MINISTRY OF HEALTH

National Public Health Laboratory Services

OPERATIONAL MANUAL FOR THE IMPLEMENTATION OF QUALITY ASSURANCE IN RAPID HIV TESTING IN KENYA

FOREWORD

Early diagnosis and rapid initiation of treatment is a key strategy in the control of HIV. Existing data suggest that HIV-infected individuals who are aware of their status are more likely to adopt risk reduction behavior than those who are not. Testing services are precisely considered as the gateway to treatment programs. However challenges to realizing universal access to HIV & AIDS services exist which includes quality assurance in testing. While significant achievements have been made in Kenya towards control of HIV&AIDS, More efforts to increase the number of people being tested as well as enrollment to care and treatment programs is needed. The same level of effort is required to ensure provision of quality services. This provides best outcomes in any intervention.

This operational manual is intended to strengthen implementation of quality assurance in rapid HIV testing in all service delivery points. Bearing in mind, that quality is not an end product of the services we provide to our people, but the very process that guarantees standards are met and client's expectation exceeded. Integration of quality assurance in HIV testing is critical to successful interventions in prevention, care and treatment program. Therefore this operations manual should be applied by all health care providers in all health care settings.

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CONTENTS

ABBREVIATIONS

AIDS	Acquired Immuno Deficiency Syndrome
CDC	Centers for Disease Control and Prevention
CHS	Centre for Health Solutions
CLC	County Laboratory Coordinator
CME	Continuous Medical Education
CVR	Centre for Virus Research
DBS	Dried Blood Spot
DMS	Director of Medical Services
DT	Diagnostic Testing
DTS	Dry Tube Specimen
ELISA	Enzyme Linked Immunosorbent Assay
EQA	External Quality Assessment
FDA	Food and Drug Administration
HBCT	Home based Care and Testing
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immuno Deficiency Virus
HTS	HIV Testing Services
IP	Implementing Partner
KEMRI	Kenya Medical Research Institute
KEMSA	Kenyan Medical Supplies Agency
KMLTTB	Kenya Medical Laboratory Technology Technicians Board
M&E	Monitoring and Evaluation
MOH	Ministry of Health
NASCOP	National AIDS STI Control Program
NBTS	National Blood Transfusion Services
NHRL	National HIV Reference Laboratory
NIST	National Institute of Standards and Technology
NPHL	National Public Health Laboratories
NPV	Negative Predictive Value
PEPFAR	Presidents Emergency Plan for AIDS Relief
PMS	Post Market Surveillance
PMTCT	Prevention of Mother to Child Transmission
PPV	Positive Predictive Value
PT	Proficiency Testing
QA	Quality Assurance

QC	Quality Control
Se	Sensitivity
SOPs	Standard Operating Procedures
Sp	Specificity
TAT	Turnaround Time
TOT	Training of Trainers
USAID	United States Agency for International Development
USG	United States Government
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization

CHAPTER 1

Introduction and Guiding Principles

1.0 INTRODUCTION AND GUIDING PRINCIPLES

1.1 The goal of the manual

This manual provides guidance for implementation of quality assurance in HIV Testing and its monitoring and evaluation of programs. Assurance of quality test results is paramount forprevention, care and treatment programs. The achievement of this objective contributes towards quality HIV and AIDS services. Thus, HIV Testing through various strategies in Kenya should meet the specified benchmarks for quality as specified in this operations manual.

1.2 Rationale

This manual is part of an ongoing effort to streamline quality in HIV testing in Kenya for various programs involved in HIV and AIDS. Various prevention, care and treatment programs in Kenya carry out testing as a key component in their operations as spelt out in their policy guidelines. As the country embarks on expanding testing services through these programs, testing operations in service delivery points will require improvements in quality management. The purpose of this operational manual is to provide guidance for quality HIV testing within the principles of a multistep quality strategy and at the same time provide a framework for monitoring and evaluation of HIV testing programs in Kenya.

1.3 Who should use this Manual

This manual is intended to provide operational and programmatic guidance to organizations providing HIV testing services. MOH facilities, private and faith based institutions, testing practitioners, partners and all other HIV programs will find this manual useful in mainstreaming quality assurance in HIV testing programs.

1.4 How to use the Manual

The processes to be undertaken in the scale-up of quality testing services are outlined in this manual. In the background of various HIV policy guidelines existing in Kenya, where testing is a major programmatic component; e.g. in HTS, PMTCT, VMMC, HBCT, injection safety among other policy guidelines, this manual is a useful tool translating testing policy into operational framework. The manual should therefore be used with reference to various HIV and AIDS policy guidelines. Key steps and essential components for quality in HIV testing are described in this manual. Reference to various tools useful for testing practice, monitoring and evaluation is made to enable service providers and managers to maintain track of various testing benchmarks and related tasks.

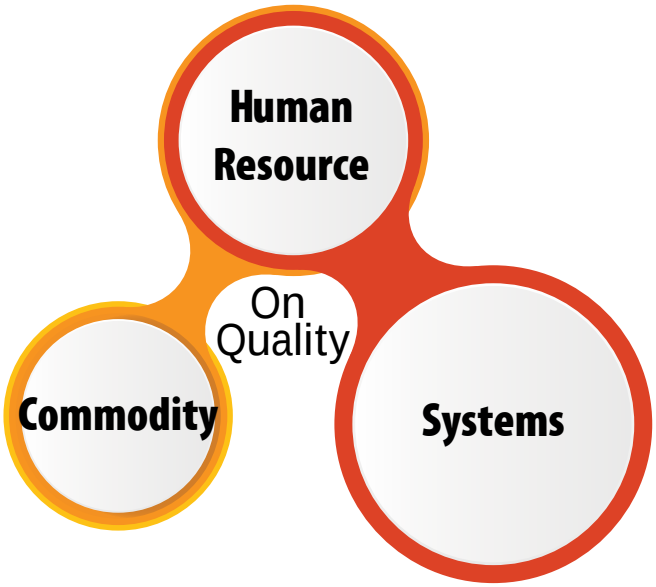
This manual is organized into 7 chapters: Some of the chapters dealing with a particular quality framework, while others combine certain related quality frameworks from the 10 quality indicators as outlined in the multistep approach to quality in HIV testing (example in the multistep approach; training and refresher training are addressed as separate entities). In this manual they are both handled as separate indicators but in the same chapter.

Essential components for operationalization of quality testing identified in this manual include:

1. The 10 quality management pillars
2. Tools to support quality in testing
3. Monitoring and evaluation framework for quality in HIV testing
4. Appendices of important and relevant SOPs.

1.5 Background

HIV rapid testing is an important tool in the fight against the HIV/AIDS. Testing enables identification of the infected individuals and risks in populations for early interventions. The rapid expansion of prevention and treatment programs in resource-limited countries is a direct outcome of testing programs. To meet the goals of prevention and treatment programs, millions of people require testing annually, especially in areas of high HIV prevalence. Sub-Saharan Africa remains the most affected region in the epidemic, where 10% of the world's population accounts for 67% of adults and nearly 90% of children infected with HIV (WHO, 2009).



Globally, efforts are being made and resource directed to mitigate the situation in developing countries (Global fund, 2009; Kate et al, 2008; GAVI, 2009; World Bank 2009; UNAIDS, 2009). Four million individuals are already receiving treatment in developing countries (WHO, 2009). However, owing to the high number of infections globally and especially in Africa, millions more will need to be tested to meet the global goal for universal treatment.

As a result of an increasing demand for testing, efforts to expand the service and ensure access have been ongoing. However, there have been challenges, partly owing to the limited number of qualified personnel to perform accurate HIV diagnosis. Traditionally, these tests are done in a laboratory by highly trained technicians using relatively sophisticated technology such as the ELISA.

The introduction of HIV rapid tests has moved testing outside the traditional laboratory and into settings such as point-of-care sites for ART, prevention of mother-to-child transmission, and volunteering counseling and testing sites, tuberculosis clinics, and sexually transmitted diseases clinics. It has also allowed non–laboratory staff, such as nurses and community counselors, to perform HIV rapid tests. This is consistent with the WHO recommendations on task shifting in support of universal access to HIV and AIDS prevention, treatment, and care (WHO, 2006; WHO, 2008). Notably, success in testing is actually attributable to the task shifting strategy in many countries where significant gains in testing have been made.

In Kenya, for example, success in HIV testing is, in many ways as a result of diversified testing approaches and task shifting. Programs such as VCT, HTS, PMTCT, VMMC, and HBCT among others have normalized HIV and made access to testing a great success. Today, it is estimated that over a million tests are carried out annually in Kenya. This success is also replicated in many other countries. Regardless of the setting, testing strategies or the personnel who perform the tests, the accuracy and reliability of diagnostics must be maintained for the success of HIV/AIDS programs. To date, it is recorded that over 86 million people have received counseling and testing for HIV from PEPFAR-supported programs. This is an enormous achievement in HIV/AIDS programming. Based on PT data from Kenya and assuming an error rate of 0.5%, 430,000 people will have received erroneous results. In Kenyan, this would translate to approximately 50,000 erroneous results. To ensure reliability and minimize errors, quality assurance measures must be in place to address all aspects of testing.

A systematic approach to ensure quality in testing is not only a desirable approach but a necessary undertaking looking forward. A three pronged approach, that includes human resources and commodity and systems management, is a critical dimension for HIV testing. The competency of personnel in providing quality HIV testing should be a continuous process through various external quality assessment schemes. Commodities and test kits should be assessed through various evaluations and post market surveillance to ensure quality. Test strategies and algorithms should be standardized among other quality assurance practices.

Naturally, the quality architecture prescribed by the 10 indicators in the multistep quality approach as described by Bharat et al, 2010 are the pillars of quality HIV testing outlined and prescribed in this manual. Implementation of these requirements is clearly illustrated to allow testing practitioners and management staff to follow in improving testing services in Kenya. Undoubtedly there is still much to do toward meeting requirements for quality. Consistent monitoring and follow-up of the quality assurance system through operationalization of the 10 commandments of quality in rapid testing (Bharat et al., 2010) is a requirement.

1.6 Objectives of the manual

Each chapter of this manual has an objective to be achieved and each chapter has enabling objectives.

1.6.1 Main objectives

1. To ensure use of evaluated HIV test kits in Kenya
2. To discuss development of testing algorithm
3. To describe quality training of trainers and service providers in HIV testing
4. To discuss external quality assessment in HIV testing in Kenya
5. To outline Monitoring and evaluation strategies for quality HIV testing

CHAPTER 2

Kit Evaluation

2.0 KIT EVALUATION

2.1 Introduction

In HIV programming, testing commodities are an essential component in quality management system. It is therefore important to ensure HIV test kits meet specified quality requirements throughout the supply chain from manufacturer to the consumer. Evaluation in the context of HIV testing kits is an important process as it provides means of confirming kits suitability for use.

The chapter provides recommendations for specimen selection, collection, storage, and testing requirements for evaluation of appropriate HIV testing strategies and technologies. The operational procedures in this chapter apply to laboratory staff and other health professionals involved in HIV testing evaluation in Kenya. Detailed technical aspects of kit evaluation including the methodology, quality assurance measures and data management requirements are addressed.

2.2 Roles and responsibilities of different players

i. Kenya Medical Laboratory Technicians and Technologist Board

KMLTTB will:

- Identification of competent laboratories for evaluating the test kits using predetermined criteria.
- Constituting technical committees.
- Coordinate development of kit evaluation protocols
- Receive new HIV test kits and forward to the evaluating laboratories.
- Receives evaluation report, approves and registers the suitable kits for use in the country.
- Publish the list of the approved HIV test kits through the office of DMS

ii. National HIV Reference Laboratory: on approval by KMLTTB will:

- Provide technical coordination of the test kits evaluation.
- Develop acceptability criteria for evaluating criteria
- Coordinate development of standard procedures for test kit evaluation.
- Compiling and analyzing evaluation data and submitting recommendations to KMLTTB.

iii. Evaluating laboratories

- EvaluateEvaluate kits
- Generate reports and submit to KMLTTB and NHRL
- Meet and maintain minimum set criteria for test kits evaluating laboratories.

iv. Implementing Partners (Refer to chapter 5)

- Provide technical assistance in lot to lot evaluation and post market surveillance. This may include sampling of test kits, training of laboratory personnel at facility level, data analysis to inform quality improvement.

- Linkage with the county health management team and the MOH at national level.

KMLTTB will utilize the evaluation report for approval of new test kit for in-county use.
NHRL will utilize the evaluation report for quality monitoring and improvement in HIV testing programming.

2.3 Levels of kit evaluations

2.3.1. WHO Test Kits Evaluation

In the global arena, WHO conducts HIV test kits evaluations. This results in the development of what is referred to as WHO prequalification list that contains kits that have been approved for use worldwide. Kit manufacturers apply to have their kits placed on this list, which is followed by a rigorous process of evaluation based on WHO regulations. This list is updated regularly. Kits can be struck off from the list if during surveillance their performance is found to be unsatisfactory.

2.3.1.1 Components of WHO prequalification program

- Application to the program and a dossier review. Product dossier (e.g. company info, test kit info, test evaluation data, regulatory approvals, kits and kit inserts), 2000 tests from lot 1, 200 tests from lot 2 and 3 each)
- Inspection of the manufacturing site
- Assessment of performance and operational characteristics of diagnostic tests. Kits are evaluated for sensitivity (should be >=99%) and specificity (should be >=99%), PPV, and NPV using world-wide specimens.
- Evaluation
- Building regulatory capacities.

2.3.2. In-country Evaluation

In-country evaluation or verification is the process of evaluating quality of test kits already listed in the WHO prequalified list. The country selects test kits for use from the WHO prequalification list which are then subjected to country specific evaluation criteria. In-country evaluation is divided into three phases:

a) New kit evaluation
b) New Lot verification.
c) Lot-to-lot test kit verification

A) New kit evaluation

In Kenya, a manufacturer who intends to introduce a new kit into the market writes an application to the MOH. The manufacturer or supplier submits samples of new kits to KMLTTB for evaluation. Once kits are received, they are distributed to the designated evaluating laboratories. According to the National HTS Guidelines, no test kit can be used for HIV screening, diagnosis, and surveillance unless they undergo the in-country evaluation.

Aim of New kit evaluations

The overall aim of new test kit evaluation is to determine performance characteristics. Specifically the aim of the evaluation is to:

1. To determine the sensitivity, specificity, and predictive values of HIV test kits.
2. To evaluate the performance of different testing algorithms based on the evaluated test kits.
3. Ensure quality and consistency of manufacturing practices of test kits
4. Guide immediate corrective action in case of identified major problems

Justification for New kit evaluation

Due to the rapid changes in technology, new rapid test kits have been introduced in the markets which need to be evaluated before use. The challenge is that kits are developed and evaluated in other countries with varied laboratory and environmental conditions. Therefore test kit evaluation and monitoring ensures consistency in performance of the kits being used in the country. In addition to sensitivity specificity and predictive values, test kit evaluation determines ease of performance, storage, and cost effectiveness kits. This safeguards the integrity of the testing facility, personnel, and quality of results. It also ensures that, in spite of varying environmental conditions, there are no clinically significant differences in the results obtained when different lot numbers of test kits are used.

Types of New test kit evaluation

New kit evaluation is divided into two phases:

(i). *Laboratory based*

This is done as a regulatory prerequisite for approval and registration for use in-country. A panel of characterized samples with equal representation of all stages of HIV infection are used to evaluate HIV test kits. WHO/NIST/FDA prescribes the use of 400-600 of characterized samples for kit evaluation. This evaluation provides preliminary results on test performance characteristics of sensitivity, specificity, predictive values and ease of performance using a standard characterized panel of test samples.

(i). *Field based*

This is carried out in a field setting using fresh specimens. It involves the evaluation of the kit under field conditions that may include test performance and interpretation by non-clinical staff. There should be clear specifications of the eventual target population in which the diagnostic test will be used. The staff performing the evaluation should be appropriately trained so that they are proficient in performing the test being evaluated and the comparator tests.

New test Kit evaluation Process

(i). Manufacturers provide the following pre-requisite documents/test kit samples to KMLTTB.

- Official application requesting for evaluation of the kit.
- WHO prequalification.
- Test kits brochures/inserts.
- Submission of sufficient test kit samples 600 tests)
- Evaluation fee.

(ii). The KMLTTB contacts and distributes the test kits samples to the evaluating laboratories.

(iii). The evaluation laboratories evaluate the test kits as per the pre-set criteria:

a. Assess physical packaging of the kits.
b. Ease of performance.
c. Need for additional requirements.
d. Technical performance (readings of positive and negative controls, sensitivity, and specificity, positive and negative predictive values).

(iv). A report of results and recommendations is prepared by each evaluating laboratory and submitted to the NHRL for compilation and submission to KMLTTB

Test kits that meet the evaluation criteria are approved and registered by the KMLTTB. Certificates shall be issued to the supplier whose kits meet the evaluation criteria. The list of the approved test kits will be available by the KMLTTB.

B) New kit lot verification

New lots of already approved test kits shall undergo performance verification prior to distribution to the health facilities. Lot verification will include an evidence-based appraisal of incoming new lots, to ascertain consistency in the quality and reliability of the new test kits.

Aim of New lot verification

The aim of new lot verification is to provide assurance that new batches of kits entering the country maintain consistency as previously evaluated. This is done by assessing samples from each new lot released by the supplier. This safeguards consumers and public health interests against declining manufacturing processes and poor business practices by:

- Ensuring that initial and subsequent test kits used in the country conform to required standards.
- Monitoring quality of test kits throughout the distribution chain.
- Ensuring that, in spite of varying environmental conditions, there are no clinical significant differences in the results obtained when different lot numbers of reagents are used.
- Guiding immediate corrective action in case of identified problems.
- To monitor lot-to-lot variation of test kits as they are deployed in country for use at the different service delivery points.

Justification for new Lot verification

New lot verification process

Assessment of each new batch of test kits procured from the manufacturer will provide reassurance that new lots of kits used at HTS sites have consistent performance. A standardized panel of samples is used to test each new batch of test kits and the results obtained must fall within the predetermined limits. Procuring agents such as KEMSA will continuously monitor the number of lots received for each test kit. They will obtain from manufacturers the performance index of new lots to be shipped. Procuring agents will submit new batches to the NHRL for verification before in-country distribution. Sampling shall be done on all lots received in-country.

Sample size will be determined by the batch size of the new lot received.

a. Test samples will be submitted to NHRL accompanied by a test kit verification request form. NHRL may perform the verification or distribute the test kits samples to approved evaluating laboratories.
b. NHRL and or approved evaluating laboratories will use standard set of panels to assess the kits for technical performance (readings of positive and negative controls, sensitivity, and specificity, positive and negative predictive values).

NB: The verification report with recommendations will be submitted to KMLTTB, KEMSA and NASCOP for decision making.

C) Lot-to-lot test kit verification

Aim of Lot to lot verification

Test kits are exposed to many variables due to conditions during transportation and storage environments in different laboratory settings. The evaluation of new lot of kits with old lot of kits is performed to ensure that, in spite of varying environmental conditions, there are no clinically significant differences in the results obtained when different lot numbers of kits are used. Characterized human samples are parallel or serially tested to ensure the known results are replicated by both lots of kits being compared. Lot-to-lot verification shall be done at facility level following laid verification procedures. The verification report should be shared with the county and sub-county medical laboratory technologist.

2.4. Post Market surveillance

Post market surveillance includes the continuous monitoring of the test kits' quality. This is achieved through the use of scientific methods that provide thorough scrutiny, supervision, and inspection of kits being used to ascertain quality conformance. In essence, post market surveillance is the pro-active collection of information on quality, safety, or performance of kits after they have been placed on the market.

Aim of Post Market surveillance

The primary aim of a post market surveillance system is to assess test kit performance and reliability under point of service conditions. Kit performance against demographic information collected at each particular site provides regular information on the quality of test kits being used in the country. Post-market surveillance is carried out to:

(i). Demonstrate in selected sites/settings and conditions that each test complies with prequalification requirements, once marketed.

(ii). Evaluate the performance of the test algorithm in the point of service setting.

(iii). Determine the quality of the test kits in the field and institute a product recall mechanisms whenever product elements of quality are compromised.

(iv). Provides a continuous feedback about the product.

(v). Evaluate transport and storage conditions (temperature, humidity, exposure to sunlight) that may affect rapid test performance.

Justification of PMS

The large numbers of rapid testing has led to increased demand leading to high turnover of kit lots in the market. Environmental factors during storage and transportation also affect quality of kits. It is therefore imperative that measures and systems should be put in place to check the consistency of test kits performance. This informs the need for PMS.

Post market surveillance approaches

(i). Proactive approach-This is geared to allow lot-to-lot comparisons and include sampling and testing from testing laboratories and sites

(ii). Reactive approach-An active vigilance system. The purpose of a reactive vigilance system is to ensure traceability of information of products and to enable coordinated action in countries where products are supplied. Reactive vigilance is triggered by complains by end users on test kits performance, reliability of the test results, e.g. whenever there is increased discrepancies in test results.

2.5. Responsibility of stakeholders in PMS

a) **Ministry of Health**

It is the responsibility of MOH through NHRL to monitor the performance of the kits in use and the information used for decision making. In collaboration and consultation with procurement agent(s) and NASCOP, NHRL will:

- Develop PMS budget and plan to carryout PMS at least once per year.
- Oversee the PMS activities.
- NHRL will provide training and documentation tools for all the staff performing sampling.
- Preparation of sampling strategies (number of samples per site/sector/source) as per the sampling tool.

- Support data collection teams in gathering all samples from site and ensure their delivery to NHRL.
- Analysis (as per manufacturer's instructions/set procedures) of representative sample of the batch for compliance with the product's specifications.
- Reporting of post market surveillance outcome. A report of post market surveillance report is forwarded to the KMLTTB and manufacturer.
- Liaise with KMLTTB and partners where necessary and share results/reports with relevant stakeholders. Where kits do not qualify during verification KMLTTB takes measures to recall such kits.

a) Procuring agent

The procuring agent is one of the main stakeholders in the procurement of the kits and should therefore participate in the decision making meetings procuring agent should be aware of the PMS process and outcomes.

i. Provide information on kits distribution i.e. the lots distributed and where distributed.
ii. Participate in discussion on findings and implementation of regulatory action as directed by KMLTTB.
iii. Implement any necessary recommendations from KMLTTB.

b) County Laboratory Coordinator

Work in collaboration with NHRL and the health facilities to conduct PMS. Reporting any testing anomalies noted during routine testing.

2.6. PMS Data Collection

Post market surveillance data will be collected using a designated tool for analysis and onward transmission to relevant stakeholders for appropriate interventions

CHAPTER 3

HIV Testing Algorithm

3.0. HIV TESTING ALGORITHM

3.1. Introduction

The combination and sequence of specific tests used make up a testing algorithm. HIV testing requires use of a number of test kits for screening and confirmation. Each country has its own national HIV testing algorithm. The number of algorithms should be limited to ensure standardization in quality monitoring and surveillance. The use of evaluated test kits is one of the quality assurance measures. This ensures quality of test results for appropriate patient management. In Kenya, MOH is responsible for monitoring of test kits within the different lots and batches. Surveillance is conducted on kits in use in the field. Only evaluated and approved test kits should be used. Selected test kits should be suitable for use in the field.

3.2. Rationale for HIV testing algorithm

It is essential to standardize HIV testing to ensure quality results and appropriate patient management. This can only be achieved through the development of an effective and robust HIV testing algorithm.

3.3. Objectives of the HIV testing algorithm

To facilitate standardization:

- HIV testing country-wide by ensuring all tests are done uniformly Proper procurement and commodity management by strengthening supply chain management systems.
- Training by following the national guidelines and curriculum.
- Quality assurance by enrollment and participation in the national external quality assurance program.

3.4. HIV testing algorithm selection criteria:

The ideal HIV testing algorithm tests should meet the following criteria:

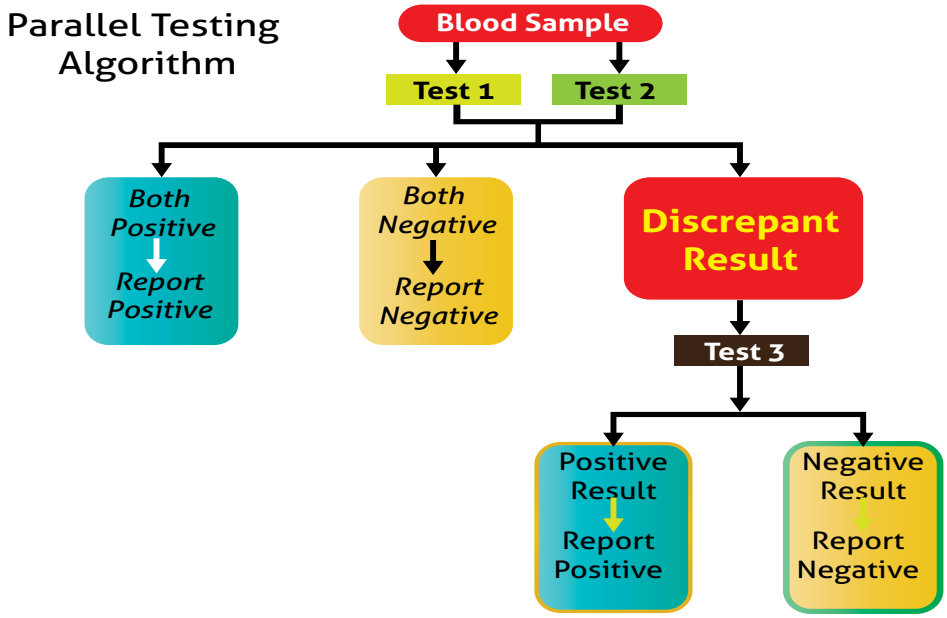
- Highly Sensitive
- Highly Specific
- High Positive Predictive Value
- High Negative Predictive Value

3.5. Types of HIV testing Algorithm and Strategies

HIV testing strategies are testing approaches used to meet a specific need, such as diagnosis, blood safety, and surveillance. For a given strategy, multiple algorithms may be used depending on the setting. A testing algorithm for the serologic diagnosis of HIV infection outlines the sequence in which assays are performed to detect HIV antibodies in body fluids. Testing algorithms use either parallel or serial testing strategies, based on a combination of screening assays.

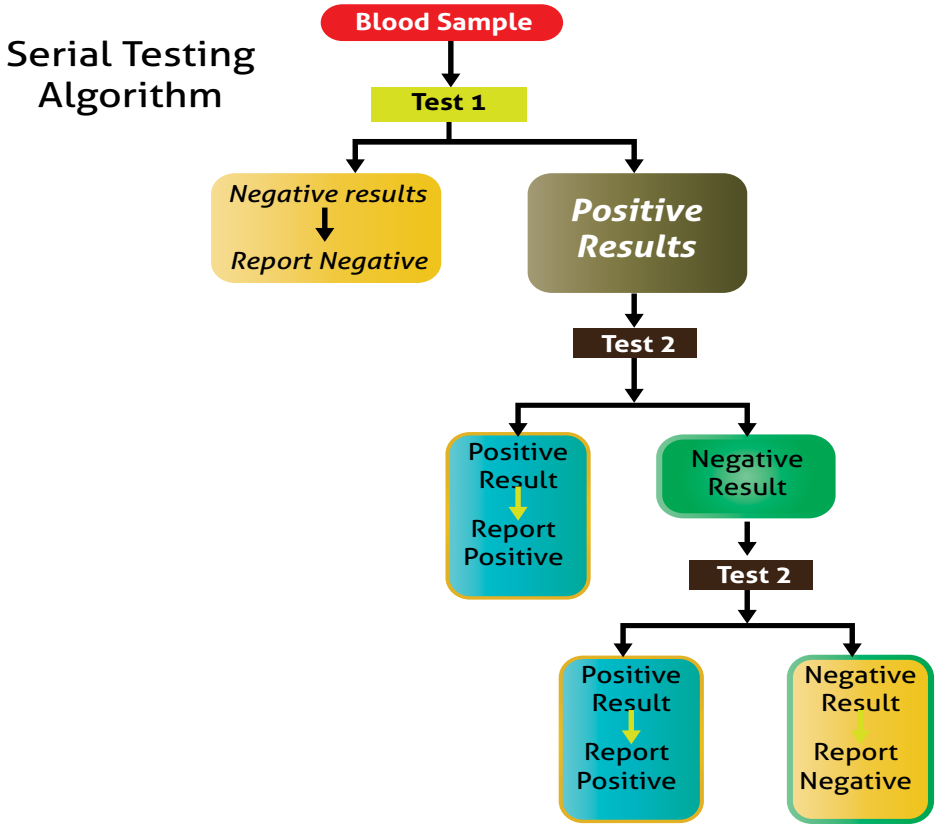
3.5.1. Parallel testing algorithm

In a parallel testing algorithm, sera are simultaneously tested by two different assays.



3.5.2. Serial testing algorithm

In a serial testing algorithm all specimens are tested first by a highly sensitive test and the results of the first test determine whether additional testing is required. Specimens that are positive (reactive) in the first assay are confirmed using a second test that has high specificity. Specimens are considered as true negative if they are negative (non-reactive) in the first test. Regardless of the testing algorithm used, the first test must be highly sensitive and the second should be highly specific.



If the two preliminary procedures do not yield similar results (discrepant results), a third tie breaker test is performed.

3.6. Developing National HIV Testing Algorithm

Test kit evaluation data is analyzed to determine the performance of tests used in a proposed algorithm, individually and in combination. As most of the testing algorithms in Kenya are serial, the use of the second test is dependent on a reactive result in the first test. The following criteria are considered when developing a national algorithm:

- Several tests are evaluated and the best performing test kits are selected. The criteria for test kit selection include:
    (i). Number of steps.
    (ii). Run time.
    (iii). Ease of interpretation.
    (iv). Overall ease of use.
    (v). Training needs.
    (vi). Recommended storage.
    (vii). Shelf life.
    (viii). Kit box size.
    (ix). Individual test packaging.
    (x). Amount of waste.

- Develop algorithm from the selected test kits.
- Pilot the algorithm in some1 selected sites.
- Build consensus (Performed by the responsible committee).
- Develop policy (Circulars are approved and issued from the Ministry of Health.
- Introduction and dissemination conducted nation-wide. (Training, purchase, and distribution).
- Review testing algorithms annually or when need arises.

3.7. Reporting results

Immediately following an evaluation, data analysis and an evaluation table is completed and reported to NASCOP. As shown below, the evaluation report typically includes the data presented in a tabular format that itemizes the test methods, and the Se, Sp, PPV, NPV for each method and combination of methods evaluated. All the reports will have details covering both technical and non-technical characteristics of the test kits under evaluation as shown below:

Table 1. Technical and Non-Technical Characteristics of Test Kits under Evaluation

No.	Characteristic	Score
Technical Operational characteristics		
1	Equipment's the test uses	
2	Number of steps involved	
3	Run time	
4	Type of specimen	
5	Specimen volume	
6	Ready to use reagents	
7	Ease of interpretation	
8	Overall ease of use	
9	Condition for storage	
10	Amount of waste generated	
11	Sensitivity >99%	
12	Specificity >99%	
13	Predictive values >99%	
14	No. of specimens used	
15	Equipment's and maintenance requirement	
16	Positive and negative kit control	
17	Use of electricity	
18	Environmental conditions	
19	Principle of test used	
Non-Technical Operational Characteristics		
1	Name of test kit	
2	Lot numbers	
3	Kit insert	
4	Number of tests per kit	
5	Manufacturer/Local agent	
6	Manufacture date	
7	Expiry date	
8	Training needs	
9	Shelf life	
10	Kit box size	
11	Individual test packaging	

CHAPTER 4

Training for Quality HIV Testing

4.0 TRAINING FOR QUALITY HIV TESTING

4.1 Introduction

Training is an important factor in quality management of HIV/AIDS. Capacity building of human resources is a prerequisite for offering quality services. Competencies are demonstrated skills or abilities, qualifications, and knowledge to perform a task or operate equipment as required. A competent person is one who has acquired skills through training, qualification or experience, the knowledge and skills required to carry out a specific task. In HIV/AIDS programs, and particularly testing, personnel need to be well trained and competent to provide quality testing services. Testing for HIV informs various program interventions, such as prevention, care, and treatment. Therefore, a well-designed training program ensures that service delivery not only meets specified requirements across the spectra but also prescribed quality benchmarks.

Training is the acquisition of knowledge, skills, and competencies required to perform essential tasks. Quality HIV testing requires a defined comprehensive curriculum, trainers, competent service providers, and a robust certification process. Appropriate implementation of the entire process of training and certification is vital in assuring quality. Delivery of the HIV curriculum should focus on the transfer of practical skills and knowledge that relate to the required competencies and should have well-defined goals of improving capability and overall performance. Finally, continuous monitoring of training quality and effectiveness is an important part of developing a training program.

4.2. Objectives

Goal: To ensure quality training in HIV testing.

Objectives: To ensure the implementation of the HIV testing training curriculum.

- To ensure training of competent trainers.
- To ensure training of competent service providers.
- To ensure all providers are adequately certified as per MOH standards.
- To ensure the monitoring and evaluation process for the training program.

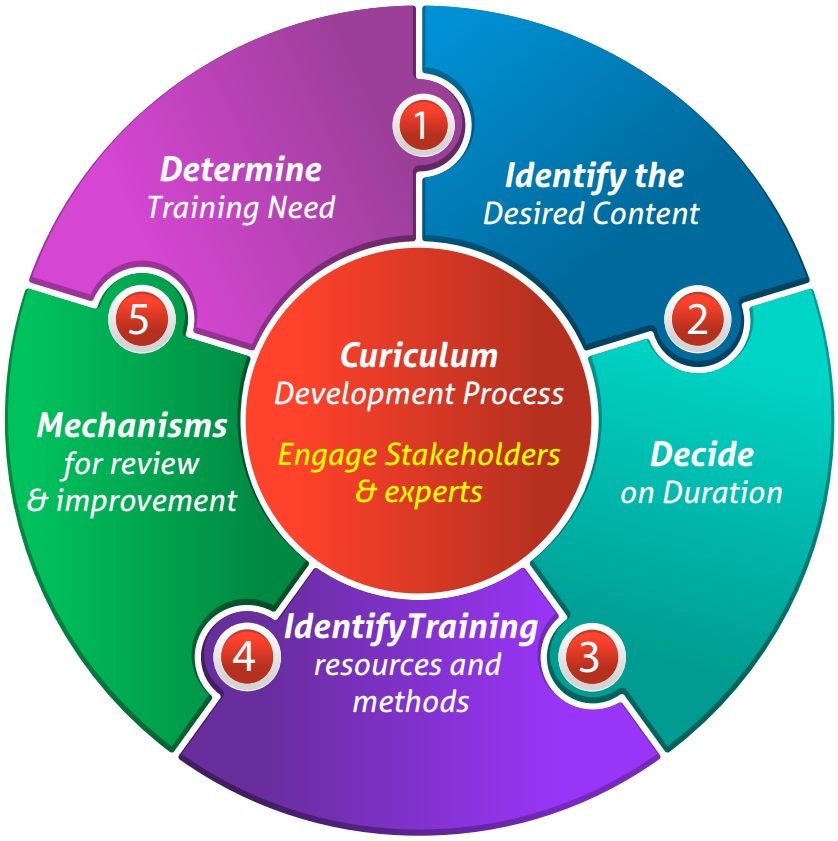
4.3. Rationale

To respond to the increasing demand for testing services in Kenya, HIV testing is carried out by providers from diverse training backgrounds. Recently, expansion of testing services to ensure access and increased uptake among the population has created a high demand for more service providers. As a result, there is a need to continuously train more personnel. However, expansion of services should be matched with quality considerations during implementation. Needless to say, quality training for both trainers and service providers is of paramount importance. Training curriculum should therefore focus on equipping service providers with knowledge and skills necessary for quality improvement. Streamlining of QA aspects in training is necessary and should therefore be a key component in the curriculum.

The existing competence evaluation and certification process is in need of improvement in providing opportunities for continuous skill development. Furthermore, proficiency testing and other external quality assurance activities for assessing testing quality is also an area in need of improvement. In addition, there is a demand for improvement of the accreditation and standardization of the existing training institutions. The development of a standard structure for conducting refresher training and continuous professional development is critical to the improvement of quality service. To this end, it is essential to implement a structured training to equip trainers and testing personnel with quality assurance skills for continued competency in HIV testing.

4.4. Development and implementation of relevant curriculum for quality HIV testing training

4.4.1 Development pathway



1. **Training needs:** These are determined based on the gaps in service delivery. This is done by assessing the trainer and service provider's performance continuously, introducing new methods, and scaling up the program, while taking under consideration emerging issues in HIV testing. The following methods can be utilized: standard checklists, desktop reviews, M&E, audit reports and face to face interviews.

1. **Training Content:** The curriculum should be composed of the following 3 documents: a trainer's guide, a participant reference manual, appropriate power point presentations, and various tools required for service delivery (e.g. data collection). Content should be guided by the existing curriculum, identified training needs, changes in technology, new approaches in testing, and emerging issues. The content shall be relevant to address the training needs and match the prevailing or anticipated testing practices in line with the existing guidelines.

   The topics covered include:
   - The virology and immunology of HIV/AIDS and the principles of test kit operation.
   - SOPs for sample collection, packaging, and transportation in relation to rapid testing, QC, and QA.
   - Infection control and prevention (biosafety) in testing and counseling settings.
   - principles of HIV testing with particular reference to rapid HIV testing, criteria for test kit selection, testing principles and procedures, the interpretation of test results, and problem-solving.
   - principles and concepts of QC and QA, particularly in testing and counseling settings; multistep approach for implementation of quality assurance in HIV testing (kit evaluation ,refresher training, data management, use of local partners, testing algorithm, certification, hands on training of trainers, corrective actions, standardized logbook and DTs PT, new kit lot verification and post market surveillance).
   - Practical sessions on sample collection, HIV testing, proficiency testing and biosafety.
   - Managing data entry and management in testing and counseling services, particularly in order to avoid transcription errors and to maintain confidentiality.
   - Utilization of logbook data to monitor and improve quality of HIV testing services
   - Logistics Management.
   - M&E on training.
   - Training methods and skills for TOTs.
   - Planning and effecting trainings.

2. **Duration:** This is mostly informed by the structure of the training implemented with a minimum of 56 hours recommended for TOT.

3. **Training methods:** These include lectures, group discussions, role plays, and practical sessions. Delivery methods take into consideration the audience and the level of the participants' previous/background training and experiences.

4. **Training resources:** These include venue, audio visual aids, practical sessions' materials, stationery etc.

4.5. Curriculum development process

There are many steps in the development of a training curriculum. The first step involves consulting all stakeholders taking into consideration their technical expertise, knowledge, and experience in HIV testing, training, and policy formulation. The process of development includes:

4.5.1 Pre-workshop.

1. Draw up an agenda.
2. Collect and assemble reference material.
3. Organize relevant logistics for workshop.
4. Book meeting venue and send out invitations.

4.5.2 During workshop.

1. Give overview of need for the curriculum.
2. Assign tasks appropriately.
3. Review progress regularly.
4. Harmonize draft.

4.5.3 Post-workshop.

1. Send to technical experts for review.
2. Building consensus by sharing with stakeholders in HIV testing.
3. Adopt draft curriculum.
4. Final review and editing.

4.5.4 Piloting of the new curriculum.

i) Two approaches are used.

- Training workshop: organize logistics, book venue, send out invitations, and hold the training.

ii) On job training: organize logistics, inform the service providers, and visit them in the service delivery points.

a) During the training, collate comments and suggestions.
b) Share feedback with stakeholders.
c) Incorporate suggestions into the curriculum.
d) Follow prescribed process for approval of the curriculum.

4.4.6. Curriculum Implementation

i) Dissemination process

a) Print document

b) Disseminate: share with stakeholders in HIV testing through various means, i.e. electronic media, hold stakeholder forums, etc.

c) Distribute: organize logistics, i.e. organize transport, reprint if necessary, packaging materials, etc.

1. Monitoring and evaluation

a) Involves measuring achievements and progress

b) Training data are collected over time

2. Provide mechanisms for curriculum review

a) Determine the timeframe for review,

b) The timeframe for review is normally every 3 years, but this can be shorter due to new technology, anticipated program scale-up, etc.)

c) The reviewed curriculum replaces the former one through a continuous cycle

4.7. Conducting training

4.7.1 Training of Trainers

Selection of TOTs: Set the criteria for selecting trainers of trainers. The following criteria are used in their selection.

- Should be Medical laboratory qualified personnel registered by the KMLTTB with experience and demonstrated competence in HIV testing
- Have hands on knowledge and skills to effectively transfer the necessary skills to their trainees

Curriculum content: This includes the duration, evaluation, subject material, certification, mode of training, post training competence assessment, which includes PT and mentorship. It is important to ensure that the training has well established QA elements to include hands-on sessions. The trainers are fully trained on how to perform their assigned tasks and responsibilities, while training is documented for each individual by using training checklists.

4.7.2 Training of Service providers

Selection of Service Providers: Set the criteria for selection. The following criteria are used in their selection. Service Providers include health workers and professional or lay counselors who have experience and demonstrated competence in HIV testing (HTS guidelines for HV testing and counseling in Kenya 2010; Current HTS training curriculum in Kenya).

Curriculum content: This includes the duration, evaluation, subject material, certification, mode of training, post training competence assessment, which includes PT and mentorship. Service Providers receive adequate training and supervision as prescribed by the guidelines.

4.8. Certification

The certificates are issued after observed practice and PT administered. Competence is used as a guide in issuing the certificates. Proficiency testing panels are sent to providers at least three times per year to ascertain competency. Renewal of the certificate is based on performance in PT and other required competencies. NPHLS shares the annual PT performance of each provider with NASCOP and other stakeholders who base the certificate renewals on this assessment among others.

Withdrawal of certificates take place for individuals who obtain unsatisfactory performance due to incorrect results their PT 3 times, inspite of of the corrective actions being implemented. NPHLS shares this information with NASCOP who then withdraw the aforementioned certificates. NASCOP informs the individuals and their respective county authority. Re-certification is conducted by retraining the individuals and followed by administration of PT. Successful individuals then have their certificates re-instated.

Competency: the following are taken into consideration in QA assessments:

- Use of proper QA/QC measures, including proper record keeping
- Ability to troubleshoot and recommend additional testing as needed
- Documentation of root cause analysis
- Monitoring of effectiveness of corrective actions

Responsibilities

- NASCOP is the issuing authority for certificates and, in coordination with NPHLS, maintain a national database for trained TOTs and service providers.
- Counties maintain their own training database of certified TOTs and provide onsite supervision. The Counties in conjunction with partners coordinate and conduct training activities through the certified TOTs. Then, they forward the training details to NASCOP, who then issue the corresponding certifications.

HTS providing facilities organize and conduct continuous professional development while ensuring adherence to national standards.

4.9. Refresher Training

This is subsequent training offered to service providers and trainers necessitated by the need to continually update their knowledge and skills for continued competency. It is an important component of re-certification. This is a requirement for all personnel involved in HIV testing and it is structured based on set national criteria. In liaison with NASCOP the institution organizing the refresher training gives a certificate of participation.

The importance of this refresher training is to:

- Provide the opportunity to sharpen the skills and enhance competencies.
- Put emphasis on QA elements.
- Highlight good laboratory practices.
- Increase one's level of satisfaction in work and the ability to perform efficiently on the job.
- Improve productivity and builds self-confidence among personnel.
- Create a forum for sharing common problems and/or concerns.
- Update new developments in testing technology.

4.9.1 Structure

Refresher training should be done at least once annually for all service providers and trainers. This can also be done through continuous professional development on relevant subject matter. Priority is given to service providers who have gaps in PT performance and individuals who have stayed for long periods without refresher. Trainers and supervisors provide the hands on training based on a standard package. The recommended training duration is a minimum of 24 hours and the mode of training include lectures and hands on sessions. Subject material includes relevant topics encompassing quality assurance in HIV testing. It is the responsibility of every facility to provide forums for CME, monthly QA meetings, update forums, on job training, and mentorship.

4.10. Evaluation of trainings

To determine the effectiveness of training, evaluation should be done using a standardized tool. This tool should cover all aspects of the training from organization, venue, presentations, trainers and content. Pre- and post-test evaluation is administered to determine the level of understanding amongst the participants or trainers before and after the training. It's important to ensure that the pre and post-test covers a wide range of topics covered during the training. For practical sessions, observations on task performance in HIV testing provide an overview of the acquisition of the skills. Key areas in observation include general organization of testing area, observance of safety measures, adherence to testing procedures, ability to interrupt results and document correctly. Evaluation of the training is a pointer to areas that need improvement. The evaluation data are analyzed and a report is compiled for use in improving subsequent trainings.

CHAPTER 5

HIV Testing Protocols

5.0 HIV TESTING PROTOCOLS

5.1 Introduction

Although HIV has been around for over 3 decades many people who need care and treatment do not yet know their HIV status. In Kenya, Based on KAIS 2012 Report only 72% of Kenyans have ever been tested for HIV (KAIS, 2013).

This is a great improvement from 34% reported in 2007(KAIS,2008).This is despite the knowledge on HIV and AIDS and the known benefits of knowing ones status. Since HIV testing is crucial for initiation to care and treatment, individuals who demand these services should be encouraged and barriers to access addressed.

Recently the Joint United Nations Programme on HIV/AIDS in partnership with other organizations recently launched the Diagnostics Access Initiative. Expanding HIV programs, including the "test and treat" strategies and the newly established UNAIDS 90-90-90 targets require increased access to reliable and accurate test results. This will facilitate achieving the goals set towards overcoming the many challenges of HIV and AIDS. In line with various existing HIV testing guidelines in Kenya, HIV testing services (HTS) should therefore be provided at every opportunity available.

The users of this manual are required to have the various HIV testing and related guidelines and standard operations procedures to ensure quality service provision

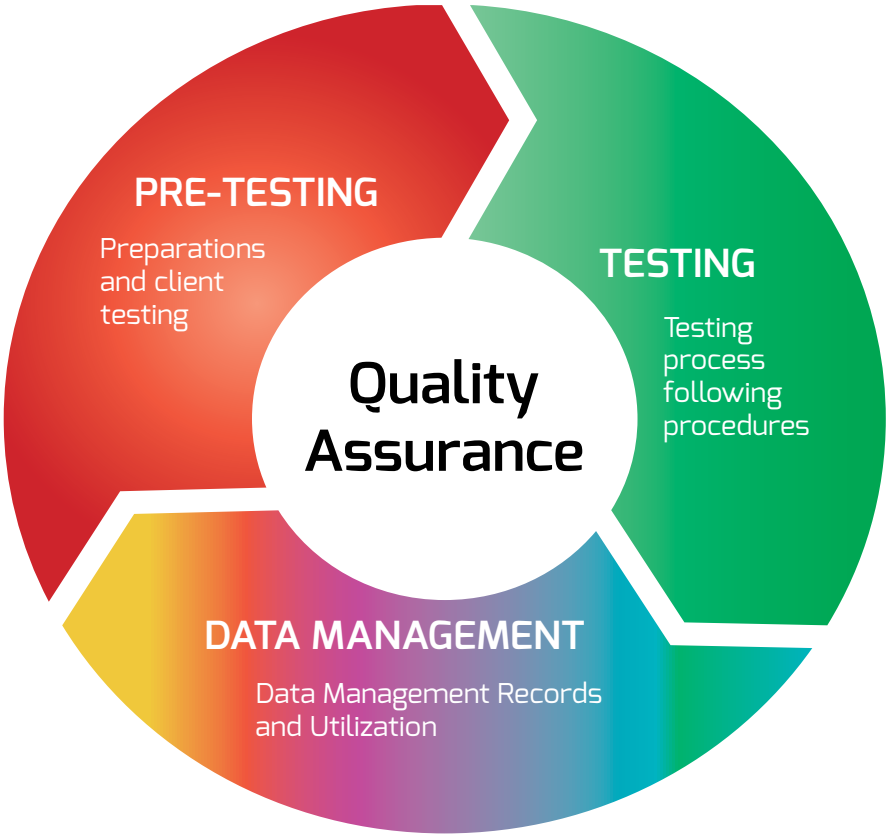
Kenya Aids Indicator Survey 2012: Preliminary Report.GOK, 2013

5.2 Objectives

- To outline the testing cascade in a HTS point
- To describe HIV testing protocols

5.3 THE TESTING CASCADE IN A HTS POINT

5.3.1 ACTIVITIES CARRIED OUT DURING TESTING



1. **Pre Testing Stage**

- Ensure there's an ideal working environment both for staff as well as clients
- Ensure all testing commodities are accessible and available all the time
- Institute measures to ensure clients are handled in a humane and professional manner
- Provide measures to ensure clients confidentiality
- Establish systems for smooth linkage to other or related services.
- Provide information on testing as maybe required to clients
- Ensure issues of consent are well handled

2. **Testing Stage**

- Ensure testing protocols are available for each test provided in your site.
- Ensure protocols are not only followed but adhered to during services delivery
- Deal with waste management and spillages according to biosafety guidelines.
- Test clients based on the prescribed algorithm
- Develop systems for capacity building and competency of staff in testing

3. **Information And Data Management Stage**

- Ensure all requirements for data collection and management are in place in your facility
- Data collection should follow the 3Cs of data management
- Results should be reported appropriately following the set criteria
- Release results through the appropriate channels either to the client or clinical staff

4. **QUALITY ASSURANCE**

References: read related chapters in this manual for quality aspects

- Ensure there is a working quality management system for running testing services
- QC and EQC measures should be applied as appropriate
- Ensure staffs are competent to handle testing
- Institute corrective actions and documentation as appropriate

5.3.2 HIV TESTING PROTOCOLS

Testing procedures vary based on the testing methods, test principles and testing algorithms Within a country the algorithm for a national program is normally standardized .Depending on the test kit used; appropriate testing procedures should be used as discussed below.

1. **Rapid testing (generic protocol)**

.....

2. **Elisa testing (Generic Protocol)**

.....

3. **Molecular testing generic**

.....

CHAPTER 6

External Quality Assessment

6.0 EXTERNAL QUALITY ASSESSMENT

6.1 Introduction and Objectives

External quality assessment is one of the components of quality management system. In the laboratory management an EQA program allows testing sites to assess the quality of testing performance against the set standards. This is achieved through analyzing proficiency testing results to review the quality of testing operations and the performance.

Objectives

1. To outline the importance of an EQA program
2. To discuss the different methods of EQA
3. To explain the national EQA program operations
4. To outline monitoring and evaluation strategies.

6.2. Justification

In order to ensure continued reliability of the quality of HIV testing services, the national health systems require putting in place a functional quality assurance program. This program should include EQA measures which will enable independent identification of quality deficiencies in provision of HIV testing. These measures are important for implementation of quality interventions.

6.3. Importance of EQA

EQA is an integral part of any QA program. It focuses on monitoring quality of performance and identifies areas for improvement. Specifically, EQA is important in the following ways;

1. Provides independent, nonpartisan evaluation of quality of services.
2. Allows comparison of performance among different test sites.
3. Provides early warning for problems associated with kits or operations.
4. Provides evidence of service providers' competency.
5. Identifies gaps in testing for quality improvement.
6. Identifies training needs.
7. Allows for corrective action before minor problems become major.
8. Reduces wastage and hence lower costs.
9. Increases confidence in staff, management, and consumers of testing services.
10. Increases peer and public reputation and acceptability of the site, hence increased demand to utilize services.
11. It identifies the training needs for the participating staff.
12. Allows exchange of information and networking between EQA participants and providers.

6.4. Methodologies of conducting EQA

There are three complementary ways in which the quality of testing services can be assessed by an external authority as outlined below:

1. Proficiency testing.
2. DBS evaluation (blinded re-checking/re-testing).
3. Technical support supervision.

6.4.1 National HIV Proficiency Testing Scheme

In Kenya, DTS based PT is used to determine the degree to which an individual has mastered HIV testing skills (competence) and performance of kits. A set of 4-8 samples, whose results are blinded to the registered testers, are used. The program is provided by NPHL.

6.4.1.2 Enrollment into the HIV PT program

All providers of HIV testing services are required to be enrolled in the national HIV PT program. Enrollment into the program is done through Submission of the details of eligible HIV testing service providers to NHRL by duly filling PT registration tool. The filled PT registration tool is submitted to NHRL by CLC for enrollment and/or data base updating into National HIV serology PT program. Enrollment may also be done online through the NPHLS website. Information collected for registration include tester's name, telephone number, facility name, staff cadre, email address and affiliated program (e.g. PMTCT, lab, etc.). Enrollment will be done at NHRL and important details of registered service providers maintained in the PT database which will be updated regularly.

6.4.1.3 PT Panel Production

The panels are prepared from plasma sourced from the NBTS. The plasma is screened for HBV and HCV. Only HBV and HCV negative plasma is used to protect users from potential exposure to hepatitis, however the panel remains potential biohazardous material and should be handled with precaution. The plasma is characterized for HIV antibodies by both rapid methods currently in use in the national algorithm as well as by ELISA. Only plasma samples from which negative results have been obtained by all kits will be used to prepare the HIV negative samples of a panel and only plasma samples from which positive results have been obtained by all kits will be used to prepare the HIV positive samples of a panel. The characterized plasma is mixed with a green dye at a proportion of 1:1000 to aid in visualization of the dried sample pellet. The dyed plasma is then aliquoted into cryiovials in portions of 20µl, dried overnight to form a pellet. The DTS cryovials should be appropriately labeled. A panel constitute of six blinded samples (positive and negative) and a reconstitution buffer for the panels. Samples stability and homogeneity testing will be performed. Panels will be packaged in a pre-determined combination of the HTS service strategies. Different strategies may receive different panel combination for the same round.

A given proportion of packed panels will be randomly picked, reconstituted and tested to confirm that the HIV antibody test results are as expected. The packaged panels are inserted into enveloped pre-addressed with details of enrolled service providers which will be obtained from the database. Each of the envelopes will contain results submission form.

6.4.1.4 Proficiency Testing Process

This involves the distribution of blinded PT panels by the PT scheme provider (NHRL) to all enrolled PT participants. The program runs in stipulated number of cycles annually. Samples are tested using provided instructions (Job Aid) and results submitted to the PT panel provider for evaluation and scoring. Feedback reports of the performance and suggested trouble-shooting procedures are then prepared and sent to the participants. Performance comparisons are captured in terms of regions (counties) and various testing strategies (e.g. lab, PMTCT,VCT etc).

6.4.1.5 PT panel distribution and results transmission

The panels are distributed to enrolled service providers through reliable and established channels. The county laboratory coordinators oversee PT panel distribution process in their respective counties. The HIV PT results are submitted to NHRL via web-based or paper based system.

6.4.1.6 PT performance evaluation and feedback

Performance evaluation is automatically done through configured system and grading done as either satisfactory or unsatisfactory. The following areas are assessed:

1. Correctness of results.
2. Completeness of results.
3. Observation of test kit expiration date.
4. Adherence to recommended national testing algorithm.
5. Completeness of data (kit and other).
6. Adherence to recommended procedure.

Feedback reports of performance and suggested trouble-shooting procedures are prepared and sent to the participant both electronically and in form of hard copies.

6.4.1.7 Data Analysis and Reporting

The data is analyzed following a predetermined analysis plan. Summary reports are prepared after every round and disseminated to the various stakeholders and counties. The reports include analyses on:

1. Participation/response rate per program (county, program).
2. Performance rate per program area/county.
3. Reasons for unsatisfactory performance.
4. Kits performance including batch to batch and kit to kit.
5. Adherence to the algorithm.
6. Training needs/gaps identified.
7. Performance comparison across counties and various testing strategies.

6.4.1.8 Corrective actions/intervention

Corrective actions involve problem identification, investigation of root cause, development of appropriate corrective action plan, implementing of corrective action, examination of effectiveness, and recording all actions and findings. A standardized tool which makes it possible to investigate and identify possible causes of unsatisfactory performance should be used for corrective action. The feedback to individual participants will guide on where intervention is required.

Corrective action strategies may be through site visits by support supervision and on job training given. It may be through forum where service providers are called to share experience and challenges. The county laboratory coordinator will oversee the technical interventions. Improvement in performance will be monitored through continuous participation in the PT program.

6.5. DBS validation

A proportion of samples from clients tested at HIV testing service delivery points using HIV rapid methods will be collected and submitted for retesting at a reference lab using a gold standard method. This proportion of samples collected for retesting is per service provider and as guided by the national HTS guidelines.

6.5.1. DBS Validation process

A DBS sample will be collected as per the HTS guidelines in the following situations:

1. Home-based testers – on an ongoing basis.
2. Testers in newly registered testing sites.
3. Testers with unsatisfactory performance due to obtaining incorrect PT results - until they obtain a satisfactory result in subsequent PT round.

A DBS sample will be collected packaged appropriately and sent to a validating laboratory accompanied with the DBS submission form The DBS samples are transported to the testing laboratory within 15 days after sample collection. Samples will be retested and results sent back within the stipulated TAT for the specific validating laboratories. DBS results will be compared with SDP test results and corrective action taken where necessary.

The County laboratory coordinator facilitates the DBS retesting process by ensuring:

1. Samples are delivered to the testing labs in a timely manner.
2. Feedback is received.
3. Corrective action is instituted.

6.6. Technical Support Supervision

HIV testing sites will periodically be visited to systematically assess sites' HIV testing quality practices. It provides an opportunity to learn "where we are", identify gaps or nonconformities, and collect information for planning & implementation, monitoring and continuous improvement

Aspects assessed during the on-site audit include:

1. Availability and use of SOPs and job aids for rapid HIV testing.
2. Record-keeping (including availability and use of HTC register).
3. Testing area (including waste management).
4. Observation of staff performance.
5. Test kit management (expiration, storage condition, and utilization and stock levels management).
6. Kit performance data.

On-site technical audit/assessments or supervisory visits can be either internal (where the site assesses itself), or external (e.g. by county health management teams or implementing partners) using a standardized checklist (site assessment tool). This should be performed on a scheduled basis, in case of unsatisfactory performance in other forms of EQA or follow up on complain or observations from the clients.

In case of unsatisfactory EQA performance, the audit should essentially allow for investigation of the root causes of the poor performance, assistance in trouble shooting procedures, and ultimately taking of corrective action/s. On job training and mentorship are essential elements for effective institution and maintenance of appropriate corrective action.

CHAPTER 7

HIV Testing Quality Monitoring Tools

7.0 HIV TESTING QUALITY MONITORING TOOLS

7.1 HTC Laboratory Register (MOH 362)

The HTC Lab register is a standardized tool used to collect data at all HTS service delivery points. The register has variables that correspond to the national data and QA indicators that are used for facilitating effective M&E of HTS services at facility. All fields of the register are filled completely and accurately for each client tested. Details on test kit information, algorithm, test results, kits consumption summary, and field supervision are key QA indicators that are obtained from the MOH 362 register.

The HTC register is also used for the following:

a) Identification of testing personnel performance with poor performance who require assistance.
b) Poor recording practices.
c) Agreement between tests.
d) Concordance rate in testing processes among service providers.
e) Concordance among test sites.
f) HIV prevalence.
g) Adherence to national algorithm.

7.1.1 HTC lab register (MOH 362) as a quality assurance tool

The HTC lab register is an ongoing quality assurance tool. It is used to monitor:

- Algorithm Adherence Assessment
  - Test sequencing
    i. Were the test kits used as tests 1, 2, 3, the ones recommended in the national HIV testing algorithm?
    ii. Were there test 1 negative (non-reactive) samples, for which test 2 was performed?
- Confirmation
    i. Were test 1 positive (reactive) samples confirmed with test 2 as per the national algorithm?
- Tie-breaking
    i. Was test 3 performed for all discrepant results?
- Review of EQA (retesting) results
  - Feedback results of DBS validation for EQA (whether positive or negative) are recorded in the register and compared with clients' results obtained at the time of collecting the DBS. This practice continues as per the guidelines and performance of service providers is monitored regularly.

- Test performance
  - It is important to determine the agreement levels between test 1 and test 2. The numbers of test 2 results are compared to the test one positive results to determine the level of agreement between the two tests from the same client's samples. The positive agreement level is determined using the following formula: No. of test 2 positive results divided by No. of test 1 positive result expressed as a percentage. Overall agreement rate between test 1 and test2 is determined by taking all positive results by test 2 divided by all positive results by test 1 and all negative results by test 1 expressed as a percentage. The acceptable level is 98% and above.
- Test results invalidity level
  - The number of invalid results obtained for each individual test is tracked. This data assists in determining the level of invalidity of individual tests compared to the acceptable level of less than1%. Since invalidity may be due to causes associated with the test or the tester, it is important to determine the cause, by considering data produced following test repeats.
  - This can be achieved by considering the number of invalid results that have been resolved as a proportion of the initially invalid results. Kits producing invalid results repeatedly are referred to the facility laboratory or laboratory in nearby facility for external quality control, followed by referral to NPHL for external quality control, if necessary.
- Change in trend
  - A change in the trend of HIV positive/negative rates at testing sites triggers the review of the quality of test results. Whenever this happens, a QA audit/check is conducted to identify the root cause (e.g. test kit performance, personnel testing competence, or other related issues) and appropriate corrective action is taken.
- Test kit management
  - Test kit management involves the review of the test kit consumption summary, which is compared with the actual number of tests captured in the register for all the tests performed (tests 1, 2, 3). It is important to take note of waste in an effort to optimize the testing capacity of the service providers.
- Site performance comparison
  - The performance of each testing site is evaluated through qualitative assessments and review of the register. Specifically, the facility or an external supervisor reviews the register data captured on a regular basis and determines the level of the site performance. This data is compiled and compared for the various test sites.
- Capture of data quality
  - In an effort to guarantee that the register continues to serve as a quality monitoring and improvement tool, the following elements are observed:
    i. Data correctness
    ii. Data completeness
    iii. Data timeliness
    iv. Data legibility

CHAPTER 8

Scaling-Up Quality Assurance in HIV Testing Through Partnership

8.0 SCALING-UP QUALITY ASSURANCE IN HIV TESTING THROUGH PARTNERSHIP

8.1 Introduction

HIV testing and counseling services have expanded rapidly in the past 3 decades (NASCOP, 2010). With the rapid expansion of these services the quality of service has not been addressed adequately. Some of the challenges included, lack of structured training on quality management in HIV and AIDS programs, weak support in quality systems, inadequate supervision of testing and inadequate external quality assurance systems. Leveraging resources from partners is critical in bridging these gaps.

The purpose of partnerships is to bring together all relevant actors within a country or region to facilitate scale up of HIV testing QA activities. This is achievable through technical assistance and support for service delivery, policy formulation, and coordinated financial commitments.

Levels of partnerships include:

1. National government with international development partners.
2. Within the different levels of government (national and county).
3. Private-public partnerships.
4. Implementing partners and county governments.

The implementation of HIV testing QA activities requires a comprehensive approach whose success can only be achieved with the deliberate involvement of all stakeholders. In order to mobilize the required technical support and financial resources, MOH through its HIV/AIDS program, Institutions and partners operating in the HIV/AIDS sector must work in consultation towards scaling up QA activities in HIV testing. For effective operationalization of the program, good coordination and clear roles for each of the stakeholders is important. This will ensure that every partner understands their obligation, scope of work and expectations from other partners, these roles need to be jointly decided and agreed upon for the overall success of the partnership.

8.2. Contribution of various stakeholders

Expected Contributions				
Objectives	**National**	**County**	**Development Partners**	**Implementing Partners**
Development of HIV testing QA policy and engagement in advocacy	1. Formulate a quality policy	Dissemination of policy	Policy advocacy	Support policy dissemination & implementation
	2. Monitor policy dissemination & implementation	Policy implementation	Support policy development	1.Support implementation of HIV testing algorithm
Development of national HIV testing algorithm	1.Design and approve national HIV testing algorithm	1.Ensure adherence to the national HIV testing algorithm	1. Offer technical assistance	1.Support implementation of HIV testing algorithm
	2.Dessemination of HIV testing algorithm			
Monitoring quality of HIV test kits used in country	1. in-country evaluation and approval of all new HIV kits	1.Ensure use of nationally evaluated HIV test kits	1.Technical support	1.Support to County government in taking corrective actions
	2.Verify performance of new HIV kit lots	2.Ensure appropriate storage and use of HIV kits at service delivery points within the County		2. support county government in coordination of PMS activities
	3.Ensure appropriate corrective actions are taken	3.Perform quality control check on new lots of HIV kits		

	4.Carry out post market surveillance of HIV test kits	4. Ensure appropriate corrective actions are taken		
	5.Ensure appropriate storage of HIV kits in central store and transportation to service delivery points	5. Participate in sampling of HIV test kits for PMS.		
HIV Proficiency Testing	1.Enroll HTS service providers into the national HIV PT program and maintain database 2.Produce and distribute HIV PT panels 3.Evaluate performance & provide feedback reports in HIV PT 4. Prepare and disseminate PT program performance reports	4. Prepare and disseminate PT program performance reports 2.maintain database of HTS service providers and PT participation in the County 3.Coordinate distribution of PT panels and performance feedback to HIV testing personnel 4.Perform corrective interventions following each PT round	Technical support	1.Support distribution of PT panels & feedback repots to HTS service providers 2. Support corrective actions following each PT round
Development & utilization of HTS lab register (MOH 362)	1. Development & dissemination of HTC lab register	1. Ensure correct and continuous use of HTC lab register at SDP	1.Technical support in establishment of QA data transmission mechanisms	1.support analysis of QA data in HTC lab register for decision making

	2.Training/sensitization of HTS service providers on use of HTC lab register	2.Analysis ofHTC lab register QA data for decision making	2.Technical support in development and dissemination	2.Support the printing and distribution of the registers
	3.Establish QA data transmission mechanisms for HTC lab register to the national level 4.Analysis of QA data in HTC lab register for decision making 5. Disseminate feedback report based on HTC lab register QA data 6.Take appropriate corrective actions	3.Transmit HTC lab register QA data to the national level	3.Support the printing of HTC lab register	3.Support training of HIV testing personnel on the use of the register 4. Support taking appropriate of corrective actions
HIV Proficiency Testing	1.Enroll HTS service providers into the national HIV PT program and maintain database 2.Produce and distribute HIV PT panels 3.Evaluate performance & provide feedback reports in HIV PT 4. Prepare and disseminate PT program performance reports	4. Prepare and disseminate PT program performance reports 2.maintain database of HTS service providers and PT participation in the County 3.Coordinate distribution of PT panels and performance feedback to HIV testing personnel 4.Perform corrective interventions following each PT round	Technical support	1.Support distribution of PT panels & feedback repots to HTS service providers 2. Support corrective actions following each PT round

				1.support analysis of QA data in HTC lab register for decision making
				2.Support the printing and distribution of the registers 3.Support training of HIV testing personnel on the use of the register 4. Support taking appropriate of corrective actions
HIV Testing Training	1.Develop of a standardized curriculum for Lab TOTs and HIV testing service providers 2.Develop training manuals, guides and package 3.Train County trainers 4. Conduct annual competency assessment & refresher trainings for County trainers 5.Certification of lab TOTs 6.Maintenance of lab TOTs database 6.Maintenance of lab TOTs database	1.Initail and refresher training to county service providers 2. Printing & distribution of training manuals to service providers 3. Carry out training needs assessment 4.Maintain County lab TOTs database 5.Resources mobilization	1.technical support in curriculum development 2.technical support in development of training manuals and packages	1.Support initial & refresher trainings of County HIV testing service providers 2.Support printing & distribution of training manuals/ tools 3.Support county training needs assessment

Role of regulatory bodies	1.Regulate HIV testing and training practices 2.Regulate commodities for HIV testing	1.Enforce HIV testing and training standards 2.Enforce standardization commodities use	1.Enforce HIV testing and training standards 2.Enforce standardization commodities use	Support dissemination of policies and guidelines as regards training in HIV QA

(Endnotes) I

8.3 Overall M&E Logic Frame

Activities	Outputs	Outcomes		
		Immediate	Intermediate	Long Term
Conduct RTK Evaluation	RT Evaluated	Availability of evaluated RTK	Improved quality of rapid HIV results	Improved quality of HTS services
Conduct Training on HTS algorithm	HTS training conducted	Increased Knowledge and skills on HTS algorithm	Improved HTS practices Increased adherence to algorithm	Improved quality of HTS services
Enroll HTS providers into EQA	HTS providers enrolled into EQA	Increased PT participation	Improved PT performance	Improved quality of HTS service
Conduct regular HTS data quality reviews	Data quality reviews conducted	Improved data collection in HTS tools	Increased HTS data quality	Improved quality of HTS service
Conduct HTS stakeholders engagement in QA	HTS stakeholders engaged in QA	Increased HTS QA support from stakeholders	Increased HTS QA sustainability	Improved HTS services

8.4 Performance Measurement

Monitoring question	Performance indicator	Data source	Freq. of data collection	Use of data
Are evaluated RTK being used to provide HTS in all settings?	Number of sites using evaluated kits	• MoH list of approved kits • HTC Lab registers • National HIV Serology PT performance data	Annually	Improve HTS

Are new kit lots evaluated before use?	Proportion of lots evaluated • Number of kit lots verified. • Number (%) of lots passed and released for distribution.	Kit evaluation data base	Annually	Improve HTS
1.Are all HTS providers in all facilities undergone comprehensive HTS training?	Proportion of HIV testing service providers trained Proportion of HTS providers refreshed.	Training data base at various levels	Annually	Improve HTS
What is the performance of HTS EQA program?	Proportion of HTS providers enrolled Proportion of HTS providers participating in PT (Returning results) Proportion of HTS providers with satisfactory performance	PT data base	Quarterly	ImprovedHTS
Has the quality of HTS Data Improved?	Proportion of facilities with complete and accurate HTS data tools	HTC register (MOH 362) Data reports	Quarterly	Improved HTS
Is HTS QA data utilized to monitor and improve quality	Proportion of HTS sites analyzing and utilizing HTS QA data to monitor and improve quality	1. HTC register (MOH 362) 2. QA data analysis reports 3. Corrective action reports		Improved HTS
Has stakeholders involvement increased HTS Quality	Number of stakeholders involved in QA activities	Stakeholders engagement reports	quarterly	Sustained quality of HTS

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APPENDIX A: DEFINITIONS OF TERMS

Lot	Group, batch, set, assortment, bunch, bundle, delivery
Batch	Lot, consignment, group, bunch, set
Evaluation	To assess, appraise
Surveillance	Close watch, inspection, scrutiny, shadowing (tailing, following, investigation)
Characterization	description, classification, categorization
In – country new kit evaluation	This the process of evaluating quality of test kits already listed in the WHO Pre-qualified list against approved gold standards in individual country. Also referred to as kit evaluation in Kenya.
Lot to lot evaluation	This is process of comparing performance of a new kit lot against a evaluateevaluated lot or previously approved lot
Batch release testing	This is the process of evaluating kits samples from a batch to ensure that products delivered meet criteria for quality and performance. Ultimately only batches with satisfactory results are distributed to all testing facilities
Post market surveillance	This is the continuous watchfulness through use of scientific methods that provide thorough scrutiny, supervision, inspection of kits being used to ascertain conformance to quality
Screening test:	A procedure that is performed to detect a specific disease (e.g. HIV). The individual may not present any symptoms of the disease. A sensitive test kit is recommended
Algorithm	For HIV testing, the sequence in which assays are performed to detect HIV antibody in a body fluid
Evaluation Panel	Set of specimens used during evaluation for which the sero-status has been previously defined or known by the gold standard
Evaluation	Process for determining whether a test system meets defined needs in the potential user's environment.
Gold Standard	This refers to a diagnostic test or benchmark that is regarded as definitive.
Quality Assurance	Planned and systematic activities to provide confidence that requirements for quality testing are met
Reference Panel	For HIV, aliquoted stable serum or plasma specimens that have been highly characterized; i.e. known cutoff points, subtype, titer, etc

Parallel testing	Samples are tested simultaneously by two different tests.
Serial testing	Samples are tested by a screening test and the outcome of the screening result determines whether additional testing is required or not.
Confirmatory test:	2nd test required after a preliminary positive result from a screening test .A specific test kit is recommended.
Tie-breaker test:	3rd test needed when two test results are different (one reactive, the other non-reactive)
Discrepant results:	Test results in which there is disagreement between screening and confirmatory tests (one is reactive , the other non-reactive)
Sensitivity (S):	It is the capacity of a test to correctly identify people that are infected with HIV. It Expresses the capacity of a test to correctly identify people that are infected with HIV. The more sensitive the test, the fewer false negative results are produced. Sensitivity refers to the lowest level at which anti-HIV can be reliably detected. The percentage of the results that will be positive when HIV is present
Specificity:	It is the capacity of a test to correctly identify people that are not infected with HIV. It is the measure of the probability of a test to correctly identify an HIV uninfected person. It expresses a test's capacity to correctly exclude people that are not infected with HIV. The percentage of the results that will be negative when HIV is not present. The more specific a test, the fewer false positive results it produces.
Positive Predictive Value (PPV):	The probability that a person who tests reactive is indeed infected with HIV
Negative Predictive Value (NPV):	The probability that a person who tests negative is not infected with HIV.
Reliability	Reliability is the degree to which a test kit produces stable and consistent results. Reliability refers to the precision or repeatability or reproducibility of a measurement.
Validity of Results	Validity of a test kit refers to the accuracy of measurement.

MINISTRY OF HEALTH

National Public Health Laboratory Services