REPUBLIC OF KENYA

National Quality Management Guidance for HIV Testing Services in Kenya

Revised 2022

Foreword

The Government of Kenya has taken the lead, with support from development and implementing partners, to systematically put in place mechanisms to ensure the achievement of universal access to HIV testing. The Ministry of Health - National AIDS and STI Control Programme (NASCOP) developed and launched the HIV testing services operational manual in Kenya. This was an important step for Kenya to keep in line with the international guidelines and recommendations on quality HIV Testing services (HTS). The Ministry of Health (MOH) through NASCOP recognizes that there is need to minimize missed opportunities for HIV Testing services. It is for this reason that there has been a push towards diversifying testing approaches in the recent past. This push has seen an unprecedented scale-up of counselling and testing models and HTS delivery points.

The scale-up, however, must be achieved while guaranteeing quality of the HTS. This will be achieved by ensuring that the service providers have the necessary capacity and structures, as well as systems to deliver increased access to quality HTS. As we seek to diversify the testing efforts, we wish to ensure that quality is maintained across all the settings where HTS is provided. This document provides a broad policy framework of quality HTS, and it is my belief that all stakeholders will be guided by this document, as they provide HIV Testing services in a manner that observes all the Standard Operating Procedures and Bio-Safety recommendations.

I encourage all HTS providers in all settings to study the quality details described here and embrace them with a view to ensuring that HTS provision is guided by quality and not only driven by the need to see an increase in the numbers tested.

It is my sincere hope that this comprehensive HTS National Quality Management Guidance Framework will go a long way in helping to strengthen the provision of quality HTS which every Kenyan deserves. I look forward to a successful fulfilment of the objectives as set out in this guidance document.

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Dr. Rose Wafula,

Head, National AIDs and STI Control Programme

Acknowledgement

The Ministry of Health through NASCOP is grateful to the various individuals and institutions that dedicated their time, energy and expertise in the revision of the NQMG framework. Their input and guidance were of great value in ensuring that this guidance document was developed for use by the target audience.

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Executive Summary

The delivery of quality HTS is critical, hence the need to manage it effectively and efficiently. The aim of the National Quality Management Guidance Framework is to provide an outline for quality HTS in Kenya. This document describes systematic approaches to assessing, monitoring, and improving the quality of HTS to consistently meet clients' needs. Quality assurance measures should be in place in all elements of HTS. Provision of quality HTS is everyone's responsibility, from service delivery points up to the national level. Therefore, this document endeavours to ensure that quality becomes an integral part of HIV Testing services in the diverse approaches and settings, as provided for in the HIV Testing services operational manual in Kenya, i.e., community based and health facility settings.

This document advocates for quality in HTS service package protocol It further recommends the application of the core principals of HIV testing services summarized as the 6Cs: Consent, Confidentiality, Counselling, correct results, Connection and creating an enabling environment. Quality testing begins at the national level with the evaluation, approval, and registration of HIV test kits. Only HIV test kits that are provided for in the national algorithm by the Ministry of Health will be used for HIV testing in Kenya. Provision of accurate HIV test results is important, and this calls for continuous quality assessment.

This document gives guidance on quality commodity management which include realistic forecasting, procurement, distribution and storage of supplies. It also provides guidance on quality data management, which ensures accurate measures of current performance.

National standardized tools shall be used for HIV Testing services data collection and management. For this document to be utilized most effectively, NASCOP through the National Quality Improvement Team, via the decentralized structures at the County and Sub County levels, will continue to provide leadership and direction. The Ministry of Health will continue working closely with development and implementing partners and to ensure provision of quality HIV Testing services.

Acronyms

AIDS	Acquired immunodeficiency syndrome
ANC	Antenatal Clinic
aPNS	Assisted Partner Notification Services
ART	Antiretroviral Therapy
CAPA	Corrective Action Preventive Action
CASCO	County AIDS and STI Control Officer
CCC	Comprehensive Care Centre
CDC	Centre for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
CHMT	County Health Management Team
CHRIO	County Health Records Information Officer
CHS	Centre for Health Solutions- Kenya
CME	Continuous Medical Education
CMLT	County Medical Laboratory Technologist
CPD	Continuous Professional Development
CQI	Continuous Quality Improvement
CQIT	County Quality Improvement Team
DAR	Daily Activity Register
DBS	Dried Blood Spot
DQA	Data Quality Assurance
EBI	Evidence Behavioral Intervention
eMTCT	Elimination of Mother to Child Transmission
EQA	External Quality Assessment
FCDRR	Facility Consumption Data Report and Request Form
FQIT	Facility Quality Improvement Team
GBV	Gender Based Violence
HIV	Human Immunodeficiency Virus.
HPV	Human Papilloma Virus
HTS	HIV Testing Services
ICF	Intensive Case Finding
IPC	Infection Prevention Control
IVD	In Vitro Diagnosis
KASF	Kenya AIDS Strategic Framework
KEMSA	Kenya Medical Supplies Authority
KHIS	Kenya Health information system
KHQIF	Kenya HIV Quality Improvement Framework
KHSSP	Kenya Health Sector Strategic and Investment Plan
KNASP	Kenya National AIDS Strategic Plan
KNH	Kenyatta National hospital
KQMH	Kenya Quality Model Health
M&E	Monitoring and Evaluation
MoH	Ministry of Health
MTRH	Moi Teaching and Referral Hospital
NACC	National AIDS Control Council

NASCOP	National AIDS and STI Control Programme
NCD	Non-Communicable Diseases
NHRL	National HIV Reference Laboratory
NPHLS	National Public Health Laboratory services
NQIT	National Quality Improvement Team
NQMG	National Quality Management Guidelines
OPD	Out Patient Department
PEP	Post exposure Prophylaxis
PMS	Post Market Surveillance
PMTCT	Prevention of Mother to Child Transmission
POCT	Point of Care Testing
PPE	Personal Protective Equipment
PT	Proficiency testing
QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement
QM	Quality Management
RTK	Rapid Test Kit
SCASCO	Sub-County AIDS and STI Control Officer
SCHMT	Sub-County Health Management Team
SCQIT	Sub-County Quality Improvement Team
SOP	Standard Operating Procedure
SQA	Service Quality Assessment
TB	Tuberculosis
TOT	Trainer of Trainers
UMB	University of Maryland Baltimore
UNAIDS	United Nation Program on HIV and AIDS
VCT	Voluntary Counselling and Testing
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization
WIT	Work Improvement Team
WRP	Walter Reed Project

Definitions of Terms

Quality	The degree to which a health or social service meets or exceeds established professional standards and client expectations.
External Quality Assessment (EQA)	This is a method that allows for comparison of laboratory testing to a source outside the laboratory.
Quality Management (QM)	Involves coordinating all activities and resources needed to maintain a desired level of excellence in healthcare. QM is considered to have three core components (Quality Assurance, Quality Control and Quality Improvement).
Quality Improvement (QI)	This is a systematic and continuous actions that lead to measurable improvement in health service delivery/better health system performance.
Quality Assurance (QA)	A process of establishing standards and using them consistently as a basis for assessing performance. Results from quality assurance monitoring lead to the quality improvement process.
Quality Control (QC)	A procedure/system that is used to ensure that a health service adheres to a defined set of quality criteria or meets the requirements of clients.
Continuous Quality Improvement (CQI)	An approach to quality management that focuses on the process (not individual) to improve health care by identifying problems, perform a root cause analysis, implementing and monitoring corrective action and studying its effectiveness.
Small Tests of Change	A method to break down change into manageable chunks and test each small part to make sure that things are improving and no effort is wasted.
Indicator	In health, it is defined as a characteristic of an individual, population, or environment, which is subject to measurement (directly or indirectly) and can be used to describe one or more aspects of the health of an individual or population (quality, quantity and time).

Inconclusive HIV status	When the testing strategy cannot provide a positive or negative HIV-status. This is different from discrepant test results.
Testing event	A testing session by a HTS provider using the approved national algorithm
Persistent inconclusive status	A situation in which there is discrepancy between screening and confirmatory tests (Screening test – Reactive, Confirmatory test – Non reactive) in 2 testing events by 2 different service providers upon testing the same client.

Chapter 1: Introduction

National Quality Management guidance (NQMG) is a framework that guide on quality assurance standards addressing the gaps in quality of HIV testing services (HTS). This guidance is a revision of the NQMG framework developed in 2010. Following the revision of the Kenya HIV Testing Services (HTS) operational manual and development of a host of many Quality Assurance (QA) related policies and guidelines on Point of Care Testing (POCT), there was need to revise the NQMG to reflect the current quality assurance standards. The revised NQMG will address the gaps in quality of HTS and reflect the quality assurance roles of the new management structures in Kenya following the devolution of health services.

1.1 Goal of the guidance

The goal of the NQMG is to provide a comprehensive framework for quality HTS in all settings and approaches in Kenya.

1.2 Objectives of the guidance

The objectives of the NQMG is to provide HTS guidance on;

- Quality training of trainers (TOT) and service providers
- Quality assurance measures in HIV counseling, screening for other conditions and linkage
- Quality assurance practices in rapid HIV testing
- Quality Logistics management practices
- Coordination in provision of quality services
- Monitoring and evaluation strategies

1.3 Target Audience

This guidance targets HTS providers, HTS trainers, health care workers and health managers working in government, faith-based and private health facilities. Programme managers and policymakers in national and county governments, non-governmental institutions, private sector, commodity procurement agencies, development and implementing partners would all benefit from this guidance.

1.4 What informs this guidance

To ensure the highest quality of HTS, this guidance is anchored on both national and international quality standards for delivery of health services. The following quality assurance and quality improvement policy

documents form the basis for the standards and procedures recommended in this guidance:

The Kenya constitution 2010

- The Kenya AIDS Strategic Framework II (KASF II) 2020/21-2024/25
- Kenya Quality Model for Health (KQMH)
- Kenya HIV Quality Improvement Framework (KHQIF) 2014
- Kenya HIV Quality Improvement Framework (KHQIF) operational manual (2014)
- The Kenya National AIDS Strategic Plan (KNASP) III
- The Kenya Health Sector Strategic and Investment Plan (KHSSP III)
- Kenya HIV Testing Services operational manual (2022)
- A guidance document for the delivery of HIV Self-Testing and Assisted Partner Notification Services in Kenya (2019)
- Quality Policy Manual for Medical Laboratory Services in Kenya (2011)
- Kenya HIV Prevention and Treatment Guidelines (2022) WHO Consolidated Guidelines on HIV Testing Services (2019)
- WHO Technical guidance update on quality assurance for HIV rapid diagnostic tests (2015)
- Point of care testing policy guideline Edition 1: 2015

1.5 Background

Rapid HIV testing is recognized as one of the main strategies for HIV/AIDS prevention, care and treatment, and other support services (WHO, 2019). HIV testing aids in identification of those who are infected with HIV and link them for early interventions. In Kenya, there has been rapid scale up of HTS since the year 2000 (NASCOP, 2015). Since the beginning of the epidemic, sub-Saharan Africa remains the most severely affected, with almost 1 in every 25 adults (4.4%) living with HIV. The region also accounts for nearly 70% of the people living with HIV worldwide (UNAIDS, 2021). To accelerate the progress towards ending the HIV epidemic, Joint United Nations Programme on HIV/AIDS (UNAIDS) developed ambitious 95 -95 – 95 fast track targets that aim to transform the vision of zero new HIV infections, zero discrimination and zero AIDS-related deaths into concrete milestones and end-points. The target is to ensure that by 2025, 95% of all people living with HIV will know their HIV status, 95% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy and 95% of all people receiving antiretroviral therapy will have viral suppression (UNAIDS, 2020). To meet the goals of prevention and treatment programs, millions of people require HIV testing, especially in areas of high HIV prevalence (Operational manual). In Kenya, it is estimated that close to 1.43 million people are living with HIV/AIDs (PLHIV), (HIV estimates, 2021).

As a result of the increasing demand for HIV testing, effort to expand the services and to ensure access has been ongoing. On average 5M test are conducted annually according to KHIS. In Kenya, there has been a policy shift that has empowered non-laboratory staff including HTS Providers to offer HIV testing services (task shifting) as per the HTS operational manual. This policy shift has been associated with the huge scale up of HTS in the country including HIV self-testing (HIVST) and index testing. The Kenya HTS operational manual (2022) recommend integration of HTS with other services like tuberculosis (TB), prevention of mother to child transmission (PMTCT), sexual and reproductive health services (SRH), voluntary medical male circumcision (VMMC) and other HIV prevention services including evidence informed behavioral interventions (EBIs). (NASCOP, 2022). Kenya HIV Prevention and Treatment Guidelines, 2022 advocate for immediate treatment after HIV diagnosis, further increasing the demand for quality HTS.

With the rapid expansion of HTS , there has been challenges that sometimes result to human or equipment errors that affect the accuracy of HIV diagnosis, leading to incorrect HIV test results (NPHLS, 2016) .Quality issues for HIV testing relate to test kit quality, testing algorithm, training, quality control/assurance, quality of new lots, quality of logistics and supply of commodities, quality management, post market surveillance, external quality assurance (EQA), data quality assurance (DQA), quality counseling and quality linkage among others.

HIV testing, like other point of care tests, requires quality assurance systems to enable service providers to adhere to minimum quality standards. A quality system that addresses all aspects of HTS is essential. Currently, quality of HIV services is guided by the NQMG framework. The framework outlines strategies used to enhance quality of HIV testing and implementation. The Kenya HTS operational manual (2022) has been revised, with emphasis on 6Cs of Consent, Confidentiality, Counseling, Correct test results, Connection (linkage to care) and creating an enabling environment. In addition, the HTS package consist of pretesting counseling, HIV testing, post-test counselling, assessment of other health related conditions, referral, and linkage. The NQMG needed to be revised to reflect the changes in the national operational manual.

Chapter 2: Approach to Quality Management in HIV Testing

There are several approaches to quality management in HIV testing. These approaches are geared towards improving HTS.

The Constitution guarantees that every person has the right to the highest attainable standard of health (Kenya Constitution, 2010). Quality is the degree to which a health or social service meets or exceeds established professional standards and client expectations (KHQIF, 2014). Therefore, HTS must embrace quality improvement (QI) at all levels (facility, sub county, county and national) to meet expectations of Kenyans. There are many quality improvement (QI) models used in healthcare. HIV testing services has adopted the Plan-Do-Study-Act (PDSA) as outlined in the Kenya Health Quality Improvement Framework (KHQIF, 2014) and KHQIF operational manual (2014).

Delivery of quality services depends on all the building blocks of health systems, including optimized management, funding, human resources for health, information systems and procurement of high-quality supplies and commodities (WHO 2019)

2.1 Quality Management (QM)

Quality management involves coordinating all activities and resources needed to maintain a desired level of excellence in healthcare. QM is done on ongoing basis to provide services that meet or exceed clients' expectations. QM is considered to have three core components (Quality Assurance, Quality Control and Quality Improvement);

- Quality Assurance (QA) is a process of establishing standards and using them consistently as a basis for assessing performance.

- Quality Control (QC) is a procedure/system that is used to ensure that a health service adheres to a defined set of quality criteria or meets the requirements of clients.

Quality Improvement (QI) consists of systematic and continuous actions that lead to measurable improvement in health service delivery/better health system performance.

2.2 Continuous Quality Improvement (CQI)

Continuous quality improvement (CQI) is the systematic process of identifying, describing, and analyzing strengths and problems and then testing, implementing, learning from, and revising solutions. More simply, one can describe CQI as an ongoing cycle of collecting data and using it to make decisions to gradually improve program processes (Estes Park Health, 2020)

CQI is an approach to quality management that focusses on the process to improve health care by identifying problems, implementing, and monitoring corrective action and studying its effectiveness. Quality improvement in HTS entails 'doing the right thing, the right way, and all the time'. Quality improvement is the key to creating this culture and this framework shows how healthcare providers and managers can identify, implement CQI initiatives, continuously measure progress, report, and disseminate best practices, and use the data generated to improve HTS services at local, facility, county and national levels.

2.2.1 Benefits of Quality Improvement

- **Safe**: Systematic and organized approach is intended towards optimizing care for the clients it serves and avoids harm. **Effective**: By improving the HTS delivery process, the chances associated with errors are reduced.
- **Client-centered**: Improved efficiency of managerial and clinical processes leaves transition space for doctors and staff to provides responsive, respectful and value-based care to a client.
- **Proactive**: Improved processes recognize and solve the problems even before they occur.
- **Cost-effective**: Quality improvement processes are budget neutral. It avoids the cost associated with process failure, poor outcomes, and errors. Reliable and streamlined processes are less expensive to maintain.
- **Efficient**: Improving process makes wasteful activities associated with equipment, supplies, ideas, and energy more obvious and makes it easier to eliminate.
- Enables standardization to ensure an acceptable level of quality services
- Encourages a multidisciplinary team approach

2.3 The PDSA cycle for Continuous Quality Improvement

The PDSA model for improvement provides a framework for developing, testing and implementing changes leading to quality improvement. It is a scientific method for testing a change—by planning it, trying it, observing the results, and acting on what is learned.

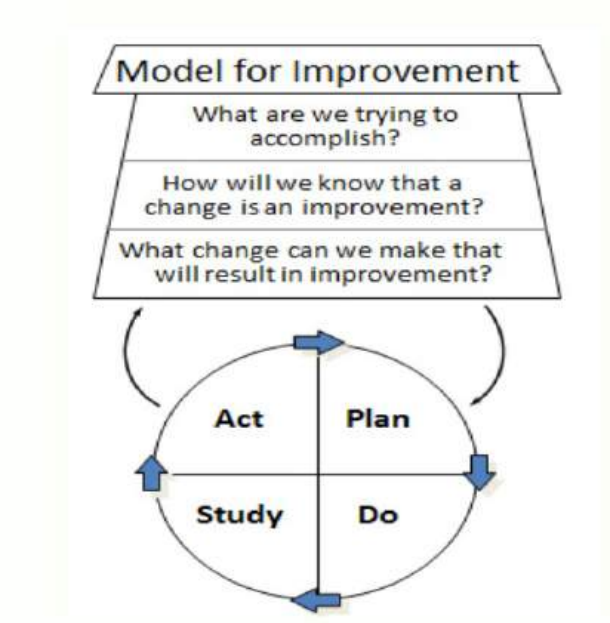


Figure 1: The Improvement Model (Adapted from the institute for Health Care Improvement)

Steps in the PDSA Cycle

Table 1: Steps in the PDSA Cycle

Steps in the PDSA Cycle	
PLAN: Plan the change	• Which process needs improvement? • What information and data do we need to understand the problem? • What is our project goal? • What change should be implemented? • How will the change be implemented? • How will the effect of the change be measured? • How will the required data be collected, documented and analyzed?
DO: Implement/ Test the change	• Implement the change • Continuously monitor and collect data per the plan
STUDY: Monitor and review the change	• Did the results match the theory/predictions? • Is there an improvement? If yes, by how much? • Are there trends? • Are there any unintended side effects? • Is the process more difficult using new methods? • Is the change scalable? Note: Studying should go on continuously throughout the improvement cycle.
ACT: Revise and plan use of lessons learnt	Did the results match the theory/predictions? • Is there an improvement? If yes, by how much? • Are there trends? • Are there any unintended side effects? • Is the process more difficult using new methods? • Is the change scalable? Note: Studying should go on continuously throughout the improvement cycle
ACT: Revise and plan use of lessons learnt	• Should the change be modified or a new change tested? (Return to Step 1: Plan) • Should the change be adopted? (continue to scale up/ maintenance phase)

Chapter 3: Quality Assurance in Counseling, Testing and Linkage

HIV Testing Services should be conducted in accordance with the best interests of the client. HTS services are guided by 6 core principles (6Cs); consent, confidentiality, counseling, correct results, connection to prevention, treatment and other appropriate post-test services and creating an enabling environment for HTS as described in the Kenya HTS operational manual,2022. Compromising quality of any aspect, affects quality of the others.

3.1 HTS Core Principles

The HTS services are guided by 6 core principles (6Cs);

- **Consent:** People receiving HTS must be well informed and voluntarily take up counselling and testing. They should be informed of the process for HIV testing and counselling and of their right to decline testing (no coercion).

- **Confidentiality:** Confidentiality in the context of HTS refers to privacy of interaction between the client and the service provider and obligation to hold in confidence medical or personal information regarding their clients. Confidentiality shall be maintained even after the patient's death. Client's names will be used in order to facilitate referral to other services and test results may be shared with other health care workers providing services to the client (shared confidentiality). Confidentiality shall be upheld except where consent has been expressly given or disclosure is allowed by law in the interest of public health. Confidentiality must be maintained when conducting all types of HIV testing and in all settings. Written documents should be stored in lockable cabinets accessible only by authorized personnel while electronic medical records should be stored in password protected computers. A person who contravenes confidentiality provisions commits an offence under the HIV and AIDS Prevention and Control Act (2006).

- **Counselling**. HTS counselling is aimed at allowing the client to make informed decisions and benefit from the HIV service package by the clients. Counseling includes pre-test counseling/information, HIV test, post-test counseling and referral and linkage to prevention, care and treatment services. Everyone who receives a HIV test is entitled to adequate information and counselling before and after the test to allow making of informed decisions. The length and scope of the counseling session will depend on the specific settings and needs of the client. It is recommended that pre-test counseling focus on providing information

to facilitate informed consent while the post-test counseling should be tailored on the outcome of the test and the individual client needs, including referrals and index testing. Post-test counselling is a critical component of client's linkage to treatment, retention and reengagement to care. Risk assessment and risk reduction counselling should be provided to all clients as part of HTS package. High risk HIV negative individuals should receive counseling tailored on the on-going risks and linkage to the specific prevention interventions.

- **Correct results:** HTS providers should strive to provide quality testing services and quality assurance mechanisms (both internal and external) should be in place to ensure the provision of correct test results to clients. Providers should adhere to the national HIV testing algorithm as part of the effort to achieve acceptable standards in test results given to clients.

- **Connection-(linkage) to prevention, treatment and other appropriate post-test services**: HTS services should be accompanied by appropriate, comprehensive and effective referral and linkage to post-test services.

    - Clients who test HIV positive should be linked to care, treatment and support services.

      Note:

        - It is the responsibility of the HTS provider to ensure all positive clients have been linked to treatment.

        - It is the responsibility of HTS provider who is retesting at the receiving facility to confirm linkage to the referring facility.

        - Confirmed Client linkage should be documented in the HTS Lab, referral and linkage register (MOH 362).

    - Those who test HIV negative and are at the risk of HIV infection should be linked to effective prevention interventions e.g PrEP, VMMC etc.
    - Clients who need post-test services, such as sexual and reproductive health (SRH) or TB services, should also be linked, as described in the Kenya HTS operational manual.

- **Creating an enabling environment for HTS:** Enabling people to make an informed and healthy choice to access HIV testing and engage in HIV treatment or prevention is a core public health function. The following are key areas to consider when creating an enabling environment for clients seeking HTS:

- Reviewing laws, policies and practices
- Reducing stigma and discrimination
- Empowering the communities
- Reducing Violence

3.2 HTS Service Package

The primary components of the HTS package are:

- Pre-test counselling/ Pre-test information
- Perform quality HIV test
- Post-test counselling
- Assessment of other health related conditions such as TB
- Referral and linkage

Note: *Before pre-test counselling, conduct HTS eligibility screening for all populations except ANC/PNC clients, children, couples and key populations to establish if the client is eligible for HTS or not*

The following minimum service delivery package should be offered for quality HTS

3.2.1 Pre-test Counselling

- Introduce and orient client to the session (ensure privacy of the setting).
- Check client's particulars and previous attendance.
- Do contracting with the client and state the time the session is likely to take.
- Address the option to opt out
- Provide information on other testing strategies (HIVST, index testing and/or SNS)
- Explain about the test procedures and reassure about confidentiality.
- Discuss potential implications of a positive and negative test result. Inform client how to interpret and read results.

- Provide information on retesting by a second provider if the HIV test is positive
- Conduct HIV risk assessment.
- Allow clients adequate time to ask questions and provide them with tailor-made information to address their concerns.
- Obtain client's consent/assent.
- Explain the benefits of ART.
- With the consent of index client, note sexual, drug injecting partners and children mentioned
- Throughout the counseling, be aware of client's mental and emotional status. If there are concerns, refer to a more experienced colleague.

3.2.2 HIV Test (as per the details in the testing section)

Guidance of approximate time taken to conduct a rapid HIV test

Table 2: Guidance of approximate time taken to conduct a rapid HIV test

Procedures	**Assay 1**	**Assay 2**	**Assay 3**
Test preparation	1 minute	1 Minute	1 minutes
Swabbing process	1 minute	1 minute	1Minutes
Pricking, harvesting and dropping blood into the test device	3 minutes	3 minutes	3 minutes
Results reading waiting time	Specific to test kit in use (Pre-test counselling to continue during this time)	Specific to test kit in use (Post-test counselling to continue during this time)	Specific to test kit in use (post-test counseling to continue during this time)
Reading the test results	2 minutes	2 minutes	2 minutes

Documentation of respective tools	5 minutes	2 minutes	2 minutes
Clearing and disinfecting the desk	2 minutes	2 minutes	2 minutes
Minimum time required for testing if above test kits are used.	Total time taken is dependent on the type of test kit used.	Total time taken is dependent on the type of test kit used.	Total time taken is dependent on the type of test kit used.

Note: The time indicated will be determined by HTS protocol e.g. counseling and testing, and specific test kits and test to be done.

3.2.3 Post-test Counselling

For Negative HIV test results

Explain that client is not infected unless within the window period (Refer to retesting guidance).

- Revisit the risk assessment
- Provide counselling on HIV prevention and risk reduction plan.
- Answer questions raised by client.
- Emphasize on retesting as per the retesting guidance if client continues risk-taking behavior.
- Emphasize on importance of knowing the status of sexual partners and information about the availability of partner and couples testing services
- Do condom demonstration as required and issue/refer for condom

For Positive HIV test results

- Explore and acknowledge client's feelings, fears and concerns, offer necessary support
- Review and encourage disclosure, and partner notification
- Discuss positive living and help client come up with a risk reduction plan

- Explain importance of immediate linkage to HIV care and treatment, including undetectable =untransmissible (U=U)
- Explain that this is a preliminary positive test result and refer the clients to CCC for retest and linkage to treatment
- Revisit index testing and HIVST to determine partner notification plan/approach
- With the consent of index client, Obtain contact information of index client contacts.
- Conduct Intimate partner violence (IPV) assessment
- Capture locator information
- Obtain a written consent to contact the index clients contact
- Discussion of the risks and benefits of disclosure to partners; couples counselling should be offered to support mutual disclosure.

Post-test counselling for inconclusive result:

- Explain the meaning of an inconclusive result
- Discuss and address the client's immediate concerns
- Normalize and validate client's feelings
- Inform the client that the test will have to be repeated after 14 days
- Conduct repeat testing as per the national algorithm

NB: Quality assurance in Assessment of other related conditions such as TB (continues during pre and post testing) should be done in line with the existing national tools.

3.2.4 Linkage to Prevention Services

Based on the client's results, high risk HIV negative clients who screen positive for various risks are effectively linked to respective prevention interventions. This package comprises but not limited to;

	Referral Service	Eligible clients	Follow up HIV testing
1	PEP	Exposed to HIV within 72hrs	Re-test at 4 weeks. For negative clients retest at month 3 after which usual guideline should apply.
2	PrEP	Client with ongoing risk to HIV infection	Retest at Month one, Re-test at month 3 then retest after every 3 months
3	STI	With STI or exposed	Retest at 4 weeks, for negative clients retest at month 3 after which usual testing guidelines apply
4	VMMC	Uncircumcised male	Tested every two years after HTS screening
5	GBV	Any client who has undergone sexual violence	Follows PEP testing schedule.

NB: For key population, the prevention services and repeat testing schedule are offered in line with the KP guidelines.

3.2.5 Quality Assurance in Assessment of Other Related Conditions

Assessment of the below listed conditions should be done in line with the existing national guideline. Screen, provide health education and/or refer for:

- Sexually Transmitted Infections (STIs)
- Tuberculosis
- Gender Based Violence (GBV)/Intimate Partner Violence (IPV)
- Alcoholism
- Triple elimination of mother to child transmission of HIV, Syphilis and hepatitis B
- Voluntary Male Medical Circumcision (VMMC)

- Family planning
- Non-Communicable Diseases (NCDs) e.g., cancer
- Psychosocial issues.

3.2.6 Referral and Linkage to Other Appropriate Health Related Services

- Support the client to decide on appropriate Referral Facility
- Encourage patient to attend HIV care/treatment site closest to his/her home that is also acceptable to him/her.
- The client should be enrolled into care on the same day after retesting by a different provider.
- Document referrals and linkages in the HTS Lab, referral and linkage register
- In line with specific national guideline, prioritize referral for any other health condition in need of further management

To adhere to the protocol, HTS Providers should have easily accessible job aids as a quick reference at each service delivery point

3.3 Quality Assurance in Counselling

Counselling is an integral and important part of HIV testing services. It offers a window of opportunity to share important HIV prevention information and empowers the clients to focus on solutions for risk reduction. It should result in appropriate timely and effective linkage to care and support services like GBV and TB screening.

HIV testing services should be guided by the following quality counselling core conditions;

- Unconditional Positive Regard
- Empathy
- Genuineness

The core principles should guide HTS providers in following a defined protocol in order to uphold Quality assurance measures in Counselling. To

achieve this and uphold quality in counselling services, the following need to be in place;

- Counselor support supervision
- Administrative support supervision
- Observed practice
- Client exit interviews
- Provider self-assessment
- Mentorship

3.4 Quality in HIV Testing

Quality in HIV testing is of utmost importance in provision of HTS. This process ensures accurate, reliable and timely results to the client. This involves; proper identification of clients, appropriate infrastructure, proper and quality testing commodities, qualified staff, adherence to job aids/SOPs, proper documentation/national approved registers (e.g. ANC, HTS and Maternity registers among others) and participation in External Quality Assessment (EQA) by way of proficiency testing and support supervision.

3.4.1 Classical Process Control in Quality HIV Testing

Process control refers to the activities and techniques that are carried out to ensure that the testing procedures are performed correctly, the environment is suitable, and the test kit works as expected to produce accurate and reliable results.

3.5 Counsellor Support Supervision

Counsellor support supervision/debriefing is a forum that gives HTS providers an opportunity to come together, discuss and process issues that arise during HTS with a qualified and experienced HTS supervisor either during group or one-on-one sessions. It is important for preventing 'burn out' of individual HTS providers and maintaining high quality communication between providers and clients. All HTS providers should attend at least one Counsellor support supervision per Quarter, with documented evidence.

3.5.1 Administrative Support Supervision for HTS

This is overall coordination and overseeing of the provision of HTS by National, County and sub-county program managers

- Administrative support supervision is aimed at strengthening management and administrative duties.
- It should be carried out at all levels. I.e. national, county, sub county and site levels.
- The national level offers technical support where required, either scheduled or need based
- At the county level, this is recommended annually facilitated by a respective CHMTs and quarterly at the sub-county level facilitated by the respective SCHMTs. It can be integrated in routine supervision for other health services
- This helps in troubleshooting the various quality issues and offer on job trainings in areas identified.
- A standardized site assessment tool will be used

3.5.2 Observed Practice

Observed practice is a mechanism of providing instant feedback to counsellors on a counselling session conducted.

- It's conducted by an experienced counsellor or counsellor supervisor, with the consent of the client.
- The observer, using a standardized check list, sits through a counselling and testing session
- Gives feedback to the counsellor at the end of the session, based on what they had observed.
- Confidentiality should be observed by all parties
- The observed sessions are done and documented on quarterly basis

3.5.3 Client Exit Interviews

Client exit interviews are structured questionnaires administered on clients that have received HTS.

- This approach is aimed at obtaining client views on the quality and their satisfaction of services received.
- This can be administered by independent interviewers or clients can pick forms and fill them as feedback.

- This is done on quarterly basis with documented evidence of implementation of recommendations

- Facilities should also provide suggestion boxes for collection of anonymous client feedback at any time, and face-to-face client feedback should also be encouraged

3.5.4 Provider Self-Assessment

Counsellors should use standardized NASCOP approved self-assessment forms to monitor the quality of their own service provision over time. This is a self-evaluation of a completed HTS session by the HTS provider.

- The tool focuses on all key components of the HTS service package.

- Counsellors are required to fill at least one self-assessment form per month.

- This will be summarized and discussed Monthly with their supervisor, as they review their performance.

3.5.5 Mentorship

HTS mentorship entails attaching a less experienced HTS provider to an experienced HTS providers for guidance and support on HTS provision. All newly qualified HTS providers should be attached to a mentor for at least 3 months.

Chapter 4: Standard Requirements For HTS Provision

A continuous and systematic approach should be put in place to guide on quality assurance (QA) practices, to ensure good quality and reliability of HTS. A set of minimum standards are used to provide guidance for compliance with the national requirements for implementation of continuous quality improvement. These standards are as outlined below:

4.1 Personnel Training and Competence Maintenance

The quality of HTS is heavily dependent on a well-trained network of providers and supervisors. Personnel providing HTS, training, and supervision are therefore subject to a minimum set of training and competence acquisition standards. These standards include:

4.1.1 Training in Approved HTS Institution

Training of HTS providers should always be conducted by institutions that meet minimum requirement of NASCOP assessment. The assessment process will involve objective physical on-site assessment as guided by a standard checklist (annex 7) to determine fulfillment of the following:

- Suitable infrastructure
- Sufficient infection Prevention Control and safety measures
- Qualified HTS Trainers
- Management structure
- Implementation of Training Quality management systems.
- Availability of Accessories and consumables for practical session
- Provision of trainees' affairs and support services
- Quality management practices
- Availability of training resources

Initial assessment of training institutions will last for a period of 2 years. Thereafter, surveillance will be conducted on annual basis to ensure maintenance of the required quality standards. Initially, approved institutions may lose their status if they are deemed to have failed to maintain the standards following findings of surveillance assessments. They will therefore

not be allowed to continue offering HTS training unless they demonstrate reinstatement of the requirements in a later assessment.

4.1.2 Trainers of Trainees

Trainers of Trainees (ToTs) should always be individuals who have undergone the NASCOP approved training program that should culminate in certification. Eligibility for this training should include possessions of diploma in social / health sciences and be proficient in HTS. ToTs should endeavor to gather relevant skill and program updates, post-qualification through refresher trainings, acquisition of new information through wide reading, attendance of conferences etc.

4.1.3 Training of Service Providers

Only eligible individuals should be enrolled and trained as HTS providers. At a minimum, individuals without any medical training should possess O-level education with a Diploma in social sciences.

Note: *Already trained and serving individuals who don't possess Diploma in social or health sciences should endeavor to fulfill the above requirement while still in service*

HTS trainees should undergo the standardized comprehensive training program. The recommended training period and sessions must be covered. As part of the training, every trainee should acquire exposure to practical sessions, during which observed practice should be conducted. The observed practice should be managed by experienced HTS counselor/HTS provider and should include sessions involving at least 4 individual clients and 2 couples. Upon qualification, service providers shall be provided with controlled national level verifiable certificate from NASCOP. The certificate will have security features that will be useful in verifying whether it is genuine. A national database of genuinely certified HTS providers will be maintained at NASCOP and will be updated from time to time. No individual will be allowed to offer HTS unless they satisfy the above requirements.

Note: *Individuals in prior possession of any level (certificate, diploma or degree) of health training will be eligible for HTS training and will therefore not be required to possess a diploma in social sciences.*

4.1.4 Refresher training

Refresher trainings are necessary for continuous sustenance of competence and skills for both HTS trainers and providers. The training should be designed to provide program updates, strengthen identified areas, and enhance knowledge in critical program areas. All service providers should undergo refresher training at least ones per two years. The trainings can be

class-based or in form of on-site training as per the HTS training guide. Certified copies of refresher training certificates or training records will be kept in an easily accessible manner.

Note: 1. *HTS trained individuals who have not been in practice for more than one year are required to undergo refresher training and provide certificate or verifiable records of training before being allowed to provide services.*

Note 2. *HTS supervisors and managers will make deliberate efforts to ensure that there are equitably and appropriately distributed personnel to ensure Service provision, supervision, comprehensive data collection, transmission and analysis as well as policy implementation and oversight.*

4.1.5 Continuous Maintenance of Competence

HTS providers are also required to access continuous means of increasing mastery and maintenance of the required work skills. This can be done through mentorship, support supervision and participation in CMEs, CPDs. Record of participation in any of these activities will be kept. Health professional will keep records that meet the standard set out by the respective regulatory bodies. Certified copies of training records will be kept in an easily accessible manner. Objective assessments of service provider continued performance will be conducted periodically.

4.2 Availability and Adherence to National HTS Operational Manual, Protocols and Procedures

HTS providers will be required to adhere to all the policies and standards as outlined in the operational manual. HTS related guidelines for specific program area (e.g. PMTCT, ART) or extracts of the guidelines that outline the key day to day operations should be available in all sites. The job aids should include but not limited to:

- Current HTS protocols for conventional HTS, HIVST and other innovative strategies.
- Current HTS algorithm
- Procedures for each of the tests currently in the algorithm
- Waste Management – segregation, disposal of sharps, infectious and non-infectious waste
- Management of blood spills
- Infection Prevention and Control
- Post Exposure Prophylaxis protocol

- Commodity management

All guidelines/extracts should be available and easily accessible at the points of service provision. They must be adhered to during the related operation/task.

4.3 Suitable Physical Facility

All HTS service provision models used in sites and facilities shall make every effort to ensure privacy and confidentiality. In health facility settings where services are provided at open Spaces e.g. wards, OPD etc. screens should be availed to provide visual privacy for clients taking up services. Otherwise whenever possible, a room shall be identified and used for HTS service delivery. HTS services provided in community settings shall be provided in a well ventilated VCT room, tent, van or home. All care will be taken to ensure that clients have privacy and confidentiality when receiving the services.

HTS will be provided in diverse settings.

a) Health facility settings

- It is desirable that a designated room with adequate space or a partition is provided to ensure safety of clients' information and confidentiality.
- Where services are provided at open spaces (e.g. wards, OPD etc.), screens will be availed to provide visual privacy for clients taking up services.
- Service space will be maintained in clean and organized state.
- The primary light source should be adequate to allow for good conditions while conducting testing as well as visualization of test results
- Monitoring of environmental temperatures to ensure that Test kit storage and testing environmental conditions are appropriate according to manufacturer's instructions
    - Where temperatures are normally higher or lower than recommended by test kits manufacturers', innovative efforts should be made to keep temperatures in control (eg use of refrigerators, Air Conditioner or sand pots)
    - Temperature should be monitored daily in the morning and afternoon
- Storage space for test kits and other supplies should be sufficient, secured and accessible to the authorized personnel.

- Service delivery points must be accessible and convenient for all the segments of the population including people with disabilities and the marginalized.

b) Community settings

- Well ventilated tent, van or home/outreach facilities should be provided to ensure that clients have privacy when receiving the services.
- Stand-alone VCT room should meet the requirements outlined for the health facilities.
- Monitoring of commodities shall be done at the linking facility using the standard bin cards and top up cards.
- The kits should have their temperature monitored at the point of storage as well as during the outreach activities. Every HTS provider should be assigned a full pack of the test kits with all its components, avoid exposure to direct sunlight and adverse conditions.
- HTS providers should use the standard HTS package while offering services in the outreaches.
- Waste disposal in community settings should follow the biosafety guidelines regarding segregation and disposal. All waste generated in the various community models should be linked to a heath facility for storage and disposal.

In all settings, hand washing facilities should be available (clean running water and soap or hand sanitizers). Similarly, there should be facilities to accommodate safety practices.

4.4 Safety Practices

4.4.1 Workplace Organization

HTS site should have organized processes in place providing for the safety of staff members, patients, community and the environment. SOPs and/or job aids should be in place to implement safety practices e.g., SOPs and/or job aids on management of sharps, infectious and non-infectious waste, blood spills. Personal protective equipment (PPE) e.g., aprons/lab coats, gloves should always be available and consistently used while providing services.

4.4.2 Waste Management

Procedure for handling sharps, infectious and non-infectious waste should involve:

- Segregated in accordance with the various categories – disposal into different color-coded biohazard bins and liners (black/white for general office waste e.g. paper and yellow for infectious waste e.g. used gloves, gauze) and sharps container (Annex 3).

- Use of puncture proof waste containers and ensuring that they are closed in between and after use.

- Three quarter full safety boxes should be closed, and waste bags tied.

- Details of waste generation source should be indicated on the waste bags.

- Regular disposal of sharp containers and waste bags as per the guidelines in the biosafety and biosecurity manual.

- The waste needs to be kept in a secured designated holding area with restricted access.

- Waste disposal from the facilities should be carried out by licensed biohazard waste holders and documentation should be available in the facility.

- Disposal of HIVST waste should follow the manufacturer's instructions.

4.4.3 Hand washing Practices

Hand washing facilities should be available in the form of clean running tap water and soap. Alternatively, functional engineered bucket/container or hand sanitizers can be used. job aid on how to handwash should be availed (Annex 4). Daily disinfection (at beginning and end of day) of work benches should be done using an appropriate disinfectant (e.g. 0.5 % sodium hypochlorite). Daily bench disinfection records should be maintained at site and recorded in the Bench Decontamination log (Annex1). Disinfection should always be done in case of blood spills (Annex 2).

4.4.4 Post-exposure Prophylaxis

In case of accidental exposure to blood through a needle prick injury, splash or other sharps injuries, the affected person should seek Post Exposure Prophylaxis (PEP) services as per the procedure outlined in the national Infection Prevention and Control (IPC) guidelines and facility standard protocol. Records of the incidence should be maintained at site/facility. Facilities should prepare their own PEP protocol.

4.4.5 Vaccination

All HTS providers are required to have Hepatitis B Virus (HBV) vaccination as protection against possible occupational exposure. The full dosage should be completed at the required time.

4.5 Pre-testing Phase Practices

Before testing, service providers and supervisors should ensure that written procedures are in place.

Quality control specimen (known HIV positive or negative sample) should be tested *(monitoring performance of test kits section)* to verify that the test kits are in good working condition. Additionally, efforts should be made to ensure test kits to be used are stored appropriately to avoid possible deterioration and that they are not expired at the date of use. Testing area should be well set up to avoid clutter and accord operational convenience. All needed testing materials should be assembled prior to conducting test procedures. Test devices should always be labeled with clients' identifiers.

4.6 Testing Phase Practices

During testing, HTS providers should always observe/adhere to the following:

- Current HTS algorithm
- Use samples collection devices specific to the test and the assigned buffer respective for the test kit.
- Accurate use of sample collection devices (e.g., capillary tube, disposable pipettes, etc.)
- Collect the correct sample as per the job aid (Annex 5)
- Written procedure for specific tests in the algorithm.
- Consistent use of functional timers during testing
- Correctly interpret test results.
- Repeat invalid test results

4.7 Participation in EQA

All HTS providers are required to enroll and participate in EQA program (Proficiency testing and technical supervision). Records for participation and performance are reviewed by supervisor and will be kept at site/facility level

and should be made available to in-charges and QA supervisors. Effective corrective and preventive actions should be carried out as required. Documentation of root cause of unsatisfactory performance should be done and records maintained.

4.8 Documentation

Complete and accurate documentation of HTS process is critical. National HTS standards require all testing points to use standardized registers with all key elements e.g., client demographics, kit names, lot numbers, expiration dates of test kits used, HTS provider name, individual and final HIV results. Total summary at the end of each page of the register should be compiled accurately. Periodic review and analysis of data from registers should be done. Trends of sudden increase/decrease of positivity, increased invalid and inconclusive results should be identified and necessary corrective measures taken that include evaluating the quality of HTS process and performance of test kits. To ensure confidentiality, all client documents and records should be securely kept throughout all phases of the testing process and when not in use and should be properly labeled and archived when full according to government regulation and quality policy manual for Medical Laboratory services in Kenya.

4.9 Commodity Management

Only nationally approved HIV tests should be available for use, kits used for provision of service should be within expiration date. Test kits should be handled and stored according to manufactures instruction. Kits and other supplies should be locked in a safe and secure place. An effective commodity management system must be put in place to ensure the accessibility of, and effective use of HIV Test kits at the service delivery points e.g., Quantification, reporting, ordering, supply and distribution.

4.10 Monitoring Quality and Performance of Test Kits

The accuracy and reliability of HIV test results is highly depended on test kits that should produce the expected results when the correct test procedures have been followed. Test kits performance should therefore be monitored as routine practice through a combination of practices which include:

4.10.1 External Quality Control

The viability of test kits will be confirmed by using known HIV positive and known HIV negative samples in the laboratory. In cases where a health facility lacks a laboratory, the Sub County Laboratory Coordinator or designee will make arrangements to ensure viability is confirmed. The External quality control specimen will be tested:

- **When a New Shipment of Test Kits is Received**

One kit from each of test types represented in the consignment will be randomly sampled. Two devices will be selected, with one being used against the known HIV positive while the other will be used against the known HIV negative sample.

- **Beginning a New Lot Number**

Two devices will be selected from a kit representing the test whose lot is changing. One of the devices will be used against the known HIV positive while the other will be used against the known HIV negative sample.

- **At the Beginning of a New Month**

Two devices will be selected from kits in current use in a service delivery point (SDP). One of the devices will be used against the known HIV positive while the other will be used against the known HIV negative sample.

- **When Test Kit Storage Conditions Change**

If there is a change in monitored conditions under which test kits have previously been stored, two devices will be selected from a kit representing the test types that are being stored in the new conditions. One of the devices will be used against the known HIV positive while the other will be used against the known HIV negative sample.

- **After an Invalid Test**

After ruling out that the test device kits are not damaged or expired, procedure for testing was followed, repeat the test. If the result is still invalid, the external quality control specimen will be tested to ensure that the test kits are working. Satisfactorily performing test kits should yield the results expected from the samples with known reactivity results ie reactive results with the known HIV positive sample and non-reactive results with known negative sample. If unexpected or invalid results are obtained, troubleshooting should be done to establish the cause. This should include investigations for possible sample contamination, wrong characterization or mislabeling. If these are ruled out, unexpected results should be interpreted to mean performance of concerned test kits is compromised and should thus not be used. The Sub County Lab Coordinator should be informed forthwith for upward reporting. If results obtained match with the expected ones, the test kits concerned should be confirmed as performing satisfactorily and deemed suitable for use. Results obtained as well as actions taken should be appropriately documented on QC logs in the registers.

4.10.1.1 Post-market Surveillance of Rapid HIV Test Kits

To ensure test kits remain safe and effective once they reach the Kenyan market, post market surveillance will be undertaken. This involves a collection of processes and activities used to monitor the performance of the test kits. The post market surveillance will be done both proactively and reactively.

4.10.1.1.1 Proactive Post Market Surveillance

This will involve identifying a potential problem before it affects accuracy of HIV test results. When shipment of new kit lot is received in the country, performance verification will be conducted pre-distribution. Performance verification will also be done post-distribution by sampling kits from the health facilities where the end users are and tested at the national HIV reference lab. This will be aimed at:

- Ascertaining that test kits continue to conform to their specifications
- Identifying any catastrophic test kits failure
- Determining variation from one kit lot to the next
- Establishing that test kits have not been adversely affected by inappropriate storage and transport conditions.

4.10.2.1.1.1 Pre-distribution Verification

This will be done once test kits are received at the central store and before distribution to testing sites to ensures that only lots with good performance are distributed. Sufficient additional quantities of RDTs should be procured to enable collection of post-market surveillance data.

4.10.2.1.1.1 Sampling at the Central Store

The process will be conducted by appropriately trained and qualified personnel. Each lot in the central store will be sampled. A representative sample of tests per lot should be taken. The number of tests will depend on the protocol in use. On receipt of HIV test kits consignment, the central stores will notify the National HIV Reference Laboratory and provide them with sampled test kits for verification and analysis of test kits performance.

4.10.2.1.1 Post Distribution Verification

In order to detect potential deterioration of performance of test that would arise over longer periods of time, continuous monitoring will be done on the same lots that were verified pre-distribution. This will also verify that transport and/or storage conditions have not affected performance of the test kits and that stability (shelf life) claims made by the manufacturer are met. A vigilance system will thus be scheduled at least annually and implemented by ensuring that every lot is sampled post distribution.

4.10.2.1.2.1 Post Distribution Sampling

A sample of test kits from the same lot should be taken in HIV testing points at different levels of the health system as follows:

- All tiers of health facilities
- Faith based hospitals
- Private hospitals
- Stand-alone testing sites

Different geographical areas should be covered, i.e., if test kits from a primary care testing level from a geographical area has been sampled, the next sampling should not involve a primary care testing level from the same geographical area.

Appropriately trained and qualified personnel constituted should do the sampling at all level. Random sampling should be done according to the PMS protocol.

A complete test kit will be sampled with a replacement of the same kit done by the team conducting sampling. The facility assessment will comprise of a structured tool to enhance information collection on test kits.

As part of good practices, a sample batch should consist of all components of the test kit as described by the manufacturer including kit inserts and any accompanying leaflets. The sampling team will ensure samples are transported to the National HIV Reference Laboratory in such a way that the integrity of the test kits is not adversely affected and that the appropriate storage conditions, as specified by the manufacturer, are maintained. Temperature log monitors should be included within the transportation package of the samples.

4.10.1.1.1 Monitoring HIV Test Kits Performance through Evaluation of EQAS and QC test results

In addition to lot verification testing and complains, performance of rapid HIV test kits can be done through assessment of data obtained from the national proficiency testing (PT) scheme and from quality control (QC) results.

Use of Proficiency Testing data: analysis of PT data may indicate errors related to the tests in use, given that large numbers of testing sites that use the same tests. The lot numbers of test kits used to test PT panels should be recorded to make this data useful. The national HIV PT scheme management will maintain data repository. Analysis will be done on the PT data to monitor the performance of test kits used already in the market after every PT round. Performance of different test kit lots will be monitored. Report of findings will be shared with stakeholders.

Use of Quality Control (QC) data: The performance of QC specimen should be documented. Trouble shooting should be done and documented for any failure noted. Unresolved cases should be reported to the next level.

4.10.2.2 Reactive Post Market Surveillance Mechanism (Vigilance system)

This occurs when a problem has been identified during use of the HIV rapid test kits. It is carried out through reporting and evaluation of complaints, including reports of adverse events, and any required actions to correct the problem and prevent recurrence. Reported adverse events should be evaluated and the information disseminated in order to provide a driving force to prevent or minimize the consequences of such events. This may involve removing the affected test kits from use. More data/information of the kit should be gathered, and appropriate corrective actions taken. Reactive Post Market Surveillance may also be triggered by information obtained from on-going external quality assessment schemes activities or operations research data. Examples of events that may raise suspicions on performance of test kits may include:

- Increased screening and confirmatory test result discrepancy (>2 %)
- Increased results invalidity (>1%)
- Insufficient clarity of reactivity markers eg faint lines
- Insufficiency of test reagents
- Presence of visible reactivity markers before device use

- Reaction with specimen other than the specified one or other substance (s) e.g., for blood-based test kits giving a reaction with urine or water.
- Inaccuracy in the labelling of the kit,
- Inappropriate instructions for use
- Insufficient /Missing information e.g., expiry date.

Service providers should document any problems with test kits using information obtained from the testing service registers, inventory records, item requisition and delivery records. These may include affected product code(s), affected lot number(s), and expiry date(s), affected consignments or test kits and any measures taken. Where possible, photographs of affected test devices and/or test kits should be taken to illustrate the problem. Users should keep and appropriately store at least 1-2 affected test kit as retention kits for later testing, if required.

In case the problem/complain is identified from data analysis, the following should be done:

- Conduct QA audit at sites level
- If unresolved, report to the county level
- In the event of testing anomalies noted from program level, the county team can review their QMS. A corrective action can then be implemented followed by reviewing of any improvements. If the anomaly persists, a report should be prepared and interventions sought from the national level.

At the National level, the course of action will involve;

- Sampling same lots associated with the anomaly from the data, if available at the site, or from neighboring sites for confirmation
- Conducting a thorough QA audit

Reports generated from reactive PMS will determine the interventions required. Such interventions may include:

- Test kits recall
- Recall of specific test kit lot
- QA auditing
- Corrective actions after root cause analysis

- Report to Ministry of Health/ Regulatory authority.

Depending on the seriousness of the test kits deficiency discovered in the post-market phase and/or potential for future harm, Ministry of Health/ Regulatory authority should consider the following possibilities as well:

- Perform additional in use surveillance of the test kits concerned
- Issue an alert giving advice to service providers
- Send the data acquired to the manufacturer and store it in a database to help identify trends that require action.
- Request the manufacturer to make appropriate changes in the design, manufacturing process or information supplied with the product;

4.11 HTS Service Delivery Point (SDP) Quality Assessment and Certification

To evaluate the extent to which HTS service delivery points have complied with the standards outlined in chapter 4, an objective service quality assessment will be carried out periodically. The assessment findings will be used to identify areas that require improvement as well as to determine whether site has attained the required level for formal recognition for implementation of quality standards.

4.11.1 Service Delivery Point Quality Assessment Process

HTS sites will require planned assessment to enable ongoing monitoring for site certification. The assessment will be conducted by trained and certified HTS site assessors while the ones for monitoring site improvement will be conducted by trained quality officers. To achieve impartiality during site certification assessment, no assessor will be allowed to participate in event involving sites in which he/she has personal or official interests. The process of site assessment can be summarized as follows:

a) Pre-assessment stage steps

- SDPs for assessment will be identified
- Identified SDPs will be notified sites and assessment dates agreed on
- Planning for assessment logistics will be done
- Checklist/assessment areas will be shared

- Assessment team will familiarize the process and tools

b) Assessment steps

- Assessment teams will be introduced to county, sub county and facility management
- Purpose of assessment will be introduced
- Assessment process will be described
- Assessment will be conducted using the standardized checklist

c) Post-assessment steps

- Debrief will be done to SDP/facility management
- Agreement on findings, action points and timelines for implementation of recommended corrective actions will be done
- Point of contacts for follow up actions will be identified

4.11.2 Assessment procedures

A standard assessment tool (the SDP Service Quality Assessment (SDP-SQA) tool) will be used (annex 6). Standard assessment procedures will be employed to provides a description of how and what data will be collected. These will include the following:

- Reviewing of records and documents to verify and confirm evidence of compliance e.g. test records, supervisory visit reports, incident reports, logs, Standard Operating Procedures (SOPs), and job aids
- **Asking open-ended questions** to clarify documentation seen and observations made.
    - Asking questions like, “show me how…” or “tell me about…”.
    - It is often not necessary to ask all the checklist questions verbatim.
    - An experienced Assessor can often learn to answer multiple checklist questions through open-ended questions with the site staff.
- **Following through the HTS provision process** whenever possible
- Follow client through the testing process

4.11.3 Grading of Assessed Service Delivery Points

At the end of the assessment, scores will be awarded against the various assessment areas. Average of the aggregate score will be used for staging SDPs to either of 5 levels ranging from level 0 to level 4.

The site scores, level and required actions will be summarized as follows:

Levels	% Score	Description of findings
Level 0	Less than 40%	Needs improvement in all areas and immediate remediation
Level 1	40–59%	Needs improvement in specific areas
Level 2	60–79%	Partly eligible national SDP certification
Level 3	80–89%	Close to national SDP certification
Level 4	90% or higher	Eligible to national site certification

SDPs that will achieve a low score in specific area will be provided additional support and corrective actions. Appropriate corrective actions will include training (both initial HTS and refresher as needed), provision of lacking QA tools e.g., job aids, guidelines, timers, PPE etc. to improve their performance. Only sites that will attain 90% (Level 4) will be considered for certification upon request by the CHMT.

4.11.4 Certification of Service Delivery Points

A certificate of recognition will be issued to eligible SDPs and will be valid for 3 consecutive years. However, such a site will undergo annual surveillance to ensure that they uphold the standard requirements. Assessment for both certification and surveillance purposes will be conducted by MOH trained and certified HTS site assessors.

However, to maintain quality standards of HTS service provision, it is advisable that SDPs be assessed quarterly. This will be done by the facility laboratory quality officer or HTS coordinator. The assessments results will be used to guide on corrective interventions. Quarterly assessments will help the sites in reaching and maintaining certification standards and should therefore be a continuous process. Documentation of the assessments and corrective interventions should be maintained in the facility and should be used to inform the management to support improvements.

Chapter 5: HTS Quality Management Structures and Coordination

HTS Quality improvement is an integral component of the general QI in all health facilities offering HTS in the country. Therefore, it is very critical to have QI teams from the national to the facility level whose mandate is to ensure quality HIV services. Interdisciplinary HTS QI teams are the best mechanisms for driving the quality culture and the QI process. It is recommended that some team members have managerial decision-making skills that can directly influence quality of service delivery.

Community involvement is critical to the continued success and improvement of health services. HTS providers and managers are encouraged to embrace participatory approaches to QI in the community and can be used to strengthen dialogue between communities and service providers. Health facilities are encouraged to invite local community volunteers to be part of facility QI teams.

Managers and service providers will strive to ensure that there is free information flow, both from service providers to the community and vice versa. Some of the functions of QI teams are illustrated in the table below:

Table 3: Functions of QI teams

LEVEL	INSTITUTIONS	RESPONSIBILITIES/FUNCTIONS
NATIONAL **(NQIT)**	• NASCOP • NPHL • NACC • KEMSA • Professional bodies eg KMLTTB and PPB • Developing and implementing partners	• Provide leadership and advocacy for QI of HTS in Kenya • Mobilizing resources for QI activities in HTS • Set quality as a priority and clearly communicate this message to stakeholders • Review and development of guidelines, curricular standards, and standard operating procedures (SOP) including National QI mechanisms, M&E tools, and approaches • Coordinating developing and implementing partners involved in QI activities • Make recommendations to NASCOP/MoH on

		issues of quality HTS provision. • Development of short- and long-term objectives for QI of HTS in Kenya • Development of an annual work plan for achieving the national QI objectives • Conducting annual quality assessment (DQA/SQA) at respective levels • Review national progress on QI and annual reports on quality of HTS in Kenya • Dissemination of information on quality of HTS to stakeholders and partners • Feedback to the relevant national systems, for facilitation of appropriate policy development • National registration, licensing, and accreditation of HTS sites and providers as required • National listing, registration, and licensing of the HTS commodities and devices • Maintenance of an updated inventory of certified HTS providers • Capacity building of county teams and other National teams involved in HTS activities • Ensure equitable and appropriate distribution of resources and logistics for HTS services • Assessment of priority areas for quality improvement, technical assistance, and capacity building needs • Technical guidance on procurement and supply chain management • Conduct HTS stakeholder's engagement meetings in QI • Holding quarterly COE or QIT meetings with stakeholders

		• Give strategic guidance on the HIV response • Coordinate post market surveillance • Provide leadership on proficiency testing • Monitoring the quality of HIV Rapid test kits pre-distribution • Ensure forecasting, quantification, management of HTS commodities in the country is done and continuous availability of HIV test kits and other QI commodities at all HTS sites within the Country.
COUNTY **(CQIT)**	• CASCO • CMLT • CHRIO • County implementing partners	• Work closely with the national and the sub county level to oversee the county HTS quality issues • Mobilizing resources for QI • Coordinating implementing partners involved in QI activities • Holding quarterly TWG or QIT meetings with stakeholders • Overseeing HTS alongside other HIV and AIDS related issues in the County • Ensure that the national policy guidelines in HTS are followed in the county and Sub County • Foresee timely, correct and quality Reporting of HTS in the county • Ensure forecasting, quantification, management of HTS commodities in the county is done and continuous availability of HIV test kits and other QI commodities at all HTS sites within the County. • Ensure QI supervisions are done in the county • Work closely with sub-county level to oversee the HTS quality issues • Ensure quality of HTS data validation and

		management is done • Ensure HTS QI support supervision and mentorship done in the county. • Warehousing and distribution of HTS commodities • Training county, sub-county, and facility teams on HTS and QI • Validation of RTK allocation at county level • Implementing HTS continuous quality improvement (CQI)
SUB-COUNTY **(SCQIT)**	• SCASCO • SCMLTs • SCHRIOs • Implementing partners	• Implementing HTS CQI • Training sub-county, and facility teams on HTS and QI • Ensure the continuous availability of RTKs and other QI commodities at all HTS sites within the Sub-County. • Redistribution of HTS commodities • Forecasting, quantification, and data management of HTS commodities in the sub-county • Ensure HTS QI support supervision and mentorship done in the sub-county. • Ensure quality of HTS data validation and management is done • Ensure QI supervisions are done in the sub-county • Ensure timely, correct and quality Reporting of HTS in the sub-county • Mobilizing resources for QI from partners • Data quality audits for HTS at the sub-county

		• Holding quarterly TWG or QIT meetings with stakeholders • Overseeing HTS alongside other HIV and AIDS related issues in the sub-County • Ensure that the national policy guidelines in HTS are followed in the Sub County • Allocation of RTKs • Oversee corrective actions of PT panels
FACILITY LEVEL **(FQIT)**	• Facility in-charges • Health records and information officers • Health workers • HTS Coordinator • Laboratory in-charge • Laboratory coordinator • Counsellor mentors • HTS Service provider	• Oversee planning, staff reshuffling, monitoring and evaluation of HTS • Mobilizing resources for QI • Ensure HTS is promoted in the facility through support and administrative Supervision. • Coordinating implementing partners involved in QI activities • Ensure proper commodity management for HTS e.g., test kits • Communicate the HTS performance targets • Facilitate timely reporting for HTS services and commodities to the relevant offices • Receive and review facility reports for decision making • Working as an interdisciplinary QI team to address issues of HTS in the facility • Conduct quality control on RTKs • Ensure quality of HTS data validation and management • Collate data from the facility and report to the relevant sub-county offices. • Initiate/offer quality HTS to all the patients/clients

		• Ensure SOPs are adhered to, etc. • Ensure HTS providers are enrolled into proficiency testing program and corrective measures undertaken where necessary. • Provide mentorship for continuous professional development • Identify and address knowledge and skills gaps amongst service providers • Organizing and attending learning sessions for different levels (Facility multi-disciplinary teams, continuous medical education) • Implementing HTS CQI • Capacity building work improvement teams (WIT)

Chapter 6: Monitoring and Evaluation

6.1 Introduction

Implementation of the NQMG shall be monitored regularly to track performance towards meeting set objectives and targets. Periodic evaluation shall be carried out to determine whether NQMG goals and objectives are being achieved, and whether an appropriate set of indicators is being utilized. This will be done through routine data collection, periodic assessment, or surveys. This will be useful to define changes in policy and identify areas of program improvement to aid corrective measures.

An M&E framework will be developed to measure overall performance in line with NQMG goals and objectives and will form the basis for routine monitoring and evaluation.

Evaluation shall be done annually or when need arises to determine if the NQMG is meeting its strategic objectives and explore the need for changes.

Facility, sub-county, county, and national committees will be involved in monitoring and evaluating the implementation of the NQMG. The committees will use various methods including meetings, support supervision, mentorship visits, and periodic performance reviews.

6.2 Monitoring

6.2.1 Quality Data Documentation

To ensure quality documentation of HTS services, appropriate tools should be utilized by all the service providers. Measures should be put in place to ensure accurate, timely recording and reporting of HTS. The tools should capture data and information related to HTS: HIV testing, counseling, integrated services, referrals, commodities management, and QA/QC. The service providers should use nationally approved tools to record client data, screen for integrated services, referrals, consumption and ordering, QA, and QC. This should be reported using the standard MOH reporting tools through KHIS2 and HCMP

These are some of the source documents that should be used-

- HTS Lab, Referral & Linkage Register (MOH 362)
- Monthly summary reporting tool (MOH 731)
- Bin/stock Card
- Facility Consumption Data Report and Request (FCDRR) (MOH 643)

- Top up forms
- Daily Activity Register
- S11
- Commodity expiry tracking chart
- TB screening tool-ICF
- Referral form
- PT submission form
- DBS submission form

These tools and records should be safely stored, reviewed as per the government regulations.

6.3 Overall M&E Logic Frame

Table 4: Overall M&E Logic Frame

Indicator	Activities	Targets	Indicator Definition	Outputs	Frequency	Data source	Responsible persons
Objective 1: To increase availability of HIV testing services in testing facilities							
Proportion of facilities with HIV rapid test kits available	Conduct an inventory of rapid test kit availability	100%	Numerator: No of facilities with HIV rapid test kits available Denominator: Total number of testing facilities	Rapid Test kits Inventory report	Quarterly	Facility FCDRR and Bin cards	NASCOP, NPHLS, KEMSA, Counties and Implementing partners
Proportion of facilities experienced stock out of HIV rapid test kits in the last three months	Conduct an inventory of rapid test kit availability	100%	Numerator: No. of facilities with stock out of HIV test kits in the last three months Denominator: Total number of testing facilities	Test kits Inventory report	Quarterly	Facility FCDRR	NASCOP, NPHLS, KEMSA, Counties and Implementing partners

Proportion of sites with expired kits	Conduct inventory of test kits expired	100%	Numerator: No. of sites with expired kits Denominator: No. of total sites with an inventory done	Test kits Inventory report	Quarterly	Facility FCDRR, Expiry tracking chart	NASCOP, NPHLS, KEMSA, Counties and Implementing partners
Proportion of facilities with complete and accurate HTS data tools	Conduct regular HTS data quality reviews	100%	Numerator: No of facilities with complete and accurate HTS data tools Denominator: Total number of testing facilities	Data quality reviews conducted	Quarterly	MoH approved tools (refer monitoring tools above),	Counties, sub counties, facilities and Implementing partners
Proportion of facilities reporting using MOH Registers	Verification of HTS recording & reporting tools (MOH 362 Registers, Referral &	100%	Numerator: No of facilities reporting using MOH Registers Denominator: Total number of testing facilities	Availability of MOH 362 Registers, Referral & Linkage Registers, MOH 731	Quarterly	MoH registers and KHIS2	Counties, sub counties, facilities and Implementing partners

	Linkage Registers, MOH 731						
Proportion of facilities/sites using HIV approved testing SOPs	Verification of approved HIV testing SOPs	100%	Numerator: No of facilities using HIV approved testing SOPs Denominator: Total number of testing facilities	Availability of HIV testing SOPs	Quarterly	HIV testing approved SOP's	Counties, sub counties, facilities and Implementing partners
Proportion of HIV testing service Providers trained and certified by NASCOP	Conduct HTS Training audit	100%	Numerator: Number of HTS providers who have been trained and certified by NASCOP Denominator: Number of HTS providers	HTS training audit Report	Every two years	Training records, database and certificates	NASCOP, NPHLS, KEMSA, Counties and Implementing partners
Proportion of eligible HTS providers received refresher training in the last 2 years	Conduct HTS refresher Training audit	100%	Numerator: Number of HTSproviders who have received refresher training in the last 2 years Denominator: Number of HTS providers offering	Refresher training audit report	Every two years	Training records, database and certificates	NASCOP, NPHLS, KEMSA, Counties and Implementing partners

			HTS at the time of refresher training				
Proportion of HTS providers who meet the national qualification standards (Minimum ''O'' level, any diploma in social science and a NASCOP HTS certificate)	HTS provider qualification audit	100%	Numerator: Number of HTS providers who meet the national qualification standards Denominator: Number of HTS providers	Training audit report	Every two years	Training records, database and certificates	NASCOP, NPHLS, Counties and Implementing partners
Objective 2: Improving quality in HIV testing sites							
Proportion of sites meeting QA thresholds for certification	Conduct site assessment	100%	Numerator: No. of sites qualified for certification Denominator: No. of total sites assessed	Assessment report	Bi-annually	Assessment report	National/ County/Sub-County Assessors/Implementing partner

Proportion of sites certified	Conduct site assessment and certification	100%	Numerator: No. of sites certified Denominator: No. of sites assessed	Assessment and certification report	Bi-annually	Assessment and certification report	National/ County/Sub-County Assessors/Implementing partner
Objective 3: Improving quality of HIV counselling services							
Proportion of HTS counselor supervised quarterly in the past year	Counselor supervision Audit	100%	Numerator: Number of counselors supervised quarterly in the past year Denominator: Total number of HTS providers	Counselor supervision reports	Annually	Supervision booklets and counselor supervision register	Counties, sub counties, facilities and Implementing partners
Proportion of observed practices per HTS providers conducted by the HTS supervisors annually	Observed practice Audit	100%	Numerator: No of HTS provider who had an observed practice conducted annually Denominator: Number of HTS counselors assessed	Observed practice reports	Annually	Observed practice reports	NASCOP, NPHLS, Counties and Implementing partners

Proportion of HTS counselors with provider self-assessment	provider self-assessment Audit	100%	Numerator: No of HTS provider who conducted self-assessment Denominator: No of HTS counselors assessed	Provider self-assessment Report	semi-annually	Provider self-assessment tool completed	Site Supervisor/County/Sub-County
Proportion of HTS providers vaccinated against Hep. B.	HEP B vaccination Audit	100%	Numerator: Number of HTS providers vaccinated against Hep. B Denominator: Total number of HTS providers at the site	Hep B vaccination audit report	Annually	Hep. B vaccination card	Site supervisor/County/Sub-County
Objective 4: Improving quality of HIV testing services							
Proportion of kit lots evaluated before distribution	Conduct RTK evaluation	100%	Numerator: Number of kit Lots evaluated and verified. Denominator: Total number of kits lots	RTK Evaluation Report	Quarterly	RTK evaluation reports	NPHLS and KEMSA

			received in the period under review				
Proportion (%) of Lots meeting the required performance criteria and released for distribution	Conduct RTK Evaluation	100%	Numerator: Number of kit lots meeting the required criteria and released for distribution Denominator: Number of kits evaluated and verified	RTK Evaluation report	Quarterly	RTK evaluation reports	NPHLS and KEMSA
Proportion of HTS providers enrolled in a PT program	PT Analysis	100%	Numerator: Number of HTS providers enrolled in a PT program Denominator: Number of HTS providers	PT analysis Report	Quarterly	PT database	NPHLS
Proportion of HTS providers participating in PT by	PT analysis	100%	Numerator: Number of HTS providers participating in PT by returning results	HTS providers participating in	Quarterly	PT database	NPHLS

returning results			Denominator: Number of HTS providers provided with PT panels	PT panel report			
Proportion of HTS providers with satisfactory performance	Feedback of PT panel performance and data analysis.	100%	Numerator: Number of HTS providers with satisfactory performance Denominator: Number of HTS providers participating in PT (Returning results)	PT panel report	Quarterly	PT database	NPHLS
Proportion of HTS providers with unsatisfactory performance where	Corrective action preventive action (CAPA) taken either through formal	100%	Numerator: Number of those with unsatisfactory performance who have taken corrective action Denominator:	PT panel report	Quarterly	PT database and county reports	Counties, sub counties, facilities and Implementing partners

corrective action has been taken	training or on job training and site supervision assessment		Number of HTS providers with unsatisfactory performance				
Objective 5: Quality of documentation							
Proportion of HTS sites analyzing and utilizing HTS QA data to monitor and improve quality	Use of data for decision making quality audit at facility and county level	100%	Numerator: Number of facilities using data for decision making Denominator: Number of HTS facilities	Report on testing trends, kit performance, data documentation	Quarterly	HTS and lab registers	Counties , sub counties, facilities and Implementing partners
Percentage of overall concordance of testing with Test 1,Test 2 and Test 3	Conduct data abstraction on concordance scores	100%	Numerator: Number of agreements among test 1, 2 and 3 Denominator: Total of test 1 , test 2 and test 3	Concordance report	Quarterly	HTS lab,referral and linkage registers	NASCOP, NPHLS, Counties, sub counties, facilities and Implementing partners

Percentage of HIV positive clients retested by the second tester	Conduct data abstraction	100%	Numerator: No. of HIV positive clients retested Denominator: No. of clients testing positive at the first tester	HTS report at CCC	Monthly	HTS report at CCC	Facility supervisor/QA Officer
Percentage of HIV positive clients referred and linked to care and treatment	Conduct data abstraction	100%	Numerator: Number of HIV positive clients referred and linked to care & treatment Denominator: Total number of client who tested HIV positive	Referral & Linkage reports	Monthly	Referral & Linkage reports	Facility supervisor/QA Officer
Percentage of HIV negative clients at risk referred and linked to HIV Prevention intervention	Conduct Data abstraction	100%	Numerator: Number of HIV negative clients referred and linked to HIV prevention Denominator: Total number of HIV negative clients	Referral and linkage report	Monthly	HTS Lab, Referral &Linkage register	Facility supervisor/QA Officer

Objective 6: Improve commodity security of test kits							
Proportion of staffs sensitized on commodity management	Conduct a SQA/DQA	80%	Numerator: No. of staffs sensitized on commodity management Denominator:No. of total staffs in a facility	SQA/DQA report	Annually	Training logbook	Facility supervisor
Proportion of facilities submitting timely consumption reports	Report rate summary analysis	100%	Numerator: Number of facilities submitting reports by 5th of the following month Denominator: Total number of reporting facilities	Reporting rate summary	Annually Monthly	KHIS,HCMP	NASCOP, NPHLS, Counties, sub counties, facilities and Implementing partners
Proportion of facilities submitting complete consumption reports	Conduct SQA/DQA	100%	Numerator: Number of facilities submitting complete consumption reports Denominator: Total number of reporting facilities	SQA/DQA report	Annually	Facility CDRR, KHIS and HCMP reports	NASCOP, NPHLS, Counties, sub counties, facilities and Implementing partners

Proportion of facilities with consumption reports matching orders.	Conduct DQA	80%	Numerator: Number of facilities submitting orders that match orders Denominator: Total number of reporting facilities	SQA/DQA report	Annually	HTS and Lab registers, MOH 731, KHIS reports,HCMP	NASCOP, NPHLS, Counties, sub counties, facilities and Implementing partners

Annex 1: Bench Decontamination Log

SECTION: _____ MONTH: _____ YEAR: _____

Maintenance Procedures	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
MORNING																															
Check cleanliness																															
Wipe dust																															
Apply disinfectant (0.5% bleach/70% ethanol																															
Staff initials																															
EVENING																															
Check																															

cleanliness																														
Wipe dust																														
Apply disinfectant (0.5% bleach/70% ethanol																														
Staff Initials																														

KEY:

 Means NOT DONE  Means DONE N/U Means NOT IN USE

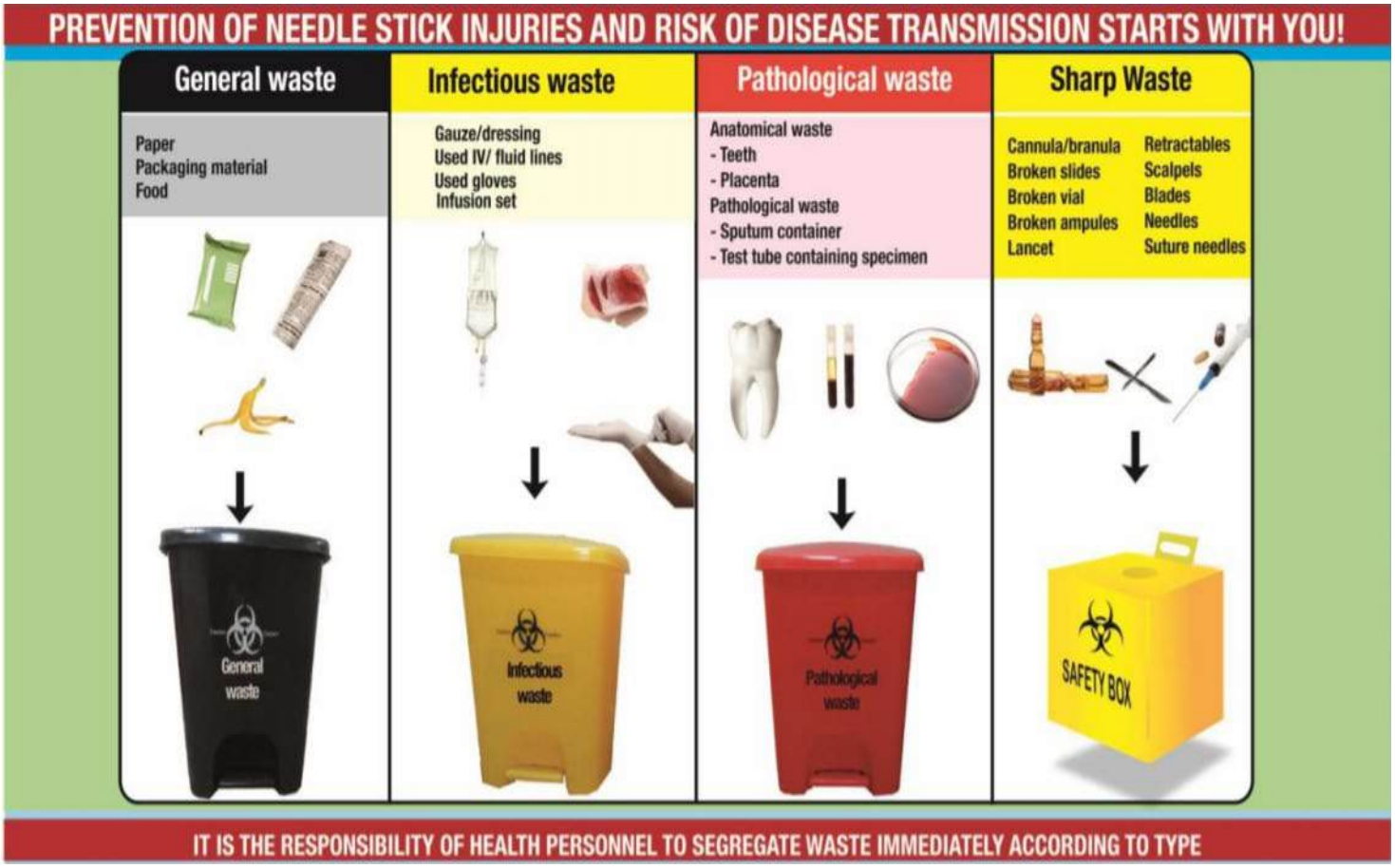
COMMENTS_____

Supervisor/Section Head_____ Date_____ Sign_____

QA / QC Review: _____ Date_____ Sign_____

Annex 2: Spill Management

Annex 3: Segregation of Medical Waste



Annex 4: Hand washing Procedure

Annex 5: Finger Prick – Job Aid

Ask client to rub/massage Hands together. Ensure the clients

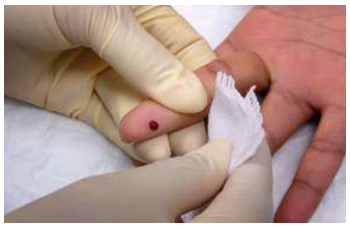
Position hand palm-side up. Choose least calloused finger (either

Apply intermittent pressure to help the blood flow

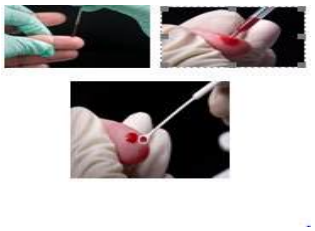
Disinfect fingertip. Start in the middle and work outward to avoid contamination.

Hold the finger and firmly place a new sterile lancet off-

Firmly press the lancet to puncture the fingertip



Wipe away the 1st drop of blood with a sterile gauze pad or cotton ball



If necessary, apply intermittent pressure on opposite side of finger for blood to flow

Apply a gauze pad or cotton ball to the puncture site until the bleeding stops

Properly dispose of all Contaminated supplies. Do not retrieve anything from the waste containers.

Annex 6: The SDP Service Quality Assessment (SDP-SQA) tool

	SECTION	YES	Partial	NO	Comments	Score
1.0	**PERSONNEL TRAINING AND CERTIFICATION**					**3**
1.1	Have all HTS service providers undergone the approved training program?					
1.2	Are training certificates available in the testing sites/facility?					
1.3	Have all service HTS providers undergone refresher training/CME in the last two years?					
1.0	**PERSONNEL TRAINING AND CERTIFICATION SCORE**					
2.0	**PHYSICAL FACILITY**					**6**
2.1	Is there a designated area for HTS provision?					
2.2	Does the designated area have sufficient space for HTS?					
2.3	Does the HTS site have facilities to accord confidentiality?					
2.4	Is the testing area clean and organized for service provision?					
2.5	Is there sufficient lighting in the designated testing area?					
2.6	Are there suitable facilities for secure storage of test kits?					
2.0	**PHYSICAL FACILITY SCORE**					
3.0	**SAFETY**					**7**
3.1	Is there provision for running water (tap or engineered bucket)?					

3.2	Is soap available for hand washing?					
3.3	Is there waste segregation facilities?					
3.4	Is waste segregation done at the HTS site?					
3.5	Is PEP protocol available in case of exposure to blood and needle stick injury, splash or any other sharps injury?					
3.6	Is PEP protocol followed in case of exposure to blood and needle stick injury, splash or other sharps injury?					
3.7	Have all the HTS providers been vaccinated against Hepatitis B					
3.0 SAFETY SCORE						
4.0 PRE-TESTING PHASE						13/14
4.1	Are there job aides **for** disposal of infectious and non-infectious waste at the testing site?					
4.2	Are there job aids for blood spills/body fluids management?					
4.3	Is there job aide outlining the national HTS algorithm?					
	Is Duo HIV/ Syphilis test being used? (Yes/No: No score to be awarded)					
4.4	Is there job aids outlining the correct Duo HIV/ Syphilis procedure?					
4.5	Is there job aids outlining the correct Assay 1 procedure?					
4.6	Is there job aids outlining the correct Assay 2procedure?					
4.7	Is there job aids outlining the correct Assay 3 procedure?					
4.8	Is kit expiry date observed before testing?					

4.9	Are the test kits kept as per manufacturer's instructions?					
4.10	Is Quality control for test kits done on receiving new consignment?					
4.11	Is Quality control for test kits done before using a new kit lot?					
4.12	Is Quality control for test kits done at the beginning of every month?					
4.13	Are QC results properly recorded?					
4.14	Are appropriate steps taken and documented when QC results are incorrect and/or invalid?					
4.0 PRE-TESTING PHASE SCORE						
5.0 TESTING PHASE			**8/10**			
5.1	Is the HTS algorithm always followed?					
5.2	Is the Duo HIV/ Syphilis test algorithm always followed					
5.3	Are sample collection devices (e.g., capillary tube, disposable pipettes, etc.) used accurately?					
5.4	Is the correct procedure for Assay 1 test followed?					
5.5	Is the correct procedure for Duo HIV/ Syphilis test followed?					
5.6	Is the correct procedure for Assay 2 followed?					
5.7	Is the correct procedure for Assay 3 followed?					
5.8	Are functional timers available for HIV rapid testing?					
5.9	Are timers routinely used for HIV rapid testing?					
5.10	Are testing results correctly interpreted?					
5.0 TESTING PHASE SCORE						
6.0 POST TESTING PHASE - DOCUMENTS AND RECORDS			**10**			

6.1	Are QC records routinely reviewed by the person in charge?				
6.2	Is there a national standardized HIV rapid testing register available and in use?				
6.3	Does the HIV testing register include all of the key quality elements? E.g., kit name, expiry date, kit lot number.				
6.4	Are all the elements in the register recorded/captured correctly? (e.g., client demographics, kit names, lot numbers, expiration dates, HTS provider name, individual and final HIV results, etc.)?				
6.5	Is the total summary at the end of each page of the register complied accurately?				
6.6	Are invalid test results properly recorded in the register?				
6.7	Are invalid tests repeated and results properly recorded in the register?				
6.8	Are all client documents and records securely kept?				
6.9	Are all registers and other documents kept in a secure location when not in use?				
6.10	Are registers properly labeled and archived when full?				
6.0 POST TESTING PHASE - DOCUMENTS AND RECORDS SCORE					
7.0 EXTERNAL QUALITY ASSESSMENT (PT, SUPERVISION)				**10**	
7.1	Are all the HTS provider enrolled in the national PT program?				
7.2	Do all enrolled HTS providers test the PT samples?				
7.3	Do all enrolled HTS providers return results to NPHL for performance evaluation (using web-based system/submitting hard copy) after testing the PT samples?				
7.4	Are PT performance feedback reports received (online or hard copy) by all participants?				

7.5	Are received performance feedback reports reviewed by HTS providers and/or the person in charge at the testing point?				
7.6	Are received performance feedback reports filed at site/facility?				
7.7	Is corrective action implemented in case of unsatisfactory performance?				
7.8	Do service providers receive periodic technical supervisory visits?				
7.9	Is mentorship/retraining done as required during the supervisory visit?				
7.10	Is feedback provided during supervisory visits and documented?				
7.0 EXTERNAL QUALITY ASSESSMENT (PT, SUPERVISION AND RETESTING) SCORE					

Annex 7: The National Assessment Tool For HTS Training Institutions

The assessment process involves assessment of the Human and physical resources of the training institutions to ensure they meet the minimum set requirements to conduct HTS trainings as per NASCOP-MOH standards.

The assessment focuses on ensuring that training institutions fulfil the requirements as described in the National Quality Management Guidelines (NQMG). Assessment is mandatory for training institutions wishing to conduct HTS related courses.

1.0	**Infrastructure (13 points)**	**YES**	**NO**	**COMMENTS**	**SCORE/13**
1.1	Availability of well-ventilated training facility (Classrooms/lecture halls)				
1.2	The facility has adequate sitting capacity for both participants and trainers (at least 28 seats)				
1.3	The facility has at least 6 standard tables/benches (2x4 feet) for lab practical with non-absorbent tops				
1.4	**The facility should have provision for the following teaching aids;** • Flip chart, white/chalk board • LCD Projector and Computer • Penile model/s • Vaginal model/s • Condoms (male and female) • Stationery • Evidence of Provision for test kits				

	• protocols as per NASCOP HTS algorithm • Latest HTS Training Package • Availability or arrangement for trainees observed practice				
	Infrastructure **Total score**				
2.0	**Infection Prevention Control and safety measures (9 points)**	Yes	No	Comment	Score
2.1	Availability of running water				
2.2	Availability of safe waste segregation and disposal systems in place (appropriately coded and labelled bins)				
2.3	Availability of adequate, suitable and clean sanitary facilities (toilets)				
2.4	Safe site for temporary storage of contaminated waste until disposal available				
2.5	Availability of Personal Protective Equipment (PPE) (gloves, 28 lab coats/gowns/apron-disposable/mask or re-usable) for practical				
2.6	Availability of appropriate disinfectants				
2.7	Pit/Incinerator or contractual arrangement in place for disposal of contaminated waste (NB. Pit latrine above 10ft)				
2.8	Provision for Post Exposure prophylaxis (PEP) services available (site or referrals)				

2.9	Availability of Job Aids and/or Standard Operation Procedure (SOPs) for Infection Prevention Control (IPC) and waste management				
	Infection Prevention Control and safety measure Total core				
3.0	**HTS Trainers Qualifications (3 points)**	**YES**	**NO**	**COMMENTS**	**SCORE**
3.1	The institution should have a minimum of 4 trainers with a minimum of a diploma in health or social sciences, trained as TOT in HTS. • Two trainers should have a counselling background • Two trainers should have a medical laboratory background and should be registered by the KMLTTB • Availability of experts to cover specific technical areas (eg. Care and treatment, Nutrition, Data) ***NB: Verify certificates for all trainers***				
	HTS Trainer qualification Total score				
4.0	**Management Structure (6 Points)**	**YES**	**NO**	**COMMENTS**	**SCORE/14**
4.1	Management structure/organogram				
4.2	Human resource bio data including job description of all staff				

4.3	Organizational training policy document in place including code of ethics and training quality management systems				
4.4	Training component in-built in the service charter/constitution of the organization				
4.5	Safety document describing Occupational Safety Health and Environment (OSHE)				
4.6	Evidence of correct, accurate and timely records kept including minutes				
	management Structure Total Score				
5.0	**Implementation of Training Quality management systems (3 points)**	**YES**	**NO**	**COMMENTS**	**SCORE/3**
5.1	Evidence of qualifications of trainers as indicated in the bio data				
5.2	Evidence of internal quality management (customer satisfaction) e.g. Suggestion boxes, customer care desks, minutes of meetings etc.				
5.3	Mechanisms in place to obtain information about the training institute and courses offered (service charter, brochures, pamphlets, web link, newspaper etc				
	Implementation of Training Quality managemnt system Total Score				
	OVERAL SCORE				
	The total points for critical criteria areas is 34				
The table below addresses other additional requirements (for the institution to qualify it must score at least 50%					
6.0	***Participants affairs and Support services (4 points)***	**YES**	**NO**	**COMMENTS**	**SCORE**

6.1	Steps to ensure safety of participants and their property is in place				
6.2	Orientation Programme for the participants in place				
6.3	Opportunity to evaluate the Programme and its content available to the trainers				
6.4	Does the institution maintain a record of participants?				
	Total score				
7.0	**Quality management (4 points)**	**YES**	**NO**	**COMMENTS**	**SCORE**
7.1	Evidence of mechanisms in place for responding to participants' complaints				
7.2	Academic and career advisory services				
7.3	Staff sensitized on HIV&AIDS				
7.4	Measures to evaluate content of the Programme and trainers				
	TOTAL SCORE				
8.0	**Training resources (7 points)**	**YES**	**NO**	**COMMENTS**	**SCORE**
8.1	Facility has a resource Centre with the updated HIV related documents/ materials available				
8.2	The training facility has adequate Information and Communication Technology (ICT) infrastructure; computers with internet access for use by trainers and trainees				

8.3	The training facility has a power back up available e.g. generators				
8.4	The training facility is easily accessible				
8.5	The training facility is situated in an environment conducive to learning				
8.6	The facility has health emergency plans including ambulance, clinics, doctor on call e.t.c				
8.7	Facility has fire safety measures in place: • Fire extinguishers • Fire alarms Fire exit routes				
	Training resources Total score				
	OVERAL SCORE				
	The total points for additional requirements areas is 14				

Annex 8: HTS Observed Session Supervision Tool

County: _____		**Facility_____** **SDP: _____** **Session Number_____**
Sub-County_____		
Observers Name: _____		**DATE: _____**
Please score as follows; 0=not done, 1=attempted with little success, 2=achieved fairly, 3= achieved successfully, NA =Not applicable		
Areas assessed	**Score**	**Comment**
Availability of guidelines and protocols • Latest National HTS guidelines • Testing algorithm • SOP for Screening & Confirmatory test • Interpretation charts • Referral directory • Referral book • Working timer		
Condition of the room/tent • Cleanliness • Two small tables • Well light and arranged room • Timers/Stopwatch available, updated and use		

Pre-test Counselling • Contracting and its limitations (Timing, confidentiality, rapport) • SOLER • Counsellor sitting at a strategic position (at the exit/door) • Sitting arrangement of the counsellor and the client according to counselling standard (sits must be of the same size and colour) • Adequate use of counselling skills such as reflecting, paraphrasing, etc • Client centred session (Clients talks more than counsellor) • Risk assessment properly done (proper screening for eligibility) • HIV Prevention is discussed (Behavioural, Medical and Structural) • *Introduced and discussed index testing* ○ *Client willingly gave out contact(s)* • *Introduced and discussed SNS* • TB and GBV/IPV Screening done • Consent for testing is done		
Testing Process • Preparation of clients for the test ○ Confirmed client's readiness to take up the test • Preparation of all requirements to conduct the test • Labelling of test kits		

• Pricking, drawing of blood and putting the right quantity • Infection preventions control measures e.g., gloving, waste management • Correct timing depending on the test kits good interpretation • Fill in the MOH 362 and other tools • Condom demonstration • *Confirm clients readiness to have their partners tested*		
Post Test Counselling **If Negative** • Confirmed result outcome • Addressed client's feelings, • Confirm how client plans to remain negative • Come up with risk reduction plan • Client reminded about possibility of discordance where applicable • Appropriate referral done based on need **If positive, confirm** • Client supported to understand the result • Support client to deal with immediate feelings • Discuss referral for Retesting & enrolment to Tx • Discuss positive living e.g., condom		

use, drug adherence, partner testing, disclosure and STI/TB screening and treatment, nutrition. • Appropriate referral done and documented **If Inconclusive,** • Test repeated and appropriate referral done • Termination		
Counsellors General Comment		
Observer General comment		
Start time_____ Stop time_____		
Name of the Counsellor:_____ Sign_____ Date_____		
Name of Observer: _____ Sign_____ Date_____		

Annex 9: List of Contributors

No.	Name	Organization	No.	Name	Organization
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6	Benard Adidi	BLAST	35	Loreen Ngarai	NASCOP
7	Betty Chepkwony	NASCOP	36	Lucy Ondicho	MOH
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9	Brandwell Mwangi	CHAI	38	Moses Baraza	NPHLS
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11	Christabel Ogola	NPHLS	40	Muthoni Junghae	CDC
12	Christine Kisia	WHO	41	Nancy Bowen	NPHLS
13	Davis Karambi	CHAI	42	Norah Talam	USAMRU
14	Edward Musau	NASCOP	43	Patricia Jeckonia	LVCT Health
15	Eric Mutua	NASCOP	44	Paul Ndambuki	NASCOP
16	Evans Imbuki	NASCOP	45	Pauline Mwololo	NASCOP
17	Franklin Kitheka	NPHLS	46	Peris Ndukele	NPHLS
18	Fredrick Miruka	CDC	47	Peter Maingi	KNH
19	Grace Mwangi	NASCOP	48	Precious Otieno	NASCOP
20	Harrizon Ayallo	PS kenya	49	Rachael Kiuna	MOH
21	Jafred Mwangi	NASCOP	50	Richard Koisok	KNH
22	Jane Onteri	NASCOP	51	Rose Kahariri	LVCT Health
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24	Jonah Onentiah	NASCOP	53	Roseline Warutere	NASCOP
25	Jonathan Mwangi	CDC	54	Ruth Kamau	NASCOP
26	Jones Mutiso	CHS	55	Samson Ndege	MTRH
27	Joseph Gatimu	Lvct Health	56	Sarah Masyuko	NASCOP
28	Josephine Wangombe	WRP	57	Sheila M. Baraza	NASCOP
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