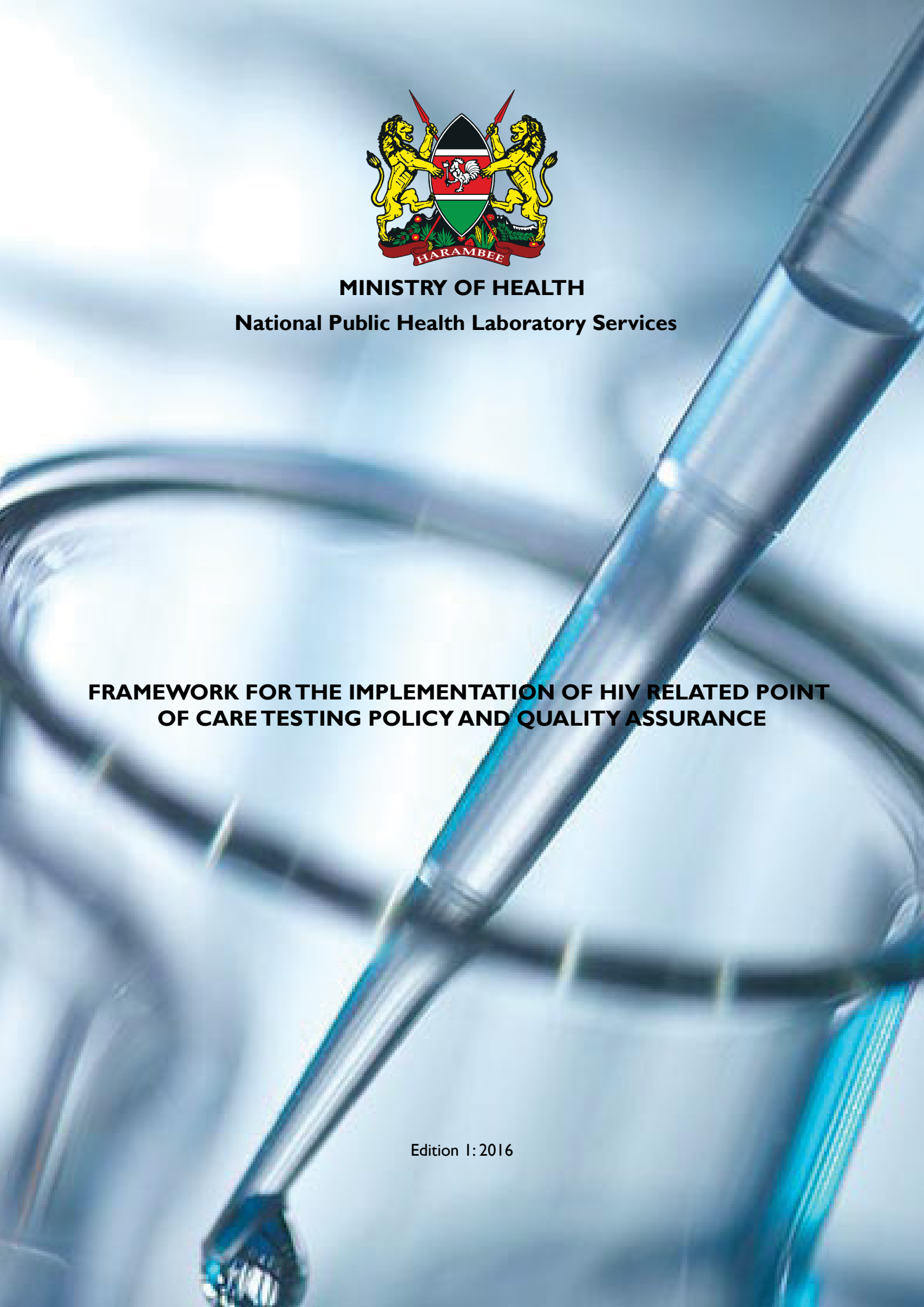

MINISTRY OF HEALTH

National Public Health Laboratory Services

FRAMEWORK FOR THE IMPLEMENTATION OF HIV RELATED POINT OF CARE TESTING POLICY AND QUALITY ASSURANCE

Edition 1: 2016

FOREWORD

This framework for the development of HIV related point of care testing (POCT) policy for implementation and quality assurance aim to support efforts towards developing and strengthening existing POCT policies and initiatives to assure reliable and accurate client results. POCT or decentralized testing is designed to be used at or near the site where the patient examination occurs. POCT technologies also may be used routinely in a clinic or laboratory by personnel trained in clinical laboratory sciences.

POCT will play a critical role towards the global community efforts to achieve a reduction in child deaths, reduce maternal mortality, attain an AIDS free generation, identify pregnant women for Option B+ and attain the international commitment of achieving the target of having 15 million people on treatment by 2015 as indicated in the UN General Assembly Political Declaration of June 2011 (A/65/L77).

POCT supports uptake, coverage, treatment and impact assessment of HIV treatment and prevention efforts. The types of POCT may include HIV RDTs, HB, CD4, Viral Load/EID, and glucose but not limited to the mentioned tests.

This framework will ensure continued quality implementation and improvement of POCT.

My gratitude go to the committee that developed this framework for the development of HIV related point of care testing policy for implementation and quality assurance for their tireless efforts. I hope the implementation and management of POCT will be carried out in accordance to the regulatory standards.

Dr. Kioko Jackson K
Director of Medical Services

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ABBREVIATIONS

MOH	Ministry of Health
CDC	Centers for Disease Control and Prevention
NPHL	National public Health Laboratories
EID	Early Infant Diagnosis
POCT	Point of Care Testing
EQA	External Quality Assurance
IQA	Internal Quality Assurance
IQC	Internal Quality Control
QA	Quality Assurance
PMCT	Prevention of Mother-to-Child Transmission
QC	Quality Control
QMS	Quality Management System
RT	Rapid Test
S DP	Service Delivery Point
SDPP	Service Delivery Point Person
SOP	Standard Operating Procedures
SPI – POCT	Stepwise Process for Improving the Quality of HIV-Related Point-of-Care-Testing Checklist
TWG	Technical Working Groups
WHO	World Health Organization
VCT	Voluntary Counseling and Testing
HIV	Human Immunodeficiency Syndrome
CLSI	Clinical and Laboratory Standards Institute
ISO	International Organization for Standardization
UN	United Nations
PICT	Patient initiated counseling and testing
HTC	HIV testing and counseling
M&E	Monitoring and Evaluation
KEMSA	Kenya Medical Supplies Agency
NLP	National laboratory policy
TWG	Technical working group
TB	Tuberculosis
PT	Proficiency testing
PIP	Partners in Prevention

DEFINITION OF TERMS

Competency	Demonstration of mastery skills in a given trade or task
Quality Audit	An assessment for compliance against a quality standard
External Quality Assurance	A system for objectively checking the laboratory's performance using an external agency or facility
Quality Control	Measure put in place in procedures to guarantee quality results
Internal Quality Control	Measures put in place within the procedure to guarantee quality results
Verification	To check on specified features specified by manufacturer in meeting the stated functions or needs of the user
Validation	Checking appropriateness and utility of the technology for the intended purposes to inform product development or use in a given setting
ISO 22870	International Standard for Quality Management System and Competency testing for Point of Care Providers
ISO 17043	An international standard for Quality Management System and Competency for EQA Scheme Providers
Healthcare Service Provider	Any individual, institution or agency that provides health services to healthcare consumers; applicable to POCT.
POCT	Testing done within the proximity of the patient setting
Mentorship	Hands on exposure guidance to nurture acquisition of necessary delivery skills in a given trade
Professional Ethics	A code of conduct required in discharging functions, duties and services in a given field - Violation of this leads to unethical conduct
Health Management Organs	Health Teams charged with managing services at National, County and Facility level

Executive Summary

The framework for the development of HIV related point of care testing policy for implementation and quality assurance, is a guide for the country's response to efficient HIV testing at all levels of health care systems which brings services closer to patients who urgently require it. It is now possible to provide a rapid test result in a timely manner in the immediate vicinity of the patient such as in the Emergency Department or the Intensive Care Unit and other designated areas. The rapidity of obtaining a result can increase clinical effectiveness and contribute to improved outcomes for patients, but it is imperative that the result provided by the device is accurate and reliable. The type of POCT may include HIV RDTs, HB, CD4, Viral Load/EID, and glucose but not limited to the mentioned tests.

POCT will play a critical role towards the global community efforts to achieve a reduction in child deaths, reduce maternal mortality, attain an AIDS free generation, identify pregnant women for Option B+ and attain the international commitment of achieving the target of having 15 million people on treatment by 2015 as indicated in the UN General Assembly Political Declaration of June 2011 (A/65/L77). With devolution of health services in Kenya, POCT can be adopted at all levels of service delivery in the context of health for all which is one of the WHO goals.

The International Organization for Standardization (ISO) and the Clinical and Laboratory Standards Institute (CLSI) have produced standards to address many operational and technical issues. These standards are nested in quality management systems and integrate the competency of the results generated to optimize POCT benefits in the long run. In this regard, the Ministry of health envisions crafting guidelines, through partner and stakeholder involvement, to streamline the implementation of POCT by healthcare service providers and guard against abuse and erroneous results.

CHAPTER 1

Introduction

1.0 Introduction

POCT or decentralized testing is designed to be used at or near the site where the patient examination occurs. POCT technologies also may be used routinely in a clinic or laboratory by personnel trained in clinical laboratory sciences; however POCT is used outside a laboratory or clinic where laboratory staff may not be present. POCT supports uptake, coverage, treatment and impact assessment of HIV treatment and prevention efforts. The following laboratory testing is usually part of the POCT: HIV RDTs, HB, CD4, Viral Load/EID, and glucose but not limited to the mentioned tests.

The figure below shows POCT within the tiered health system.

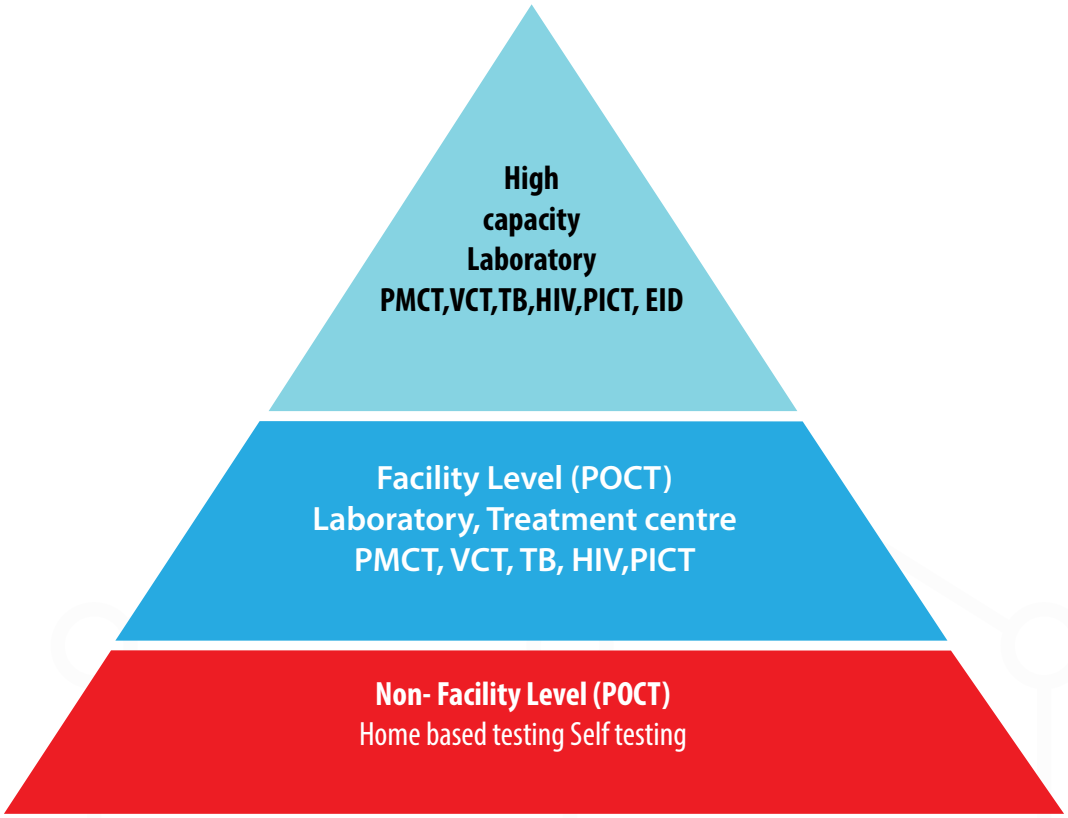


Figure 1. POCT within the tiered health system

1.1 Purpose

The purpose of this document is to support efforts towards developing and strengthening existing POCT policies and initiatives to assure reliable and accurate client results. The national POCT policy ensures continual quality implementation and improvement of POCT that are in use; evaluation of technologies for POCT as they become available; and deciding if, how and where these new assays can be used effectively and efficiently.

1.2 Goals and Challenges

The goals of POCT are to increase access to patient diagnosis and support uptake, coverage, treatment and impact outcomes of HIV prevention, clinical care and treatment. As the global community strives to achieve a reduction in child deaths, reduce maternal mortality, attain an AIDS free generation, identify pregnant women for Option B+ and attain the international commitment of achieving the target of having 15 million people on treatment by 2015 as indicated in the UN General Assembly Political Declaration of June 2011 (A/65/L77), POCT can play a critical role.

There are several POC tests for HIV and HIV co-infection or related infections, including HIV, CD4, viral load, early infant diagnosis, hepatitis C, hepatitis B, syphilis, malaria, TB, and other Cryptococcal infections. Careful consideration to smart innovation, sound policy development, participatory strategic planning and collaborative implementation are central to realizing the opportunities for improvements in health that can be gained by use of these tests.

The challenges of HIV/AIDS, malaria, TB, hepatitis C, hepatitis B, syphilis, cryptococcal infections and other co-infection prevention, treatment and care have been a major driver for the development of testing technologies for POCT. Usually, these technologies can provide test results for clinical decisions or referrals within the period of patient examination and eliminate the need for a return visit, thereby reducing the number of patients lost to follow up, provided that the services are organized in such a way that the test results lead to appropriate patient management decisions at the same visit. Treatment and prevention can be initiated sooner with associated improved health outcomes since clinical decisions can be made with the patient at first visit.

HIV RDTs, one of the early successes in POCT, brought HTC to persons living at a distance from larger health care facilities and laboratories. Moving this testing out of traditional laboratory settings helped more people learn their HIV status and HIV-infected persons to receive effective ART earlier in the course of disease. More persons were provided risk prevention counseling with knowledge of their HIV status. In 2013 for instance, more than 57 million individuals were provided with HTC using HIV RDTs in PEPFAR-supported sites.

The many advantages of HIV POCT have aided better health outcomes for HIV-infected persons and reduced transmission of infections. The demonstration of feasibility that testing could be moved out of the laboratory and results could be trusted has opened up many possibilities for POCT as well as the need for quality assurance systems to ensure the integrity of the system. The advantages of and improvements associated with POCT are many.

a) Test results available to aid more timely treatment decisions, resulting in significant improvements to patient outcomes and reduced patient loss-to-follow-up.

b) POCT, which requires less space than traditional laboratory methods, can be set up near to patient examination and counseling.

c) On-site testing reduces the need for costly, logistically difficult specimen transport to a laboratory and slow return of a test result from the laboratory to the provider and patient.

d) In view of the current underutilization of conventional laboratory instrument, POCT instruments can be more cost-effective than conventional instruments when deployed in settings where the number of tests performed per day is less than the maximum capacity of POC technology due to low volume of samples received on a daily basis.

e) POCT can be performed by trained non-clinical personnel or trained clinical personnel whose primary training is not in laboratory sciences

By increasing patient access to testing services, HIV, syphilis and malaria POC tests have shown that diagnostics can be taken out of the laboratory and decentralized to the most rural points of access in the healthcare system and performed by non-laboratory staff. POCT has made access to test services a reality in health centers, dispensaries, maternal health, PMTCT centers, and HTC sites. In resource-limited settings, POCT offers options for more accessible testing services and improved health.

1.4 Organization settings

POCT can be placed at any level in the health care system but is primarily intended for use in locations where they provide added advantage to conventional laboratory testing and ensure more rapid provision of care to the patient. These sites include program locations for VCT, PMTCT, PICT, treatment centers, and TB/HIV clinics. POCT may be provided in facilities, community locations or homes. Home POCT includes testing provided by trained users.

1.5 Situational Analysis

As the first step to inform policy development, it is important to identify gaps in diagnostic testing services and the feasibility for POCT to supplement these services and integrate into the patient care system at all levels. The information from this analysis should provide the information that Ministry, government agencies, partners and stakeholders need to develop a national policy for POCT implementation. Refer to Appendix I for processes for developing a national POCT policy.

The situation analysis assesses the laboratory system and its environment including standards, recommendations, challenges and best practices in current use. It is important to identify and address gaps in resources that entail core elements of funding, human resources, processes, systems, and infrastructure. Part of the situational analysis will involve:

- Review of existing policies and plans for laboratory and non-laboratory testing sites.
- Analysis of the current national health system organization and infrastructure for providing HIV related testing services from laboratory and current POCT settings.
- Identification of gaps in diagnostic service capacity and coverage for HIV-related testing based on national strategic plans.
- Analysis of clinical, laboratory and program management positions that have responsibility for POCT.

Guidance on a situational analysis is available in the POCT Operational Procedures document. Refer to Appendix II for table format template for activities and initiatives. This format can be used for all sections of the policy development to include planned activities and initiatives, timelines, responsible parties and objectives/results. The responsible party designation should be as specific as possible and related to the ministry of health organogram.

CHAPTER 2

Implementation of POCT

2.1 Implementation of POCT

The following objectives are intended to guide implementation of POCT within each objective, a monitoring and evaluation tool should be developed and implemented to measure activities associated with POCT implementation.The purpose is to demonstrate accountability of resources and guide investments; document country's capability and capacity for POCT (strengths, opportunities, and measurement of progress); standardize and systemize practices; and inform strategic and program planning.Therefore, it is important that a designated body or authority ensures that the evaluation recommendations are used for evidence-based programming to maximize impact and drive smart investments.

Objective 1: Describe and define POCT system components for review, evaluation or validation, approval, selection, placement and post-market surveillance of POCT technology.

Justification: Setting clearly defined POCT system component requirements for technology will enable programs/responsible stakeholders to ensure the quality, selection, placement, and surveillance of technologies.

Core Elements

The policy shall:

- Define requirements for technology review, evaluation/validation, approval and post-market surveillance, product and site selection.
- Define procedures for listing approved POCT technologies, current approved POCT technologies, and procedures for updating approved technology list.
- Describe requirements for performance testing and National EQA program for POCT.
- Describe requirements for registration and monitoring of POC assays.
- Describe expected quality for POCT.
- Ensure establishment of regulatory and supply chain framework.
- Address monitoring and evaluation:
- Establish requirements for monitoring and evaluating post-market POCT activities and outcomes (for each responsible stakeholder) to collect data on facilities/locations, types and number of tests performed, equipment status, supply/reagent status and personnel at each site to inform reviews of POCT technology review and approval.

- Define the role and responsibilities of the components of the National health system with regard to POCT implementation, monitoring and evaluation.

Objective 2: Describe and define the regulations, procedures, and protocols for regulation/ evaluation of POCT technologies, and development of testing algorithms, based on internationally-accepted standards (e.g. ISO 22870) as needed.

Justification: Setting clearly defined standards for regulation/evaluation of POCT technologies and development of testing algorithms will enable programs/responsible stakeholders to ensure its quality as part of the quality assurance.

Core Elements

The policy should:

- Identify the tiers (levels) of the National health system and non-laboratory locations (e.g., VCT) and the types of POCT that may be approved tests for selected sites in each tier (i.e., POC menu of tests to supplement tiered health system menu of laboratory tests) for effective operational planning of required QA activities at each level of the National tiered network (Refer figure 1 &3).
- Define POCT to guide regulation and quality management.
- Outline requirements for National POCT QA schemes for POC tests on the diagnostic test menu and for all POCT settings.
- Inform development of SOPs and protocols for POCT approval, algorithm development and post-market surveillance, address National safety guidelines, including PEP as appropriate, for use with POC tests.
- Define provision of in-service training, supervision and accreditation to improve QA.
- Address M&E: Develop metrics that measures quality of POCT, based on internationally-accepted standards.

Objective 3: Define the requirements to assure sufficient supply of devices, commodities and reagents to POCT sites to meet quality-assured testing.

Justification: A National procurement body responsible for ensuring adequate supplies at POCT sites that meet defined requirements will enable the sites to conduct quality testing using quality-assured devices, commodities and reagents.

Core Elements

The policy should incorporate, as part of roles and responsibilities, a Ministry of Health National procurement body (KEMSA) who will be responsible for the following:

- Review procurement and distribution and redistribution procedures through national procurement body.
- Define distribution mechanisms (push or pull).
- Review and strengthen logistics information system.
- Management of equipment based maintenance and servicing.
- Define requirements for supply chain management of POC tests to ensure quality including temperature monitoring during transportation and storage, mechanisms to prevent expired products and stock-outs.
- Address M&E: Develop metrics to monitor quality of commodities and reagents to POCT sites.
- Develop a platform for logistics data sharing.

Objective 4: Data reporting, surveillance and M&E strategies.

Justification: A national body with oversight of M&E and planning will ensure that POCT data is collected, managed and analyzed systematically to evaluate and inform programs.

Core Elements

The policy shall incorporate, as part of roles and responsibilities, a Ministry of Health body/ department that oversees M&E and planning who shall:

- Develop and review governance of data: confidentiality of data, data ownership, and harmonization of reporting.
- Develop and review systems for paper based data collection for non-equipment based POCT.
- Develop and review systems for connectivity of data from equipment based POCT.
- Ensure adequate human resources for data collection and analysis.
- Define requirements for a national data management system for an effective coverage and impact evaluation.
- Oversee confidentiality for data shared through wireless connection by the manufacturers as part of QC (may be a statement of confidentiality consideration).

- Define mechanisms for analyzing and interpreting the collected data (M&E) for timely decision-making such as organizing specific supervisions, improving poor sites, sustaining effective sites and expanding the system with more sites.
- Define mechanisms for possible linkage to supply chain systems to reduce frequency of stock-outs.

Objective 5: Human resource capacity development

Justification: An adequate number of trained health workers will ensure quality testing as part of quality assurance.

Core Elements

The policy should:

- Define the different cadres required to perform POCT and the training and certification process, roles and responsibilities of each cadre; establish requirements for each cadre (e.g. quality managers) related to POCT in programs and at all levels of the health care system.
- Identify regular training and professional development programs required for POCT.
- Identify and address gaps in resources (e.g. trainers, training centers) required to support staff development for quality-assured POCT, and to identify innovative strategies to ensure sustainability.
- Define national standards for training and certification requirements to which laboratory and non-laboratory personnel are held to ensure quality of POC tests.
- Define the role of MOH in advocacy and support for pre- and in-service training of laboratory and non-laboratory personnel who may perform and oversee quality management systems for POCT.
- Address M&E: Develop metrics to monitor human resource development and management.

Objective 6: Roles and responsibilities of stakeholders

This shall be informed by the situation analysis. Resources required include human resources and infrastructure that would support the processes in the system. Required financial resources should also be factored and be addressed in the strategic plan. This shall be supported by innovative strategies and entrepreneurship opportunities to drive implementation, uptake

and sustainability of quality-assured POCT and in the greater health system. This objective provides a comprehensive overview of the required resources for each objective.

Justification: Defining required resources will guide strategic planning and enable a country to meet the standards and requirements defined by the Policy for POC quality-assured testing. International and national partnership is essential to meet the demand of the national laboratory system being improved and/or expanded.

Core Elements

The policy shall:

Identify human resources required to implement and sustain POCT in resource requirements and budgeting. (Refer to objective 5)

- Define the roles and responsibilities of stakeholders for POCT implementation and quality assurance. This includes (but not limited to) technical working groups and stakeholders.
- Define budgeting and resource mobilization strategies and set provision to establish partnership with national and international organizations, including civil society and community based associations.
- Address M&E: develop metrics for resources required to implement and sustain POCT activities.

CHAPTER 3

Quality Assurance and Improvement Strategy

3.1 Quality Assurance and Improvement Strategy

The quality assurance cycle for POCT is critical to ensure reliable and accurate results. It is important that QA is embedded within each objective discussed below.

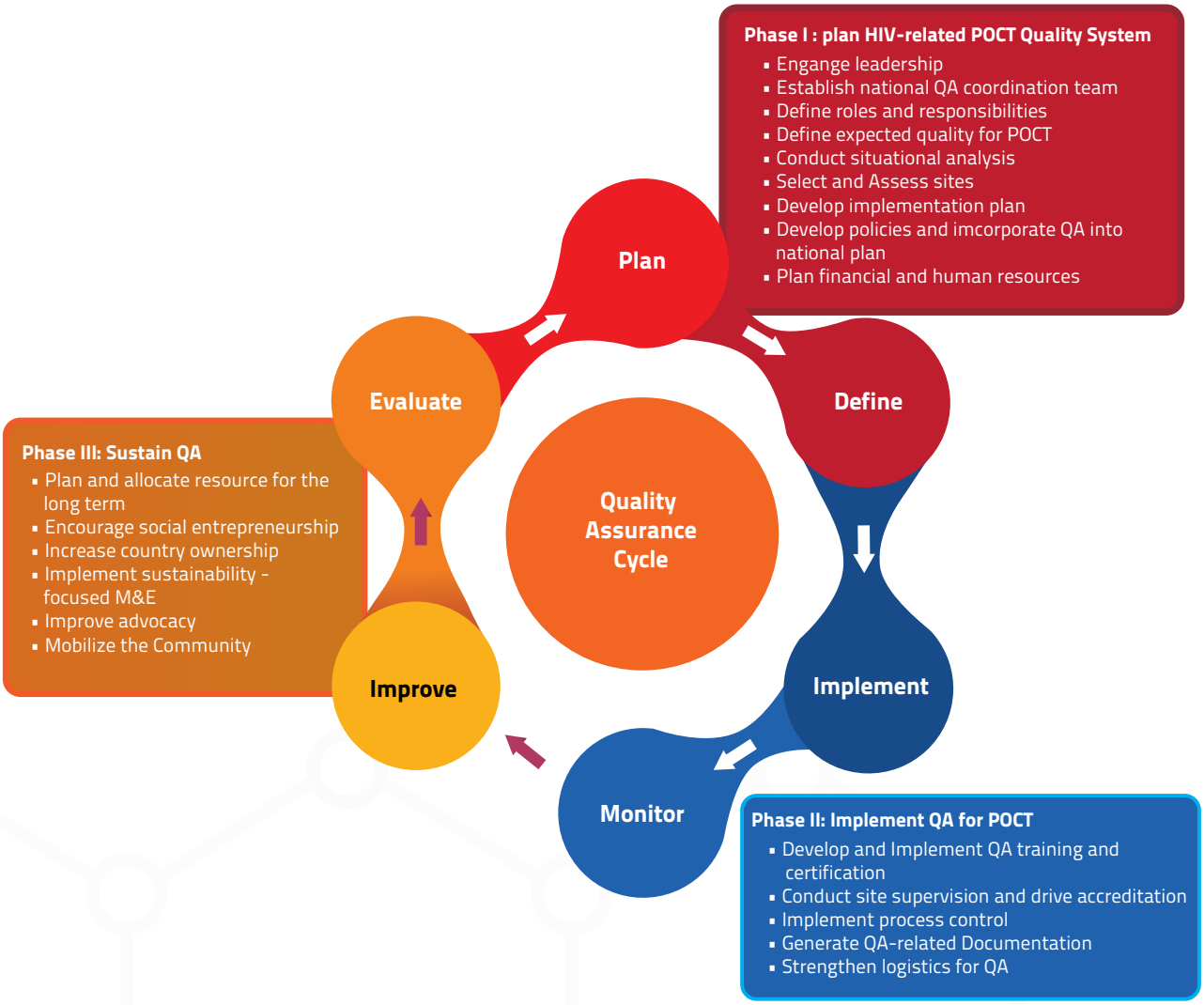


Figure 2: Quality Assurance & Improvement Strategy

3.2 Stepwise Process for Improving (SPI) the Quality of HIV-Related POCT assessment

Assessment of quality assurance practices in HIV-Related POCT is to ensure the delivery of a high quality, accurate and efficient POCT HIV testing process. In the assessment, SPI-POCT checklist will be used to grade various HIV and other HIV-Related POCT sites (Appendix III).

PURPOSE

The SPI-POCT checklist for use in HIV-related testing is primarily intended for use as a guide to assist and promote consistency in the application of quality management systems to improve healthcare services in resource-constrained settings and in low and middle-income countries. Additionally, this checklist serves as guidelines for the establishment of the National or regional laboratory coordinator and other authorities in each Country to provide the POCT services with the tools needed to standardize the quality management processes by ensuring patient safety and quality in HIV-related tests.

BACKGROUND

Recent scientific, technological, and public health innovations, including prevention programs have dramatically contributed to lower the rate of new HIV/AIDS infections worldwide. A strong National public health laboratory system is essential for responding effectively to HIV and other opportunistic infections. Early diagnosis and rapid initiation of treatment remain key strategies for controlling HIV infections. Technological advances in the form of low-cost, rapid POCT have drastically transformed the diagnosis and management of HIV in resource-limited settings. POCT allow rapid detection of HIV; this allows for rapid initiation of therapy and monitoring of antiretroviral therapy. Despite the numerous advantages POCT may offer, there is urgent need to implement the quality systems that help POCT sites to establish standards that make effective management more strategic and efficient.

In addition, ensuring the quality of HIV testing is critical for accuracy of HIV diagnosis in HTC and PMCT settings for HIV care, prevention, and treatment programs. Rapid testing should be performed in an environment to facilitate high quality of testing and sites should participate in key activities to monitor and improve quality of HIV rapid testing on an ongoing basis. These activities include:

- Participation in comprehensive hands-on training program resulting in certification/re-certification of testing sites and testers
- Participation in DTS based proficiency testing and QC program
- Use of standardized logbook/register and routine review of data
- Corrective actions based on QC, PT and logbook data
- Appropriate inventory management and adherence to SOP for performing the rapid tests
- Safety measures and disposal of biohazard materials.

The SPI-POCT checklist covers all essential elements for testing personnel and site certifications that are critical for performing RT. The SPI-POCT checklist is a framework for improving quality assurance practices to ensure the delivery of a high quality, accurate and efficient POCT HIV testing process. This process is intended to encourage, support and recognize the implementation of QMS in POCT sites to ensure accurate, timely and reliable results for patient care and public health purposes in a safe environment. QA must be in place at all times to ensure that the HIV rapid tests results are accurate and to ensure confidence in the testing. Adequate resources, training, and the implementation of quality assurance practices will be critical in ensuring the proper administration of the HIV rapid testing and the correct interpretation of the test result at the POCT sites.

The SPI-POCT Checklist is laid out in sections that align with standard requirements. Working through the SPI-POCT checklist format in a step-by-step manner will enable managers of an organization to recognize quality gaps and shortcomings and will help them identify areas for improvement. This checklist provides guidance on QA practices for sites using or planning to use the HIV RT to detect antibodies to HIV.

The checklist specifies requirements for quality and competency aimed to develop and improve POCT services, raising quality to established National standards. The elements of the POCT Quality improvement process Checklist recertification are based on ISO standard 22870:2006, ISO 15189:2012, College of American Pathologists (CAP) Point-of-Care Testing Checklist, 2011, and Clinical Laboratory Improvement Amendments '88.

This checklist consists of three different levels:

- Level 1 meets a minimum-level QMS with score between 55-75%.
- Level 2 represents achievement in meeting score greater or equal to 75% and less than 95% specific requirements of QMS.
- Level 3 comprises achievement in meeting ≥95% requirements of QMS. Any score less than 55% results in no recognition.

A POCT site that achieves less than a passing score on any one of the applicable standards will work with the regional office laboratory coordinator to:

- Identify areas where improvement is needed
- Develop and implement a work plan
- Monitor quality progress
- Implement quality assurance elements
- Continue steps to achieve Level 3

Certification of Testing Personnel and Sites

Due to the complexity of laboratory medicine and its importance in quality patient care, POCT testing personnel must possess the qualifications necessary to ensure professional competence. The certification programs can help improve POCT quality and maintain testing personnel performance and competency. This checklist applies to all personnel who perform HIV-related tests on human specimens. This checklist sets minimum standards for all testing personnel working in the POCT sites, ensuring quality testing and proper patient care.

The certification of testers in each POCT site is an effective tool to encourage testing professionals to possess the skills and expertise needed to perform quality testing. These personnel standards must include the following essential elements: direct observation of testing, competency assessments, knowledge of QA/QC, corrective action and preventive actions, troubleshooting, data management and use of HIV Logbook, test-specific training, and pre- and post-evaluation.

To become a certified tester, each training element must be evaluated. Each of the elements (direct observation of testing, competency assessments, knowledge of QA/QC, corrective action and preventive actions, troubleshooting, data management and use of HIV Logbook, test-specific training, and pre- and post-evaluation), will be scored as pass or fail. Acceptable test performance requires a "pass" score of 80% or higher in all of the eight criteria.

This checklist (Part I) provides guidelines and requirements for establishing a certified POCT site with HIV rapid testing personnel. To become a certified POCT testing site, the site must meet the following essential requirements: maintaining certified testing personnel, implementing QMS, establishing the basic Infrastructure and maintaining 2-year certification programs. For an individual POCT test site to be certified, each element must be evaluated and scored.

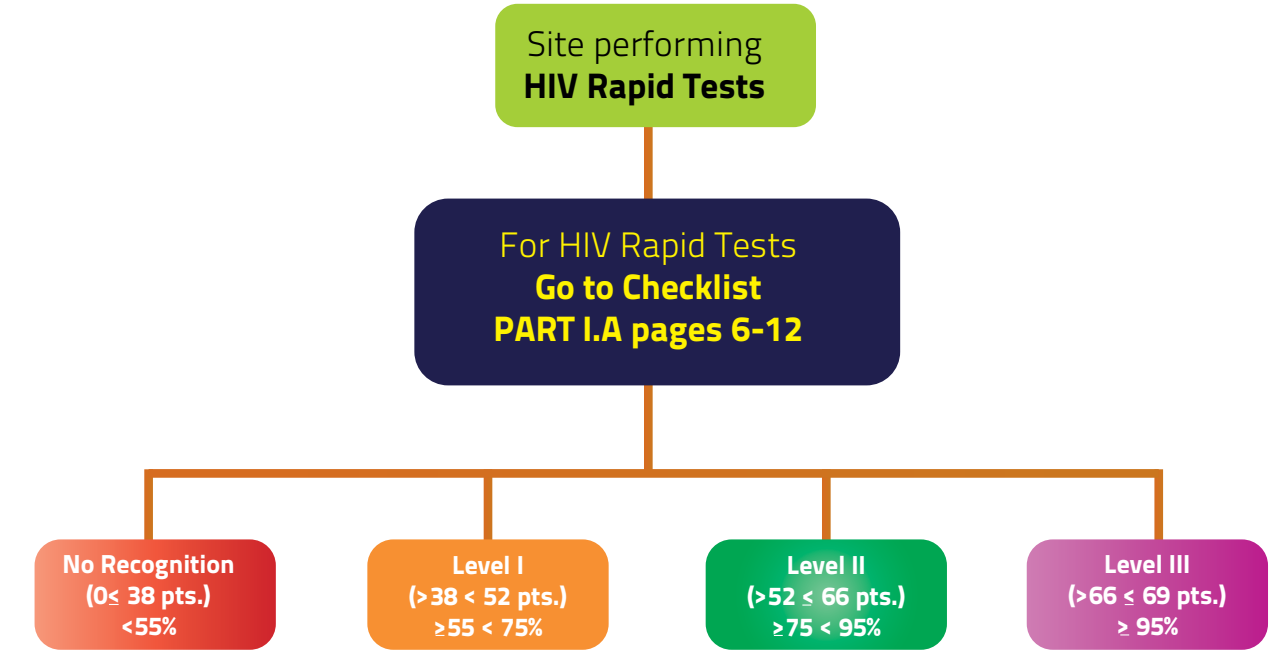
This SPI – POCT Checklist has two parts:

Part I. Checklist for POCT

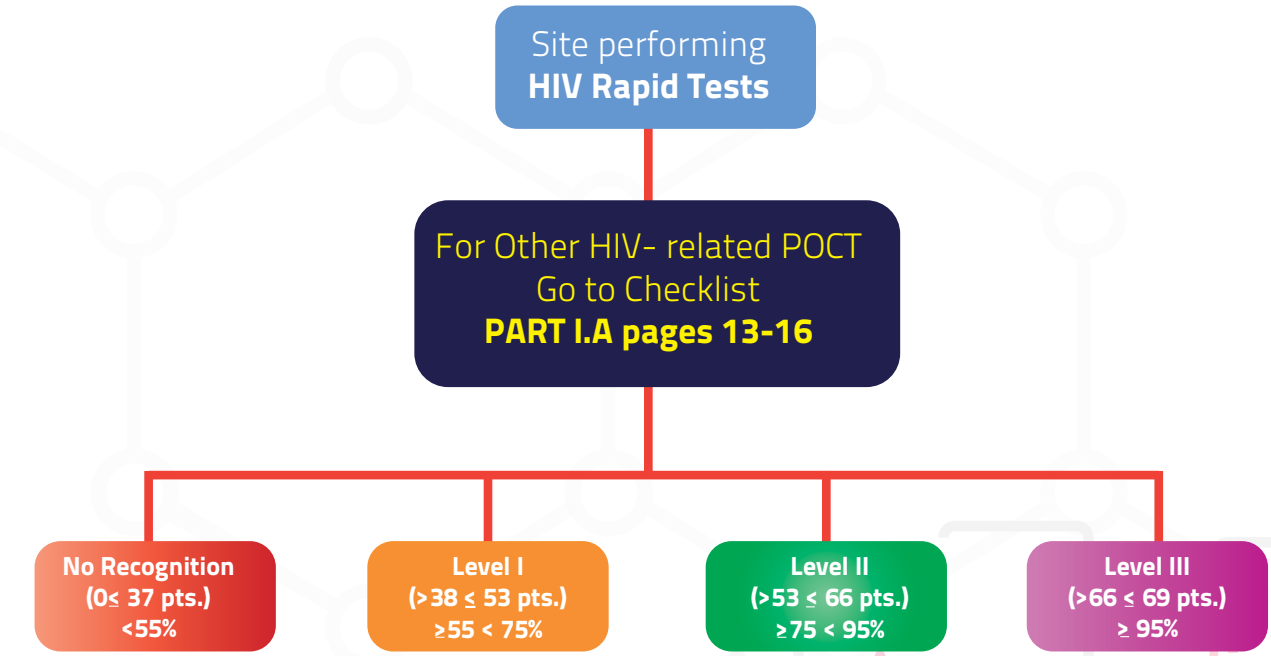
A: HIV Rapid Testing Sites and Testing Personnel (pages 9 - 12)

B: Other HIV Related POCT (pages 13 - 16)

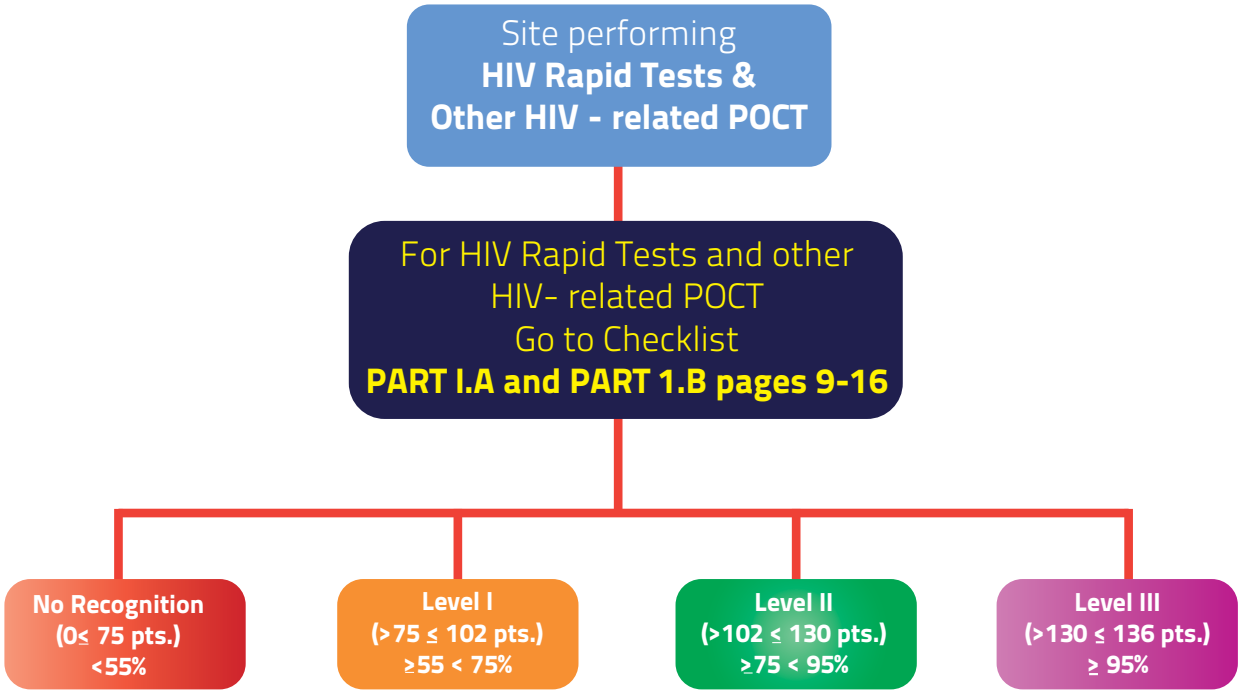
C. Sites performing HIV rapid tests and other HIV related POCT (9 – 16)



Flow Chart 1. Sites Performing HIV RT



Flow Chart 2. Sites Performing Other HIV-related POCT



Flow Chart 3. Sites Performing HIV Rapid Tests and Other HIV Related POCT

The HIV RT site audits are an effective means to:

- Determine if a site is providing accurate and reliable results
- Determine if the HIV RT is well-managed and is adhering to good laboratory practices
- Identify areas for improvement. Auditors complete this audit using the methods below to evaluate laboratory operations per checklist items and to document findings in detail.

Review HIV RT/site records

Review HIV Rapid Test/site records to verify that the HIV RT site quality manual, policies, personnel files, equipment maintenance records; audit trails, incident reports, logs, SOPs and other manuals (e.g., safety manual) are complete, current, accurate, and annually reviewed.

Observe the HIV Rapid Test site operations to ensure:

- All testing follows written policies and procedures in pre-analytic, analytic and post-analytic phases of testing.
- The HIV RT procedures are appropriate for the testing performed.
- Deficiencies and nonconformities identified are adequately investigated and resolved within the established timeframe and documented.

Ask open-ended questions

Ask open-ended questions to clarify documentation seen and observations made. Ask questions like, "show me how…" or "tell me about…" It is often not necessary to ask all the checklist questions verbatim. An experienced auditor can often learn to answer multiple checklist questions through open-ended questions with the testing staff.

Follow a specimen through the HIV RT Site

Follow a specimen through the HIV RT site from collection through registration, preparation, analyzing, result verification, reporting, printing, and post-analytic handling and storing samples to determine the strength of operations. Confirm that each result or batch can be traced back to a IQC run and that the IQC passed. Confirm that IQC results are recorded for all IQC runs and reviewed for validation. Confirm PT results and the results are reviewed and corrective action taken as required. Evaluate the quality and efficiency of supporting work areas (e.g. phlebotomy, data registration and registration and reception, messengers, drivers, cleaners, etc.). Talk to clinicians to learn the users' perspective on the HIV RT site, if applicable. Clinicians often are a good source of information regarding the quality and efficiency of the test site. Notable findings can be documented in the summary and recommendations section at the end of the checklist.

AUDIT SCORING

The following 13 sections are audited and scored according to the SPI-POCT checklist

Section		Points
1	HIV rapid testing sites	56
2	HIV rapid testing personnel	11
3	Document control	4
4	Personnel and competency assessment	5
5	Quality management system	6
6	Specimen handling and processing	6
7	Pre testing, testing and post testing phases	23
8	Test results reporting	3
9	Test results reporting	5
10	Equipment	4
11	Safety	8
12	Confidentially and conflict of interest	2
13	Procurement and supply	3

Part II. Summary of Audit Findings

This part of the audit checklist summarizes comments by the auditors which include: commendations, noted challenges and recommendations.

APPENDICES

Appendix I. Process for developing a national POCT Policy for implementation and quality assurance

A. Pre-planning and organization.

B. Consultation, situational analysis and document review.

C. Framework for Development of HIV Related POCT Policy for Implementation and Quality Assurance.

- Draft zero policy
- Development of recommended policy by stakeholder consultative meeting
- Collation and final cleaning

D. Review and approval by MOH, and implementation.

A. Pre-planning and organization by MOH.

A lead TWG should be appointed by MOH. A consultant and/or staff resources are assigned to support the working group. The TWG drafts a scope of work and presents a plan to MOH for approval to assure buy-in to the process.

- Review the framework and process including estimated financial implications of policy mandates
- Review the scope of work
- Letter from MOH to stakeholders with enclosures: terms of reference, example framework and scope of work with expected outcomes and timeline.

B. Consultation, situational analysis and document review.

1. For MOH, review existing National laboratory policy (NLP) and strategic plans, regulations for laboratories and organizational charts for guidance. If there is a current National laboratory policy, the TWG may recommend the POCT Policy be added as a supplement, integrated into the existing Policy or issued as a stand-alone document, with future revisions added to or kept as a stand-alone policy.
2. Status of existing policy and planning documents are reviewed and considered to assure policy is consistent with and supports national priorities and the National Health Plan
3. Contact other ministries and agencies in the country that have responsibility in the area of diagnostics, shipping, transport and imports, medical laboratory education and training, e.g., drug regulatory and inspectional authorities, national drug quality control laboratory, customs and revenue authorities, ministry of education.

- Disease prevention and surveillance programs especially HIV, malaria, and TB
- Ministry of Finance, Customs Agency, Regulatory Agencies as to their existing policies and procedures, interest in POCT
- Implementing partners and donors
- iv. Clinical care leadership and representation of the tiered health care system

1. If a current NLP exists, then POCT policy can be developed as an integrated revision of NLP, or developed as a standalone supplement
2. If no NLP exists, proceed with POCT policy development but initiate discussion on development of NLP. POCT policy development should not be delayed.
3. POCT policy development should look to integrate practices into the existing tiered health system for clinical care and diagnostic services. Use existing strategic and operational plans, if available, to guide policy development.
4. POCT is human diagnostic testing and the system must be integrated as an extension of the overall national health system. The existing national laboratory system roles and responsibilities for POCT are defined.
5. Review WHO guidelines and international standards that relate to laboratory policy issues. Review any other country policies, regulations or guidelines that may be relevant to POCT.
6. Discuss funding options for POCT QA with the Minister or Permanent Secretary, and with donors and partners.
7. TWG uses the information from direct meetings, interviews and document reviews to draft a situational analysis report including a SWOT analysis to review, edit and prepare a final report.
8. Based on the situational analysis, the TWG uses the Framework for Development of HIV Related Point of Care Testing Policy for Implementation and Quality Assurance to develop a Draft Zero to be presented at a stakeholders' meeting.

C. Development of HIV Related Point of Care Testing Policy for Implementation and Quality Assurance (POCT QA Policy)

1. TWG invites stakeholders to participate in the development of the POCT QA Policy (suggest a working group of 20-30 or larger depending on stakeholder community).
2. The TWG leads the process to develop the POCT QA Policy.

3. The TWG and stakeholders meet over 2-4 days to develop the recommended POCT QA Policy.

4. TWG presents the situational analysis including the SWOT and gaps, the National laboratory policy and the Draft Zero POCT QA Policy for discussion

5. In addition to development of the various elements of the POCT QA Policy, the group advises on the issue of incorporation or integration into an existing National Laboratory Policy or stand-alone POCT QA Policy.

6. In a series of breakout group sessions, each section of the draft policy is reviewed, discussed and revised.

7. In plenary sessions with TWG facilitation, breakout group rapporteurs present the revised sections for discussion, comment, further revision and acceptance.

8. Collation and final cleaning:

    i. TWG incorporates the work of the stakeholders' meeting and produces a Final Recommended POCT QA Policy.

    ii. TWG submits the final document with recognition of the stakeholders to MOH for approval

    iii. Final document is distributed to the stakeholders for information only and notice that the document has been submitted for Ministry review and approval

D. Review and approval by Ministry

1. TWG Chair is responsible for follow up with MOH to assure timely review and approval.

2. MOH must establish an office for POCT QA to plan, coordinate and monitor testing services.

3. Following approval by the Ministry, distribution of the document to MOH divisions with responsibilities and roles, and to stakeholders.

4. Operational plans using a stepwise approach are developed by the implementing divisions within MOH to include coordination with other agencies and stakeholders. Preparation or revision of existing plans can be accomplished while awaiting the approval by MOH so that immediately following policy approval, implementation activities begin.

Appendix II: Sample template for Strategic Planning

Objective	Activity	Responsible person	Timeline				Indicator	Results
			1st quarter	2nd quarter	3rd quarter	4th quarter		
	i)							
	ii)							
	i)							
	ii)							
	iii)							
	i)							
	ii)							

Appendix III- Stepwise Process for Improving (SPI) the Quality of HIV-Related POCT Assessment

Name of testing site:								
Type of testing site (circle one):	VCT	PITC	PMTCT	TB	Center	Regional	District	Others
If other please specify:								
Location/Address:								
Name of the Auditor:								
Date:								

For each item, please check Yes (Y), Partial (P), or No (N) column. All elements of the item must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.	Y	P	N	Comments	Score
	☐	☐	☐		

A	CHECKLIST FOR HIV RAPID TESTING SITES AND TESTING PERSONNEL					
1.1	HIV RAPID TESTING SITES					
1.1.1	To become a certified individual POCT site, the site must meet the following essential requirements:					
1.1.2	a. Are there plans in place for certifying testing personnel?					
1.1.3	b. Are there QA logbooks and other QA measures (i.e quality control, proficiency testing etc) in place for rapid testing?					
1.1.4	d. Are there plans for maintaining 2-year certification programs in the future?					
1.1.5	e. Is there a strategic plan for use of results for Patient Care?					
1.2	PHYSICAL FACILITY					
1.2.1	Is there a designated area for HIV testing at the testing site?					

1.2.2	Does the testing site have computer, printer, fax and internet capabilities?					
1.2.3	Is there continuous power supply?					
1.2.4	Is sufficient lighting available in the designated testing area?					
1.2.5	Is there sufficient storage space for test kits and other consumables?					
1.3	**SAFETY**					
1.3.1	Are there written procedures in place at the testing site to					
1.3.2	Is there clean water available for hand washing?					
1.3.3	Is there a First Aid kit available to staff?					
1.3.4	Are the appropriate personal protective equipment (i.e. gloves, lab coats or aprons) available at the testing site?					
1.3.5	Are sharps and waste containers available at the testing site?					
1.3.6	Is there an appropriate disinfectant (i.e. bleach, precept tablets, etc.) available at the testing site?					
1.3.7	Does the testing site have procedures in place to dispose of infectious and noninfectious waste?					
1.3.8	Are there procedures in place to manage spills of blood and other body fluids?					
1.3.9	Are there procedures in place if test site personnel are exposed to potentially infectious body fluids through a needle stick injury, splash or other sharps injury?					
1.4	**PRE-TESTING PHASE**					11
1.4.1	Are there routine testing guidelines available that cover all HIV testing at the testing site?					
1.4.2	Is the testing algorithm used at the testing site current and updated according to national guidelines?					
1.4.3	Are there written procedures in place for each HIV rapid test used in the testing algorithm?					
1.4.4	Do the test site personnel have a clean and organized work space for HIV testing (i.e. area is neat and supplies within reach)?					
1.4.5	Are there sufficient supplies available for specimen collection and HIV rapid testing (i.e. lancets, gauze, alcohol swabs, plaster, rapid test kits, etc.)?					
1.4.6	Are only MOH approved kits available for use?					
1.4.7	Are testing supplies stored in a secure cabinet or room?					
1.4.8	Are test kits stored according to manufacturer recommendations?					
1.4.9	Is supply inventory updated periodically and expired materials discarded?					
1.4.10	When a kit in the testing algorithm is expired and there is no other kit available: a. Is testing suspended until more kits become available? b. Is an alternate algorithm used?					

1.5	TESTING PHASE					14
1.5.1	Are job aides on specimen collection available and posted at the facility?					
1.5.2	Are job aides on HIV testing procedures available and posted at the testing site?					
1.5.3	Are job aides on testing algorithms available and posted at the testing site?					
1.5.4	Are timers available and used routinely for HIV rapid testing?					
1.5.5	Are reagents used within expiration date (First Expired, First Out principle)?					
1.5.6	Are test kits labeled with date received, date opened, and initials?					
1.5.7	Are test devices properly labeled (i.e., client ID) during use?					
1.5.8	Is there a nationally standardized register/logbook in use?					
1.5.9	Are the kit names, lot numbers, and expiration dates recorded?					
1.5.10	Is the name of testing personnel recorded for each test?					
1.5.11	Are invalid tests recorded in a register/logbook, and then repeated?					
1.5.12	Are positive and negative quality control (QC) specimens routinely used (i.e. daily or weekly) according to country guidelines?					
1.5.13	Is QC specimen data recorded in a standardized logbook?					
1.5.14	Are appropriate steps documented and taken when QC specimens fail?					
1.6	POST-TESTING PHASE					7
1.6.1	Have supervisors been trained to routinely review logbooks/registers (e.g., detecting high rates of discordant results between test 1 and test 2)?					
1.6.2	Are QC records reviewed by a supervisor routinely?					
1.6.3	Are registers/logbooks and other documents or records kept in a secure location?					
1.6.4	Are registers/logbooks properly labeled and archived when full?					
1.6.5	Are sharps (e.g., lancets and needles) disposed into appropriate containers after the fingerprick procedure is performed?					
1.6.6	Are test devices disposed of properly after testing?					
1.6.7	Are waste containers emptied regularly?					
1.7	EXTERNAL QUALITY ASSESSMENT FOR HIV RAPID TESTING (PT AND SITE ASSESSMENT)					6
1.7.1	Does your POCT program verify the results of controls for acceptability before reporting results?					
1.7.2	Is the testing site enrolled in a proficiency testing program?					
1.7.3	If the site is enrolled in a PT program, are the proficiency samples tested by all personnel?					

	Are personnel retrained when they fail a PT round?					
	Are all proficiency testing evaluations reviewed and documented?					
	Is a direct observation of routine patient test performance done, including, as applicable, patient identification and preparation, and specimen collection, handling, processing and testing?					
2.0	**HIV TESTING PERSONNEL**					
2.1	**TRAINING AND CERTIFICATION**					**10**
2.1.1	Have personnel received a comprehensive hands-on HIV rapid test training?					
2.1.2	Are personnel trained on the use of standardized registers/logbooks?					
2.1.3	Have supervisors been trained to routinely review logbooks/registers (e.g., level of agreement between test 1 and test 2)?					
2.1.4	Are testing personnel trained on safety and waste management procedures?					
2.1.5	Are there signed records of all procedures read and understood by HIV rapid testing personnel?					
2.1.6	Is annual HIV rapid test refresher training offered for testing personnel?					
2.1.7	Is there evidence that testing personnel received adequate, specific training prior to patient testing to ensure competence – are training records kept for each staff member on site?					
2.1.8	If there is a national certification system, are the site and/or personnel certified?					
2.1.9	Are only certified tester allowed to performing testing?					
2.1.10	Are certified tester required re-certifications every two years?					
2.2	**CONFIDENTIALITY AND ETHICS**					**1**
2.2.1	Does the laboratory ensure confidentiality of patient information throughout all phases of the testing process that is under its control?					
B	**CHECKLIST FOR OTHER HIV-RELATED POCT**					
3	**DOCUMENT CONTROL**					4
3.1	Does your point-of-care-testing (POCT) program have a system in place to control all internal and external documents/registers/logbooks?					
3.2	Does your POCT program maintain all documents and records properly?					
3.3	Does your POCT program retrieve or access documents and records easily?					
3.4	Are records maintained and stored under conditions that ensure proper preservation?					
4	**PERSONNNEL AND COMPETENCY ASSESSMENT**					5
4.1	**PERSONNEL**					2
4.1.1	Does your POCT site have an organization chart indicating the levels of authority, responsibility and accountability?					

4.1.2	Is there evidence that testing personnel received adequate, specific training prior to patient testing to ensure competence?					
4.2	**COMPETENCY ASSESSMENT**					3
4.2.1	Does your POCT program have a documented program to ensure that each person performing POCT maintains satisfactory levels of competence?					
4.2.2	The following elements should be included: Direct observations of routine patient test performance, including, as applicable, patient identification and preparation, and specimen collection, handling, processing and testing?					
4.2.3	Review of test results or worksheets, quality control records, proficiency testing results and preventive maintenance records?					
5	**QUALITY MANAGEMENT SYSTEM**					6
5.1	Does your POCT program establish and maintain written policies and procedures that implement and monitor a quality system for all phases of the total testing process (pre-analytic, analytic, and post-analytic)?					
5.2	Does your POCT program have a documented system in operation to detect and correct significant clerical and analytical errors, and abnormal test results in a timely manner?					
5.3	Does your POCT program have a suitably trained individual from the laboratory, nursing service or medical staff available on all shifts to assist with troubleshooting?					
5.4	**QUALITY CONTROL**					3
5.4.1	Does your POCT program document control results for quantitative and qualitative results, as applicable?					
5.4.2	Does your POCT program document evidence of corrective action when control results exceed defined acceptability limits?					
5.4.3	Does your POCT program verify the results of controls for acceptability before reporting results?					
6	**SPECIMEN HANDLING AND PROCESSING**					6
6.1	Does your POCT program have a documented procedure describing methods for patient identification, patient preparation, specimen collection and labeling, specimen accessioning, and specimen preservation (if applicable) prior to testing?					
6.2	The following procedures apply to the use of POC devices;					
6.2.1	a. Do personnel always wear gloves when performing finger sticks?					
6.2.2	b. Do personnel always use disposable lancets when performing finger sticks?					

6.2.3	c. Does the POCT site have a written policy that forbids re-use recapping, bending or breaking of lancets?					
6.2.4	d. Are countertops and surfaces that have become contaminated with blood cleaned immediately with an approved disinfectant?					
6.2.5	e. Do personnel remove gloves and wash hands immediately with soap and water after becoming contaminated with blood?					
7	**PRE-TESTING PHASE**					
7.1	Are there routine testing guidelines available that cover all HIV testing in the facility?					
7.2	Is the testing algorithm used at the facility current and updated according to national guidelines?					
7.3	Are there signed records of all procedures read and understood by HIV rapid testing personnel?					
7.4	Are personnel trained on the use of standardized registers/logbooks?					
7.5	**TESTING PHASE**					
7.5.1	Does your POCT program establish and follow written policies and procedures that ensure positive identification and optimum integrity of patient sample from time of receipt through completion of testing and reporting of results?					
7.5.2	Are job aids on specimen collection available and posted in the designated HIV testing area?					
7.5.3	Are reagents used within expiration date (FEFO principle)?					
7.5.4	Are test kits labeled with date received, date opened and initials?					
7.5.5	Are test devices properly labeled (i.e., client ID) during use?					
7.5.6	Is there a nationally standardized register/logbook in use?					
7.5.7	Are the kit names, lot numbers and expiration dates recorded?					
7.5.8	Is the name of testing personnel recorded for each test?					
7.5.9	Are invalid tests recorded in a register/logbook and then repeated?					
7.5.10	Are positive and negative quality control (QC) specimens routinely used (i.e. daily or weekly) according to country guidelines?					
7.5.11	Is QC specimen data recorded in a standardized logbook?					
7.6	**POST TESTING PHASE**					
7.6.1	Have supervisors been trained to routinely review logbooks/registers (e.g., detecting high rates of discordant results between test 1 and test 2)?					
7.6.2	Are QC records reviewed by a supervisor routinely?					
7.6.3	Are registers/logbooks kept in a secure location?					

7.6.4	Are registers/logbooks properly labeled and archived when full?					
7.6.5	If the site is enrolled in a PT program, are the proficiency samples tested by all personnel?					
7.6.6	Are all proficiency testing evaluation reviewed and documented?					
7.6.7	Are personnel retrained when they fail an EQA activity?					
7.6.8	If there is a national certification system, is the site and/or personnel certified?					
8	**TEST RESULTS REPORTING**					
8.1	Does your POCT program have a documented procedure for entering POC test results into the patient's record?					
8.2	Does your POCT program have a documented procedure for reviewing POCT test results prior to release?					
8.3	Does your POCT program have defined turnaround times for each of its tests?					
9	**REAGENTS**					
9.1	Does your POCT program/site store all reagents as recommended by the manufacturer?					
9.2	Does your POCT program/site have a written policy defining elements required for reagent labeling?					
9.3	Does your POCT program/site use all reagents within their indicated expiration date?					
9.4	Does your POCT program/site establish criteria for acceptability of new reagent lots and/or shipments to ensure that quality control ranges are similar to those from the previous lot?					
9.5	Does your POCT program/site use the same components of reagent kit within the same kit lot unless otherwise specified by the manufacturer?					
10	**EQUIPMENT**					
10.1	Is a written SOP that addresses the monitoring of temperatures in refrigerators used in other HIV-related testing?					
10.2	In your POCT program, have all testing personnel satisfactorily completed initial training on all instruments/methods applicable to their assigned job?					
10.3	Does your POCT site use all validated equipment and reagents?					
10.4	Does your POCT program maintain the records for calibration/verification-related functions as required by the manufacturer?					
11	**SAFETY**					
11.1	Does your POCT program have a program to assure the safety of patients and health care personnel commensurate with the scope of its activities?					

11.2	Does your POCT program have a Laboratory Safety Manual available, accessible and up-to-date?					
11.3	Does your POCT program have a written policy for deposing of infectious and noninfectious waste?					
11.4	Does your POCT program have personnel protection equipment (PPE) readily available at the site?					
11.5	Does your POCT program have current and available records of standard precaution and PPE training?					
11.6	Does your POCT program have a written policy for handling hazardous chemical/material properly?					
11.7	Does your POCT program handle "sharps" and dispose properly in "sharps" containers?					
11.8	Does your POCT program include fire safety as part of the laboratory safety?					
12	**CONFIDENTIALITY CONFLICT OF INTEREST**					
12.1	Does the laboratory ensure confidentiality of patient information throughout all phases of the total testing process that is under its control?					
12.2	Does your POCT program have a written policy for avoiding potential conflicts of interest and commercial, financial, political or other pressures that may affect the quality and integrity of operations?					
13	**SUPPLY MANAGEMENT**					3
13.1	Is there an effective supply inventory control system in operation?					
13.2	Is there system for monitoring supply stock and ordering procedures?					
13.3	Does your POCT program have a written policy for deposing of infectious and noninfectious waste?					

PART II: SUMMARY OF AUDIT FINDINGS
Noted Commendations:
Noted Challenges:

Recommendations:

ACTION PLAN (if Applicable)			
Follow up Actions	Responsible Persons	Timelines	Signature

MINISTRY OF HEALTH

National Public Health Laboratory Services