is a need of POC.

- Capacity assessment should be conducted to those non-public sites with capacity to test HVL and MOU can be signed with those sites/centers so that they provide HVL to all clients in their catchment areas.
- There should be coordination of HVL testing laboratories' initiatives towards expansion so that all laboratories are ready to expand HVL testing services within the same time frame.

Renovation of HVL Testing Laboratories

- HVL testing laboratories should suit the favorable testing environment (unidirectional workflow and storage capacity)
- Each laboratory shall have two (2) different testing platforms (one for HEID and one (1) for HVL) depending on the testing capacity.

Note 1: There is a need to balance work between DNA PCR for HEID and RNA PCR for HVL monitoring.

Note 2: Reagent rental placement is recommended for equipment

- Renovations shall take into account backup mechanisms on all HVL testing laboratories including backup for sample referral
- Operational characteristics (infrastructure requirements):
 - Power supply
 - Climate control
 - Dust
 - Instrument footprint
 - Ancillary equipment
 - Additional rooms for extraction and amplification
 - Health facility tier

Capacity Building

- HVL testing laboratory should have at least three (3) dedicated health laboratory practitioner
- Heads of HVL testing laboratories should be encouraged to train existing health laboratory practitioners and reallocate them to perform HVL testing.

- HVL testing subject should be included in curricula of all health laboratory sciences learning institutions.
- Training of HVL testing for health service providers should focus on competence
 - Training of HVL health service providers should be followed by competence assessment
- Aligning existing funding with human resource (HR) required to scale up access to HVL
- Assessment for HR requirement for HVL testing

PROCUREMENT AND MAINTENANCE OF HVL TESTING EQUIPMENT

- Equipment placement arrangements should be considered, where a vendor is responsible for supplying equipment, service and maintenance of the equipment under an agreement that the customer buys consumables exclusively from the vendor.
- HVL testing equipment already in use should be considered for Service Level Agreement (SLA)
- Health care technical services zonal workshop capacity should be strengthened to support HVL testing equipment maintenance.
- Consider bundling services (reagents, consumables and SLA) and negotiate price with the vendor/supplier
- Equipment should be covered in maintenance contract to prevent equipment downtime

SUPPLY CHAIN MANAGEMENT

- MSD should be sensitized on the importance of effective procurement, storage and timely distribution of reagents and consumables to meet the demands of the HVL testing laboratories.
- Improve quantification process by strengthening the collection and utilization of consumption data from HVL testing laboratory reagents and consumables.
- Build capacity to carry out quantification and monitoring of supply chain
- Process of national quantification should take into account the reduction of CD4 services for monitoring to shift resources for scale up of HVL testing services
- MSD should have the capability for cold chain, storage requirements and shelf life

EXPAND HVL TESTING SERVICES TO EXISTING PMTCT AND C&T SITES

- The program should start with 25% of sites by 2015 and will be gradually increased to 50% by 2017.
- A selection criterion of the 25% for sites with high volume of HIV clients, site readiness and accessibility.
- Promote health education and community awareness on the availability and the importance of HVL testing

SUSTAINABILITY OF THE PROGRAM

- The government to increase its health budget as per Abuja Declaration 2001
- Encourage sense of ownership and responsibility to the health service providers.
- Sample transportation and logistics of consumables should be budgeted in Comprehensive Council Health Plans (CCHPs)
- Harmonisation of HVL testing implementation among all stakeholders in the country
- Health laboratory practitioners should be trained on forecasting and budgeting.

SAMPLE REFERRAL SYSTEM

- There should be an efficient HVL sample referral system.
 - HVL specimen referral network will adapt existing CD4 or EID sample referral systems depending on the type of specimen
- The system should clearly spell out the role of stakeholders involved in HVL sample referral system.
- Plasma sample should be separated and transported to the testing laboratory within 24hours after collection
- The turnaround time should be three (3) days within the HVL testing laboratories.
- The total turnaround time from sample collection to results received at the facility shall be less than fourteen (14) days.

HEALTH LABORATORY INFORMATION SYSTEM

- All HVL testing laboratories should have a HLIS linked to a web-based data management system, where results can be accessed and retrieved by authorized health service providers.
- HVL laboratory data should be hosted in a national database for program management and decision-making.
- For sites with no Internet access, HVL focal person(s) per hub supported by DLTs should be facilitated to print and distribute HVL test results to respective facilities.

HVL TESTING QUALITY ASSURANCE

- HVL testing laboratories should enroll in an HVL EQA program
- Develop HVL EQA program at NHLQATC that will support HVL testing laboratories.
- Implement Quality Management Systems in all HVL testing laboratories
- Strengthen accreditation process for HVL testing facilities through SLIPTA or SLMTA

PERFORMANCE BASED RECOGNITION

- Recognition (in-kind) should be introduced in the HVL testing laboratories as a means to improve performance. Some of the criteria for recognition are:
 - HVL testing laboratories that process and give results within the acceptable turnaround time
 - Participate in EQA and achieve 100%
 - Accreditation
 - Rejection rates of <2%

MONITORING AND EVALUATION

- There should be an established national monitoring and evaluation framework for the HVL testing program that will align with the National Health Sector HIV Strategic Plan III (HSHSP III) and national care and treatment program indicators.

SAMPLE REPOSITORY AND DATA ARCHIVING

- There should be an established National HVL sample repository system
- There should be an established system for HVL sample archiving for future use.
- There should be a national HLIS back up for the information and data from the HVL testing laboratories
- There should be an established access control of both sample and data archives

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APPENDICES

Appendix 1: Name of Participants

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