THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

Point of Care Testing

Policy and Implementation Guidelines

Edition One

August 2017

TABLE OF CONTENTS

FOREWORD i
ABBREVIATIONS AND ACRONYMS iii
ACKNOWLEDGEMENTS iv
BACKGROUND 1
1.1 Introduction 1
1.2 Definition of Point of Care Testing (POCT) 1
1.3 Situational Analysis 2
1.4 Justification 2
1.5 Scope 3
1.6 General Objective 3
1.6.1 Specific Objectives 3
2.0 Regulation 4
2.1 Country entry protocol for POCT technologies 4
2.2 Roles of stakeholders 5
2.3 Selection Criteria 6
2.4 Evaluation and approval of POCT technologies 6
2.5 Organization and management of POCT services 7
3.0 QUALITY ASSURANCE AND QUALITY CONTROL 8
3.1 External Quality Assurance (EQA) 9
3.2 Internal Quality Control (IQC) 9
3.3 Quantitative and Qualitative POCT 10
4.0 BIORISK MANAGEMENT 11
5.0 PLACEMENT OF POCT 12
5.1 Site Selection 12
5.2 Integration of conventional testing with POCT 13
5.3 Installation, Calibration, Troubleshooting and Performance Verification 14
5.4 Maintenance Program, Performance Calibration, Service and Repair 15
6.0 SUPPLY CHAIN MANAGEMENT SYSTEM 15
6.1 Guidelines for Vendor relations 17
8.0 TRAINING, MENTORSHIP AND SUPERVISION 19
9.0 MONITORING AND EVALUATION 20
APPENDICES 22

APPENDIX I: Country Entry Protocol 22
APPENDIX II: Criteria for equipment evaluation and approval 23
BIBLIOGRAPHY 24

FOREWORD

In resource limited countries like Uganda, affordable, but accurate, quick, and easy to use. laboratory testing technologies are required to guide prompt diagnosis and treatment of diseases, both infectious and non-infectious, such as malaria, HIV, Hepatitis Diabetes and cancer. Such diagnostics enable immediate initiation of treatment and are crucial for efficient monitoring of efficacy of medicines used and proper management of patients.

In the prevailing HIV pandemic, limited access to timely diagnostic and treatment monitoring testing has been one of the major set-backs to efforts of scaling up access to HIV/AIDS prevention, care and treatment. The currently available complex conventional diagnostic technologies for virological and immunological testing are expensive; require sophisticated equipment and laboratory infrastructure, continuous electricity supply, specialized equipment maintenance services and highly trained laboratory workforce. Multiple Point of Care (POCT) technologies that are easy to use with minimal training, stable ready-to-use reagents, and requiring minimal or no maintenance are becoming increasingly available and popular. These technologies are primarily meant to improve accessibility to diagnostics by remote hard–to-reach populations and reduce the turn- around time of test results to be used in patient management.

The major advantages of POCT Technologies are reduction of turn-around-time hence minimizing patient loss to follow up, increasing number of patients initiating treatment due to same day on-site test results and improving monitoring treatment efficacy. Some of the drawbacks of the POCT include the low throughput of the devices per day, managing the supply chain, implementation of external quality assessment programs due to the large number of testing sites and difficulty of monitoring and evaluation of data from the various decentralized sites.

Although there are many POCT technologies such as HIV and Malaria Rapid Test kits already being extensively used in our health delivery system, recently a few new ones such as POCT CD4 devices have been introduced into the market and more others are in the pipeline including POCT devices for viral load, EID testing and Tuberculosis.

In order to harness the full benefits of these technologies, it is imperative that they are systematically selected, evaluated and introduced for use based on guiding principles that aim at enabling the laboratory system to favorably respond to the demands of the health care services. In country evaluation of POCT technologies should, therefore, include the operational characteristics of each, such as throughput, ease of use, cost and environmental requirements.

In Uganda, although there is extensive experience in evaluating and implementing POCT technologies for HIV testing, evaluation and adaptation of POCT technologies is at an infancy stage.

The most recent POCT evaluation conducted by the Ministry was for the Alere Pima for POCT CD4 testing. Data from this evaluation has provided evidence to consider this POCT device for introduction in to selected health facilities providing ART services and are currently depending on specimen referral system for CD4 testing.

This policy document has been adopted by the Ministry of Health to serve as a national guiding document for the selection, evaluation, adaptation, implementation, monitoring and evaluation of POCT Testing in Uganda. It is also intended to be used as a reference document for the preparation of generic and test specific detailed implementation guidelines.

The Ministry of Health believes that this strategic document will help to standardize and ensure the systematic introduction and roll out of POCT technologies in the Ugandan context. The Ministry hereby expresses its sincere gratitude and appreciation to all who contributed to the preparation of this important document.

. ……..
Dr. Diana Atwine
Permanent Secretary - MOH

ABBREVIATIONS AND ACRONYMS

ART	Antiretroviral Therapy
ASLM	African Society for Laboratory Medicine
CDC	Centers for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
EID	Early Infant Diagnosis of HIV/AIDS
EQA	External Quality Assessment
HIV	Human Immunodeficiency Virus
IQC	Internal Quality Control
JMS	Joint Medical Stores
LIS	Laboratory Information System
NMS	National Medical Stores
NTLP	National Tuberculosis and Leprosy Control Program
PMTCT	Prevention of Mother-to-Child Transmission of HIV/AIDS
POCT	Point of Care Testing
QA	Quality Assurance
QC	Quality Control
RRH	Regional Referral Hospital
SOP	Standard Operating Procedure
TOT	Training of Trainers
UHSC	Uganda Health Supply Chain
UNHLS	Uganda National Health Laboratory Services
UNICEF	United Nations Children's Fund
UVRI	Uganda Virus Research Institute
VHF	Viral Hemorrhagic Fever
VL	Viral Load
WHO	World Health Organization

BACKGROUND

1.1 Introduction

Despite efforts by government and partners, communicable diseases continue to be a major public health problem in Uganda. There has been notable improvement in provision of services in the areas of HIV/AIDS, Tuberculosis and Malaria management through increase in the number of functional health facilities. In order to strengthen the efforts for effective scale-up and sustainability of priority healthcare interventions laid out by the government, affordable, accurate, and rapid diagnostic tests are crucial.

The current laboratory structure requires sophisticated infrastructure and equipment and the need for highly trained technicians to deliver high quality diagnostic services. These are critical barriers to access to life saving diagnostics in areas with limited geographical reach to the conventional laboratory system. Although sample referral has linked centralized specialized laboratory services to the periphery, this system presents logistical challenges.

In recent years, great technological advances have been made, and rapid, reliable and affordable Point of Care (POCT) diagnostic tests that require minimal or no equipment and minimal training have become available. These technologies are available for HIV diagnosis, CD4 testing, syphilis, hepatitis screening, and malaria diagnosis. POCT diagnostics for Viral Load (VL) and Early Infant Diagnosis (EID) have also become available.

These technologies are primarily meant to provide client centered laboratory services and improve access to diagnostics in areas with limited diagnostic testing as well as high patient volume sites which could potentially benefit from on-site, same day testing facilities to minimize client loss to follow up.

However, in the absence of regulations and clear criteria for introduction and licensing of new POCT diagnostic tests, over diversification and/or the widespread use of substandard POCT tests could become problematic.

It is the responsibility of the UNHLS to develop a strategy and standardized implementation guidelines for evaluation, selection, service and maintenance, quality assurance, monitoring and evaluation of POCT technologies, and training and certification of health care workers to ensure quality and appropriate use of the diagnostic tests. In line with the Master Plan for Public Health Laboratories, a national strategy and implementation guidelines for POCT testing technologies was developed to guide introduction of new technologies in the country.

1.2 Definition of Point of Care Testing (POCT)

Point of Care Testing (POCT) is defined as medical testing at or near the site of the client/patient care so as to bring the testing services conveniently and immediately to the client/patient to increase the likelihood that the patient, physician and the care team will receive the results quicker, and allow for immediate clinical management decisions to be made.

The critical elements of Point-of-care testing are:

- Rapid turn-around of results so that it can impact on clinical management. Rapid can be a range from a few seconds to minutes to a few hours – while the client/patient waits.
- Convenience to patients and care providers derives from the fact that the diagnostic process is completed in the same clinical encounter, and client/patients do not have to come back for results or go far away for testing.
- Examples of POCT technologies include: RDTs, CD4 Testing, VL, Glucometers, HB meters etc.

1.3 Situational Analysis

The effective, efficient and equitable delivery of diagnostic testing services to the public is essential for implementation of the Uganda National Minimum Health Care Package (UNMHCP). Critical to the community extension of diagnostic services, is the development and employment of novel point-of-care testing (POCT) technologies. Both rapid diagnostic kits and portable diagnostic devices complement conventional testing services. Point of care testing services increase access to quality diagnostics in resource constrained healthcare settings characterized by inadequate power supply, limited human resource capacity and poor infrastructure.

In the last decade, health laboratory services have experienced remarkable increase in the variety of point of care diagnostics on the market. A number of POCT technologies have been approved by WHO for diagnosis of malaria, tuberculosis, HIV and other diseases. However, many POCT technologies on the market have not been validated for use in-country. In addition, more efforts are needed to increase the scope of POCT in diagnosis of sophisticated tests like HIV and hepatitis B viral load, multi-drug resistant TB testing and other infections critical to the control of HIV/AIDS.

The development of guidelines, standards and protocols to evaluate, verify and approve new POCT technologies and reagents for use in Uganda has been finalized. Thus the implementation POCT policy and guidelines will create a framework for effective use of POCT technologies in Uganda.

1.4 Justification

Point-of-care testing allows diagnosis of patient's conditions at the bedside, at home, in the field or in the hospital. Uganda has a high burden of many diseases such as malaria, tuberculosis, HIV, hepatitis, sickle cell disease, cancer and others, thereby creating high demand for affordable, simple, quick but high quality testing technologies such as the POCT.
Many platforms of POCT technologies are already in the country being used for self - testing, in private clinics, and in health facilities at different levels, but there has not been national guidance on their appropriate use, regulation and quality control.

The stake holder's forum that discussed the in-country evaluation report on the PIMA CD4 POCT platform identified the lack of policy on POCT as a gap and recommended its development and implementation.
The development of this policy and implementation guidelines will therefore, go a long way to streamline the acquisition, rationalization, proper use and disposal of POCT technologies. This, in turn, will impact positively on the overall health delivery system in Uganda.

1.5 Scope

The scope of these policy and guidelines covers the management philosophy of POCT, the levels where POCT may be undertaken, the range of results, the qualifications of the personnel involved in testing and interpretation of results and the timeliness of the service. Initiation of the service, training, monitoring of quality, accreditation and safety management. The policy guidelines are also intended to assist those responsible for the delivery of POCT, and to ensure that risks to patient health and safety are minimized. It is recommended that every health facility in Uganda utilizes this POCT policy and guideline which are consistent with the National Health Laboratory Policy.

1.6 General Objective

To develop a national policy and implementation guidelines which will provide strategic direction and guidance for implementation of Point of Care diagnostics in order to increase access to medical diagnostics in Uganda.

1.6.1 Specific Objectives

1. To provide guidance for regulation of POCT technologies.
2. To guide development of POCT product and site selection criteria.
3. To provide guidance on how to integrate POCT into the existing health diagnostic system.
4. To provide a framework for standardization of POCT at service delivery points.
5. To provide a basis for development and implementation of a comprehensive Quality Assurance system for POCT that is integrated into the overall national health laboratory quality assurance framework.
6. To provide a framework for capacity building of health providers and end users of POCT through, training, mentorship and supervision.
7. To guide development of communication strategy to ensure effective uptake of POCT.
8. To guides the development of M&E framework for POCT that is aligned with the National Health Laboratory M&E framework.

2.0 Regulation

The POCT Policy will not be implemented in isolation, but will be used along with already existing normative documents on laboratory services. UNHLS will regulate the acquisition and use of POCT technologies in Uganda.

The authorized regulatory body puts measures in place to ensure the quality, safety and efficacy of new POCT technologies. Additionally, the body puts measures to encourage market place competition, and ensure timely availability of and access to innovative POCT technologies

Policy Objective

To provide guidance for regulation of POCT technologies.

Policy Statements

1. UNHLS shall be responsible for the regulation of POCT technologies in the country.
2. UNHLS shall ensure that the manufacturer has effectively demonstrated that all potential risks associated with the device are identified and adequately addressed.
3. UNHLS shall ensure adherence to the approved country entry protocol (see appendix).
4. UNHLS shall commission the operational research studies for new POCT diagnostic technologies evaluation and implementation pilot studies.
5. UNHLS shall ensure registration, premarket approval and post market surveillance of POCT technologies in the country.

2.1 Country entry protocol for POCT technologies

This section provides guidance to manufacturers/suppliers and other stakeholders on the necessary steps required to introduce a POCT technology in country.

Policy Objective

To provide guidance on entry of POCT technologies in the country.

Policy statements

1. The UNHLS shall set an approved pathway for manufacturers/suppliers to introduce new technologies.
2. UNHLS shall regularly review and provide entry and approval guidelines for manufacturers/suppliers to introduce new technologies in the country.
3. UNHLS shall define roles and responsibilities of stakeholders to identify and approve new equipment for deployment in the public sector.

Implementation guidelines

2.2 Roles of stakeholders

1. Director General of Health Services (DG)
   The DG will be the focal point for all communication regarding entry of new POCT technologies in the country. He/she will make the final recommendations regarding entry of new POCT technologies in the country.

2. Director UNHLS
   The director UNHLS will provide technical advice on entry of new POCT technologies in the country. He/she will task the Laboratory Technical sub Committee on Equipment and supplies to conduct the review of information from manufacturers/suppliers. The technical committee shall set and follow a criteria for determining whether an in country technical evaluation of new POCT technologies is necessary. The head UNHLS will provide technical guidance on evaluation of new POCT technologies and will advise the DG and other stakeholders on findings and recommendations of the LTC regarding the outcome of evaluations. UNHLS shall provide a list of approved POCT technologies to National Drug Authority (NDA) for registration.

3. The Laboratory Technical Committee
   The LTC will review information from manufacturers/suppliers. The LTC will also identify suitable institutions to conduct evaluation of new POCT technologies and advise the head UNHLS based on these findings.

2.2 Selection and acquisition of POCT technologies

This section describes the criteria for the selection and acquisition of new POCT equipment for use in the National Laboratory Network. The lab network includes Regional Referrals, District, HCIV and HCIII lab facilities. UNHLS will establish a system for objectively selecting and acquiring the new technologies for evaluation, implementation and scale up.

Policy Objective

To provide guidance on selection and acquisition of appropriate POCT technologies.

Policy Statements

- UNHLS shall put in place criteria for selection and acquisition of appropriate POCT technologies for use in-country.
- UNHLS shall set minimum requirement for selection and acquisition of POCT technologies.
- UNHLS shall conduct the necessary needs assessment to provide information that will guide the selection of new technologies.

Implementation process
Manufacturer's submissions for the technology will be reviewed against the national standards. UNHLS will verify information provided by suppliers during the selection process to make informed decisions. Refer to Appendix I

2.3 Selection Criteria

Description of the POCT technology
Size, mobility, simplicity of operation, user friendliness, power source, availability, routine maintenance requirements, throughput capital cost of equipment, environmental tolerance, connectivity, EQA compatibility, infrastructure requirements, radioactivity, storage of results.

Testing procedures:
Calibration requirements, simplicity of the procedure, type and amount of sample required, internal and external quality control, requirement for precise sample measurement, possibility of batching, waste generation and management.

Reagents, consumables and supplies
Storage requirements, packaging, transportation requirements, shelf life, cost, temperature requirements, user safety, reagent stability, reagent form. of reagents, type of tubes for samples, need for centrifuges or other equipment, preparation of reagents and controls, expiration period or other equipment and costs of reagents and consumables.

Technology maintenance and management
Availability of in-country supplier/agent, maintenance and service requirements, shelf- life, technical support and installation.

Acquisition Criteria
Acquisition criteria includes: purchase or lease equipment, operational and maintenance costs; installation of equipment and training are included in the purchase agreement; warranty includes a trial period to verify equipment performance; equipment maintenance; vendor's responsibilities for installation.

2.4 Evaluation and approval of POCT technologies
New technologies are rapidly becoming available across many test categories including CD4, EID, and viral load and Syphilis diagnosis among others. This section describes evaluation and approval of new POCT technologies before deployment and scale up.

Policy Objective
To assess the technical performance of the technology and its adaptability to the environment.

Policy Statements
1. UNHLS shall set criteria for in-country entry, evaluation and approval of POCT technologies.

2. UNHLS shall evaluate or commission other approved institutions to evaluate new technologies per set guidelines.
3. UNHLS shall approve or reject all the evaluations conducted or commissioned based on the recommendations.
4. UNHLS shall determine the operational characteristics through evaluations of the new POCT technology and its adaptability in Ugandan health care facilities.
5. UNHLS shall develop objectives to guide the evaluation process.
6. UNHLS shall consider evaluation results from international recognized institutions.

Implementation guidelines

1. Evaluations of new POCT technologies will follow standardized protocols.
2. As new POCT technologies become available, UNHLS may recognize evaluation results coming from other institutions based on WHO recommendations.
3. In-country evaluation will include (but not limited to) the following:
    - A thorough literature review and needs assessment as required for unknown technologies and new platforms to ensure a clear scientific understanding of the field.
    - Study design, site selection and preparation, and determining the appropriate sample size for the evaluation.
    - Protocols for data collection, training of operators.
    - Guidelines for analysis of data and writing of a final report that can be disseminated to various stakeholders.
    - Ethical consideration.
    - Verification of the methodology for evaluation at a variety of sites.

2.5 Organization and management of POCT services

Offering POCT services requires a well-organized and coordinated system that clearly addresses storage requirements, documentation, and operational aspects of providing POCT services including results reporting. Worldwide there it has been recognized that to ensure quality of these POCT diagnostics, proper quality management and laboratory support is essential for accurate and useful results. Strategic plans are a cornerstone for strengthening coordinated efforts, build synergies, and develop sustainable POCT systems.

Policy Objective

To promote quality testing, identify errors early enough and take appropriate preventive and corrective actions.

Policy Statement

UNHLS shall organize and coordinate all POCT activities in the country through the existing programs and committees.

Implementation guidelines

1. All POCT devices will have the capacity to transmit data to the UNHLS LIMS.

2. Quality coordination and continual re-evaluation of POCT will be through a multi-disciplinary QA teams consisting of staff from the clinical laboratories and the wards/clinics.
3. Facilities will set up QA teams for POCT to monitor equipment performance and document QC data for transmission to UNHLS and district POCT committee.
4. All POCT supporting documentation will be developed by UNHLS and disseminated to health facilities.
5. Any POCT user will have capacity to recognize the merit and/or limitations of the device, hence, maintain accountability for any undesirable consequences or outcomes of its use.
6. For each measuring instrument, there will be written instructions/procedures for equipment maintenance/use and a technical description.
7. For each point of care method, there shall be a procedural description, in respect of how the testing shall be performed, possible sources of errors and reporting protocols for the measurement result.
8. Analysis of results from POCT will be properly documented in the patient's laboratory request forms.
9. Any users of POCT will comply with any relevant standards that will be required under national and international regulations.

3.0 QUALITY ASSURANCE AND QUALITY CONTROL

It is important to ensure that results produced at all health facilities with POCT for accurate, reliable and prompt for diagnosis and management. This is achieved through continuous quality improvement with the goal of getting Accreditation for POCT testing services.

Policy objective

A quality management system and competency monitoring systems shall be mainstreamed to support POCT product selection, testing processes to guarantee the reliability of test results generated for use in clinical decision-making.

Policy Statements

- Internal quality controls materials shall be run and passed before running test samples, interpretation of tests based on the acceptable ranges.
- Trouble-shooting mechanisms shall be put in place for Internal Quality Control results that fall outside of the acceptable ranges.
- All health facilities with POCT shall enroll in an external quality assessment schemes (EQAS) either nationally or internationally and be provided with all procedures necessary for testing.
- All POCT points at health facility level shall demonstrate competence in service delivery based on ISO 22870 and ISO 15189

Implementation guidelines

Raising the quality of care for patients, whilst delivering efficiency and productivity, is a key principle for all healthcare services. Accreditation is a tool that can be used by consumers of laboratory services to support informed and effective decision making, good governance and public confidence. Accreditation demonstrates that the service provider complies with defined standards and best practices. It provides authoritative assurance of the competence of the service, reduces risk and can act as a leverage for service improvement. Accreditation to ISO 15189 and ISO 22870 provides confidence in the site providing POCT testing services.

ISO 22870:2016 Point of Care testing- particular requirements for quality and competence is applied in conjunction with ISO 15189 (Medical Laboratories- particular requirements for quality and competence to provide a platform for using international standards in the accreditation of POCT testing conducted in health facility settings. While patient self-testing in a home or community setting is excluded, from the standard, elements of ISO22870 can be applied**.**

It is important to note that ISO 22870 is not a standalone standard, it needs to be used in conjunction with ISO 15189 ISO 22870 is seen as a supportive standard, which means that the POCT Testing site must also be accredited to ISO 15189

Patient self-testing is excluded from ISO 22870, but is covered specifically in ISO 15197 In vitro diagnostic test systems – requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus, and ISO 17593 Clinical laboratory testing and in vitro medical devices – requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy.

3.1 External Quality Assurance (EQA)

1. The quality of results will be compared with different methods and different testing sites. This comparison between different testing sites is often referred to as peer comparison.
2. All participating POCT sites will analyze an identical unknown specimen on their POCT device and send the results to the EQA provider.
3. The EQA provider will send reports to the POCT users detailing their performance.
4. If EQA material is unavailable, comparison testing will be done using conventional methods already enrolled on EQA.
5. Sites that will not meet the requirements/do not pass will implement corrective actions to identify and mitigate non-conformance.

3.2 Internal Quality Control (IQC)

1. All warehouses will distribute IQC materials to facilities along with reagents (all suppliers of reagents to provide IQA materials).
2. Facility POCT users will run IQC according to SOPs, document and report data to POCT committee through the hub coordinator.
3. Sites that will not meet the requirements/don’t pass will implement corrective actions to identify and mitigate non-conformance

3.3 Quantitative and Qualitative POCT

1. QC material may have an assigned or 'target' value for each POCT test being measured and set limits for acceptable performance around that target.
2. Where QC materials are not available direct patient comparison with UNHLS method may be substituted. Set limits for acceptable performance should still be in place.
3. Record the date on which the QC testing is performed and the operator's name (or initials).
4. The results of QC testing will be compared to assigned values and limits for acceptable performance that are set for each QC. As stated, each QC may have an 'assigned value' that is set by the manufacturer and what is called 'limits for acceptable performance' which can be set by the UNHLS or the manufacturer. The QC results will be recorded electronically or manually for traceability.
5. For QC test result that is outside the limits of acceptability, corrective action will be taken and recorded following the protocol developed by the POCT Coordinator. POCT user will ensure that QC results for the device is in control before the device can be used.
6. The POCT user will compare the QC results with the assigned value and the set QC limits hence, can obtain an immediate internal assessment of the POCT device's performance and the testing system's suitability to continue.
7. The key performance indicator for QC testing is imprecision. As the number of QC tested builds up, calculate the imprecision (or degree of reproducibility) of your QC results on the POCT device.
8. Generally, the lower the imprecision, the better the performance of the device.

Qualitative POCT

1. Qualitative POCTs (HIV, Hepatitis, Dengue, Malaria, Urine Pregnancy Tests, and Urine Chemistry etc.) do not yield absolute values and only shows either 'positive' or 'negative' results. These tests are in immune-chromatographic strips and have an internal control which is built into each test strip to ensure that specimen volume is adequate and solution flow through the device as intended.
2. When the built in internal control line develops, this indicates that the patient's specimen has been correctly loaded and traveled through the test strip and therefore the test is valid. If the internal control does not develop, the test result for the patient is not valid. The result cannot be reported. Do troubleshooting and repeat the test. If a second invalid result occurs, external controls or known controls should be used to evaluate as described below before repeating the test a third time.
3. Known reactive and non-reactive specimens (positive and negative controls) are available from the manufacturer/supplier to sites purchasing the qualitative POCT kits. They are used to evaluate the accuracy of the test and to check if the person conducting the test performs it correctly. Whenever possible, a weakly reactive positive control should be included that has been validated to yield weakly reactive results on all test kits used.

4. To verify that the POCT device is accurate, external positive and negative controls must be tested on a scheduled basis especially when
    - There is a change of lot numbers.
    - A new operator (a trained staff member who has not been doing testing for a while or a newly trained operator) is performing test.
5. Each QC test must be read and validated by two trained POCT users/operators and must be recorded into an IQC/EQA report log.
6. When IQC and external controls provide incorrect results, none of the tests that were run since the last time control results were correct, can be considered valid. This means that everyone who was tested since the last time controls ran correctly will need to be called back and retested (unless a confirmatory test by another method was ordered).

4.0 BIORISK MANAGEMENT

Biorisk management is a key component of laboratory quality management systems and ensures prevention, control and protection from unintended and intended exposure to biological agents and toxins, during work in laboratories and other service delivery points.

Policy Objective

All POCT processes and procedures shall be undertaken in a way that does not put the patient, POCT service providers and environment at risk of contamination with infectious and toxic materials.

Policy statement

In compliance with ISO 15190, there shall be strict adherence to laboratory safety policies and guidelines.

Implementation Guidelines

1. All POCT operators will be trained in Biorisk Management.
2. POCT facilities will adhere strictly to safety standards.
3. There will be close liaison between the Safety Officers of the testing site and the respective POCT Committees.
4. Standard Operating Procedures for waste management will identify all specific safety precautions to be followed.
5. Disposal of laboratory wastes and retiring of equipment will follow the established country guidelines.
6. Chemical waste disposal will be implemented by the aid of material safety data sheet (MSDS).
7. Ensure Personnel Protective Equipment (PPE) is used appropriately.
8. There will be Post Exposure Prophylaxis (PEP) in case of accidental exposure to contaminated blood and body fluids.
9. There will be immunization of POCT service providers for Hepatitis B to protect them against Hepatitis B acquisition.

5.0 PLACEMENT OF POCT

5.1 Site Selection

POCT testing is not ideal for every site, and should not replace conventional testing or existing laboratory infrastructure. It is important to recognize that different POCT technologies will be optimal for different settings, and therefore clear site selection criteria are needed. Recognizing the significant life-saving potential of POCT testing, maximizing patient impact should be the guiding principle for the prioritization of sites for implementation of these technologies. The deployment of POCT testing will also be different for various test types.

A robust and objective methodology is needed to select appropriate sites for implementation of POCT testing, in order to ensure that the impact of POCT technologies is maximized and that the network of testing sites can be managed as efficiently as possible. During the development of implementation plans for each type of POCT test, UNHLS in collaboration with the Ministry of Health and partners will develop this methodology to map and prioritize health facilities for POCT implementation. POCT implementation will be conducted using a phased approach, so sites will be prioritized for POCT testing in order to maximize the impact of POCT testing, to provide for efficient management of the entire network of testing sites, and to achieve the ultimate goal of the most rational deployment of multiple POCT products in each product class.

Policy objective

To prioritize testing sites for efficient implementation of POCT technologies to have maximum impact on the patients.

Policy statements

The selection for use of POCT technologies shall be informed by coverage of clinical laboratory services, conditions to be tested, implementing capacity, level of healthcare testing infrastructure, workload and personnel and expansive geographical coverage.

Implementation Guidelines

The most important site selection criteria used to guide POCT implementation will be:

- Already providing a service.
- Expected/available number of patients
- Accreditation compliance
- Adherence to quality testing requirements
- Trained/Adequate number of personnel
- Adherence to Infrastructural guidelines such as space and safety requirements
- Availability of amenities; water, power
- Complexity of equipment; technological requirements, ease of use
- Availability of POCT machines
- Environmental considerations; humidity, temperature, dust
- Data storage, sharing and connectivity capabilities.
- Access to diagnostic testing (equity, geographical considerations)

- Ownership (Public, private, PNFP, PFP)
- Availability of Implementing partner (external support/Financial/technical support).
- Local political support

5.2 Integration of conventional testing with POCT

There are both advantages and disadvantages of the current POCT Technologies available, and it is not expected that POCT testing will completely replace the existing conventional laboratory-based testing networks. With the current POCT technologies available and expected in the next few years, there are constraints that prevent universal adoption of POCT testing. Currently, many laboratory-based technologies achieve higher efficiency than POCT testing from a health system standpoint, due to their lower cost per test and higher throughput. POCT testing is also difficult to implement in some settings due to challenges in supply chain, device maintenance, and quality assurance, poor linkages to care and treatment, and limited staff to perform tests, interpret results, and provide counseling at the health center level. POCT testing can help reduce wastage of test results. Test wastage can occur when long turn-around-times from conventional laboratory testing cause failure of results to reach clients and/or their records. POCT testing, therefore, is well suited to complement existing conventional laboratory testing.

Ultimately, the introduction of POCT testing will be critical to continue the expansion of access to diagnostics and to improved care and treatment for high priority diseases. However, the shift to POCT testing will be a gradual process, and for the foreseeable future there is an important role for both POCT and conventional laboratory based testing. Over the years, the MOH has invested significantly in conventional laboratory based diagnostics, and does not intend to make obsolete these technologies that have already been deployed. Reference laboratories, as well as regional and district hospital laboratories, will play an important role in achieving universal health access by providing efficient high-volume testing in densely populated areas, and by providing training and quality assurance for the growing number of POCT testing sites.

However, in the development of implementation plans for POCT testing in each test type, it will be critical to take a client-centered approach, pursuing a solution that is equitable in terms of access and quality. In settings where it is feasible and cost-effective to do so, POCT testing will be implemented to drive the significant patient benefits to the greatest number of patients possible. Additionally, POCT implementation may be more extensive for a test such as viral load, which has currently not seen much investment in conventional laboratory based infrastructure, compared to other established tests. The optimal balance between POCT and conventional laboratory-based testing will be determined while conducting POCT technology evaluation and during the development of specific implementation plans for each testing platform and site selection. That balance will be different for each testing platform, and across a variety of different setting.

Policy Objective

To balance conventional laboratory based testing with POCT testing by gradually introducing and expanding access to POCT diagnostics to improve care and treatment for high priority diseases.

Policy statement

POCT testing shall be implemented in sites determined by good supply chain, device maintenance, and quality assurance, good linkages to care and treatment, and adequate number of competent staff to perform tests and interpret results.

Implementation Guidelines

1. POCT will be applied majorly in lower level facilities (IV & III) and conventional in high level facilities i.e. Regional and general hospitals).
2. POCT will act as a backup to the conventional method in high level facilities.
3. Consideration of POCT platform applicability.

5.3 Installation, Calibration, Troubleshooting and Performance Verification

To harness the full benefits of POCT technologies, it is imperative that they are correctly installed, calibrated and verified to enable favorable response to the demand of the health care services with reliable, accurate and quick diagnostic services at point of care.

Policy objective

To ensure correct installation and operation of POCT equipment and enable users troubleshoot POCT equipment operational errors to ensure accuracy of test results.

Policy Statement

The equipment, devices and reagents shall be installed/calibrated to ensure suitability for intended use and the manufacturer or appointed vendor shall implement this process through MOH and appointed authorities.

Implementation Guidelines

1. Installation and calibration will be by vendors following the Manufacturers recommendations and will be coordinated by UNHLS through the existing program.
2. The vendors will provide onsite training for health care service providers undertaking the various types of POCT.
3. Training will include calibration, testing procedure and trouble shooting.
4. Vendors will provide user manuals in an understandable language.
5. Vendors will provide start up kits and controls enough for the laboratory trial runs and measurement of uncertainty.
6. Manufacturer’s performance specifications will be verified on all installed POCT equipment.
7. The laboratory will perform equipment validation and ensure certainty of performance specifications.
8. If verification fails, the vendor should be contacted to replace it with another one.

5.4 Maintenance Program, Performance Calibration, Service and Repair

POCT technologies are often labelled as maintenance-free though minimal maintenance and performance calibrations may still be required. The level of maintenance and performance calibration will differ from one technology to another. This calls for a need to acquire POCT technologies with lower maintenance requirements and higher time to first repair.

Policy objective

To ensure uninterrupted service delivery at all time during health care provision with accurate and reproducible results from POCT testing equipment.

Policy statements

1. An equipment maintenance program shall be put in place to ensure proper and continuous functionality of the POCTs.
2. All qualitative POCT kits shall be validated for their suitability before being put in to use.

Implementation Guideline

1. UNHLS will negotiate agreements for POCT equipment service maintenance by vendors before they are rolled out to include spare parts, service frequency, acceptable TAT for any repairs required.
2. Service and repair reports will include all areas required by standards such as; occurrence, immediate actions taken, root cause analysis, corrective action and preventive action.
3. The vendors will train UNHLS biomedical engineers and certify them on POCT servicing and repairs.
4. Facilities will develop maintenance logs for all POCTs and establish scheduled preventive maintenance as advised by the manufacturers.
5. UNHLS will validate all POCTs technologies before purchasing them for their performance characteristics as per the manufactures report.
6. All qualitative POCTs should be supplied with longer expiration.
7. The validation report will be disseminated to stakeholders in a meeting (IPs, MOH, DHO, and HC facilities).
8. All POCTs will be retired in line with Public Procurement and Disposal of Assets (PPDA) act.

6.0 SUPPLY CHAIN MANAGEMENT SYSTEM

Supply chain management system of POCT technologies shall ensure uninterrupted availability of quality assured testing services. The existing supply chain management system implemented through the National warehouses will be used to replenish stocks of POCT commodities from certified suppliers/local agents for the registered POCT technologies. Consumption data

transmitted through device connectivity will help inform accurate quantification and supply. As technologies evolve for replenishing stocks of reagents and related commodities, a pull system shall be preferred.

Policy objective

To ensure timely and continuous provision of the right POCT technologies and commodities.

Policy statements

Commodities Management

1. A supply chain management system shall include procurement, storage, distribution and inventory management.
2. The Procurement, distribution and inventory management of POCT commodities shall be coordinated by UNHLS Logistics Department through national warehouses**.**
3. Procurements of all POCT commodities shall comply with PPDA act which will guide the modes of tendering and procurement of commodities.
4. The number of new POCT technologies introduced in each category shall be guided by product selection criteria.
5. Storage and distribution of POCT commodities shall be conducted through national warehouses following the existing system.
6. Guidelines for pre and post market surveillance shall be developed and implemented to ensure the ongoing compliance with quality and regulatory requirement. This shall include but not limited to lot verification testing.

Equipment management (consider merging with 5.4 in chapter five under this section)

1. Suppliers shall have in country agents (Local Technical Representatives) responsible for supporting the ongoing service and maintenance of equipment, and this shall be clearly stipulated in the contract.
2. UNHLS shall sign a contract with the manufacturer/suppliers of POCT technologies to provide service, repair and maintenance.
3. The equipment shall be purchased with a minimum of two-year warranty after equipment installation, training, validation and deployment inclusive of the swap-out service.
4. The facilities shall be encouraged to identify backup equipment in same or other facilities in the event of equipment failure/breakdown.

Implementation Guidelines

1. All POCT technology introductions will be coordinated by MOH/ UNHLS and national warehouses.
2. PPDA act will guide the procurement process including the modes of tendering and establishing prices and reagent rental.
3. The number of new POCT technologies introduced in each category will be limited to not more than three different types to ease supply chain management system.

4. All National warehouses should have a standard item description and coding of POCT technologies and consumables.
5. Replenishing stocks of reagents and related commodities will follow the "Pull system".
6. All POCT supplies will be received at facilities with not less than four months of shelf life to avoid wastage.
7. Regular, updated consumption and stock status reports will be collected bimonthly including the equipment operational status through UNHLS and national warehouses.
8. At all levels, the principle of first-expiry-first-out (FEFO) will be applied to control stock. Expiry dates of products will be checked on arrival. Post marketing surveillance will be done to ensure the ongoing compliance with quality and regulatory requirement.
9. There will be contracts with manufacturers/suppliers to provide maintenance, service and repair of POCT equipment. The cost of this contract will be paid either outright or integrated into reagent cost.
10. The POCT equipment will be purchased with a minimum of two-year warranty after equipment installation, training, validation and deployment inclusive of the swap out service.
11. Swap-outs will be made within a week of failure notification. Each facility will designate responsibility for the day-to-day care of the equipment as well as performance equipment calibration and quality control and maintenance log.

6.1 Guidelines for Vendor relations

Supply chain management system integrates vendor relations to eliminate hidden costs of poor relationships, reduce waste and increase trust through closer relationships. Communication reduces on these costs through avoiding duplication, excess inventory or supply bottlenecks. The growth of outsourcing and electronic commerce and ICT demands for closure supplier and organization relations.

Policy Objective

To build and manage relationships with those who supply POCT products and services to the organization ensuring that vendors meet or exceed their contractual obligations.

Policy Statements

UNHLS shall manage the balance in vendor relationships to support the achievement of agreed supply chain management system outcomes.

Implementation Guidelines

1. Evaluate potential suppliers using developed and agreed criteria to support alignment and understanding of the expectations and requirements of engagement.
2. Monitor and report on the performance of selected vendors to ensure delivery in line with contractual obligations and performance metrics.
3. Manage the tender process in a way that minimizes burden to the supplier and contract terms are adhered to.
4. Manage outward communication to vendors to facilitate understanding and awareness of organizational strategic direction, changes and challenges.

5. Respond promptly, courteously and efficiently to inquiries and compliments.
6. Manage the interaction between vendors and internal program delivery leaders to provide adequate visibility of interdependent initiatives and programs.
7. Liaise with procurement partners to review, report on and revise contractual agreements as necessary.
8. Professional standards will be complied with in the award of contracts and or follow international standards.
9. Preservation of highest standard of honesty, impartiality and objectivity will be observed in customer vendor relations.

7.0 COMMUNICATION STRATEGY

Timely, complete and accurate information for patient health care management is essential. This further guides the planning and implementing of health care services.

Policy objective

To share timely, complete and accurate information for patient health care and management.

Policy Statements

1. UNHSL shall develop a communication framework to promote visibility of POCT in the country.
2. UNHLS shall establish a communications committee to advocate and promote the utilization POCT.
3. Healthcare practitioners shall share timely, complete and accurate information for patient health care and management.

Implementation Guidelines

1. UNHLS will operationalize the national communication frameworks for promotion and utilization of POCT
2. Sensitization of all stakeholders to increase knowledge/awareness and uptake of POCT services.
    - UNHLS will develop targeted communication messages to increase knowledge, awareness and uptake of POCT services
    - UNHLS will translate key messages in the key local dialects
    - UNHLS will collaborate with partners in development of IEC/BCC material in line with the strategy
3. UNHLS in collaboration with implementing partners will disseminate the policy and implementation guidelines at all levels of health care.
4. Enhance the interpersonal communication skills of service providers and caregivers.

8.0 TRAINING, MENTORSHIP AND SUPERVISION

Implementation of any POCT testing requires appropriate training, followed by mentoring and or supervision of provider sites and services. Training, certification, and performance standards and guidelines for healthcare workers to perform POCT testing are vital requirement for POCT sites. The goal is to produce accurate, reproducible and reliable results, while ensuring safety and health of the end users.

Policy objective

To offer quality technical training, mentorship and support supervision to the end users.

Policy Statements

1. Uganda National Health Laboratory Services shall coordinate POCT training and decentralize to lower facility levels.
2. POCT training should be integrated into the current UNHLS training coordinating offices.
3. There shall be Performance needs assessment to inform on the design, management and evaluation of the training.
4. Certified, experienced trainers and mentors shall be available to offer trainings and mentorships to the health providers and other end users of the device.
5. POCT Healthcare Service Providers (HCSP) shall be adequately trained and certified to perform the testing.
6. Health Professionals training institutions shall incorporate POCT technologies in the curriculum.
7. POCT testing support supervision shall be integrated into the existing support supervision structures.

Implementation Guidelines

1. Training mechanisms will be put in place to ensure adequate numbers of POCT providers are available to offer services at National, Regional and Community levels.
2. UNHLS will use the training coordination office to select TOTs for POCT training and have them certified.
3. POCT trainings and mentorships will be conducted at appropriate training venues and certified POCT sites.
4. UNHLS training coordinating office will develop and implement the training curriculum and manual for POCT devices
5. Ministry of Education will update and incorporate POCT technologies in the curriculum for health training institutions.
6. A training manual, either in hard copy and/or electronic form, will be provided to all POCT users attending training.
7. Training should cover both theory and practice of all but not limited to;
    - Action on improper and unsafe use of a POCT device
    - Procedure for recording of adverse incidents with POCT devices.
    - Compliance with accreditation requirements (where appropriate).
    - Understanding of method, standard reference ranges and correlation study.

- Sample collection requirements per health and safety regulations and the manufacturer's stated requirements (including correct preservative or anticoagulant).
- Reagent preparation and kit storage.
- How to perform the test on the device (including calibration).
- How to interpret report and act on POCT results.
- Quality Assurance Procedures.
- Calibration and quality control requirements, to include performance, appropriate record keeping and required actions for failed calibration and QC rules.
- Assignment of operator identification numbers to certified POCT users.

8. Competence assessment will be regularly conducted and monitored using predefined criteria. Trainee competency shall be determined by written and/or practical assessment in a log book.
9. Successful trainees will receive a competency certificate at the completion of initial training. Operation of POCT devices will be limited to staff whose training and competence has been established and documented.
10. Post training follow up of competency will be undertaken by regular review of quality control and quality assurance testing results.
11. If a POCT operator fails a competency review, then they should be retrained before being recertified. Attendance at retraining sessions should be viewed as mandatory. Registry of trained staff and renewed competency certificates should be prepared and maintained by the POCT coordinating office.
12. Mentorship activities will be structured through pre-planning and post-evaluation to ensure smooth mentoring encounters. There should be a follow up on mentorship to review progress on previous action points made, implementation and decide on future improvement strategies.
13. POCT testing support supervision will be conducted using an integrated approach with appropriate POCT checklist.

9.0 MONITORING AND EVALUATION

Adequate monitoring and evaluation of the implementation and/or performance of POCT is essential to ensure effective and efficient patient access, diagnosis, care and treatment. The policy statement thus gives guidance to the implementation of POCT.

Policy Objective

To establish mechanisms for monitoring and evaluation of the implementation and/or performance of POCT services.

Policy Statements

1. UNHLS shall implement an M&E system, which will provide, timely, reliable and relevant information on POCT services.

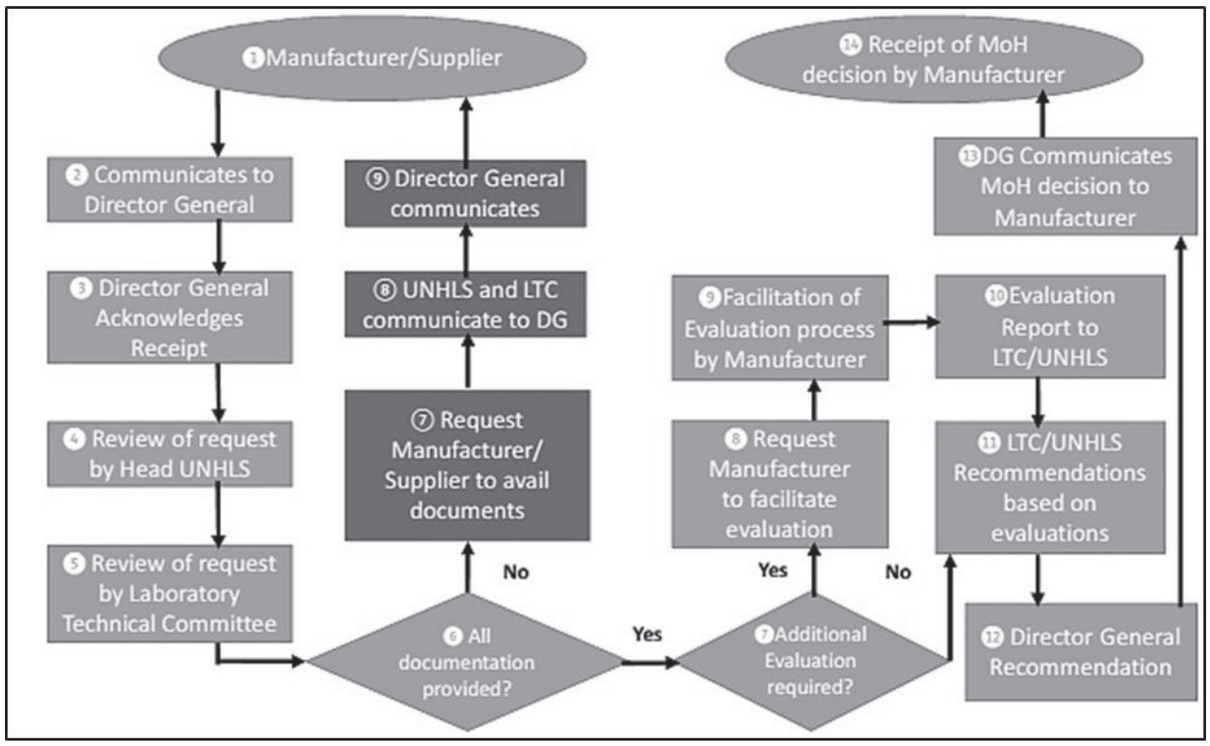
2. Measurable performance indicators shall be developed and periodically monitored according to laboratory M&E plan.
3. The M&E performance indicators or POCT shall be incorporated in the health laboratory information management system routine reporting protocols.
4. Data quality, verification and assessment protocols shall be developed to ensure effective data collection, storage, retrieval and reporting at all levels.
5. Data tools will be developed and/or revised to capture, aggregate and report on POCT platforms.
6. Data shall be collected and analyzed to track performance of POCT services at all levels of service delivery.
7. There shall be device connectivity for all quantitative POCT devices to allow data sharing, reporting and utilization.
8. There shall be training of health workers on POCT data collection, analysis, reporting and data utilization

Implementation Guidelines

1. POCT M&E system will be incorporated in the existing HMIS and HLIMS to provide, timely, reliable and relevant information to inform POCT implementation in the country.
2. Data sources for POCT will be the existing HMIS tools; these include both the paper based and electronic versions.
3. Data will be collected routinely and/or periodically to inform the POCT M&E indicators.
4. Performance measurement indicators for POCT will be analyzed routinely and periodically to inform POCT implementation.
5. Reporting on product utilization, tests conducted, quality assurance, reporting rates, supplies and reagents availability and positivity rates and as required will be conducted. Device connectivity will be provided to ensure ease of data reporting.
6. Periodic display of product utilization, tests conducted, quality assurance, reporting rates, supplies and reagents availability and positivity rates among others to inform decision making will be conducted.
7. POCT data will be disseminated routinely and periodically at all levels using the existing channels and/or in POCT specific data review meetings.

APPENDICES

APPENDIX I: Country Entry Protocol



APPENDIX II: Criteria for equipment evaluation and approval

Parameter	Yes	No
Availability of operation and maintenance manual		
Infrastructure requirements (space,power supply,water, temperature)		
Environmental conditions (effects of humidity)		
Laboratory work load:staff skills,on-the-job training on operations		
Vendor support: reliability and availability		
Availability of local service,technical and training support:		
Availability of aftersale services		
Availability of replacement parts (Downtime<2weeks)		
Simplicity of operation: ease of maintenance and calibration		
Trackrecord of performance (domestic and/or international)		
Test menu(consider scalability for various volumes)		
Open or closed test/reagent system		
System costs (includes equipment,services, reagents and supplies);cost per reported test		
Specimen types		
Through put (amount, output)		
Turn Around Time		
QC and QA requirements		
Availability of EQA andinter-laboratory comparison		
Data management capability;interface capability		
Technical safety		
Availability of back-upmethods		
Supply chain management capability		

BIBLIOGRAPHY

1. National HIV Point of Care Testing Generic Implementation Guideline for Health Care Settings, Tanzania, September 2015
2. Strategy for the Implementation of POCT in Ethiopia, Ethiopian Health and Nutrition Research Institute June 2013
3. Strategic Plan, Infectious Disease Institute(IDI), 2013
4. National Point of Care Testing Policy and Guidelines, Malaysia, July 2012
5. IFBLS' Guidelines regarding Point of Care Testing (POCT), Kenya
6. Policy Analysis, Lecture notes, Richard Nuwamanya, Makerere Institute of Adult and Continuing Education,2005
7. Logistics Accounting and Financial Management, Lecture notes, Kitale Chris, MaK Institute of Adult and Continuing Education(IACE), 2004
8. Communication and Vendor Relations Management, Jane Kamungi, Makerere University Institute of Adult and Continuing Education(IACE),2004
9. Clinical and Laboratory Standards Institute,CLSI:www.clsi.org
10. International Organization for Standardization,ISO:www.iso.org
11. www.cap.org
12. United Kingdom National External Quality Assessment Service, UK NEQAS www.ukneqas.org.ok
13. Point of Care: The Journal of Near-Patient Testing &Technology

Ministry of Health Uganda
P.O. Box 7272 Kampala