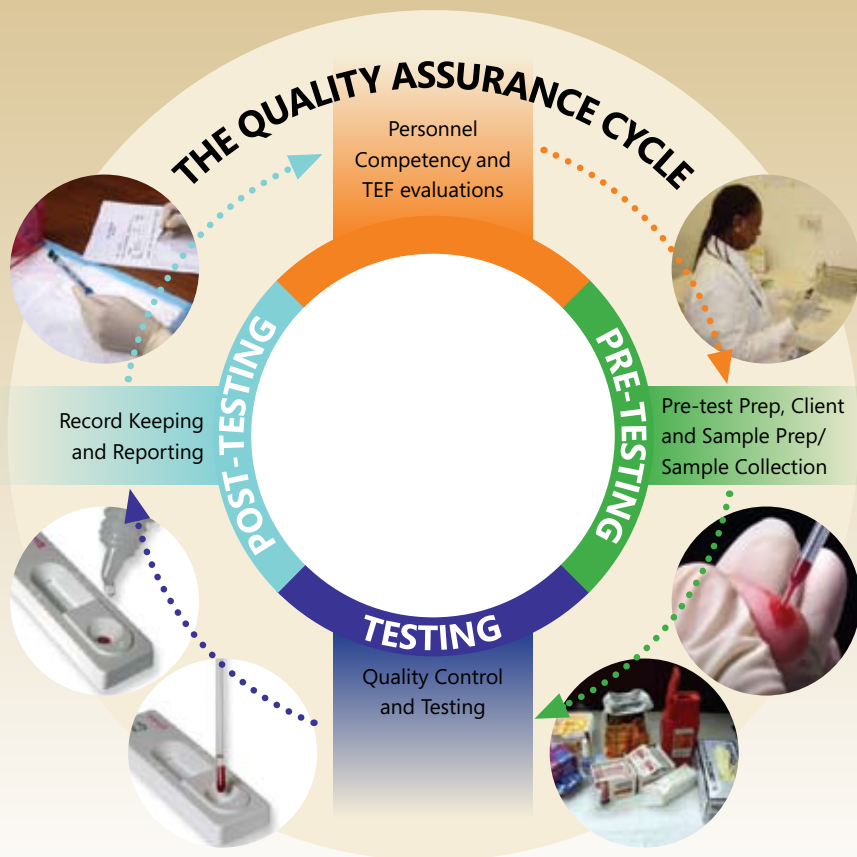


GUIDELINES

for assuring the accuracy and reliability of HIV
rapid testing: *Applying a quality system approach*



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Guidelines for assuring the accuracy and reliability of HIV rapid testing:

Applying a quality system approach

National Department of Health 2009

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Preface

Rapid HIV tests to detect the presence of antibodies to human immunodeficiency virus (HIV) in individuals are playing an increasingly important role in the efforts to address the national HIV and AIDS epidemic. With the exponential growth of HIV and AIDS care, management and treatment programmes, these tests form an essential tool for HIV diagnosis. The use of rapid HIV tests will facilitate this in many settings e.g. Voluntary Counselling and Testing (VCT), Prevention of Mother to Child Transmission (PMTCT), Sexually Transmitted Infections (STI) and Tuberculosis (TB) programmes.

However, the quality (accuracy and reliability) of the test results produced in any setting is critical to the success of these HIV and AIDS programmes. In order to ensure the quality of testing and minimise errors, a quality system that addresses all aspects of the testing (policies, processes, procedures and any other activities) is essential. A quality management system is important in any testing setting and applies to all testing and activities, including the simple to perform rapid tests.

Most of the rapid HIV tests used today are single-use, disposable devices that may be used to directly test whole blood, serum/plasma samples. These simple HIV tests present unique challenges – testing is often performed by persons without formal laboratory training, there is no residual sample that can be checked or re-tested, conventional quality control methods cannot be used, and there are special problems associated with efforts to provide conventional external quality assessments (e.g. proficiency testing).

The purpose of these guidelines is to facilitate adoption of a quality system approach that encompasses all aspects essential to assuring accurate and reliable rapid HIV testing. It is intended to provide assistance to all persons involved in rapid HIV testing service (quality planners/manager, programme managers, trainers and testers). With the expansion of rapid HIV testings to large numbers of testing sites, it will be very important to implement these guidelines, and monitor the processes to assure quality and reliability of rapid HIV test results.



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Table of Contents

Glossary of terms	6
Acronyms	7
1. Introduction	8
2. Rationale for the Quality System Guidelines	11
2.1 Aims	11
2.2 Objectives	11
2.3 Requirements for HIV rapid testing Quality Assurance (QA) program	12
3. Organisation and Management	13
3.1 National	13
3.2 Provincial	13
3.3 Testing sites and facilities	14
3.4 National Reference Laboratory (NICD)	15
4. Personnel	16
4.1 Training	16
4.2 Personnel competency	16
5. Process Control	17
5.1 Standard operating procedure	17
5.2 Evaluation of HIV rapid test kits	18
5.3 Testing protocol and algorithm	19
5.4 Quality control	20
5.4.1 Procedural control	21
5.4.2 Independent quality control	21
5.4.3 Recording and monitoring of quality control results	21
5.5 External quality assurance	22
5.5.1 Proficiency testing	23
5.5.2 On-site monitoring	23

6. Documents and Records	25
6.1 Documents	25
6.2 Records	25
6.3 SOPs	25
7. Equipments	27
8. Inventory	27
9. Information Management	27
10. Occurrence Management	27
11. Process Improvement	28
12. Service Satisfactory	28
13. Facilities and Safety	29
13.1 Facilities	29
13.2 Safety	29
14. References	30

Glossary

The aim of the glossary of terms for HIV Counselling and Testing is to standardise the interpretation of terms used in the guideline, existing guidelines and protocols in the context of counselling and testing services provision in South Africa.

Algorithm	The combination and sequence of specific tests used in a given strategy.
Antigen	A substance which is recognised as foreign by the immune system and often triggers the production of antibodies. Antigens can be part of an organism or virus, e.g., virus envelope or core protein (p24).
Antibody	A protein (immunoglobulin) produced by the body's immune system to recognise and attack foreign substances
Quality	The ability of a product or service to satisfy stated or implied needs of a specific customer, achieved by conforming to established requirements and standards.
Quality System	Implies the organisational structure, responsibilities, processes, procedures, and resources for implementing quality management.
Quality Assurance	A set of planned and systematic activities providing adequate evidence that the requirements for quality will be met.
Quality Control	Measures taken to ensure that the testing process has been carried out properly and that the kit reagents are performing as intended.
Parallel Testing	Testing is performed simultaneously by two different tests.
Serial Testing	A first test is performed and the result of this test determines whether additional testing is required.
Sensitivity (Se)	The capacity of a test to correctly identify individuals that are infected with HIV (HIV positive)
Specificity (Sp)	The capacity of a test to correctly identify individuals that are not infected with HIV (HIV negative).
Positive Predictive Value (PPV)	The probability that a person who tests positive is indeed infected with HIV.
Negative Predictive Value (NPV)	The probability that a person who tests negative is not infected with HIV.

Acronyms

AIDS	Acquired Immunodeficiency Syndrome
CDC	Centres for Diseases Control and Prevention
CLSI	Clinical Laboratory Standards Institution
CT	Counselling and Testing
ELISA	Enzyme Linked Immuno Sorbent Assay
EQC	External Quality Control
EQA	External Quality Assessment
FDA	US Food and Drug Administration
GMP	Good Manufacturing Practice
HCT	HIV Counselling and Testing
HIV	Human Immunodeficiency Virus
IQC	Internal Quality Control
ISO	International Organisation for Standardisation
NDOH	National Department of Health
NICD	National Institute for Communicable Diseases
PT	Proficiency Testing
QA	Quality Assurance
QC	Quality Control
QS	Quality System
RCT	Routine Offer of Counselling and Testing
SOP	Standard Operational Procedure
STI	Sexually Transmitted Infection
VCT	Voluntary Counselling and Testing
WHO	World Health Organisation

1. Introduction and background

As part of the South African HIV and AIDS comprehensive plan and one of the priority areas in South Africa, Counselling and Testing (CT) is implemented in various health facilities in all nine provinces since 2000. CT is aimed at increasing access to HIV & AIDS care, prevention and treatment programmes to the general population of South Africa.

HIV rapid testing considered within the context and framework of the ethical and human rights considerations as the response to the HIV epidemic is a rights based one. All public health facilities that offer CT utilise HIV rapid test kits to diagnose HIV infection. All testing for medical diagnosis, including HIV rapid testing, consists of a series of processes and procedures that must be carried out correctly in order to obtain accurate results. An approach that monitors all aspects influencing HIV rapid testing is crucial to:

1. ensure the quality of the overall process
2. to be able to detect and reduce errors as they occur
3. to improve consistency between testing sites
4. contain costs

This approach to quality is called a quality system. The quality system includes policies, quality assurance, and quality improvement.

The quality of HIV testing in support of prevention and care efforts was identified as a priority by the World Health Organisation (WHO). The use of HIV rapid tests is widely practiced by a variety of HIV prevention strategies, as a result, accuracy and reliability of testing is critical to the success of HIV and AIDS programmes.

The approach to quality system follows a similar pattern as the “Quality System Framework” developed by the World Health Organisation (WHO) and Centres for Diseases Control and Prevention (CDC) for assuring the accuracy and reliability of HIV rapid testing. This system includes the following components:

- **Organisation:** addresses responsibilities at the national, provincial, site levels and national reference laboratory.
- **Personnel:** addresses requirements for the competency of testing.

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- **Equipment:** addresses issues of equipment calibration and maintenance if used in conjunction with testing e.g. fridges.
 - **Purchasing and Inventory:** deals with stock management at all levels i.e. national, provincial and site.
 - **Process Control:** refers to all the activities that should be carried out to ensure validity of test performance.
 - **Documents and Records:** deals with the standardisation and management of documents to ensure conformance with the national standards and the recording of the results from all processes and procedures that are carried out at the sites.
 - **Information Management:** refers to the management of all the records captured (manual or electronic).
 - **Occurrence Management:** refers to the management of adverse incidents, errors and problems.
 - **Process Improvement:** refers to continuous efforts to look for potential causes of problems and taking corrective actions.
 - **Service and Satisfaction:** deals with evaluation of customer satisfaction and response to customer complaints.
 - **Facilities and Safety:** looks at the suitability of the physical space and environment for testing and reagents storage and safety of testers and clients.
 - **Assessment:** this includes activities used to objectively assess site conformance to quality standards and includes overall site operations.

The basic concepts of “Quality Management” applied in this guide for assuring quality of HIV rapid testing include:

Quality System (QS): organisational structure, responsibilities, resources, processes and procedures needed to implement quality management. It implies all activities which contribute to quality of tests, directly or indirectly.

Quality Assurance (QA): planned and systematic activities to ensure that processes are adequate for an adopted system to achieve accurate and reliable results e.g.

- Establishing standard operating procedure (SOPs) covering all quality assurance (QA) phases (i.e. pre-testing, testing, and post-testing) requirements.
- Implementing Quality Control (QC) and External Quality Assessment (EQA) measures.
- Management and organisation around HIV rapid testing.

Quality Control (QC): a set of procedures used internally by operators to ensure validity of test performance and kit reagents stability. Response to any deviation from the expected result is always immediate. Examples include:

- Deciding if a sample is acceptable for testing.
- Reading the control band when interpreting test results if a control is incorporated into test device.
- Analysing known positive and negative samples or control material.

External Quality Assessment (EQA): a set of activities performed through an external source used to objectively evaluate testing site operations. Response to deviations is only after a report is generated. Examples include:

- Proficiency testing (PT)
- Re-testing.
- On-site assessment.

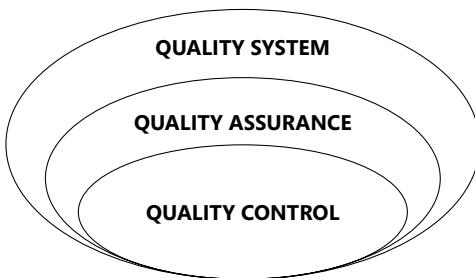


Fig 1: A Simplified "Quality Management System" Structure

The performance of HIV rapid testing in non-laboratory settings presents special challenges when undertaking measures to assure test reliability and accuracy. HIV rapid testing in these settings is conducted by health care professionals who do not have specific laboratory experience. The training of these non-laboratory staff members around laboratory testing quality system provides laboratory knowledge and skills needed for accurate and reliable HIV testing. In addition there is sufficient time for practical hands-on work and measures to provide proof of competency. The quality system measures that assure accuracy and reliability of all laboratory tests, including the easy to perform HIV rapid tests, should be implemented in any setting where the test is performed.

2. Rationale for the Quality System Guidelines

The implementation of the national HIV rapid testing QA programme has been guided mainly by normative guidance and recommendations from WHO Agencies and the CDC. This guideline provides the basis for the implementation in this country of the QA programme around HIV rapid testing as HIV and AIDS intervention programmes continue to expand.

A good quality, standardised, uniform, equitable, affordable and sustainable QA programme that is supported by a firm human rights base is necessary. The implementation of this HIV rapid testing guideline should:

- Lead to increased and professional usage of HIV rapid test kits.
- Assist in mobilising sectors and communities to facilitate utilisation of HIV prevention, treatment, care and support services.
- Encourage individuals to assess personal risk to HIV infection, to initiate and make the most of prevention and care interventions.

2.1 Aims

The aim of this guideline is:

- To provide a framework for the implementation of a QA program around the HIV rapid testing process.

The aim of the QA programme is:

- To ensure that the process of HIV rapid testing is performed accurately and reliably in a safe and professional manner.

2.2 Objectives for the guideline

Principal Objectives

- Provide assistance to persons involved in HIV rapid testing policy development, training and QS planning and QA programme.
- Help testing sites implement and maintain a QS and QA programme that traditional

laboratories use to ensure accuracy and reliability of test activities, simple or complex.

- Provide information useful for HIV rapid testing personnel.

Secondary Objectives

- To ensure adherence to quality testing requirements comprehensively.
- To ensure correct HIV diagnosis for clients.
- To set the standard for level of quality.
- To provide means to prevent, detect and correct problems.
- To facilitate monitoring, evaluation and improvement of the system.

2.3 The requirements for HIV rapid testing Quality Assurance programme

According to the current legislation, a trained health care professional (registered nurse, doctor, dentist, oral therapist or oral hygienist) is responsible for administering the HIV test (Human Tissue Act No. 65 of 1983 section 23).

All facilities conducting HIV rapid testing must have guidelines that describe the following:

- Organisation and management around HIV rapid testing (responsibilities at the national, provincial, testing sites and National Reference Laboratory).
- The process control guide necessary for assuring accuracy and reliability of HIV rapid testing.
- Finger-prick blood collection guidance necessary for assuring quality of specimen.
- Country-approved testing strategy and algorithm.
- Current test kits available on tender.
- Test performance guidance (pre-test, testing, post-testing phases).
- Guidance to result interpretation.
- Client result and quality data recording tools.
- Client result reporting.

Trained HIV and AIDS counsellors and professional health workers must always be available during the operating hours of the facility.

3. Organisation and Management

The National Department of Health (NDOH) HIV & AIDS and STI Cluster through the Counselling and Testing (CT) programmes will lead the overall QA program.

Roles and Responsibilities

3.1 National Level

- Establish national quality system guidelines and extend to all spheres.
- Oversee the management of HIV rapid testing.
- Facilitate a national tender for the supply of HIV rapid test kits.
- Facilitate the correct administration of the HIV rapid testing according to the national HIV Counselling and Testing (HCT) policy guidelines.
- Ensure that HIV rapid testing is strictly conducted according to the national HCT policy guidelines.
- Ensure that the suppliers of each product conduct training on the correct administration of the various products as per the national tender specifications.
- Facilitate participation of all stakeholders in the adoption and implementation of the guidelines.
- Facilitate participation and compliance of stake holders.
- Facilitate collaboration between all stakeholders at all levels to improve the quality of HIV rapid testing.
- Mobilise, disburse and account for resources availability for the implementation of the guidelines in the public sector.
- Develop standardised training programmes around HIV rapid testing.
- Establish testing infrastructure and training capacity to support QA implementation.

3.2 Provincial Level

- Guide the implementation of a national QS and QA plan according to the national guidelines.
- Map service providers in the province and provide systems for QA
- Develop and implement relevant SOPs.

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- Adhere to all QS and QA aspects outlined in this QS guideline document.
 - Implement the guidelines, identify training needs and facilitate training as needed in the province.
 - Develop QA programme plans, budgets and ensure adequate monitoring.
 - Ensure that information management systems are in place.
 - Facilitate an uninterrupted supply of all commodities.
 - Facilitate enrolment to EQA scheme of all facilities conducting HIV rapid testing.
 - Receive EQA results from the National Institute for Communicable Diseases (NICD) and support implementation of corrective action measures.
 - Perform on-site assessment of sites operations and communicate outcomes and recommendations to the facilities.
 - Manage the implementation of corrective action from on-site assessment
 - Monitor and maintain all site records (client and quality records).
 - Identify and investigate non-compliance like discordant results, invalid results etc.

3.3 Testing sites and facilities Level

- Implement and maintain the national QS and QA plan in accordance with the national guidelines.
- Adhere to all QS and QA aspects outlined in this guideline document.
- Identify a quality officer per site or any designated individual who will be responsible for quality management of HIV rapid testing.
- Ensure that testing is performed according to the national HCT policy guidelines.
- Ensure supervision of all test operations and personnel at the site.
- Evaluate test kits performance on receipt from the depot (visual checks and internal quality control (IQC) run).
- Enrol on a EQA scheme approved by NDOH.
- Receive EQA results from province and implement corrective action measures.
- Monitor, keep and maintain all site-generated records (client and quality records).
- Identify and investigate non-compliance like discordant results, invalid results etc. and communicate outcomes to supervisors.
- Communicate all outcomes to supervisors.
- Implement and manage corrective actions from non-compliances identified e.g. IQC, EQA, on-site assessment.

3.4 National Reference Laboratory

The NICD has been identified by the NDOH as a National Reference Laboratory that will assist the department with technical support including training of QA for HIV rapid testing in the country.

The responsibilities of the NICD are as follows:

- Provide QS and QA initial training for programme staff trainers and those who provide oversight and monitoring.
- Provide support on planned subsequent provincial training programmes.
- Provide continuous technical support and advice at the national and provincial levels.
- Provide assistance in the development and implementation of IQC plans
- Assist in the management of EQA and PT scheme.
- Perform in-country validation of HIV rapid test kits for government tender purposes.
- Perform lot-to-lot test kit evaluation prior to new batch distribution.
- Conduct post market surveillance of HIV test kits used by the government.

4. Personnel

To ensure accurate and reliable HIV rapid testing, careful attention should be given to competencies of the individuals performing these tests. Direct support for the testing personnel should include initial and on-going training on essential QS and QA aspects and periodic evaluation of each person testing. Standardised training programmes should be developed.

4.1 Training should include:

- The importance and relationship of the QS and QA essentials.
- How to perform the test, covering all parts of the test process from the sample collection to reading and interpretation, recording and reporting of the results.
- A hands-on component – all parts of the testing process included.
- Biohazard safety measures – protection and waste disposal means.
- Training of those who provide oversight and monitoring, trainers, and programme staff who may not be performing the testing but who need information about how the tests are conducted and how they work.
- Provision for on-going in-service training and continuous mentoring and evaluation of the effectiveness of training.

4.2 Personnel competency should include:

- Capacity of the personnel to set up a testing environment consistent with the described SOPs.
- Conformance to test performance (skill) ensuring that all steps are carried out correctly (through observation).
- Correctly identifying the reactivity of known samples provided for analysis to ensure that staff can obtain correct results.
- Evaluation of the personnel capacity to correctly interpret the results.
- Conformance to all results recording procedures.

Note: Personnel form the most critical part of a quality system/assurance programme.

5. Process Control

Process control refers to activities and techniques that are carried out to ensure the following:

- The testing procedures are correctly performed.
- The environment is suitable for reliable testing.
- The test kits work as expected to produce accurate reliable results.

Steps in the testing process follow the path of workflow and begin with tasks done before testing, followed by tasks done during and after testing. The path of workflow is summarized as pre-testing, testing and post testing. When using HIV rapid test kits there are a number of steps in this three path workflow that need to be taken into account to ensure accurate and reliable test results. These include:

- Use of pre-evaluated test kits only.
- Monitoring of storage and testing room environmental conditions.
- Standardising all activities in the testing process path of workflow.
- Application of IQC procedures to validate test performance.
- Application of EQA procedures to assess quality of test operations.
- Management and supervision of all process control activities.

5.1 Standard operating procedure for the testing process

An SOP should be developed that provides instructions on all aspects of the testing process, to include storage and inventory information, environmental requirements, specimen collection, test performance, quality control, test interpretation, recording and reporting results and appropriate use of testing algorithm. Each testing product will need its own SOP that must be followed when conducting tests. The work instructions should include the following steps:

Pre-testing phase:

- Check storage and test room temperatures.
- Set up testing workstation (materials and supplies for testing).
- Check inventory information as needed.
- Conduct kit performance evaluation as needed (testing known negative and positive samples).
- Record all needed data, such as kit lot number, operator identity etc.

Testing phase:

- Follow biohazard safety precautions.
- Correctly complete client information, date and other relevant information.
- Collect blood specimen according to SOP.
- Perform the test according to the manufacturer instruction/SOP.
- Interpret the test results following manufacturer instructions/SOP.
- Dispose of all waste in accordance with waste disposal instructions.

Post-testing phase:

- Re-check client identifier and record the results.
- Clean and dispose of biohazard waste.

5.2 Evaluation of HIV rapid test kits

- All HIV rapid test kits that are supplied to provinces must have been evaluated for performance in-country irrespective of the US Food and Drug Administration (FDA) and Good Manufacturing Practice (GMP) approval.
- It is the responsibility of the National Reference Laboratory i.e. NICD to perform initial country level evaluation.
- Country level evaluation of HIV rapid tests will take place at three different levels all aimed at maintaining stability and accurate outcome of HIV rapid testing.
- The selection of test kits for in-country performance evaluation will be based on previous assessment by WHO and CDC or other independent international organisation with relevant expertise.

At national level test kits are evaluated by the National Reference Laboratory as per requirement to exclude all those that don't meet the performance specifications.

- The NDOH has a well established process through which HIV rapid test kits are supplied in the country.
- A national tender is awarded for a period of two years to suppliers for screening and confirmatory test kits respectively.
- Performance evaluation of HIV rapid test kits as part of the tender specifications requires that a sample of 500 test devices for each test kit is tested by the NICD.
- The test kits should have a sensitivity and specificity of greater than 99% i.e. it should yield Positive Predictable Value (PPV) and Negative Predictable Value (NPV) of more than 99%.

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- Successful bidders have to submit one test kit package (1 box/packet) from all new batches to the NICD for lot-to-lot evaluation before supplying provinces.

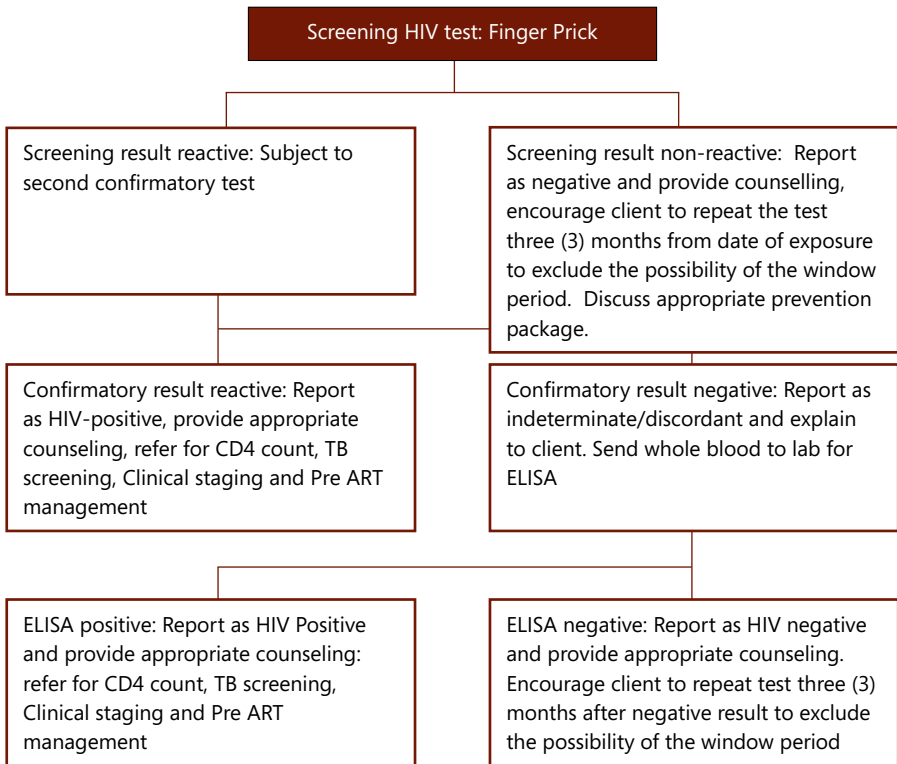
The successful bidders will only supply provinces with the ordered kit stock only when new batches have been evaluated for performance by the NICD and the report submitted to NDOH and the depot procuring stock. On receipt of the kit stock the provincial depot must:-

- Verify the NICD report with the supplied batch numbers.
- Verify storage temperature during transit.
- Stock kept for three months and more should be evaluated by re-submitting ten test strips to NICD.
- The same procedure should be followed by facilities if stock is kept for three months and more.

5.3 Testing protocol and algorithm

- The NDOH approves the use of HIV rapid test kits that can detect antibodies against both HIV Type 1 and HIV Type 2 in human blood.
- A finger prick blood sample should be adequate to perform HIV rapid test and obtain accurate and reliable result.
- The NDOH approves the use of a serial algorithm as standard in CT programmes.
- Clients are screened for HIV using an approved screening HIV rapid test kit.
- If the screening test is non-reactive, the client is counselled and a negative result is issued.
- If the screening test is reactive, a confirmatory test is performed using a different approved confirmatory HIV rapid test kit.
- If both screening and confirmatory tests are reactive, the client is issued a positive result, counselled and referred accordingly.
- If the screening test is reactive and the confirmatory test is non-reactive the result is referred to as discordant. In this case:
 - Venous blood should be collected for enzyme-linked immunosorbent assay (ELISA) and the client should be advised to come back for results in 3-5 days.
 - The ELISA results will be interpreted as final outcome of the test.

HIV Serial Testing Algorithm



5.4 Quality control

Quality control procedures are essential to ensure that the testing process has been carried out properly and that the test kits and reagents are performing as intended. Most HIV rapid tests have a procedural control built into the device which generally provides information about the adequacy and quality of specimen and whether the kit is working properly. This type of quality control will always be a part of the testing procedure and the test results cannot be interpreted without its presence. In addition to this control, an independent control that is external to the device/kit should be used. This type of quality control involves testing of known positive and negative samples which are used to evaluate the accuracy of the test and to check if the person doing the test performs it correctly.

5.4.1 Procedural quality control (in-built control region):

This is built into the test device, and it forms part of the test process each time a test is performed. This control does not provide much information except to indicate that sufficient volume of either sample and/or diluent reagent is added. Results must not be issued if the control band does not appear and the test should be considered invalid and should be repeated. (See the flow chart for corrective action – Table 1).

5.4.2 Independent quality control:

The known negative and positive control materials can be procured separately from the NICD or commercial manufacturer. These controls work to evaluate the accuracy of the test kits and the person performing the test. Frequency of use of these controls is dependent on several factors including:

- Recommended routine evaluation of the test accuracy.
- When beginning to use a new test kit with a new lot number.
- Whenever a shipment of test kits is received.
- If test kits have been exposed to environmental conditions that fall outside the range needed for stability as defined by the manufacturer.

Any time a quality control deviates from the expected outcome, a cause for deviation should be identified and corrective action taken immediately.

5.4.3 Recording and monitoring of quality control results:

- A standard worksheet for daily recording of IQC results should be completed.
- A flow chart for corrective action must be provided. This shows the steps to follow when IQC results do not read as expected.

Table1: Quality Control Troubleshooting Guide

Problem	Potential causes	Action
No control line or band present	Damaged test device or controls	Repeat the test using new device and blood sample
	Proper procedure not followed	Follow each step of testing according to SOP Re-check buffer and/or specimen volumes Wait for the specified time before reading the test
	Expired or improperly stored test kits or controls	Check expiration date of kits or controls. Do not use beyond stated expiration date Check temperature records for storage and testing area Facilities to have thermometers and temperature charts.
Positive reaction with negative internal/ external control, i.e. false positive	Incubation time exceeded	Re-test negative control using a new device and read results within specified time limit
Extremely faint control line	The control line can vary in intensity	No action required. Any visible line validates the results
Negative reaction with Positive control i.e. false negative	Incubation time shortened	Re-test positive control using new device and read results. If still negative report immediately and request for another batch of test kits.

5.5 External quality assessment

Methods of EQA recommended for the testing sites include, proficiency testing and on-site monitoring visit to evaluate site test operations using a suitable tool e.g. standard checklist.

Benefits of EQA are to:

- Provide an objective assessment of a test site's operations and performance by an external agency or personnel.
- Provide a platform to evaluate the performance of a testing site from outside the testing sites.

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- Provide objective evidence of testing quality.
 - Provide early warning for systematic problems associated with test kits or operations.
 - Indicate areas that need improvement.
 - Identify training needs.
 - Allow comparison of performance and results among different test sites.

5.5.1 Proficiency testing

Proficiency testing will be facilitated by the Cluster HIV and AIDS and STI and implemented by the NICD as follows:-

- NICD will send panels of blind specimens to each province to be distributed to all the testing sites.
- Testing sites will perform tests on the blind samples and send the results back to NICD for analysis.
- The NICD will generate a report and send it back to the province for review.
- Results should indicate quality of site overall test operations and personnel performance.
- Results should also be compared across several testing sites to see which sites perform poorly and need assistance.

5.5.2 On-site monitoring

EQA can be accomplished by a careful on-site observation of the testing process and procedures, carried out by knowledgeable persons in a team. A standard checklist that allows the assessment of all parts of the QS is an important tool for an on-site evaluation.

Periodic site visit also referred to as audit, assessment, or supervisory visits:

- Focuses on how the facility monitors its operations and ensures testing quality by evaluating all essential aspects of a QS.
- Should include observation of testing with specimen of known reactivity.
- Should occur at least twice a year.
- Should be instructional and provide mentoring experience.

-
- Can be used to monitor progress.
 - Provides information for internal process improvement.
 - Is part of every facility quality system and should be given major emphasis.
 - Provides information that can be used to measure gaps or deficiency.
 - Provides information for:
 - Quality planning and implementation processes.
 - Continuous monitoring and quality improvement.

Fig. 3: Schematic diagram showing the EQA process



Problem-solving team: (NDOH and Province)

- Investigate root causes.
- Develop appropriate corrective actions.
- Implement corrective actions.
- Examine effectiveness.
- Record all actions and findings.

6. Documents and Records

6.1 Documents

Standardised documents as provided by the NDOH should be used to assure conformity and ease for use in collecting data. Documents and records must always be up to date, readily accessible and protected from damage and deterioration. Examples of documents may include:

- SOPs for an approved HIV rapid test.
- Manufacturer test kit inserts.
- Country testing algorithm.
- Safety manual.
- Temperature log (blank form).
- Quality control record (blank form).

6.2 Records

Records result from carrying out processes and procedures within a testing process. Examples of records may include:

- Client test results.
- Quality control results.
- Temperature chart (completed).
- Stock card (completed).
- EQA report.
- Report of corrective actions.

Note: All documents and records need to be managed with tracking system to assure that all testing sites have current information on hand and outdated ones are removed from the system. Retention times for archived documents and records should be established.

6.3 Standard operating procedures

These are written documents that describe step-by-step instructions on how to

perform various operations a testing site. Detailed instructions on all aspects of testing must be available in all testing facilities.

The purpose of the SOPs is to:

- Describe how to perform various operations in a testing site.
- Provide step-by-step instructions to operators.
- Provide a training tool for new staff members.
- Assure:
 - Consistency.
 - Accuracy.
 - Quality.

Ideal SOPs that should be on hand at the sites should include:

- Daily routine schedule.
- Country policies and algorithm.
- Safety manuals encompassing safety precautions, accidental spillage management, preparation of disinfectant, post-HIV exposure guidelines.
- Blood collection including finger prick and venous blood.
- Test procedures.
- IQC/EQA instructions.
- Reordering of supplies and kits.
- Equipment use and maintenance.

All site SOPs must be approved for use and consist of the following document control feature:

- Title, identification code and version number.
- Name of the author and approving authority.
- Date written and approved.
- Date on which it became effective.
- Review date.

Note: SOPs should be reviewed periodically or as the need arises in order to meet the requirements for testing and quality standards at all times. SOPs followed when performing tests will be re-established when new test kits are brought on tender.

7. Equipment

If any equipment is used at the site (e.g. refrigerators for storing reagents, QC materials etc.), time keeping devices e.g. timers, procedures for maintenance/service/calibration must be documented and followed all the time.

8. Inventory

Test sites must keep inventory of all supplies and materials used for testing to ensure interruptions to testing do not occur. A test site should:

- Maintain an inventory record for test kits and other supplies used for testing.
- Be able to determine re-order levels for each item in the inventory.
- Perform quality checks on receipt of new test kits and supply and update inventory record.
- Avoid expiration of test kit reagents by following the “first expiry, first out” concept.
- Be able to store test kits appropriately and in accordance with manufacturer instructions.

9. Information Management

Site records may be kept manually (filing of hard copies) or electronically (using computer technology). Site records include clients’ data and quality information e.g. IQC results, EQA reports, corrective actions, daily temperature records, etc. It is important that a tracking system to ensure traceability of site records is established e.g. effective filing system and/or computer system. Confidentiality of private information must be strictly observed.

10. Occurrence Management

Errors can occur anywhere in the testing process and affect accuracy of the test results. It is with this regard that a quality system is implemented to help sites detect errors as they occur and take corrective actions and prevent them from re-occurring. A quality system will include those activities that help detect errors and a method to resolve them.

The following steps are important in resolving incidents, problems and errors:

- Investigate the error or problem and identify the cause.
- Take action to resolve the cause.
- Communicate with all relevant persons e.g. supervisors.
- Keep record of all errors and incidents.
- Keep records of corrective actions.

11. Process Improvement

Process improvement is the action of revising a process based on the information gathered. A quality officer or any designated person may resolve to investigate a certain aspect in the testing process – this requires collecting data over some time, analysing gathered data, implementing change and evaluating the effectiveness. A process improvement may be triggered by IQC results, EQA report, incidences, customer complaints and many other things. Process improvement can also be a result of occurrence management and client service satisfaction response.

12. Service and Satisfaction

For HIV rapid testing in CT settings, clients who come for testing are programme customers. Methods should be established to evaluate how well the testing site is meeting the needs of the clients. Efforts should be made to serve the needs of clients for the benefit of HIV and AIDS intervention programmes. Policies and procedure should be established for responding to all suggestion and complaints from customers.

13. Facilities and Safety

13.1 Facilities

Each site or set-up where HIV rapid testing is performed must have an appropriate physical space for testing. Appropriateness of the physical space includes that for the storage of test kits and QC samples and other supplies used for testing. Facility for the transportation of test kits and IQC/PT samples must also be appropriated to meet the requirements for their storage. Facility appropriateness should include:

- Adequate and leveled surface for performing tests, that can be cleaned.
- Assurance that environmental factors e.g. temperature, degree of humidity do not affect test kits integrity and test performance.
- A cooling system where temperatures exceed expected ranges.
- Hand washing facility.

13.2 Safety

Testing sites should implement all safety measures to ensure safety of all workers that may come into contact with biohazard materials including safety of the clients attending the sites. Personnel should always adhere to universal safety rules when testing.

Procedures for handling biohazards should include:

- Instructions on use of gloves, protective clothing, hand washing, handling of sharp objects, and management of blood spillages.
- Visible basic safety instructions posted in the testing room
- Display of general instructions such as “no eating, drinking, or smoking”.
- Availability of procedures for safe disposal of contaminated waste at the site.
- Procedures for workers to follow when an accidental exposure to biohazard material occurs.

14. References

HIV Rapid Testing: Training Package, Centers for Disease Control and Prevention (CDC), World Health Organisation (WHO), Office of the United States Global AIDS Coordinator, and the US Department of Health and Human Services (DHHS).

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