World Health Organization

CDC
CENTERS FOR DISEASE
CONTROL AND PREVENTION

HANDBOOK

HIV DIAGNOSTICS

IMPROVING THE QUALITY OF HIV-RELATED POINT-OF-CARE TESTING:
ENSURING THE RELIABILITY AND ACCURACY OF TEST RESULTS

DECEMBER 2015

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ABBREVIATIONS AND ACRONYMS

ISO International Organization for Standardization
NGO nongovernmental organization
TB tuberculosis
UNAIDS Joint United Nations Programme on HIV/AIDS

ACKNOWLEDGEMENTS

DEFINITIONS

Connectivity

The ability to transmit data from testing conducted at the point-of-care site to a central database, such as a laboratory information system, for analysis and review. The data can be reviewed for the purposes of quality assurance. Connectivity may be through equipment-based testing devices that have connectivity capabilities or through future application of smartphone devices for non-equipment-based testing such as rapid diagnostic testing.

External quality assessment

Defined as a system for objectively checking the performance of a testing site (including the testers and the system used for testing) using an external agency. External quality assessment is sometimes used interchangeably with proficiency testing; however, external quality assessment can also be carried out using other processes such as retesting of samples by another accredited facility and site visits.

Point-of-care testing

Point-of-care testing has no universal definition; however, the core components of point-of-care testing are: (1) testing is carried out at or near the person being tested, (2) the results are returned to the person being tested during the same visit and (3) the results of point-of-care testing can be used immediately for patient care and referral. Point-of-care testing can be implemented in hospitals (critical care units, emergency care, surgery, maternity and neonatal units), laboratories, nursing homes, outpatient settings (physician's offices, pharmacies and remote locations) and in patients' homes. Different point-of-care tests are applicable at different levels of health-care systems; for example, non-equipment-based point-of-care rapid diagnostic testing has been fully decentralized to the community level (level 1), whereas equipment-based point-of-care testing (CD4 testing, future point-of-care early infant diagnosis testing and viral load testing) is suitable for point-of-care facilities down to primary health care facilities (level 2). This handbook refers to HIV-related testing to describe HIV diagnostic testing including rapid diagnostic testing and early infant diagnosis

as well as point-of-care tests for monitoring people living with HIV who are receiving antiretroviral therapy such as CD4 testing and viral load testing. This handbook can also be used for other point-of-care testing programmes including tuberculosis (TB), sexually transmitted diseases, malaria and hepatitis.

Quality assurance

The continuous and systematic approach to monitor, evaluate and include actions to improve the quality of testing. Quality assurance is the core topic of this handbook and adapts many of the quality assurance principles that have been developed for laboratory testing. The continuous assessment of quality is described as encompassing various elements such as quality control, external quality assurance, documentation, supervision, safety and inventory management.

Quality control

Procedures used routinely to assure that a test run is valid and the test results are reliable and include internal kit controls and/or external quality control samples with well established results.

Quality corps

A group of volunteers hired temporarily to assist with quality assurance activities. This concept is based on a successful pilot programme in Africa to recruit volunteer personnel from the community where testing is carried out who are trained in specific elements of quality assurance and can undertake these activities such as expedited dispatch of proficiency panels, quality control specimens or standardized logbooks and rapid return of results, enabling deeper access and penetration at rural sites where testing is being carried out.

Quality improvement

An integral part of the quality assurance cycle that responds to the assessment and improvement activities, leading to better testing and health care outcomes using evidence-informed approaches and standards such as this handbook and associated tools.

EXECUTIVE SUMMARY

HIV-related point-of-care testing technologies have become widely available in last the few years and can potentially play a major role in achieving the UNAIDS 90–90–90 targets through increasing access to diagnostics in low- and middle-income countries. However, challenges remain regarding the appropriate use of point-of-care testing to ensure accurate patient results. Maintaining a high quality of testing while increasing access is critical for better patient care. Access to accurate diagnostics is a fundamental right of every individual; inaccurate diagnoses can have devastating consequences for an individual, resulting in stigma, loss of family, loss of job and loss of other opportunities. As point-of-care testing access expands in low- and middle-income countries, accuracy and quality of diagnostic methods should go hand in hand with the expansion of this endeavour. Quality assurance activities are an integral part of point-of-care testing and should be planned and implemented in a sustainable manner in parallel with point-of-care testing expansion, which will require a strong commitment from all stakeholders.

Expanding point-of-care testing in resource-limited countries will require innovative approaches to ensure sustainable quality assurance practices that lead to accurate, reliable patient results and improved public health outcomes. A systematic approach should be adopted at the country level that includes development of appropriate policies around point-of-care testing and a stepwise approach to include planning, implementation and the sustainability of quality assurance.

This handbook has been created to address the weaknesses identified in existing point-of-care testing programmes and to assist service providers in adhering to a new set of minimum standards that promote and ensure quality assurance for HIV-related point-of-care testing. These new minimum standards include (a) greater emphasis on certification of point-of-care testing staff and sites; (b) enhancing quality assurance human resource networks for point-of-care testing supervision, data collection and corrective action; and (c) establishing more comprehensive data collection analysis through innovations in data connectivity.

This handbook describes the quality assurance cycle, a three-phased process developed to assist health-care providers and stakeholders in planning, implementing and

sustaining quality assurance for HIV-related point-of-care testing. The activities recommended in this handbook follow the flow of the three-phased quality assurance cycle.

• **Phase 1.** Planning that involves establishing and strengthening a national quality assurance coordination team or technical working group, setting minimum standards and roles, developing quality assurance policies, conducting situation analysis, assessing point-of-care testing sites and product selection as well as financial planning for quality assurance activities.

• **Phase 2.** Implementation that highlights the need to strengthen training and certification of point-of-care testing staff, conducting frequent site visits for supervision through enhanced networks of human resources, and site certification using the standardized checklist for point-of-care testing. New recommendations for the use of internal quality control and external quality assessment are provided as well as innovative use of connectivity for data collection, documentation and improving the supply chain.

• **Phase 3.** Sustainability closes the quality assurance cycle by emphasizing improved monitoring and evaluation, post-market surveillance, advocacy and community ownership and the use of ongoing operational research to stay abreast of emerging point-of-care testing technologies.

In addition, the annexes include tools for implementing quality assurance programmes. Key inclusions are the checklists for the stepwise process for improving the quality of rapid testing (Annex 1) and for instrument-based point-of-care testing (Annex 2). These checklists enable quality assurance performance to be assessed at all testing sites, which can then be used to monitor and improve quality over time at the site level and the national level. In addition, special consideration boxes are provided for quality assurance of point-of-care testing in specific programme areas including hepatitis, HIV testing and counselling, children, preventing mother-to-child transmission, sexually transmitted infections and tuberculosis (Annex 16).

This handbook is a valuable resource to engage and to assist health ministry HIV programme managers, donors and test providers in the planning, implementation and sustainability of quality assurance for HIV-related point-of-care testing.

INTRODUCTION

In 2013, more than 118 million people received HIV tests in 124 low-and middle-income countries *(1).* This expansion in HIV testing has largely been possible because of the scale-up of rapid HIV testing. Similarly, implementation and scale-up of other HIV-related point-of-care testing, in particular CD4, has been rapid during the past five years, with 23% of CD4 testing in 2013 reportedly being performed using point-of-care technologies *(2).* Point-of-care testing provides an opportunity to greatly reduce test turnaround time and increase the availability, expanding scope and coverage of testing beyond urban centres to reach the rural population. Point-of-care testing has been shown to reduce patient loss to follow-up and increase access to antiretroviral therapy *(3).* The expedited diagnosis afforded with point-of-care testing has been reported to decrease disease transmission and improve health outcomes *(3).* Rapidly scaling up point-of-care testing without simultaneously building the capacity of quality assurance is counterproductive if service providers are unable to guarantee adherence to minimum quality standards with accurate and reliable results *(4).* This has been observed in both HIV rapid testing and, more recently, CD4 point-of-care testing programmes, with high rates of misdiagnosis of HIV and errors being reported. There have been many reports across multiple countries, both published and unpublished, of unacceptably high misdiagnosis rates of HIV using rapid diagnostic tests *(5–9).* In particular, false-positive results have been reported in up to 10.5% of the people tested, resulting in significant numbers of HIV-negative people incorrectly being put on lifelong antiretroviral therapy and enduring immeasurable stress, stigma and discrimination *(6).*

Several factors can lead to seeing such incorrect results; however, all indicate a need to improve the quality of testing. These include test quality–related causes such as poor choice of tests comprising a testing algorithm, which can lead to false-positive results because of the low specificity of a second or third test or a poor choice of test for the target population because of the cross-reactivity associated with other infections or pregnancy. Suboptimal performance of new kit lots can also be a key factor in the absence of new lot monitoring. Operator- or system-based causes include the use of poor-quality specimens (such as insufficient volume or air bubbles in the specimen), incorrect interpretation of results (such as confusion about interpreting weak lines), recording errors such as clerical errors or non-compliance with the test procedure or algorithm (such as altered reading time or using a second-line assay as the first-line assay).

Point-of-care CD4 testing has also been fraught with similar test errors, albeit with less grave patient consequences but with unacceptably high economic costs. High rates of invalid tests of up to 14% have been reported across many country programmes using point-of-care CD4 testing *(10,11).* It is widely accepted that most causes of errors in point-of-care CD4 testing are caused by operator errors associated with specimen quality and handling.

Addressing these common quality-related causes of incorrect results and errors requires making a concerted effort at all levels to significantly step up efforts to systematically improve and assure the quality of testing. To ensure the provision of high-quality patient care, health-care providers and all stakeholders (such as health ministers, programme managers and donors) should mandate the implementation of quality assurance programmes to monitor and improve the quality of HIV-related testing. Improving the quality of testing will reduce the rate of incorrect results that negatively affect national HIV programmes *(1,12–14).* Quality improvement requires reassessing and addressing current weaknesses across algorithm design, test commodity logistics, human resources, supervision and training, quality assurance programmes, data collection and monitoring and evaluation programmes. This new handbook, with associated tools, underscores the need for strong leadership, dedicated funding for quality assurance, advocacy, new innovations and better coordination for continuous quality monitoring and improvement.

Purpose

In February 2014, a consensus meeting of major stakeholders and partners was held at the United States Centers for Disease Control and Prevention in Atlanta that clearly identified the need for new recommendations for improving the quality of HIV-related point-of-care testing. The purpose of this handbook is to address the weaknesses in current point-of-care testing quality assurance programmes, identify key activities that will help in developing and implementing sustainable high-quality HIV rapid diagnostic tests and HIV-related point-of-care testing within laboratory and non-laboratory settings. This handbook seeks:

- to emphasize the importance of quality assurance and quality improvement for point-of-care testing;

- to strengthen existing quality assurance and quality improvement practices for point-of-care testing;

- to highlight the need for a cadre of quality officers and a network of point-of-care testing testers;

- to provide new innovative quality assurance and quality improvement strategies; and

- to share a comprehensive package of established and new quality assurance and quality improvement tools for point-of-care testing.

Audience

This handbook is intended for use in policy development, planning and implementation by HIV technical officers and laboratory technicians within the health ministry in countries and implementing partners for HIV rapid diagnostic testing and HIV-related point-of-care testing. The health ministry employees should take ownership and be responsible for ensuring that HIV testing programmes address all aspects of quality assurance and quality improvement outlined in the handbook.

SCOPE AND SETTINGS FOR USE

This handbook is applicable to HIV rapid diagnostic test and HIV-related point-of-care testing for patient specimens in clinical, laboratory and community health settings and covers the following specific point-of-care testing areas:

- all point-of-care HIV rapid diagnostic tests, CD4, viral load and early infant diagnosis tests (the latter two – viral load and early infant diagnosis – are not yet widely available); and

- quality assurance activities for HIV rapid diagnostic tests and other point-of-care testing platforms (CD4, viral load and early infant diagnosis).

The main focus of this handbook is HIV rapid testing and point-of-care CD4 testing, since they are currently being used in country testing programmes; however, the quality assurance principles equally apply to future applications of point-of-care testing, including new CD4, early infant diagnosis and viral load testing. In addition, this handbook aims to extend beyond HIV testing and monitoring, since its principles also apply to other HIV-related point-of-care testing, including TB and sexually transmitted infections, which are described in the special considerations sections in Annex 16 and may also be used for other point-of-care testing such as malaria, haemoglobin and blood chemistry. Throughout the handbook, where possible, HIV rapid diagnostic testing, CD4, viral load and early infant diagnosis are discussed separately, although in many sections the content is relevant to all test types (and often extends beyond these test types).

Point-of-care testing can be provided in many settings (Fig. 1). The five-tiered health system (Fig. 1) illustrates where point-of-care testing for HIV is most likely to be performed and the level of the health-care worker who would normally perform the test. Typically, point-of-care testing would be performed at the lower level (levels 1–3) health facilities as depicted in Fig. 1; however, point-of-care testing can also be used at higher-tier health and laboratory settings.

Fig. 1. Point-of-care testing within the tiered health system

National reference laboratory:
senior laboratory supervisors, trainers and senior technicians

Validating point-of-care testing, training and certification, coordinating quality assurance, proficiency testing, confirmatory testing, collecting and analysing data, corrective action

5

Regional or provincial reference laboratory:
laboratory supervisors, trainers and senior technicians

Rapid diagnostic tests, point-of-care tests for CD4, early infant diagnosis and viral load, coordinating regional training and quality assurance, collecting and analysing data, corrective action

4

District-level laboratories:
laboratory technicians

HIV rapid diagnostic tests, point-of-care tests for CD4, early infant diagnosis and viral load, supervising sites, corrective action

3

Primary care:
health-care workers

HIV rapid diagnostic tests, point-of-care tests for CD4, collecting dried blood spots for point-of-care tests for early infant diagnosis

2

Community outreach:
community health-care workers
HIV rapid diagnostic tests

1
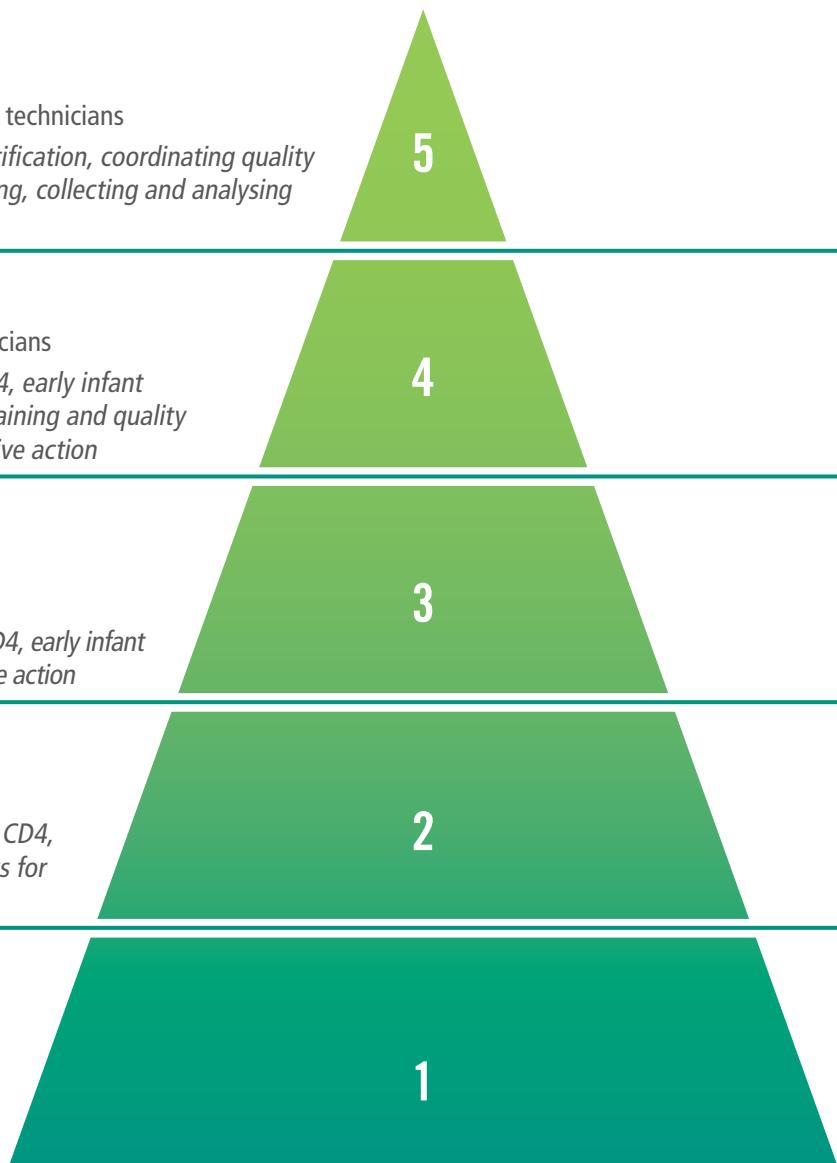
STRUCTURE OF THIS HANDBOOK AND ITS TOOLS

This handbook is designed to provide a basic outline of what is required to improve quality for HIV-related point-of-care testing and who is responsible for carrying out the tasks and includes necessary tools for how to implement enhanced quality improvement activities. This handbook provides minimum requirements for activities to improve the quality of point-of-care testing.

What is new in this handbook?

1. It introduces a method for certifying or accrediting point-of-care testing sites and upcoming quality improvement training modules.

2. It takes innovative approaches for increased coverage, uptake and impact of quality assurance activities through increased human resources networks.

3. It emphasizes data collection, analysis, corrective actions and use of the data for quality assurance of point-of-care testing.

4. It encourages piloting and scaling up of innovative methods for connectivity for data collection and quality assurance.

The handbook describes each of the three main phases in the quality assurance cycle (Fig. 2). An overview is provided at the beginning of each section, and a summary table is provided at the end of each section. This handbook describes the three main phases of the quality assurance cycle.

- Phase 1: planning quality assurance for HIV-related point-of-care testing: describes engaging leadership from national HIV programmes to drive the quality agenda by redefining standards, policies, priorities, resources needed and roles and responsibilities for supporting quality assurance and quality improvement efforts.

- Phase 2: implementing quality assurance for HIV-related point-of-care testing: describes key action items that require systematic strengthening including training, tester certification, site certification and quality assurance procedures (documentation, external quality assessment and quality control).

- Phase 3: sustaining quality assurance for HIV-related point-of-care testing: describes the use of data for monitoring and evaluation, new quality indicators to measure a site's progress on quality assurance programmes as well as innovative approaches for communication, community involvement and social entrepreneurship.

A key inclusion and focus in this guidance are the tools provided in the attached annexes, which are referred to within each section. Key tools that are central to this handbook are Annexes 1 and 2: the stepwise process for improving the quality of HIV-related point-of-care-testing checklists. Additional tools that are too large to include here or are currently being developed will be made available online to supplement these tools, including tools for a stepwise approach to quality improvement projects and training modules. In addition, a share point will be set up to supplement this handbook for sharing country tools and to encourage sharing of best practices and achievements. Annex 16 in this handbook is a series of special considerations for point-of-care testing in specialized settings, including HIV testing and counselling, preventing mother-to-child transmission and considerations for children or using tests that are not covered within the body of the text, including point-of-care testing for hepatitis, sexually transmitted infections and TB. Annex 17 provides a quality assurance checklist for maternal, newborn and child health settings.

Quality assurance cycle for improving the accuracy of point-of-care testing

The core of this handbook is the quality assurance cycle depicted in Fig. 2. The activities of quality improvement and the quality assurance assessments are often depicted in a cycle to underscore the importance of their continuous and unceasing nature; quality is not a one-off activity. The inner circle is based on the quality assurance cycle described in the *Handbook for improving HIV testing and counselling services (4)* with some additional components. Phase 1 involves planning and defining, followed by phase 2: implementing and monitoring, followed by phase 3: evaluating and improving, which feeds back into phase 1 again. This handbook also adds another layer of structure to these building blocks with the addition of defined activities for improving the quality assurance cycle. These activities are assigned to the three phases of the quality assurance cycle: planning,

implementing and sustaining quality assurance for point-of-care testing. Although depicted as a cycle, some of the activities can take place in parallel. For example, developing policies may take significant time for clearance and should not prevent the implementation of quality improvement activities.

Most countries have already begun implementing a quality assurance programme for point-of-care testing, such as setting up proficiency testing programmes; however, each country is unique in how it develops quality programmes for point-of-care testing. Regardless of the stage of quality assurance implementation of each country programme, all countries should begin at phase 1 in the quality assurance cycle to plan, implement and sustain quality assurance and quality improvement for point-of-care testing.

Fig. 2. Quality assurance cycle: a continuous quality assurance and improvement process

Phase 1: Planning quality assurance for HIV-related point-of-care testing

1. Engage leadership
2. Establish the national coordination team for the quality assurance of point-of-care testing
3. Define roles and responsibilities
4. Develop or review policies and incorporate quality assurance into the national plan
5. Define standards for the quality of point-of-care testing
6. Conduct situation analysis
7. Develop and implement the plan
8. Plan financial and human resources
9. Select and assess sites
10. Select products

Phase 3: Evaluate, improve and sustain quality assurance for HIV-related point-of-care testing

1. Post-market surveillance
2. Use monitoring data for decision-making
3. Advocacy and communication of best practices
4. Encourage social entrepreneurship and public-private partnerships
5. Increase country ownership
6. Operational research

Phase 2: Implement quality assurance for HIV-related point-of-care testing

1. Improve training and ensure that all point-of-care testers are certified
2. Strengthen and innovate the documentation related to quality assurance
3. Implement quality assurance process control
4. Strengthen the supply chain for quality assurance
5. Supervise and certify the sites

Plan · Define · Implement · Monitor · Evaluate · Improve

Quality assurance cycle

Ensuring accurate results

PHASE 1: PLANNING QUALITY ASSURANCE ACTIVITIES FOR HIV-RELATED POINT-OF-CARE TESTING

It is vital that all HIV-related testing programmes revise and strengthen their HIV programme plan given the evidence of misdiagnosis and errors and the need for strengthening quality assurance. To ensure success, impact and sustainability and to enable a systematic scale-up of a comprehensive quality management system, the planning phase should include all levels of the health system. Phase 1 involves engaging leadership from national HIV programmes to drive the quality agenda and define standards, policies, priorities, resources needed and roles and responsibilities for supporting quality assurance and quality improvement efforts.

Various settings may currently be operating in different phases of point-of-care testing programmes. Whether a site has already implemented point-of-care testing or whether a site may be considering point-of-care testing, the guidelines presented in this handbook can be considered and amended to meet the current needs. This handbook can also serve as a tool for process improvement for sites in which point-of-care testing has been previously initiated. Familiarization with local existing programmes can be a valuable resource for new point-of-care testing sites.

Engage leadership

A strong commitment from the health ministry and partners is essential for successfully reinvigorating and strengthening the overall national quality assurance programme. A significant ramp-up and resource contribution is likely to be required in many cases, and strong leadership and advocacy is therefore crucial. The health ministry, including national laboratory leaders with appropriate government authority, should engage leadership to ensure buy-in at the highest level for the quality assurance programme. National laboratory leaders will need to provide strong leadership to advocate for resources and motivate laboratory and programme managers throughout the quality assurance process. The leadership of the programmes for care and treatment, preventing the mother-to-child transmission of HIV, maternal, newborn and child health, sexually transmitted infections and TB, national regulatory authorities and professional regulatory bodies also need to be engaged. Other stakeholders, partners and collaborators, such as private health centres, local universities and nongovernmental organizations (NGOs) could be included to participate in this process to offer input and buy-in, where appropriate.

Establish the national coordination team for quality assurance of point-of-care testing

Although some countries may have a strong quality assurance and point-of-care testing coordination team in place, countries without such a coordination group should consider establishing such a body for systematic planning and implementation. A multisectoral body identified by leadership as a national quality assurance coordinating team or technical working group for quality assurance in point-of-care testing should be formed to provide leadership and direction for the increased quality assurance activities, including planning for and defining quality (phase 1), implementing new quality improvement activities (such as certifying testing sites and enhanced supervision of human resources) and strengthening existing quality assurance activities that require improvement such as training and external quality assessment (phase 2) and continuous quality improvement in a sustainable manner (phase 3), such as collecting and using quality assurance data for accurate patient results.

If not already in place, national or regional quality assurance managers should be appointed; they will be responsible for coordinating the multisectoral team overseeing the quality assurance process at the national and regional levels. The quality assurance managers should have expertise in point-of-care testing procedures and quality assurance.

The multisectoral team should include individuals with expertise in laboratory services, supply chain, HIV programme management (HIV testing and counselling, providers of services for preventing the mother-to-child transmission of HIV and care and treatment providers), quality improvement and monitoring and evaluation. The team may also include other nongovernmental partners at the health ministry's discretion. As needed, community leaders may be involved to assist in identifying informal testing points, which would be missed in the situational analysis without the support of community leaders. Various country settings may be organized slightly differently; however, care should be taken to ensure that all aspects of quality assurance are addressed and made accountable to the appropriate team members. It is an opportunity to review the membership and terms of reference of existing quality assurance and point-of-care testing or other related and overlapping technical working groups to ensure that optimal configurations and outcomes are achievable.

Define roles and responsibilities

Defining roles and responsibilities is an integral component of the planning process to make the implementation process efficient and successful. Assuring the quality of point-of-care testing requires planning, oversight, coordination and implementation of quality assurance measures at all levels of the health system. Table 1 the summarizes roles and responsibilities for assuring quality in point-of-care testing at each level of the health system. If the roles and responsibilities for quality assurance are already clearly defined, it is crucial for the responsible technical working group to review and revise the roles and responsibilities to incorporate new activities described in this handbook.

Table 1. Roles and responsibilities of key stakeholders

Entity	Roles and responsibilities
Health ministry	Establish a national office of quality assurance or quality management
	Appoint national or regional quality managers
	Develop and review a point-of-care testing quality assurance policy or incorporate it into existing related policies, such as laboratory policy or HIV testing
	Form and engage a national quality assurance coordination team
	Allocate resources for quality assurance, including a group of quality officers to perform proficiency testing, logbook distribution, data collection, direct observation and on-site assessment
	Formulate requirements for the use of point-of-care testing with high standards that include comprehensive training and certification of testers and sites
	Establish or strengthen a network of testers and test sites that encompasses all the tiers of point-of-care testing
National reference laboratories	Engage in the national quality assurance coordination team
	Develop quality assurance work plans and the testing network
	Coordinate all training, certification and supervision of sites and personnel
	Validate the relevant HIV-related point-of-care testing assays and platforms
	Develop testing algorithms
	Develop standard operating procedures, job aids, training materials and checklists
	Develop a strategy for post-marketing surveillance
	Provide technical advice to the health ministry
	Coordinate all quality assurance activities, including proficiency testing programmes and follow up with timely corrective action
	Central hub for data collection for the quality assurance of point-of-care testing
Programme managers	Implement quality improvement activities
	Training and supervision of quality assurance activities at the site level
	Prepare sites for certification
	Monitor and evaluate data to assess the implementation of quality assurance and quality improvement
	Pilot innovations including: connectivity, electronic transfer of quality control data
Regulatory bodies	Clearly define and communicate regulatory requirements
	Support countries in getting high-quality test kits for point-of-care testing in a more timely fashion
	Respond to field safety notices and provide assistance for post-marketing surveillance
Nongovernmental partners	Support country policies and plans
	Lobby for accurate and reliable results that include quality assurance
	Implement country quality assurance and quality improvement activities
	Assist in enforcing standards
	Train and supervise quality assurance activities at the site level
	Support sites for certification
	Pilot new innovations and technologies, including new point-of-care testing, connectivity innovations and electronic quality control logs

Develop or review policies and incorporate quality assurance into the national plan

Developing a national policy for quality assurance of point-of-care testing is a critical first step to ensure national commitment for successfully using point-of-care testing for increased access and accurate results. The technical working group or coordination team should identify and review current policies that address quality assurance for point-of-care testing. Engagement with leadership to update policies and national plans is critical. A framework for policies for point-of-care testing and quality management procedures is currently being developed that may be used to shape a revised or new point-of-care testing quality assurance policy. Countries may consider incorporating essential elements of this framework into existing laboratory policies, as appropriate for their country setting. The process of developing and approving a policy can be slow and should not prevent progress in implementing the new quality improvement and quality assurance activities described in this handbook.

Define standards for quality for point-of-care testing

Defining and setting the standards for quality is important and will inform expectations for quality for a given point-of-care test. If the standards are already in place, they should reviewed and revised as needed for successful implementation as described in phase 2. Standards should also be considered for different types of point-of-care testing such as rapid diagnostic testing and point-of-care CD4 testing. Critical elements that should have standards set for each point-of-care testing technology include training and certification requirements, supervision, process control (quality control, external quality assessment, proficiency testing and standard operating procedures), documentation and activities for strengthening quality assurance. Poor communication, lack of adequate training or oversight and lack of dissemination of standards, guidelines and tools can result in limited understanding of quality standards. The authorities at the national level are responsible for defining the minimum standards for quality assurance for providers of point-of-care testing. Quality standards and goals are end points towards which the national HIV programme will direct its efforts and resources to assure the quality of point-of-care testing. These should be defined within the implementation plan described in phase 2 and regularly reviewed.

Analyse the situation

This may be the first tasks of the technical working group: to review point-of-care testing currently in use, the justification and need for new point-of-care testing devices, current training and quality assurance practices to ensure accuracy and provide evidence for gaps and need for improvement. It is also critical for countries to regularly assess data to identify whether problems such as misclassification exist in current point-of-care testing programmes. Regardless of the situation of country programmes with quality assurance, complete assessment is important to identify major gaps and considerations that may influence the quality of HIV-related point-of-care testing. This assessment should include both a centralized desk review of policies, guidelines and strategic plans, enquiries with various stakeholders as well as data collected from the site level, which can be achieved using site assessment, using site selection and product selection tools

and checklists, described below. (Annex 3 provides an example of a country situation analysis for CD4 testing.) The following items should be addressed:

- policies for point-of-care testing and quality management procedures;

- the current status of existing quality assurance related to HIV rapid testing and other point-of-care testing in use in the country;

- mapping the coverage and impact of each of the quality assurance elements: (1) training, (2) certification, (3) supportive supervision that focuses on specific point-of-care testing procedures, (4) a proficiency testing programme, (5) quality control, (6) standardized data registers for quality assurance review (such as a logbook), (7) collecting and analysing quality control data, (8) the integrity of the supply chain and the frequency and severity of stock-outs, (9) corrective action and (10) how the quality assurance process influences overall quality improvement;

- the mapping will be specific to each testing technology (HIV rapid diagnostic testing, CD4, viral load and early infant diagnosis) and geared to identify gaps;

- for introducing new point-of-care testing, understanding the local gaps in terms of testing coverage and needs for point-of-care testing in the context of disease prevalence and access to services;

- understanding existing regulatory frameworks, supply chain management systems and laboratory and point-of-care testing networks, including at the zone, regional, district and facility levels;

- costs (both up-front and recurring costs) related to supplies, training, implementation (such as logistics and maintenance) and quality assurance play a major role in selecting point-of-care tests;

- site selection and successful linkage to care and treatment, including considering the need to provide clinical care at the site of testing or to refer patients for care and treatment;

- an analysis of existing clinical and laboratory infrastructure, including facility requirements, staff availability, certification and training programmes for initiating point-of-care testing;

- assessing the supply chain management of test kits and reagents before implementation;

- quality assurance elements are often implemented selectively based on convenience and other factors, but all quality assurance elements are critical to ensure that testing has been performed properly and that test results are reliable, accurate and delivered to clients in a timely manner; and

- plans to develop the documentation of quality assurance performance and how each of the quality assurance elements influence monitoring and improving the quality of testing.

Develop and implement a plan

These new recommendations should be incorporated into existing plans addressing quality assurance, point-of-care testing, HIV testing and/or laboratory testing. If needed, a new plan may need to be developed. The following are key considerations for reviewing or creating a quality assurance point-of-care testing plan.

Gradually scale up comprehensive quality assurance

The national quality assurance coordinating team should meet to discuss and develop implementation plans for comprehensive quality assurance for point-of-care testing devices, both existing and new ones, in a stepwise manner and keeping in mind that quality assurance is not complete unless the quality assurance cycle is completed; that is, quality assurance efforts are being measured and data is evaluated and used for quality improvement purposes. Large number of testing sites (such as rapid testing sites) may make it difficult to have total coverage at once, but a deliberate and systematic approach that targets sites requiring improvement is essential while aiming to cover all sites gradually.

Setting priorities for implementing quality assurance (which quality assurance elements and where)

Knowing where to start can be challenging, and a site may not incorporate all elements at once. The available resources for quality assurance and the sheer magnitude of the quality improvement work may require setting priorities for the quality assurance elements at the sites with the highest patient impact. The national quality assurance coordinating team should work with stakeholders to develop annual goals so that they are well understood and embraced by everyone at each level of the health system. Setting priorities helps to direct resources towards the issues that need it the most. The following criteria, although not all-inclusive, can be helpful to the quality assurance coordinating team in setting priorities for annual goals for improving point-of-care testing:

- throughput: the number of people receiving the results of point-of-care testing;

- impact: the effects on people's health if they do not receive correct results (such as incorrectly being or not being put on antiretroviral therapy, stigma, morbidity and mortality);

- quality assurance cycle: completing the quality assurance cycle to show improvement in the accuracy of testing; and

- feasibility: can something be done about this problem with the resources available?

Develop a detailed action plan

Information from the situation assessment and quality assurance measures already in place can be used to assess the quality of point-of-care testing. Data from these sources should be used to develop a detailed action plan that:

- identifies the problems (comprehensive list of all issues);

- sets priorities among the problems (based on the criteria noted above);

- defines the problem to be addressed and the goal or target of improvement efforts;

- defines the indicators for monitoring and evaluating solutions to overcome the problem;

- defines what activities will be implemented to address the problem, who is responsible and the timeline for completing action steps; and

- identifies what resources are needed.

Plan financial and human resources

Quality assurance activities are integral components of testing and essential to ensure accurate and reliable results. The cost of implementing quality assurance should therefore not be viewed as an unnecessary and additional cost of testing. Without proper planning of the costs of quality assurance, many efforts will fall short of targets and the quality of testing will be compromised. This handbook calls for quality assurance–specific costs that should be planned for in upcoming funding proposals, including concept notes for the Global Fund to Fight AIDS, Tuberculosis and Malaria and funding for the United States President's Emergency Plan for AIDS Relief (PEPFAR) and, importantly, in annual activity budgets within the health ministry. Achieving the suggested level of quality assurance improvement defined within this handbook requires significant financial commitment and planning. The costs of inaccurate test results at the individual level and at the programme levels are enormous because of the large volume of testing in programmes. The gain in the reliability and accuracy of test results by strengthening quality assurance should therefore more than offset the cost incurred. The feasibility and cost–effectiveness of scaling up point-of-care testing sites, including the need for additional quality officers, should be taken into account, especially given limited available resources. The following additional factors need to be considered as financial plans are being developed for quality assurance for point-of-care testing:

- trained personnel needed to assist with quality assurance activities, including a quality corps;

- travel for activities related to quality assurance;

- training and refresher training;

- strengthening logistics systems;

- strengthening data capture systems and personnel;

- monitoring and evaluating programmes;

- checklist and certification of the stepwise process for improving the quality of HIV-related point-of-care testing;

- activities for improving quality assurance that include corrective action; and

- piloting and scaling up the use of electronic data capture and connectivity.

Annex 4 provides a costing tool, and Annex 5 provides a human resources model for quality assurance.

Select and assess sites

The quality of testing, in part, depends on the correct location of testing technologies to maximize benefit. Inappropriate placement of point-of-care testing can lead to many compromises in the quality of testing, including inadequate human resources, lack of infrastructure, inadequate use of the technology and inventory management issues.

A coordinated approach to selecting sites is needed, using a clearly defined method for assessing needs and reviewing sites. Most countries that will use this handbook already have an extensive number of sites that use point-of-care testing. It is therefore important to reassess the site selection and to develop a sound method to ensure that testing sites are appropriate and can adequately support the quality assurance of point-of-care testing. Several organizations have developed criteria tools for selecting sites for point-of-care testing. Such tools are valuable if they are adapted for the country setting and the test type in question and are used uniformly. A site selection tool developed by the Clinton Health Access Initiative for CD4 point-of-care testing is available *(15)*.

This tool requires planners to enter the site-level information such as numbers of patients, distance (or time) from the nearest testing hub and the type of on-site CD4 machine at each site, if any.

A selection tool should assess both essential minimum requirements for a site to conduct high-quality point-of-care testing as well as criteria for assessing and setting priorities among sites. The health ministry and partners, assisted by technical working groups in point-of-care testing, must develop a method of selection to assess proposed and existing point-of-care testing sites for suitability. During the planning phase, before implementing point-of-care testing, proposed sites must be mapped out and assessed as outlined above. If existing point-of-care testing sites are found not to meet a defined minimum requirement, measures must be put in place to improve the site or to relocate testing to a more appropriate site.

Essential minimum requirements

Rapid diagnostic tests and non-equipment-based point-of-care testing

The minimum requirements are:

- sites with adequate staffing resources to incorporate testing into the clinic workflow;

- sites with at least the minimum infrastructure available:

  ° bench space;

  ° private testing and counselling space for patients;

  ° adequate lighting for interpreting results;

  ° climate control: adequate temperature-controlled storage space (for test kits and consumables; testing and storage area should not exceed 30°C (check specifications on test kits); and reduce or eliminate dust;

  ° provisions for safe biohazardous waste disposal; and

  ° provisions for hand washing and personal protective equipment;

- sites are serviced by the logistics required for point-of-care testing consumables, quality control samples and reporting; and

- availability of care and treatment at site or linkage and referral network in place.

Equipment-based CD4, early infant diagnosis and viral load point-of-care testing

The minimum requirements should include all the elements listed above for rapid diagnostic tests and non-equipment-based point-of-care testing plus the following:

- connectivity of site by phone, fax, SMS printer, Internet etc. with central laboratory for quality control, data capture and communication for supervision;

- reliable electricity supply (if required by the platform) and provision of surge protection, uninterrupted power supply devices and backup power;

- infrastructure requirements – instrument footprint and ancillary equipment;

- some tests require refrigeration of test kits, and reliable refrigeration at the site must therefore be available; and

- capacity for centrifugation for some close to point-of-care tests that may require plasma separation or sample preparation steps.

The criteria for assessing and setting priorities for new point-of-care testing sites are:

- sites that are located within areas with a high prevalence of HIV infection;

- sites that experience delays due to batch testing, resulting in long turnaround time;

- sites with high rates of loss to follow-up because of referring samples to laboratories for testing;

- sites that require a rapid result, such as HIV testing and counselling sites and antenatal clinics;

- sites that are able to initiate and sustain antiretroviral therapy; and

- sites that can implement critical quality assurance elements for a given type of point-of-care test for accurate and reliable testing.

Select products

Together with the process of selecting sites described above, sites should also be equipped with a point-of-care testing product that is appropriate for the setting. For sites that already have point-of-care testing in place, it is important to carry out country-level assessment to ensure that a robust method has been used. If not, this should be carried out retrospectively to ensure the quality of testing; for any new technologies, assessment should be carried out prospectively as outlined in this section. The choice of a high-quality point-of-care testing product is a key first step in planning quality assurance for point-of-care testing. The product selection should consider both performance characteristics as well as operational characteristics to ensure that the product is suitable for the setting of use and is considered in an integrated approach to a point-of-care testing menu. The operational and programmatic characteristics of each point-of-care testing product must be considered within the context of the existing or planned testing network, human resources and infrastructure. In some programmes, combining different testing platforms (both point-of-care and laboratory based) may be optimal to best suit different settings. Each platform and specimen type should be validated to ensure high-quality results for its intended use. The compatibility or availability of appropriate quality assurance materials (quality control specimens and a proficiency testing programme) may further guide product selection as well.

Performance characteristics

The performance characteristics of a potential testing platform include predefined performance metrics using the intended specimens and include sensitivity, specificity, precision and accuracy around defined thresholds, positive and negative predictive values and lower and upper limits of detection.

To accurately assess the performance characteristics of candidate point-of-care testing products, country programmes should refer to independent, high-quality, published and unpublished peer-reviewed data from WHO or other independent groups evaluated in a laboratory. Field evaluation data from multiple countries, ideally within the same region, may further provide additional support about product selection in the context of in-country use. Extensive in-country evaluation is not necessary in every setting, unless significant data are not available. Implementers should also consider the status of regulatory approval for the candidate diagnostics as outlined below.

Operational characteristics

Operational and programmatic variables should be evaluated in selecting and implementing point-of-care testing, including:

- specimen requirements;

- human resource requirements;

- training requirements;

- infrastructure requirements – power supply, climate control, dust, instrument footprint, ancillary equipment, additional rooms for extraction and amplification and health facility tier;

- quality assurance – use with existing external quality assurance services, internal controls and quality controls;

- logistics – cold-chain requirements (refrigeration versus freezing), storage requirements and shelf life;

- technical support – availability in country or region, especially for automated systems: training, maintenance, service, warranty and help desk;

- ease of use – number of steps, automation, protocol, job aids, workflow, cross-contamination risk, barcoding system and maintenance and cleaning required;

- safety and waste – biohazard risk (closed or open system), solid and liquid waste;

- data management – connectivity, backup and storage, results reporting, laboratory information management system;

- durability – lifespan, planned obsolescence and company experience and track record;

- polyvalence (utility for other purposes) – early infant diagnosis, TB, hepatitis, gonorrhoea, human papillomavirus, chlamydia, outbreak surveillance, etc.; and

- costs, including set-up cost: equipment and infrastructure changes; and recurring costs: test commodities, additional consumables, controls, quality assurance material, maintenance contracts and staff time (Annex 4).

Product selection tools and guidance documents

Several organizations have developed tools and guidance to assist countries in selecting high-quality products using a standardized tool for assessment. Product selection tools may be useful for countries in selecting high-quality and appropriate point-of-care testing products, and site selection can aid in ensuring the appropriate placement of products. The Clinton Health Access Initiative has developed a site and product selection tool *(15).*

Manufacturer technical support and maintenance

When potential candidates for implementing point-of-care testing are being assessed, it is important to ensure that ongoing manufacturer support is available and to assess the track record of the company in the region. Each candidate manufacturer should be assessed according to its available service capacity and contractual provisions regarding maintenance contracts, especially for equipment-based point-of-care testing. Further, many manufacturers have in-country representation, which may significantly facilitate the installation of equipment and the maintenance and supply of required controls and reagents. Some manufacturers may also have training materials and job aids that can facilitate the improvement of personnel competencies.

Approvals and regulation

National and international regulatory and supply chain management bodies have necessary roles in selecting point-of-care testing. Approval, registration and post-market surveillance are essential for implementing and procuring high-quality point-of-care testing products. Donor procurement policies, such as the policy implemented by the Global Fund to Fight AIDS, Tuberculosis and Malaria, recommend product selection based on WHO-prequalified products or products approved by regulatory authorities of the founding members of the Global Harmonization Task Force *(16)*. The European Conformity CE mark (List A, Annex II), Health Canada (Class IV), Australian Therapeutic Goods Administration (Class 4), Japanese Ministry of Health and Welfare (Minister's approval), United States Food and Drug Administration (PMA) clearance or approval and/ or WHO prequalification are the main criteria for eligibility of procurement.

Table 2. Phase 1: planning implementation for quality assurance related to point-of-care testing

Task	Who	What	How
Engage top-level leadership	National reference laboratories, programme managers	Ensure buy-in at the highest level	Organize informational meeting with health ministry Provide update about point-of-care testing quality assurance as per international and regional standards and ministerial declarations Seek resource commitment from health ministry
Form a national quality assurance coordinating team	Health ministry	The team oversees quality assurance for point-of-care testing Get multisectoral input Develop a consensus, high-impact approach	Identify experts and key people who can facilitate the quality assurance process Appoint a national quality assurance officer
Define roles and responsibilities	Health ministry and national reference laboratories, national quality assurance officer, national quality assurance coordinating team	Identify entities responsible for implementing the quality assurance process at all levels of the health system	Conduct situation analysis to determine what quality assurance efforts are currently being implemented and who is responsible for overseeing them Use information from situational analysis to identify what human resources are needed to implement quality assurance procedures and implementation plans identified by the national coordinating team (see situation analysis and developing the implementation plan below)
Develop policy	Health ministry and partners	Develop policy for quality assurance of point-of-care testing Include quality assurance for point-of-care testing in national plan	Review current policy and plan documents for laboratory quality and testing Develop policy and implement through training and dissemination
Define standards of quality	Health ministry and national reference laboratories, national quality assurance officer, national quality assurance coordinating team	Define minimum standards for the quality of point-of-care testing	Review manufacturers' performance specifications for each point-of-care test Review available quality assurance data to determine the performance level in the field Set goals and standards that point-of-care testing providers must attain
Conduct situation analysis of point-of-care testing and quality assurance	Health ministry, national reference laboratories, programme managers, partners	Systematic and gradual planning Existing point-of-care testing and associated quality assurance	Review current placement and coverage of point-of-care testing and quality assurance Identify gaps related to quality assurance What is required to fill in the gaps? Is the cycle being completed?

Table 2. (continued)

Task	Who	What	How
Develop a timeline to implement the plan	National reference laboratories, programme managers, partners	Develop an implementation plan	Develop a timeline for each step Forecast the needs (quality assurance tools as described further) Allocate responsibilities
Plan resources	Health ministry, national reference laboratories, programme managers	Identify resource needs, estimated costs and budgeting	Human resources Technical assistance Activities of the implementation plan
Assess and select sites	National reference laboratories, programme managers	Set priorities for the sites Develop a phased approach for quality assurance	Define criteria for priorities • Sites with highest impact: such as services for preventing the mother-to-child transmission of HIV • Linkage to care and treatment • Sites with certification • Remote sites to increase access
Select products	National reference laboratories, programme managers	Ensure that appropriately regulated products are selected	Use available tools to determine appropriate products by setting

PHASE 2: IMPLEMENTING QUALITY ASSURANCE FOR POINT-OF-CARE TESTING

Following systematic planning (phase 1), the next step is implementing quality assurance activities for selected point-of-care tests. The implementation of validated point-of-care testing technology should follow a logical approach, which includes (1) selecting and assessing sites, (2) training and certifying testing personnel and sites, (3) preparing quality assurance activities, including a proficiency testing programme and quality control specimens, (4) recruiting and training quality assurance officers and quality corps to assist in monitoring performance, (5) collecting and analysing data and (6) taking corrective action to improve the quality of testing. Training and certification are critical components of quality assurance programmes, and as such, activities to carry out these procedures should be clearly developed, documented and executed. The results of such activities form evidence on which sites can illustrate their improvements in quality processes. In addition, data analysis of test results by increased connectivity as well as external quality assessment should also be considered priorities within the quality assurance system. Although many countries are already training and certifying testers, run an external quality assessment (proficiency testing) programme and have implemented standardized data management tools (logbooks), these programmes have many weaknesses, especially related to data collection, analysis and corrective action. Strengthening the collection and analysis of quality assurance data and immediate follow-up are critical for improving the quality of testing.

New efforts are recommended to begin a site certification and stepwise improvement programme for all testing sites using the stepwise process for improving the quality of HIV-related point-of-care testing (Annexes 1 and 2) and upcoming quality improvement training modules that are central to this handbook. The gaps include (1) collecting, analysing and using quality assurance data (including data from external quality assessment) for timely corrective action and (2) retesting newly diagnosed individuals using a second specimen to rule out possible technical or clerical errors. More comprehensive approaches are therefore recommended to be adopted to ensure more regular on-site supervision, mentoring and assessment of sites. The need to ramp up supervision and visitation activities requires the availability of a cadre of quality officers to carry out this responsibility.

Improve training and ensure certification of all point-of-care testers

Well standardized hands-on training, certification and ongoing supervision are crucial in ensuring the quality of a point-of-care testing programme. Lack of training, certification and supervision are major reasons for poor test results. Classroom or on-site training for point-of-care testing is often too short and does not cover comprehensive quality assurance content. Although point-of-care tests are considered simple to perform, implementing point-of-care testing in a quality-assured manner requires understanding and training beyond the steps required to carry out the test.

Activities for developing and implementing a training and supervision plan include developing training curricula for trainers, supervisors and testers that should be standardized by the health ministry and their partners through the technical working group on point-of-care testing during the planning phase before implementing point-of-care testing. The training package should incorporate the following: (1) the basics of technology and familiarity with point-of-care testing, (2) hands-on training with a known panel of specimens, (3) the frequency and appropriate use of quality control specimens as part of the routine testing, (4) a proficiency testing programme (external quality assessment) that will be rolled out as part of the monitoring process, (5) a standardized data management tool and how to use it, (6) troubleshooting in case of unexpected results and (7) written and practical examinations that include blinded testing of a panel of unknown specimens requiring the participants to use quality control specimens, a data management tool and reporting as part of the training. The certification criteria should be based on high standards and should result in a network of certified professionals who can maintain and enhance competence through interaction among network members and other experts. Annex 6 provides more details on training, including a link to a training package for HIV rapid testing.

Training of trainers

Training plans should provide for training staff members who will be directly responsible for conducting training sessions (training of trainers). When they complete training, master trainers should demonstrate competence by passing practical and written examinations. Regular re-training and competence assessment should be implemented to ensure that trainers maintain proper qualifications.

Training of testers

Experience in some countries suggests that initial training programmes for point-of-care testing can be conducted over 2–5 days, depending on the previous education and training of those being trained. Further, training should be available for management staff, who may not be performing the testing but need information about how the tests are conducted and how they will work in their setting. Much of the training should be devoted to hands-on training that also incorporates all quality assurance elements, and competence should be assessed before awarding certification. Annex 6 has a guide to training content and assessment as well as an online reference to training curriculum.

Site supervision and site certification

With the rapid expansion of both HIV rapid diagnostic testing sites (some countries with several thousand) and, more recently, point-of-care CD4 sites, many countries face a situation with inadequate engagement of sites, leaving testers without an adequate support, lack of external quality assessment and/or poor follow-up for corrective action, resulting in suboptimal performance. This handbook urges countries to implement much more robust and comprehensive supervision programmes established at the national level to penetrate throughout the entire network of testers. A new group of devoted quality officers is recommended that are placed or identified within the testing network or community and can conduct much more regular site supervision to perform external quality assessment, mentoring, assessment for certification, data collection and to provide a vital link in logistics. In the planning for scaling up quality assurance for point-of-care testing, the health ministry should ensure that adequate numbers of quality officers and funds are available to service the supervisory needs of point-of-care testing sites. In addition, partners can play an active role in regular site supervision to ensure coverage and impact through the leadership of the health ministry. The costs of supervision models for quality assurance programmes for point-of-care testing should be considered and planned appropriately. Annex 5 provides a model of the human resources that would be required in a model setting.

Supervisory visits should take place at least every 3–6 months at every testing site, and quality officers should be trained and certified by regional and/or national laboratories before carrying out supervisory duties. Supervisory visits should use a standardized checklist to assess sites and testers (see the example in Annex 7). Activities should include observing tester performance while testing the proficiency testing panel and patient testing, and assessing the documentation, testing environment and logistics. The on-site visits can also be used to identify training needs, provide important refresher training and collect testing data (such as for rapid testing and page totals from the registers). Data should be collected at centralized hubs (such as district laboratories) and sent to the central level (regional or national) for analysis, corrective action and programme improvement.

All testing sites should also be subject to regular assessment for certification as determined by health ministry policy. Annexes 1 and 2 provide the two recommended checklists for the stepwise process for improving the quality of HIV-related point-of-care testing: rapid diagnostic testing and other point-of-care testing *(17–20)*. This is based on ISO 15189:2012, ISO 22870:2006, the College of American Pathology point-of-care checklist and the WHO Stepwise Laboratory Improvement Process Towards Accreditation checklist. The checklist provides a stepwise improvement process leading to certification. A point-of-care testing site that achieves a low score in specific area can be provided additional support to improve the score and staging of levels (levels 0 to 4). Based on the success of the Strengthening Laboratory Management towards Accreditation programme, training and improvement project modules for certifying point-of-care testing sites are currently being developed. A trained pool of qualified auditors is essential to roll out this tool. This handbook provides the framework for both the quality assurance and quality improvement activities that should be incorporated in training package and testing practices at the site level.

Implement quality assurance process control

Without adequate quality assurance process control, point-of-care testing would occur without any measures to assess the accuracy of testing procedure and test kit specifications. Quality assurance process control can ensure that test results are correct both to the tester at the site level on a day-to-day basis and also at the overall testing programme level. In the absence of any quality assurance process control measures, potential errors in procedure or test kits could continue undetected.

Quality-assured process control refers to activities that are carried out to ensure that the testing procedures are correctly performed, that the environment is suitable for reliable testing and that the test kit or diagnostic equipment works as expected to produce accurate and reliable results.

The three essential components for quality assurance process control emphasized here are:

• standard operating procedures and job aids (Annex 8)

• quality control

• external quality assessment.

Most country programmes are already carrying out and addressing all three aspects of process control. However, this handbook offers new and simpler recommendations for carrying out process control. New recommendations, specifically for external quality assessment, are presented below as well as new tools and recommendations for point-of-care CD4. The health ministry and partners should coordinate the development and planning of all quality-assured process control activities for point-of-care testing. The technical working group for point-of-care testing should develop and revise standard operating procedures and job aids during the planning phase and pilot these tools during the implementation phase, with revision carried out annually or as needed. The technical working group should plan for quality control specimens and develop proficiency testing programmes during the planning phase. Implementation should provide the planned level of quality assurance specimens to point-of-care testing sites following training. If quality control specimens and external quality assessment panels are produced within a country, the coordinating laboratories need to develop a clear plan for obtaining the samples. Table 4 outlines specific roles and responsibilities for carrying out quality assurance activities.

The significant efforts to establish quality control and proficiency testing programmes can be wasted if the results are not used in a timely fashion. Programme managers need to ensure the collection of all results for analysis, and reporting or corrective action needs to be coordinated at the central level. However, the task force of quality officers needs to carry out the distribution of samples and collection and follow-up of results and site visits for corrective action and supervision. These activities require regular close contact with testing sites and regular communication and follow-up. Without these arms of the programme, the quality assurance activities will not have the intended impact.

Standard operating procedures and job aids

Developing a set of standard operating procedures is key to a successful quality assurance programme. Standard operating procedures should provide detailed instructions on all aspects of the testing, including test requesting, environmental requirements, specimen collection and management, test performance, a stepwise process for conducting the test, quality control instructions, test interpretation, reporting and recording results, appropriate use of the testing algorithm, storage and inventory information and any internal and external quality assurance requirements. Written standard operating procedures should be available at each testing site for each test kit and should always be followed when conducting tests. Annex 8 includes examples of standard operating procedures for point-of-care testing. WHO and the United States Centers for Disease Control and Prevention will develop similar standard operating procedures for point-of-care viral load testing and early infant diagnosis as part of a package of tools for the quality management of point-of-care testing. These will be available on the WHO website starting in 2015.

Laminated pictorial charts showing a simplified version of the procedure steps (job aids) are extremely useful in everyday practice. Job aids simplify work instructions, outline summary steps to be taken during the test process and ensure quality, proper documentation and assist with troubleshooting. Job aids should be mounted on the wall in the testing area so that they are clearly visible to testing personnel performing the test. Annex 8 provides examples of job aids for point-of-care technologies.

Quality control

Quality control is an important means of verifying for the test user that the test kit and the procedures used are performing according to the manufacturer's intended specifications. Built-in internal quality controls, such as control lines on rapid diagnostic tests, usually do not check the entire testing process. These quality controls generally provide information about the adequacy of specimens and/or operational conditions and whether the testing device is working properly. Operators should be well trained on interpreting internal quality controls to ensure that the test results are valid.

Two broad types of quality control should be used as quality assurance measures when performing point-of-care testing: (1) built-in quality controls and (2) the use of quality control specimens. The results of quality control specimens should routinely be recorded and analysed to ensure the validity of the results.

Built-in quality controls

This type of quality control is built into the testing device, forming an intrinsic part of the testing process and usually requiring no additional input from the operator. A control line or spot on rapid diagnostic tests, for example, is part of the device and indicate whether the proper procedure was followed. In some cases, the appearance of a control line indicates that all steps were correctly followed, including addition of the blood sample (human immunoglobulin G). In others, the appearance of a control line is not a process control for all steps but indicates that liquid has reached

beyond the HIV line. Caution must therefore be exercised in interpreting the built-in control. In all cases, the absence of a control line or spot indicates invalid results, and the test should be repeated with a new sample. Currently, new technologies for image capture and interpreting the results for immunochromatographic test devices are being piloted that could provide an effective means of interpreting built-in internal controls and data capture for quality assurance. Equipment-based point-of-care CD4 test platforms may have test device internal controls and/or separate internal control beads (low and normal) available for purchase from the manufacturer and should be run in accordance with the manufacturer's instructions, usually at the start of each day. The results should be logged in the standardized logbook, and data stored on the device should be routinely analysed to assess the trend in internal quality controls.

Quality control specimens

Because of the limitations of built-in control, routinely using quality control specimens with known status or level of biomarker is an important quality assurance measure, if feasible. Currently, quality control specimens are not widely used at all testing sites because of the logistical difficulties. However, this should be considered as an additional and key step in ensuring the quality of results. Well characterized bulk volume specimens can be acquired from blood banks or other sources and prepared as quality control for distribution, especially as dried tube specimens for rapid diagnostic testing *(21).* Quality control specimens can be prepared in large quantity for early infant diagnosis (dried blood spot) and viral load (dried tube specimens) using inactivated spiked virus *(22).* Quality control specimens for point-of-care CD4 can be prepared using fixative but may require more frequent preparation. If quality control specimens are implemented, the following provides guidance on their use, with further details in Annex 9.

Quality control specimens are used to evaluate the accuracy of the test and to check whether the person doing the test performs it correctly. Quality control specimens must be tested periodically to assure that the test system is performing properly. The regularity must be determined by programme managers and must be uniform across a programme. An example of the regularity for running quality control (for HIV rapid diagnostic testing) may be:

- daily before starting to test patient specimens;

- once a week, preferably at the beginning of the week;

- when a new operator (or a trained staff member who has not done testing consistently) is performing testing;

- when using a new test kit with a new lot or batch number;

- whenever a new shipment of test kits or controls is received; and

- if rapid test kits or controls are exposed to environmental conditions that fall outside the range needed for stability as defined by the manufacturer.

External quality assessment

External quality assessment enables the performance of a testing site to be regularly evaluated by an external laboratory or national quality assurance programme. External quality assessment is designed to identify sites and testers needing assistance. External quality assessment can be conducted in multiple ways: (1) a proficiency testing programme, (2) retesting a subset of specimens or all positives by another qualified tester, facility or laboratory and (3) assessment through site visits. Proficiency testing programmes are the most common and required external quality assessment method for all certified or accredited laboratories. Many countries already have an external quality assessment programme (such as retesting people testing positive for confirmatory purposes and proficiency testing) in place for HIV rapid diagnostic testing and point-of-care CD4 testing, whereas other countries require further implementation. For countries that have not instituted external quality assessment efforts, including retesting newly diagnosed HIV-positive individuals and proficiency testing, it is imperative for programmes to implement these quality assurance measures to identify and prevent any misdiagnosis. Further, additional efforts must be made now to close the loop of external quality assessment programmes. Critical activities such as data collection, analysis and timely reporting of results to sites, followed by corrective action, are often lacking. The extensive resources deployed to send out external quality assessment panels can be lost if these critical follow-up steps are not in place. In addition, evidence indicates that external quality assessment results often mask problems in quality assurance at testing sites if assessment is carried out without appropriate supervision and mentoring on site. External quality assessment panels are therefore recommended to be used during each supervisory visit so that testing practice and environment can be assessed on site and appropriate training and mentoring is provided. Regardless of the stage of development of the external quality assessment programme, the updated guidance below is important for all countries since it outlines more simplified approaches.

Proficiency testing

At regular intervals (one to three times a year), panels of well characterized specimens should be distributed to all testing sites for blind testing. Participants test the specimens and return the results to the reference laboratory. The data are analysed, and information is provided back to the participating testing sites. External quality assessment panels can either be procured and, in some cases, obtained free of charge (see the list and more details on external quality assessment in Annex 9) or prepared in the country as part of a national external quality assessment programme. (Annex 10)

Retesting HIV-positive patients

For newly diagnosed individuals, a positive HIV test result should be confirmed by repeating the national HIV testing algorithm to rule out errors in the testing process *(9)*. Retesting newly diagnosed HIV-positive individuals before initiating antiretroviral therapy is good practice and should adhere to the following.

- A new specimen needs to be collected for retesting (a second venepuncture or finger prick) to rule out specimen mix-up or collection error.

- A second tester should conduct the retesting to rule out operator error.

- Retesting should be done in accordance with the national HIV testing algorithm.

- Retesting should be conducted at the point of antiretroviral therapy initiation, which may be at the same visit or site for HIV-positive women identified in programmes for preventing the mother-to-child transmission of HIV or may be at a separate visit or site for those who do not initiate antiretroviral therapy on the same day as testing.

- If retesting provides a HIV-negative result, the result is inconclusive.

- If inconclusive, HIV status can be resolved by further testing with Western blot or HIV-1/2 Multispot in a facility in which these complex but more specific tests can be conducted to confirm HIV status.

- Use of ELISA is not recommended to resolve inconclusive status. Although ELISA is very sensitive, it is not ideal for confirming HIV infection because of low specificity.

For individuals already receiving antiretroviral therapy, routine retesting is not recommended unless warranted on a case-by-case basis. The sensitivity of serological (rapid diagnostic testing and laboratory-based) and most virological tests can be reduced by exposure to antiretroviral therapy because of seroreversion and viral suppression, making these methods unreliable in confirming an HIV-positive diagnosis. Confirmation of HIV infection among those receiving antiretroviral therapy may require a testing algorithm that includes DNA polymerase chain reaction and will be dealt with separately in WHO guidance publications. Further evidence is required to determine the most suitable method for assessing the HIV status of people receiving antiretroviral therapy in resource-limited settings to ensure accurate retesting results.

Retesting for external quality assessment using dried blood spot specimens

Programmes are no longer recommended to use retesting as an external quality assessment measure on a proportion (such as 5–10%) of individuals (both positives and negatives) using dried blood spot specimens. Some countries have used dried blood spot retesting as a tool for monitoring laboratory or testing performance, but this has proven to be logistically challenging to sustain given the magnitude of HIV rapid testing in some countries and the sample size required to be statistically relevant. Most programmes fail to close the loop by returning retesting results to sites in a timely manner and are often unable to follow up with the individual, who may have received an incorrect diagnosis. Dried blood spot retesting for quality assurance purposes is therefore considered to be a low priority, and programmes are instead encouraged to focus on external quality assessment in the form of proficiency testing and retesting all people testing

positive before starting antiretroviral therapy. Limited retesting using dried blood spot specimens may be considered for the purpose of accrediting new sites and/or users.

Programmes must allocate resources at the national and regional levels to implement more comprehensive external quality assessment programmes that include routinely retesting all newly diagnosed HIV-positive individuals, proficiency testing, data collection, analysis, supervision and follow-up. External quality assessment programmes should be implemented in a stepwise fashion to ensure that scaling up is sustainable and includes the complete cycle, including analysing data, returning results, providing feedback to sites and corrective action when needed. An effective external quality assessment programme has to provide timely corrective action and is not useful if data are not collected and analysed in a timely manner or if sites are not provided with appropriate feedback, corrective measures and recognition of performance. Annex 10 provides tools to assist in developing national external quality assessment programmes.

Strengthen and innovate documentation related to quality assurance

Without accurate and complete documentation, analysis of data and reporting back to sites with corrective action, a point-of-care testing programme cannot be evaluated for its quality and performance. Many countries have implemented a standardized logbook system for HIV rapid diagnostic tests, but there are gaps in terms of how paper-based data within log sheets is used both at the site level and whether it can be used for quality assurance at a more central level. Programmes should be seeking innovative ways to ensure

that the data captured in logbooks for point-of-care testing can be analysed and used for early detection of quality assurance issues. Using a paper-based system means that good supervision is required to capture data and feed them back to a central level for analysis. Although this is the only current option for HIV rapid diagnostic tests, this handbook urges programmes to shift towards electronic methods of logging testing data at sites such as electronic logbooks linked to a laboratory information management system and phone-based test readers that can capture results and send them to a central site for analysis. Equipment-based point-of-care testing (CD4, viral load and early infant diagnosis) has a great advantage in data capture with the availability of connectivity, which offers a huge advantage for quality assurance of testing and also for logistics purposes.

Documents and records should be developed and reviewed annually at the national level with input from programme and laboratory managers from all levels of the health care system and distributed widely to assure the conformity and accuracy of key data collected for monitoring the quality of testing programmes. Documents and records must be up to date, accurate, readily accessible to authorized users and maintained securely. When possible, electronic versions should be available to improve connectivity, data sharing and analysis for point-of-care testing.

Personnel records on training, competency evaluation should be kept. All incidents (including safety-related and other errors) and any corrective action taken should also be recorded.

The documents and records shown in Table 3 should be used at the testing sites to ensure the quality of point-of-care testing.

Table 3. Documentation required for quality assurance

Document or record name	Purpose	Means of verification	Frequency of verification
Standardized logbook with page total summary, quality control and proficiency testing recorded (Annex 11)	Central document for accurate quality-assured recordkeeping and identifying quality problems	Supervisory visits and corrective action	Monthly or more often for rapid diagnostic testing and other point-of-care testing
Test reporting forms (Annex 12)	Test usage for procurement, national data on test coverage	Sent to centralized hub for monitoring and evaluation	Monthly
External quality assessment results form (Annex 9)	Assessment of test performance, testing personnel proficiency	Sent to centralized hub for analysis and reporting back to site	1–3 times a year (depending on the proficiency testing scheme)

Data connectivity

Equipment-based CD4, viral load and early infant diagnosis point-of-care testing provide an excellent opportunity for quality assurance through the storage, transmission and use of data. Most point-of-care testing instruments on the market and in the pipeline have built-in wireless connection capabilities, which is an extremely useful tool in remotely monitoring point-of-care testing. National policy should have a provision prescribing the inclusion of point-of-care testing sites into a wireless network. Coordination of data analysis by national reference laboratories or by regional quality officers at hubs is an important component of equipment-based quality assurance and should be exploited for point-of-care testing wherever possible. Partners should support pilots and assist with setting up electronic data recording and logbooks and rapid diagnostic testing reading devices such as those being developed for smartphones to enable connectivity of data in real time between testing sites and central hubs, where data should be analysed and corrective action administered through supervision by networks of quality assurance officers. For community-based testing, laptops or tablets could be used to log patient data in standardized formats.

Point-of-care connectivity can be used for:
• real-time data for tracking gradual or acute deviations in internal controls (Levy-Jennings plots);
• post-market surveillance;
• supply chain and logistics, remote monitoring of the use of reagents and surveillance of the level of reagent stock;
• retrieving and capturing proficiency testing results;
• determining error rates and types;
• determining usage and equipment downtime; and
• determining user profiles and the effectiveness of training and certification.

Annex 13 presents an example of a site performance report generated by a reference laboratory through equipment-based point-of-care CD4 data.

Strengthen the supply chain for quality assurance

The quality of point-of-care testing depends strongly on reliable availability of test kits and consumables at testing facilities. With the rapid increase in the roll-out of point-of-care testing to increasingly rural and remote testing sites, a large burden has been placed on already weak logistics systems to ensure that commodities for testing can now reach further field sites. Many testing sites performing HIV testing using two rapid diagnostic tests may run out of one test, and in an attempt to provide testing to clients, use only one test, use an expired test or use an alternative, unvalidated test, which can lead to testing errors and should be avoided.

It is vital that the health ministry and their partners focus on strengthening the supply chain and logistics to ensure that high-quality test kits and consumables are available to testing sites and that stock-outs are minimized.

The health ministry is a key hub for organizing logistics and supply chain coordination, devising and overseeing strategic planning, to ensure that policies and plans are implemented accordingly. Programme managers need to ensure inventory control at the site level.

Table 4 describes the necessary steps to ensure that quality assurance systems have been implemented and that desired outputs are obtained.

Table 4. Key roles and responsibilities to ensure that quality assurance is implemented

Task	Who	What	How
Quality-assured training and certification	Donors	Support the development of training materials	Funding of technical working group and technical assistance to develop and produce high-quality training tools
		Support training and certification of point-of-care testing	Funding for training activities
	Health ministry and partners	Develop and approve training materials	Through point-of-care testing working group and technical assistance using tools developed by other organizations and manufacturers as a starting-point
		Coordinate the training of sites in a phased approach	Assess what country-specific changes need to be made
			Develop train-the-trainer programmes
		Coordinate the supervision of sites	Set assessment and proficiency criteria for certification and site accreditation
			Coordinate an annual plan for training and execute the plan
			Collect data from training for monitoring and evaluation
			Develop and execute supervisory plan with appropriate human resources dedicated for point-of-care testing
	Programme managers	Assist in developing training materials	Programme managers should be part of the technical working group for point-of-care testing and contribute to developing training materials
		Deliver training to sites	As appropriate, become certified as a trainer and deliver training
			Develop a checklist for certifying trainees (Annex 6)

Table 4. (continued)

Task	Who	What	How
Site supervision and certification	Donors	Support staff positions and site supervision	Funding of human resources (quality officers) for regular supervisory visits to all testing sites
	Health ministry and partners	Develop method and plan for assessing point-of-care sites	Coordinate supervisory site visits
			Train and certify quality officers (reference laboratories)
		Analyse findings from assessments	Collate data centrally from assessments
			Coordinate accreditation of all point-of-care testing sites (Annex 1)
		Provide certification and guidance on improvements	Work with programme managers to provide quality improvement activities (modules pending)
			Develop summary report and disseminate
			Use data for monitoring and evaluation purposes
			Provide feedback to sites
			Consider combining site certification visits with external quality assessment panel distribution and site supervision
	Programme managers	Ensure that sites are ready for certification and implement quality improvement activities	Use rapid diagnostic testing and point-of-care testing checklists for all sites currently performing or planned for point-of-care testing
			Ensure that sites receive feedback and follow-up for corrective action
Quality-assured process control	Donors	Support the development of a testing network for quality assurance activities	Funding for a comprehensive network of human resources to support and coordinate quality control and external quality assessment sample preparation, distribution and results analysis and reporting
			Support pilots and innovations for data connectivity and electronic logbooks
			Funding for strengthening logistics information systems
	Health ministry and partners	Develop standard operating procedures and job aids	Through a technical working group and technical assistance, standard operating procedures should be written and approved for dissemination at training and reviewed annually
		Develop, map and resource defined network of quality assurance for point-of-care testing	Establish what level of quality assurance will be used and develop a national plan for quality assurance for point-of-care testing
		Develop internal quality and proficiency testing panel preparation at reference laboratories	Plan the human resources needed including a network of quality assurance personnel that can develop quality assurance materials at accredited labs or procure externally
		Develop central coordination of the results of quality assurance activities	Support and coordinate a human resources network for quality assurance to support the distribution of quality assurance materials and the collation of data for reporting results to sites
	Programme managers	Implement quality assurance activities at site levels	Coordinate quality assurance activities at sites
			Ensure that the most up-to-date version control of standard operating procedures and job aids are available at sites
			Regular supervision of documentation practices for quality assurance, mentoring and improvement
			Support for timely reporting of results, documentation and receipt of quality control and external quality assessment samples
			Feedback and liaise with coordinating laboratory and quality officers on areas that require improvement
			Ensure that corrective action is implemented

Table 4. (continued)

Task	Who	What	How
Documentation for quality assurance	Donors	Support the development of documentation	Funding for technical assistance and training of documentation and connectivity
			Support pilots and scaling up of electronic logbooks
	Health ministry and partners	Develop standardized logbook and report forms for point-of-care testing	Through the technical working group on point-of-care testing and technical assistance, coordinate a standardized logbook and report form and approve and disseminate it for training and use
			Support piloting and scaling up of electronic standardized logbooks, connectivity and the use of logbook data for quality assurance and logistics at a central level
	Programme managers	Implement standardized logbook and report forms	Ensure that the logbook and report forms are available and that all staff members are trained how to correctly use them. Supervise use and take corrective action appropriately
			Support pilots of electronic logbooks and connectivity innovations
Strengthening logistics for quality assurance	Donors	Support activities for strengthening logistics	Funding for increasing human resources for logistics
			Funding for strengthening logistics information systems
			Funding support for electronic logbooks to capture usage data at a central level for logistics
			Funding for improved infrastructure in storage facilities and warehouses and transport network extension
	Health ministry and partners	Assess the current logistics for sites doing point-of-care testing	Carry out situation analysis to assess the current strengths and weaknesses in the logistics system
		Develop and implement a new logistics plan for point-of-care testing	Develop plan to strengthen logistics for delivering point-of-care commodities to all point-of-care sites
			Implement improvements to logistics, including logistics information system and strengthened human resources
			Incorporate point-of-care test commodities into a national procurement plan
			Ensure the use of a standard operating procedure for the procurement and logistics of testing commodities
			Implement electronic consumption monitoring to improve the forecasting and planning of supply procurement
			Strengthen logistics management information system
	Programme managers	Train and supervise site-level staff on inventory management	Ensure that all staff members are trained and carrying out inventory management and reporting and correct any weaknesses in inventory management such as stock-outs
			Implement site consumption monitoring to improve the forecasting and planning of supply procurement
			Monitoring usage of consumables and test kits

PHASE 3: EVALUATING, IMPROVING AND SUSTAINING QUALITY ASSURANCE

The quality assurance of HIV-related point-of-care testing must be sustained for the long term and kept flexible so that new technologies and standards can be readily accommodated. To this end, stakeholders benefit from collaboration to develop monitoring and evaluation tools geared towards measuring and ensuring sustainability at every level and during all phases of the quality assurance cycle.

Post-market surveillance

A post-market surveillance system should be developed to ensure the ongoing compliance of diagnostics with quality and regulatory requirements. This should include proactive steps such as following the protocol for lot verification testing (Annex 14) as well as reactive reporting (such as field safety notices and notifications to or from manufacturers and regulatory authorities) for the notification and evaluation of vigilance events, enabling national regulatory authorities to take appropriate action *(23,24).*

Use monitoring data for evaluation and decision-making

Indicators that monitor HIV-related point-of-care testing must be chosen to reflect long-term implementation activities. The selected indicators should be easy to collect and supported by procedures for data collection, handling, analysis and use in reporting. Realistic benchmarks will enable successful strategies to be determined over the long term and will enable the comprehensive evaluation and subsequent implementation of improvement measures.

Developing a comprehensive monitoring and evaluation programme will require long-term resources (human and financial) to support ongoing assessment. In Malawi and the United Republic of Tanzania, HIV testing and counselling registers have been revised to incorporate key quality indicators for HIV testing (Annex 15 has examples of monitoring and evaluation indicators). WHO provides more detailed information about monitoring and evaluation programmes more generally *(25).*

Monitoring and evaluation

The attainment of goals must be evaluated through the appraisal and comparison of indicators, reports, data and country objectives. Stakeholders, including health ministries, programme managers, partners and donors, will measure national-level indicators, review monitoring and evaluation reports and implementation plans and compare data to predefined indicators (examples provided in Annex 15) to identify goals that are fulfilled and unfulfilled and determine the reasons for incomplete or non-achievement of goals.

Advocacy and communication of best practices

Stakeholders must communicate feedback to programme implementers, site-level trainers and end users regarding current progress and areas needing improvement. Major gains have been made in advocacy for quality-assured testing. However, a restructured approach is essential to realize needed financial and non-financial resources and expand understanding, particularly at the community level. Existing structures must be used to bring HIV-related point-of-care testing quality to the community. Non-monetary incentives are essential to motivate the network of testers and encourage pride in the high-quality work in which they are involved. Achieving greater advocacy requires strengthening partnership with regional organizations and highlighting and communicating the successes on the national and international stages.

Encourage social entrepreneurship and public–private partnerships

Social entrepreneurs draw on business and not-for-profit methods in pursuing innovative solutions to social issues. Social entrepreneurship provides an opportunity for private enterprises, faith-based organizations and academic institutions to develop innovative solutions to sustaining HIV-related point-of-care testing quality throughout the health system. Social enterprise networks (comprising both for-profit and non-for-profit entities) are important, since they create strength and solidarity, produce market opportunities and increase partnership opportunities to develop a business-based model for motivating the implementation of quality testing throughout the health system *(26).*

By creating new organizational and financial models for point-of-care testing, social entrepreneurship may be applied in a couple of ways within the context of sustaining the quality of HIV-related point-of-care testing *(24).* First, local private entities and academic institutions have the opportunity to participate in proposals to expand high-quality testing services. Second, expanding HIV-related point-of-care testing increases opportunities for small businesses supplying products or services at the community level.

The success of the quality of HIV-related point-of-care testing rests on the community of volunteers, many of whom are willing to provide services in kind or with minor reimbursement. It is critical to stimulate the desire for quality testing from the ground up by raising awareness in the community and educating patients and clients to demand quality services and products from certified testers and providers.

Traditional approaches to quality assessment programmes, such as blinded rechecking, external quality assessment and site visits, have met limited success in sustaining the quality of HIV-related point-of-care testing. To maximize the numbers of individuals invested in ensuring high-quality testing, innovative approaches such as the creation of a quality corps network of volunteers (community-based quality champions) could therefore improve the likelihood of programme sustainability. The quality corps fellows are identified from the community

(such as new graduates) and trained on specific tasks of the quality assurance cycle. For example, the quality corps can facilitate completion of the cycle by distributing proficiency test panels to sites or testers, on-site supervision of sites performing proficiency testing, collecting proficiency testing results, returning the proficiency testing results to participating sites after analysis and providing corrective action when necessary. They are paid for their transport and expenses when recruited temporarily to cover a proficiency testing round or specific quality assurance activities. The establishment of this new type of worker within the country should be coordinated with the health ministry, and the national reference laboratory can provide a low-cost solution for the human resources needed to accomplish the job.

Increase country ownership

Country ownership is critical to achieving the required scale up of HIV-related point-of-care testing, increasing national investment in quality testing and attaining integration with national health goals and systems *(27)*. Importantly, country ownership extends beyond government and throughout the community. Civil society stakeholders must be educated and empowered to demand high-quality HIV-related point-of-care testing through the support of local service and product providers.

Implementers of quality assurance programmes for HIV-related point-of-care testing should collect data on the resource requirements that inform the planning process at the health ministry and at the donor level. Although catalyst funding streams from donors are common ways to initiate programmes such as quality assurance for point-of-care testing, a commitment and stepwise plan to absorb this costing into the health ministry or finance ministry must be made and carried out to ensure ownership and sustainability.

Operational research

As new point-of-care technologies emerge, it is important for country programmes to stay abreast of developments and implement a robust evaluation programme. Reviewing existing validation data available through peer-reviewed publications or shared by agencies such as the United States Centers for Disease Control and Prevention and WHO is critical to minimizing the need to perform in-country evaluation where existing data can fill this gap.

An operational research unit should be established at the central public health laboratory or national reference laboratory for reviewing existing evaluation data for new technologies and, where appropriate, conducting necessary in-country validation.

Table 5. Key activities and responsibilities for sustaining quality assurance

Task	Who	What	How
Evaluate monitoring data for decision-making	Health ministry and national reference laboratories, monitoring and evaluation and quality assurance officer	Monitor at the national level	Measure the national-level indicators defined in phases 1 and 2
			Review monitoring and evaluation reports from programme managers and partners
			Compare data with the indicators defined in the implementation plan
			Convene a technical working group to identify strengths (best practices) and gaps (areas for improvement)
	Programme managers and partners	Monitor site-level indicators	Compile and review reports from sites
			Compare data with the indicators defined in the implementation plan
			Convene a technical working group to identify strengths (best practices) and gaps (areas for improvement)
	Donors	Monitor grantee-level indicators	Review reports from the national level
			Compare data with the indicators defined in the implementation plan
			Convene a technical working group to identify strengths (best practices) and gaps (areas for improvement)
	Health ministry, partners, programme managers	Monitor the progress of the implementation plan	Review the objectives of the implementation plan and assess the progress to date
Communicate the best practices and lessons learned	Health ministry, partners, donors	Provide feedback on progress and areas requiring improvement	Communicate feedback to implementers, trainers and end users (such as testing providers) on areas needing improvement
	Health ministry, programme managers and partners	Sharing best practices and lessons learned	Generate a dashboard where data can be reviewed
			Compile best practices from national monitoring and evaluation reports
			Hold stakeholder meetings
			Publicize at national and international meetings and in journals
	All	Advocate for quality as a core component of policies and plans	Communicate the importance of the quality of HIV-related point-of-care testing to donors and international agencies

Table 5. (continued)

Task	Who	What	How
Scale up and sustain	Health ministry	Create an enabling environment for innovative programmes	Support the inclusion of social entrepreneurship programmes in national policies and plans
			Encourage internal capacity-building and leveraging of internal resources by universities, local NGOs, faith-based organizations and private entities
	National reference laboratories	Support innovation by expanding scope	Expand the network of stakeholders to include local universities, local NGOs, faith-based organizations and private entities
			Drive collaboration, pool resources and join forces to respond to proposals
	Donors	Create a structure under which social entrepreneurship can flourish	Encourage the inclusion of social entrepreneurship programmes on requests of proposals
			Provide grading criteria incentives in reviews of proposals
	Programme managers	Implement quality of HIV-related point-of-care testing through a tiered system	Implement programmes such as quality corps and volunteers by providing training and supervision and reporting to the health ministry
			Create a network of testers at each level
	Partners	Expand the implementation of the quality of HIV-related point-of-care testing at the community level	Encourage social entrepreneurship (build internal capacity and leverage internal resources) by engaging local universities, local NGOs, faith-based organizations and private entities
			Build internal capacity and leverage internal resources by engaging local universities, local NGOs, faith-based organizations and private entities
	Health ministry, programme managers, implementers	Mobilize and empower the community	Work to create programmatic leadership such as quality assurance champions
	Donors	Country ownership	Mandate, in grant proposal submissions, the quality of HIV-related point-of-care testing as part of the national strategic plan
			Require countries to include the quality of HIV-related point-of-care testing in responses to requests for proposals and in country work plans
			Include the quality of HIV-related point-of-care testing as a separate and strong component of programme plans, training in obtaining research grants and monitoring and evaluation
	Donors	Support quality assurance programming at the health ministry level	Mandate, in grant proposal submissions, the quality of HIV-related point-of-care testing as part of the national strategic plan
			Require countries to include the quality of HIV-related point-of-care testing in responses to requests for proposals and in country work plans
			Include the quality of HIV-related point-of-care testing as a separate and strong component of programme plans, training in obtaining research grants and monitoring and evaluation
Close the quality assurance cycle	Stakeholders	Ensure communication and feedback across all involved	Allocate resources
			Provide feedback and ensure that it is adequately addressed in policy and plan updates
			Follow national strategic policies and plans

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Annex 1. Checklist for the stepwise process for improving the quality of HIV rapid testing (Version 3.0)

Part A. Characteristics of the facility or testing point audited

Before you complete the checklist, it is important to characterize the testing point to be audited. Please provide relevant information in the summary table below.

Date of audit (dd/mm/yyyy):

Testing facility name:

Testing point name:

Audit round number:

Testing facility ID (if applicable)

Type of testing point (circle one)

Voluntary testing and counselling or HIV testing and counselling

Provider-initiated testing and counselling

Services for preventing mother-to-child transmission

TB clinic

Laboratory

Treatment centre

Other (please specify):

Location or address:

Level (circle one and specify name)

Region, province or zone:

District:

Referral centre:

Health centre:

Dispensary:

Health post:

Other (please specify to reflect the country context):

Affiliation (circle one)

Government

Private

Faith-based organization

Nongovernmental organization

Other

Number of testers:

Average number tested per month:

Name of the auditor 1:

Name of the auditor 2:

Part B. Checklist

For each of the sections listed below, please check "yes", "partial" or "no", where applicable. Indicate "yes" only when all elements are satisfactorily present. Provide comments for each "partial" or "no" response. State "not applicable" in the comments section for those marked with an asterisk (*) or where otherwise appropriate..

Section		Yes	Partial	No	Comments	Score
1.0 Personnel training and certification						**10**
1.1	Have all testers received comprehensive training on HIV rapid testing using the nationally approved curriculum?					
1.2	Are the testers trained on using standardized HIV testing registers or logbooks?					
1.3	Are the testers trained on external quality assessment or the proficiency testing process?					
1.4	Are the testers trained on the quality control process?					
1.5	Are the testers trained on safety and waste management procedures and practices?					
1.6	Have all testers received refresher training within the past two years?					
1.7	Are there records indicating that all testers have demonstrated competence in HIV rapid testing before testing client?					
1.8	Have all testers been certified through a national certification programme?					
1.9	Are only certified testers allowed to perform HIV testing?					
1.10	Are all testers required to be recertified periodically (such as every two years)?					
Personnel training and certification score						
2.0 Physical facility						**5**
2.1	Is there a designated area for HIV testing?					
2.2	Is the testing area clean and organized for HIV rapid testing?					
2.3	Is sufficient lighting available in the designated testing area?					
2.4	Are the test kits kept in a temperature-controlled environment based on the manufacturers' instructions?					
2.5	Is there sufficient and secure storage space for test kits and other consumables?					
Physical facility score						
3.0 Safety						**11**
3.1	Are standard operating procedures and/or job aids in place to implement safety practices?					
3.2	Are standard operating procedures and/or job aids in place on how to dispose of infectious and non-infectious waste?					
3.3	Are standard operating procedures and/or job aids in place to manage spills of blood and other body fluids?					
3.4	Are there standard operating procedures and/or job aids in place to address accidental exposure to potentially infectious body fluids through a needle-stick injury, splash or other sharps injury?					
3.5	Is personal protective equipment always available to the testers?					
3.6	Do all testers consistently use personal protective equipment?					
3.7	Do all testers properly use personal protective equipment throughout the testing process?					
3.8	Are clean water and soap available for hand washing?					

Section		Yes	Partial	No	Comments	Score
3.9	Is an appropriate disinfectant available to clean the work area and equipment?					
3.10	Are sharps and infectious and non-infectious waste handled properly?					
3.11	Are containers for infectious and non-infectious waste emptied regularly in accordance with the standard operating procedures and/or job aids?					
Safety score						

4.0 Pre-testing phase — 12

Section		Yes	Partial	No	Comments	Score
4.1	Are national testing guidelines specific to the programme (such as on HIV testing services, preventing the mother-to-child transmission of HIV or TB) available at the testing point?					
4.2	Is the national HIV testing algorithm being used?					
4.3	Is there a process in place for an alternative HIV testing algorithm in case of expired test kits or shortages?					
4.4	Are standard operating procedures and/or job aids in place for each HIV rapid test used in the testing algorithm?					
4.5	Are only nationally approved HIV rapid testing kits available for use currently?					
4.6	Are all the test kits in use within the expiration date currently?					
4.7	Are test kits labelled with the date received and initials?					
4.8	Is a process in place for managing stocks?					
4.9	Are job aids on client sample collection available and posted at the testing point?					
4.10	Are sufficient supplies available for collecting client samples?					
4.11	Are there national guidelines describing how client identification should be recorded in the HIV testing register?					
4.12	Are client identifiers recorded in the HIV testing register in accordance with national guidelines and on test devices?					
Pre-testing phase score						

5.0 Testing phase — 9

Section		Yes	Partial	No	Comments	Score
5.1	Are job aids on HIV testing procedures available and posted at the testing site?					
5.2	Are timers available and used routinely for HIV rapid testing?					
5.3	Are sample collection devices (such as capillary tubes, loops and disposable pipettes) used accurately?					
5.4	Are testing procedures adequately followed?					
5.5	Are positive and negative quality control specimens routinely used (such as daily or weekly) in accordance with country guidelines?					
5.6	Are quality control results properly recorded?					
5.7	Are incorrect or invalid quality control results properly recorded?					
5.8	Are appropriate steps taken and documented when quality control results are incorrect and/or invalid?					
5.9	Does the person in charge routinely review quality control records?					
Testing phase score						

6.0 Post-testing phase – documents and records — 9

Section		Yes	Partial	No	Comments	Score
6.1	Is there a national standardized HIV rapid testing register or logbook available and in use?					

Section		Yes	Partial	No	Comments	Score
6.2	Does the HIV testing register or logbook include all the key quality elements?					
6.3	Are all the elements in the register or logbook recorded or captured correctly (such as client demographics, kit names, lot numbers, expiration dates, tester name and individual and final HIV results)?					
6.4	Is the total summary at the end of each page of the register or logbooks completed accurately?					
6.5	Are invalid test results recorded in the register or logbook?					
6.6	Are invalid tests repeated and the results properly recorded in the register or logbook?					
6.7	Are all client documents and records securely kept throughout all phases of the testing process?					
6.8	Are all registers or logbooks and other documents kept in a secure location when not in use?					
6.9	Are registers or logbooks properly labelled and archived when full?					
Post-testing phase – documents and records score						

7.0 External quality audit (proficiency testing, supervision and retesting)   8/14

7.1	Is the testing point enrolled in an external quality audit or proficiency testing programme?					
7.2	Do all testers at the testing point test the external quality audit or proficiency testing samples?					
7.3	Does the person in charge at the testing point review the external quality audit or proficiency testing results before submitting them to the national reference laboratory or designee?					
7.4	Is an external quality audit or proficiency testing report received from the national reference laboratory and reviewed by testers and/ or the person in charge at the testing point?					
7.5	Does the testing point implement corrective action in case of unsatisfactory results?					
7.6	Does the testing point receive periodic supervisory visits?					
7.7	Is feedback provided during supervisory visits and documented?					
7.8	If testers need to be retrained, are they being retrained during the supervisory visit?					

If the country external quality auditing programme includes retesting of serum or dried blood spots, proceed with questions 7.9–7.14. Otherwise, stop here.

7.9*	Does the site collect samples for retesting according to country guidelines (such as collecting every 20th client serum or dried blood spot sample)?					
7.10*	Are the serum or dried blood spot samples collected for retesting properly documented?					
7.11*	Are serum or dried blood spot samples collected properly (such as at least three complete circles or correct volume and correct tubes, etc.)?					
7.12*	Are serum or dried blood spot samples stored properly (such as away from sunlight, separated by glassine paper, desiccant or at 4°C or 20°C)?					
7.13*	Are the identifiers of serum or dried blood spot samples sent for retesting properly recorded?					
7.14*	Are the serum or dried blood spot results received from the referral laboratory properly documented and recorded in the HIV testing register or logbook?					
External quality audit (proficiency testing, supervision and retesting) score						

*Those marked with an asterisk are only applicable to sites at which sample retesting is performed.

Part C. Scoring criteria

Each element marked is assigned a point value.

Items marked "yes" receive 1 point each.

Items marked "partial" receive 0.5 points each.

Items marked "no" receive 0 points each.

The total points scored for each section should be tallied and recorded at the end of the section.

The overall total points obtained by each HIV testing point audited will be weighed to correspond to a specific performance level.

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

Part D. Auditor's summary report for assessing the stepwise process for improving the quality of HIV rapid testing

Facility name:
Site type:
Staff audited name:
Number of testers:
Duration of audit:
Total points scored (exclude N/A) = a
Total score expected = b
% score = (a/b) x 100

Section no.	Deficiency or issue observed	Corrective action		Auditor's comments	Recommendations	
		Immediate	Follow-up		Action	Timeline or person responsible

Staff audited: name and signature:
Person in charge: name and signature:
Auditor: name and signature:
Date (dd/mm/yyyys):

Annex 2. Checklist for the stepwise process for improving the quality of HIV-related point-of-care testing: instrument-based point-of-care testing (Version 2.0)

Level (specify all appropriate names)	Affiliation (circle one)
Region or province:	Government
District:	Private
Referral centre:	Faith-based organization
Health centre:	Nongovernmental organization
Dispensary:	Other:
Health post:	
Other:	

Name of point-of-care testing facility or site:
Location or address of point-of-care testing facility or site:
Location of point-of-care testing service:
Point-of-care tests offered (list all):
Supervisor or point of contact of the point-of-care testing facility or site:
Name of the auditor:

Signature of the auditor:	Date of the audit:

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

For each of the sections listed below, please check "yes", "partial" or "no", where applicable. Indicate "yes" only when all elements are satisfactorily present. Provide comments for each "partial" or "no" response. State "not applicable" in the comments section for those marked with an asterisk (*) or where otherwise appropriate.

Section	Yes	Partial	No	Comments	Score

1.0 Integration of point-of-care testing services for patient care — Score: **6**

Point-of-care testing services should be offered so that the results are interpreted and used to support the care of people living with HIV, in accordance with national, subnational or facility guidelines, policy and regulations

1.1	Does the facility or site have a testing algorithm or guidelines for using point-of-care testing results for patient care?					
1.2	Does the testing algorithm or guidelines specify on which patients point-of-care testing should be performed and when?					
1.3	Does the testing algorithm or guidelines include steps for interpreting the results?					
1.4	Does the testing algorithm or guidelines specify when to provide results to the patient for medical review?					
1.5	Is there a plan or policy for an alternative algorithm or testing facility in case the point-of-care testing facility or site is unable to provide point-of-care testing? (stock-outs, expired reagents, equipment failures, etc.)					
1.6	Are the testing algorithm or guidelines current? Have they been reviewed and/or approved within the last two years?					

2.0 Personnel training, competence and certification — Score: **9***

Point-of-care testing services should be offered so that the results are interpreted and used to support the care of people living with HIV, in accordance with national, subnational or facility guidelines, policy and regulations

2.1	Does the point-of-care testing facility or site have a policy specifying which types of health workers may perform point-of-care testing?					
2.2	Does the point-of-care testing facility or site have a policy specifying the qualifications of the point-of-care testing personnel?					
2.3	Have all point-of-care testing personnel received training on collecting and processing specimens for each point-of-care test? Has the training been documented?					
2.4	Have all point-of-care testing personnel received training on the point-of-care testing procedure? Has the training been documented?					
2.5	Have all point-of-care testing personnel received training on recording and interpreting the results? Has the training been documented?					
2.6	Have all point-of-care testing personnel received training on quality control testing and interpreting quality control results? External quality assessment and proficiency testing? Has the training been documented?					
2.7	Does the point-of-care testing facility or site have documentation to ensure that all point-of-care testing personnel annually maintain a satisfactory level of competence?					
2.8	For assessing competence, does the direct observation of routine test performance, include, as applicable, identifying and preparing patients, collecting and processing specimens, testing procedures and recording results?					
2.9	For assessing competence, is the performance of point-of-care testing personnel reviewed: reporting and interpreting results, quality control testing, external quality assessment results and/or equipment maintenance?					
2.10	*If available, are all point-of-care testing personnel certified to perform each specific point-of-care test?					

Section		Yes	Partial	No	Comments	Score
3.0 Physical facilities **The point-of-care testing facility or site should be adequate to provide safe and effective point-of-care testing services.**						**5**
3.1	Are there designated areas for point-of-care testing?					
3.2	Are the designated point-of-care testing areas clean and organized for point-of-care testing?					
3.3	Does each designated area have adequate space, lighting and environmental control to perform point-of-care testing?					
3.4	Is there sufficient and secure storage for point-of-care testing reagents, supplies and equipment?					
3.5	Is there environmental monitoring of temperatures for the point-of-care testing area and reagent storage?					
4.0 Safety **The point-of-care testing facility or site should have an organization and processes in place providing for the safety of staff members, patients and the community.**						**6**
4.1	Does the point-of-care testing facility or site have documented procedures for handling and disposing of biohazardous material?					
4.2	Does the point-of-care testing facility or site have documented procedures and/or policies for safety in the workplace?					
4.3	Are standard operating procedures and/or job aids in place to manage spills of blood and other body fluids?					
4.4	Are all point-of-care testing personnel trained in handling biohazardous material, workplace safety and managing spills? Is this training documented?					
4.5	Is personnel protective equipment always available? Gloves or other personnel protective equipment, as appropriate, must be available.					
4.6	Are biohazardous waste and sharps containers available and appropriately labelled?					
5.0 Pre-testing phase **The point-of-care testing facility or site should have a standardized system for handling and identifying patients, collecting and processing specimens and recording information on patients and specimens.**						**6**
5.1	Are standard operating procedures and/or job aids available for handling and identifying patients?					
5.2	Are standard operating procedures and/or job aids available for collecting and processing specimens, including specimen storage conditions?					
5.3	Are standard operating procedures and/or job aids available for recording patients and specimens? Including specimen identification?					
5.4	Are standardized forms, registers, logbooks or electronic files available for recording information on patients and specimens?					
5.5	Are all standardized forms, registers, logbooks or electronic files complete and legible?					
5.6	Are pre-testing procedures being adequately followed, including safety practices and disposal of biohazardous waste? (direct observation)					
6.0 Testing phase **The point-of-care testing facility or site should have a standardized system to perform point-of-care testing, including quality control testing and troubleshooting guides**						**5**
6.1	Are standard operating procedures and/or job aids available for the point-of-care testing procedures?					

Section		Yes	Partial	No	Comments	Score
6.2	Do the standard operating procedures and/or job aids for testing specify how each sample is identified during the testing procedure and linked to the patient or specimen?					
6.3	Do the standard operating procedures and/or job aids for testing specify when and how to perform quality control testing?					
6.4	Do the standard operating procedures and or job aids include the interpretation of patient results and troubleshooting sets for failed or invalid results?					
6.5	Are testing procedures adequately followed (direct observation)?					

7.0 Post-testing phase
The point-of-care testing facility or site should have a standardized system for point-of-care testing results to be recorded and reported and include a system for recording quality control results **5**

Section		Yes	Partial	No	Comments	Score
7.1	Are standard operating procedures and/or job aids available for recording and reporting point-of-care testing results?					
7.2	Are standardized forms, registers, logbooks or electronic files available for recording patient and quality control results for point-of-care testing?					
7.3	Are all standardized forms, registers, logbooks or electronic files for recording point-of-care testing results complete and legible?					
7.4	Are standard operating procedures and/or job aids available for recording the quality control results for point-of-care testing? Are the quality control results recorded?					
7.5	Are all standardized forms, registers, logbooks or electronic files properly labelled and kept in a secure location?					

8.0 Supplies, reagents and equipment
The point-of-care testing facility or site should have adequate and reliable stocks of supplies and reagents and functioning equipment and instruments. **5/8***

Section		Yes	Partial	No	Comments	Score
8.1	Are supplies available and in date for collecting specimens? (lancets, gauze, alcohol swabs, plasters, tubes, etc.)					
8.2	Are point-of-care testing reagents and supplies available and in date?					
8.3	Are all supplies and reagents for point-of-care testing and collecting specimens stored as recommended by the manufacturer?					
8.4	Are all supplies and reagents for point-of-care testing and specimen collection inventoried monthly?					
8.5	Are there procedures and/or policies for ordering and receiving supplies and reagents?					
8.6*	Are all equipment and instruments functioning?					
8.7*	Are there standard operating procedures and job aids available for maintaining equipment and instruments, including troubleshooting steps and procedures?					
8.8*	Are routine maintenance and troubleshooting or repairs for equipment and instruments documented?					

9.0 Monitoring quality
The point-of-care testing facility should have a quality monitoring system to ensure accurate and reliable results of point-of-care testing. **6**

Section		Yes	Partial	No	Comments	Score
9.1	Does a site supervisor or external monitor regularly review all point-of-care testing results? Does this review included the completeness and timing of patient result reporting, error or invalid test rates, interruption in testing and the performance of individual point-of-care testing personnel?					

Section		Yes	Partial	No	Comments	Score
9.2	Does the point-of-care testing facility or site verify the quality control results for acceptability before reporting results?					
9.3	Does a site supervisor or external monitor regularly review quality control results?					
9.4	Is the point-of-care testing facility or site enrolled in an external quality assessment or proficiency testing programme?					
9.5	Does the point-of-care testing facility or site report external quality assessment or proficiency testing results to the programme provider within the set time frame?					
9.6	Has a feedback report on external quality assessment or proficiency testing been received and reviewed? Does the point-of-care testing facility or site implement corrective action in case of unsatisfactory results?					

Auditor's summary report for assessing the stepwise process for improving the quality of HIV-related point-of-care testing: instrument-based point-of-care testing

Point-of-care testing facility or site name:

Audit date:

Total scored (a)=

Point-of-care tests offered:

Length of audit:

Total possible score (b)=

Number of point-of-care testing personnel:

% score (a/b)=

Section no.	Score	Possible score (exclude "not applicable" responses)	Auditor's comments	Recommendations
1. Integration of point-of-care testing service for patient care		6		
2. Personnel training, competence and certification		9 - 10		
3. Physical facilities		5		
4. Safety		6		
5. Pre-testing phase		6		
6. Testing phase		5		
7. Post-testing phase		5		
8. Supplies, reagents and equipment		5 - 8		
9. Quality monitoring		6		

Auditor's summary report for assessing the stepwise process for improving the quality of HIV-related point-of-care testing: instrument-based point-of-care testing

Additional auditor's comments	Recommendations

Auditor's summary report for assessing the stepwise process for improving the quality of HIV-related point-of-care testing: instrument-based point-of-care testing

Name and signature of the site supervisor

_____

Date

Name and signature of the auditor:

_____

Date

Sources:

Stepwise Laboratory Improvement Process towards Accreditation (SLIPTA) checklist. Brazzaville: WHO Regional Office for Africa; 2012.

Laboratory general checklist, CAP Accreditation Program. Northfield, IL: College of American Pathologists; 2012.

Point-of-care-testing checklist, CAP Accreditation Program. Northfield, IL: College of American Pathologists; 2011.

Medical laboratories – ISO 15189: particular requirements for quality and competence. 3rd edition. Geneva: International Organization for Standardization; 2012.

ISO 22870:2006: Point-of-care testing (POCT) – requirements for quality and competence. Geneva: International Organization for Standardization; 2006

Audit checklist. Pretoria: South African National Accreditation System; 2012 (SANAS, F 209-01).

Clinical laboratory improvement amendments (CLIA). Atlanta: United States Centers for Disease Control and Prevention. Laboratory Science, Policy and Practice Programme Office; 2014 (http://www.cdc.gov/osels/lspppo/CLIA.html).

Clinical laboratory improvement amendments (CLIA). Washington (DC): United States Centers for Medicare and Medicaid Services; 2014 (http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html).

Quality management: approaches to reducing errors at the point of care. Approved guideline. Wayne, PA: Clinical and Laboratory Standards Institute; 2010 (CLSI document POCT07-A).

Annex 3. Country example of situation analysis for point-of-care testing

Ministry of Health and Social Welfare
of Republic of Tanzania
National AIDS Control Programme
CD4 assessment report

April 2014

Introduction

The HIV Care and Treatment programme in the United Republic of Tanzania was started in 2004. The services have since been scaled up in both public and private health facilities, with the number of care and treatment centres currently at 1156 by the end of 2012 from 96 in 2005. However, early initiation of treatment is still a challenge. The national guidelines recommend the use of CD4 testing to determine the eligibility of initiating treatment. Approximately 60% of the care and treatment centres have access to on-site CD4 testing, with 250 conventional platforms and 450 point-of-care devices.

Despite the country having 60% access to on-site CD4 testing, there are challenges in access to CD4 testing in lower-level health facilities, where there is a lack of diagnostic equipment as well as the infrastructure to support sample transport. Consequently, patients who get an HIV test take a long time to get a CD4 test and to initiate treatment if found eligible. The Ministry of Health and Social Welfare through the National AIDS Control Programme in collaboration with the Clinton Health Access Initiative aims to improve access and timely initiation on to care and treatment through increasing access to CD4 testing through point-of-care testing. To determine access to CD4 counts through point-of-care testing, a CD4 assessment was done with aim of knowing the status of CD4 testing in the country. The results from the assessment will be used to correctly guide the country on product and site selection of new point-of-care CD4 tests and to improve CD4 testing, including reallocating Alere Pima® point-of-care devices in the country to suitable sites for Pima point-of-care testing.

Method

The National AIDS Control Programme, in collaboration with the Clinton Health Access Initiative and regional and council health management teams, conducted an extensive CD4 assessment between August and September 2013. In the assessment, 320 antiretroviral therapy facilities were visited in 25 regions of the United Republic of Tanzania. Of 320, 230 were point-of-care sites, 25 conventional sites and 65 sites with neither point-of-care nor conventional equipment. The CD4 landscape was mapped for all antiretroviral therapy sites in the country. The assessment consisted of both qualitative and quantitative interviews at health facilities with facility managers, laboratories, care and treatment centres and pharmacy staff members. The quantitative data were also collected from a number of sources (laboratory testing registers, care and treatment centre databases etc.).

Data analysis

The data were entered into Epi Info and Excel and analysed. The analysis covered:
- patients on care versus antiretroviral therapy in all facilities visited;

- level of health care workers trained on CD4 testing;
- computer availability for data management and the type of data management available at the site;
- Internet access and mobile network coverage;
- sample transport and challenges on logistics around sample transport, sample collection methods;
- distance between testing hub and the satellite sites and the turnaround time from sample collection to results received;
- conventional and point-of-care (Pima) equipment functional status, equipment downtime and the utilization of equipment on site;
- Pima error statistics;
- trained users on Pima operation;
- routine access to clinical chemistry and haematology tests to monitor toxicity; and
- external quality assessment participation and panel frequency.

Results

1. Clients enrolled in HIV care and treatment

The number of patients enrolled in care in the 320 facilities during the assessment period was 266 195, and of these, 185 824 (70%) were receiving antiretroviral therapy.

2. General equipment status

Of 320 care and treatment centre facilities visited, 46 facilities were conventional, 212 were Pima and 62 had none. This shows a slight difference from the baseline CD4 landscape used before the assessment, which showed that, of 320 facilities, 25 were conventional, 230 were Pima and 65 had none. This means that the conventional facilities have increased from 25 to 46, Pima has decreased from 230 to 212 and facilities with none decreased from 65 to 62.

3. Computer accessibility and data management

Of 320 care and treatment centre facilities visited, 67% had access to computers for data management and 62% of the available computers were functioning. The data managed on the computers were care and treatment centre data (61%), whereby the data clerk (57%) was tasked to enter data.

4. Internet and mobile coverage

All 320 care and treatment centre facilities visited during the assessment had stable mobile network coverage, with Airtel and Vodacom being most accessible in many facilities. Internet is accessible in only 26% of the facilities.

5. Sample referral system

A total of 105 (62 neither point-of-care nor conventional and 43 Pima) care and treatment centre facilities were referring CD4 samples to the high-level testing facilities. The average number of CD4 samples referred per week was 25. The sample transport systems adopted were mainly public transport and ambulance (71%) and motorbike (17%), with the Ministry of Health and Social

Welfare supporting 86% and partners supporting 14%. The average distance between referring and referral sites was 19 km, and the time to return the results from testing facilities was 1–6 days.

6. Conventional and Pima equipment status

Of the 46 conventional care and treatment centre facilities visited, 43 (93%) had functioning equipment. The average number of tests performed per month was 768, with an average of 1–2 days of turnaround time for delivering results to the patients who had on-site testing. Of the 212 Pima sites visited during the assessment, 210 (99%) had functioning Pima equipment. The average number of tests performed by the Pima equipment per month was 210. Based on a two-year warranty for Pima, 8 Pima devices were out of warranty during the period of this assessment. The most common reason for Pima downtime was lack of cartridges, accounting for 91% of all facilities visited being stocked out of cartridges at least once in the year.

7. Pima end user operation

Most health-care workers (87%) interviewed in Pima facilities said that operating the Pima equipment was easy.

8. Pima end user training

Of 212 Pima facilities assessed, 129 (61%) had staff members who got formal Pima end user training, mainly from the Ministry of Health and Social Welfare.

9. Pima errors

The most common Pima error received by facilities was end user error, which accounted for 79% of total errors. Fig. 1.1 shows the percentages of types of errors encountered within the facilities visited. Of 212 Pima facilities assessed, most sites (41%) indicated that they would appreciate receiving Pima error reports weekly, followed by 38% of facilities that suggested monthly. On modes of sending the error report, most facilities (67%) proposed using SMS alert as a mode of report feedback.

10. Drug toxicity tests

Drug toxicity tests that are offered in care and treatment centre facilities are chemistry and haematology tests. From the assessment, 132 facilities had on-site laboratory systems for monitoring drug toxicity. Table 1.1 summarizes the toxicity tests from 132 facilities.

Table 1.1. Summary of toxicity tests from 132 facilities

Type of test	Total tests	Test category	Total tests
Chemistry	33	Renal	32
		Liver	33
Haematology	99	Haemoglobin	71
		Folate-binding protein	28

11. External quality assurance

32 CD4 testing facilities participate in a CD4 external quality assurance programme of 258 facilities (212 Pima and 46 conventional).

Fig. 1.1. Types of Pima errors encountered by facilities
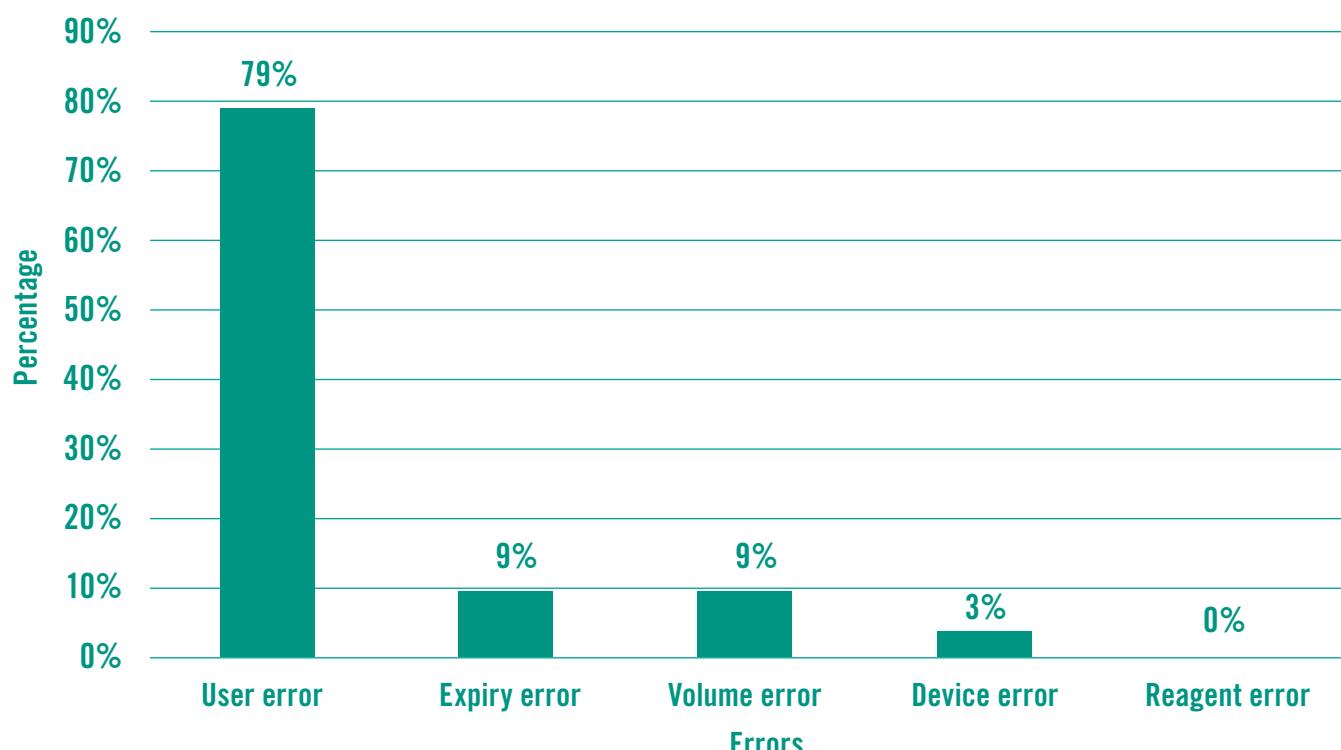
Conclusion and recommendations

CD4 testing is considered important for early initiation to treatment. Delay in CD4 testing results in late initiation of antiretroviral therapy, which translates to a higher mortality rate for the people living with HIV. The assessment found that 70% of clients enrolled in care and treatment centre facilities were receiving antiretroviral therapy. This indicates good management of HIV clients, but effort must be made to ensure that clients are not lost once they are enrolled into treatment.

For the successful management of care and treatment programmes, data management needs to be improved. The use of electronic databases and Internet availability at care and treatment centre facilities needs to be scaled up. The sample transport system also needs to be enhanced, especially in areas relying on public transport. Point-of-care technology can be used as an alternative solution in the referring facilities to increase access to on-site CD4 testing.

The assessment showed an update on the CD4 fleet of devices in the country, since some facilities that were reported as Pima facilities were found to have conventional equipment. This means that a country survey on equipment inventory is needed to understand the equipment landscape, since this will assist in reallocating the equipment and also advise on the future purchase and deployment of point-of-care devices.

Pima is the only point-of-care test available in the country. Deploying Pima devices has significantly improved access to CD4 testing, with an additional 210 monthly tests performed per month in addition to tests performed across the conventional sites. However, an interrupted supply chain for Pima commodities hinders the maximum utilization of the device, since this was found in the assessment as one of the main reasons for equipment downtime. Also, comprehensive mentorship and refresher training are highly recommended to reduce end user errors through building the capacity of superusers (District laboratory technician and laboratory implementing partners) who visit these sites frequently to deploy a sustainable site supervision and mentorship model for the country.

HIV laboratory drug toxicity tests still have significance in managing HIV clients. The assessment found that few sites had full access to drug toxicity tests. As demonstrated by the results of the assessment, the country and the global community need to begin complimentary point-of-care testing that can address the gaps in routine clinical chemistry and haematology tests that are required to monitor toxicity among people receiving antiretroviral drugs.

Annex 4. Costing and resource considerations

Capital costs

Establishing a point-of-care testing network and/
or introducing new point-of-care testing sites requires
comprehensive assessment of the associated costs and
savings. Upon cost estimation, the following elements can be
taken into consideration:

- human resources

- national coordinator of point-of-care testing

- external consultant

- data managers

- master trainers and certified trainers

- point-of-care testing personnel

- quality corps volunteers

- infrastructure and facility

- connectivity

- transport and logistics

- supply management system

- national plan for procurement and distribution

- logistics management information system

- human resources

- infrastructure in facilities and warehouses

- monitoring and evaluation

- equipment and supplies

- HIV diagnostic kits

- cost of capital equipment and equipment maintenance for instrument-based technologies

- reagents and supplies for instrument-based technologies

- external quality assessment programme subscription

- extra supplies for quality control (1–2%)

- control material

- extra cost associated with procuring kits that include quality control

- environmental monitoring equipment and supplies

- registers, refrigeration, printing, etc.

- establishing and maintaining the quality assurance programme

- internal quality control and external quality assessment

- supervisory visits

- transport and per diem for the quality assurance coordination team

- monitoring and evaluation

- corrective and preventive action

- hold stakeholder meetings for policy

- training

- production of materials

- venue

- training sessions and continuing education

- certification

Source:

Dawson J. No time for quality? Reasons to reevaluate and reinvest in a lab quality program. Med Lab Manage. 2013;2(5):6 (http://www.medlabmag.com/article/1124/SeptemberOctober_2013/No_time_for_Quality_Reasons_to_Reevaluate_and_Reinvest_in_a_Lab_Quality_Program).

Annex 5. Human resources model for quality assurance: country example on using quality officers to support HIV point-of-care testing sites

|	
Number of reference laboratories	6
Number of regional laboratories	27
Number of district laboratories	133
Number of rapid diagnostic testing sites	3740
Number of CD4 testing laboratories	168
Number of CD4 point-of-care testing sites	>300

Province X Map: Hub and Spoke model of Laboratory Systems and human resource needs

81 quality officers

Supervision of test sites

Coordination of quality assurance

Collection of data
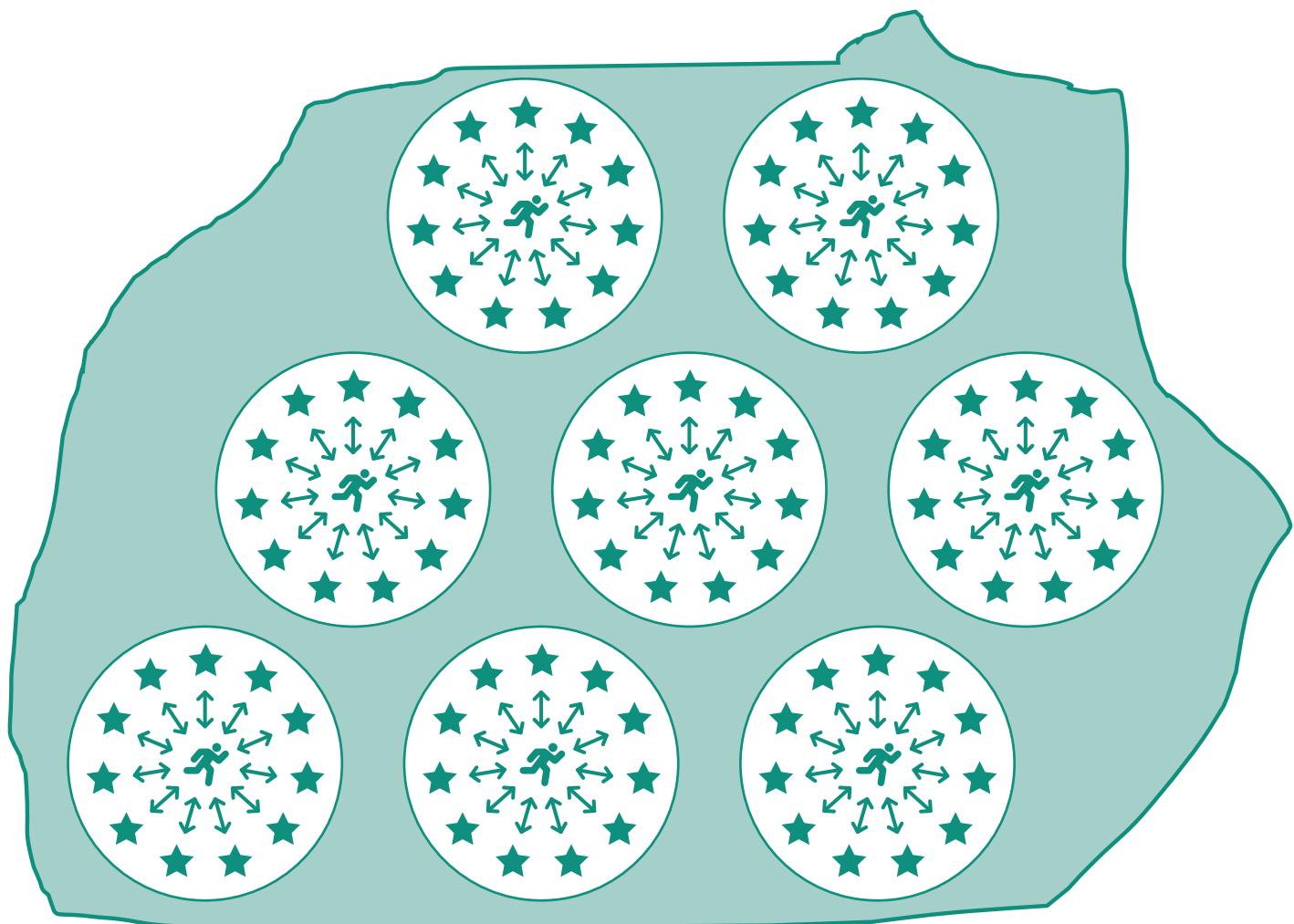
Annex 6. Training content and assessment

The training of testers should be coordinated to take place in a phased approach, centrally coordinated through a health ministry training plan and implemented by programme managers.

Training should be assessed following training and reassessed regularly (see later). Programme managers should develop assessment criteria and develop a database of certified testers and reassessment dates.

• Training material specific to the elements of quality assurance should be developed specifically for quality assurance providers. For example, key personnel at the national reference laboratory or other partners responsible for providing a proficiency testing programme should be trained in this specific area. This covers various aspects of proficiency testing programmes, including preparation, distribution, data collection, data analysis and follow-up corrective actions, as needed.

Training curricula
When developing training materials, the health ministry and partners should draw heavily on existing resources developed by other organizations (such as WHO and the United States Centers for Disease Control and Prevention) where available and revising resources to ensure country appropriateness.

• A package of training materials should include the following tools:

• participant and facilitator manuals;

• slide sets;

• standard operating procedures;

• job aids and troubleshooting guides; and

• videos (if appropriate).

An HIV rapid test training package for testers is available at: http://www.who.int/diagnostics_laboratory/documents/guidance/rt_training/en.

However, several countries have customized and revised this rapid test training package to ensure the inclusion of newly developed quality assurance tools such as dried tube specimen–based internal quality control and proficiency testing programmes and the use of standardized registers as an ongoing quality assurance tool.

Training of trainers
Training plans should provide for training staff members who will have direct responsibility for conducting training sessions. Upon completion of training, master trainers should demonstrate competence by passing practical and written examinations. Regular retraining and competence assessment should be considered to ensure that trainers maintain proper qualifications.

Trainers should be thoroughly prepared and assessed for competence through train-the-trainer programmes for point-of-care testing. Much of the training should be devoted to hands-on training that also incorporates all quality assurance elements. Programme managers should train trainers in consultation with manufacturers and other available experts, and this should take place before training testers.

Training of testers
Experience in some countries suggests that initial training programmes for point-of-care testing can be conducted over a 2–5 days, depending on the previous education and training of those being trained. Further, it is important to make training available for management staff who may not be performing the testing but who need information about how the tests are conducted and how they will work in their setting.

Training for any point-of-care testing should include:

• theoretical modules (classroom teaching);

• practical exercises;

• test procedure (at least two practice sessions);

• quality control testing (internal quality assurance samples and proficiency testing panels);

• group exercises;

• introduction of new quality assurance concepts specific to point-of-care testing (such as dried tube specimens);

• documentation practices;

• clinical workflow exercises (clinical integration); and

• inventory exercises.

The theoretical component of the training should include:

• principles of the point-of-care test;

• collecting and processing specimens (demonstrations)

• methods of using point-of-care testing (demonstrations), standard operating procedures;

• reading and interpreting the results;

• quality assurance (internal quality assurance and proficiency testing);

- biosafety;

- documenting, recording and reporting the results; and

- managing inventory.

Peer-assisted learning can also be developed to advance training goals and continual assessment.

Assessing and certifying competence

Following training, all personnel carrying out point-of-care testing should be assessed and certified using clearly defined assessment criteria (below). Testing personnel should be reassessed regularly (such as every two years or as technologies change). Supervising and mentoring the personnel performing point-of-care testing is essential beyond the initial training to ensure that testing in routine practice is performed to a high standard of quality and that corrective action is being applied as needed.

Competence assessment during initial training for trainers and testers should include attendance (100%), practical

competence (100%) and written assessment (80%).

Assessment of practical competence during the initial training should be evaluated in:
- routine test performance, including specimen collection, processing and testing;

- reporting and recording test results;

- operating equipment (if applicable); and

- internal or external quality assurance.

At the completion of a training programme, participants should also complete a written examination on the material presented during the training and a practical examination, such as proficiency testing.

It is recommended to award certification only after successful assessment of competence and completion of a recognized, standardized training course. The following is a guide for criteria for assessing testers during initial training.

Certification assessment checklist for initial training

Training assessment worksheet

Training name:

Training date:

Facilitators' names:

Certification criteria:

1. Training attendance: 100%

2. Practical examination: pass/fail for the initial four categories (repeat for some participants if necessary)

3. 80% for the written post-test

Participant name	Training attendance (%)	Practical examination using proficiency testing samples (pass/fail)				Written post-test (%)	Certified (yes or no)
		1. Safe practice (personnel protective equipment, waste)	2. Correct labelling	3. Correct procedure	4. Correct results and recording		
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

Annex 7. Supervision checklist for HIV testing facilities and technicians

This checklist is intended to be used for the ongoing monitoring of testing sites.

Please answer all sections as completely as possible adding comments wherever necessary. If there is insufficient space in the "comment" box, complete the entry in the "additional comments" section on page 9. Once this survey is completed, the reviewer and the site manager (or designated person) should sign it. One copy should be kept on file at the testing site and the original brought back to be retained at the health ministry or central public health laboratory for central recordkeeping.

Is any action required to be taken following this review? (see page 8) YES NO

This entry is intended to immediately indicate whether any issues at a given laboratory require urgent attention

Review conducted by: _____
(Print name)

_____
(Signature)

Date: _____

Testing site manager: _____
(Print name)

_____
(Signature)

General information

Review conducted by	
Date of present review	
Date of previous review	
Has the required action from previous review been satisfactorily completed? If no, then comment	Yes No N/A
Facility name	
Address	
Facility manager	
Manager's contact telephone number and email address	
Number of technicians employed	
Technician name(s)	1) 2) 3)
General notes and observations	

Part 1: Quality control assessment

1. Internal quality control

		Comments
Were the results from reference serum consistent with known sero-status?	Yes	
	No	
Were the results from internal controls logged?	Yes	
	No	
Were the serum samples stored in a freezer?	Yes	
	No	

2. External quality assurance scheme

		Comments
Has the site participated in more than 85% of the rounds of the external quality assurance scheme?	Yes	
	No	
Did the testers pass the external quality assurance consistently?	Yes	
	No	
If necessary, was any assistance provided to rectify problems?	Yes	
	No	
What is their experience of participating in the external quality assurance scheme?	Good	
	Bad	Explain:

Part 2: Questionnaire

To be completed by taking a tour of the site with the site manager or assigned technician to answer a series of questions and show the reviewer evidence around the site of their facility's capacity. For example, if you ask them whether they have guidelines, it is not enough to accept a yes or a no: they must show them to you at the site. Make comments as required in the right column. For example, "Monthly reports were not sent for the last four months because no paper was available."

General safety and hygiene

		Comments
Are printed national guidelines on safety precautions available?	Yes No	
Are printed material safety data sheets available and up to date?	Yes No	
Are there records of laboratory personnel training in safety precautions and material safety data sheets?	Yes No	
Are printed national guidelines on post-exposure HIV prophylaxis available? Are they followed?	Yes No	
Are printed national guidelines on post-exposure hepatitis B prophylaxis available? Are they followed?	Yes No	
Are printed guidelines for decontaminating spilled infectious materials available as above?	Yes No	
Is the floor free of trip hazards?	Yes No	
Are the benches clean and well ordered, with adequate working space?	Yes No	
Are appropriately marked biohazard disposal bins available?	Yes No	
Are appropriately marked sharps disposal bins available?	Yes No	
Is an incinerator or other appropriate facility for disposing of biohazards and sharps available?	Yes No	
Is there sufficient stock of fuel for the incinerator?	Yes No Not applicable	
Is the contaminated waste inaccessible by non-laboratory personnel (locked)?	Yes No	
Is the testing area sufficiently illuminated?	Yes No	
Is the testing area sufficiently ventilated and/or air conditioned?	Yes No	
Is the testing area free of all foodstuffs, drinks, betel nut and smoking?	Yes No	

Stock

		Comments
Are printed guidelines for maintaining stock levels available?	Yes No	
Are printed guidelines for the disposal of expired and/or damaged reagents and consumables available?	Yes No	
Has the site run out of stock at any time since the last review?	Yes No	
Have there been any problems with keeping kits or reagents at the appropriate temperature?	Yes No	
Is stock appropriately shelved so that older kits are rotated to the front and used first?	Yes No	
Is there a first-aid kit that is appropriately stocked?	Yes No	
Is there a handwashing station or basin?	Yes No	

Documentation

		Comments
Are monthly report forms completed?	Yes No	
Are consumable request forms completed and submitted at appropriate times?	Yes No	
Is the test register correctly, legibly and neatly filled out?	Yes No	
Is the test register complete and up to date?	Yes No	
Is there an incident report system in place for documenting any accidents in the laboratory?	Yes No	
Is there logging of external quality assurance scheme results and participation?	Yes No	
Is a log kept for staff training?	Yes No	

Part 3: Observation of testing technicians to ensure correct procedure

Before clients come in, sit down with the technician and explain that you will be observing him or her and taking notes. Ask the technician the pre-testing questions before the client arrives in the testing area. Be sure to correct the technician if he or she is making errors that will affect the client's result or harm the study. Otherwise, just observe and make notes at each stage of the testing procedure sequentially with this form.

Technician 1: _____

(Print technician name)

Pre-testing questions for technician

		Comments
Is the technician aware of laboratory standard operating procedures and knows the location of printed reference material?	Yes / No	
Is the technician aware of the procedure to follow should the technician, or anyone else, be exposed to infectious material?	Yes / No	
Observation of the HIV testing procedure		
The use of which assay kit(s) was observed?	Yes / No	
Did the technician take due care in ensuring personal safety?	Yes / No	
Was the technician wearing a closed, long-sleeved laboratory coat? Was the technician using eye protection?	Yes / No	
Did the technician have closed toe shoes?	Yes / No	
Was the technician wearing protective gloves?	Yes / No	
Did the technician dispose of biohazardous materials appropriately?	Yes / No	
Did the technician dispose of sharps appropriately?	Yes / No	
Was sufficient time allowed for the kit to produce a result (in accordance with the manufacturer's instructions)?	Yes / No	
Was the kit's maximum time exceeded before the results were read (in accordance with the manufacturer's instructions)?	Yes / No	
Were all tubes and tests neatly and accurately labelled with patient ID and date?	Yes / No	
Did the technician follow the correct procedure for venous blood collection?	Yes / No	
Were the test results accurately transcribed into the register (not applicable if the testing was performed on standards from the national reference laboratory)?	Yes / No / Not applicable	

Technician 2:

(Print technician name)

(Cross out page if there is only one technician)

Pre-testing questions for technician

		Comments
Is the technician aware of laboratory standard operating procedures and knows the location of printed reference material?	Yes No	
Is the technician aware of the procedure to follow should the technician, or anyone else, be exposed to infectious material?	Yes No	
Observation of the HIV testing procedure		
The use of which assay kit(s) was observed?	Yes No	
Did the technician take due care in ensuring personal safety?	Yes No	
Was the technician wearing a closed, long-sleeved laboratory coat? Was the technician using eye protection?	Yes No	
Did the technician have closed toe shoes?	Yes No	
Was the technician wearing protective gloves?	Yes No	
Did the technician dispose of biohazardous materials appropriately?	Yes No	
Did the technician dispose of sharps appropriately?	Yes No	
Was sufficient time allowed for the kit to produce a result (in accordance with the manufacturer's instructions)?	Yes No	
Was the kit's maximum time exceeded before the results were read (in accordance with the manufacturer's instructions)?	Yes No	
Were all tubes and tests neatly and accurately labelled with patient ID and date?	Yes No	
Did the technician follow the correct procedure for venous blood collection?	Yes No	
Were the test results accurately transcribed into the register (not applicable if the testing was performed on standards from the national reference laboratory)?	Yes No Not applicable	

Action to be taken

Describe in detail any action that needs to be taken and include a date by which it should be completed.

Be sure to return to the first page and answer the question "Is any action required to be taken following this review?"

Action to be taken	Date to be completed

Additional comments

Annex 8. Example of standard operating procedures for point-of-care testing

This standard operating procedure has been provided to illustrate the kinds of information that need to be captured and followed to ensure accurate performance and interpretation of test procedure. The site in which testing is performed may have specific requirements that will need to be incorporated in this standard operating procedure and other collective documents.

A. Test procedure using HIV rapid test kit

Check the expiry date and use kits within the expiry date.

Intended use

The XXX HIV test is a single reagent assay for detecting antibodies to HIV types 1 and 2 in serum, plasma or whole blood.

Principle of the procedure

Synthetic peptides of diagnostic relevance representing the highly immunoreactive sections of the envelope proteins of HIV-1 and HIV-2, glycoprotein gp41, gp120 (HIV-1) and glycoprotein gp36 (HIV-2), respectively, are immobilized at the test region of the nitrocellulose strip. The peptides are also linked to colloidal gold and impregnated below the test region of the device. A narrow band of the nitrocellulose membrane is also sensitized as a control region.

During testing, one drop of serum, plasma or whole blood is applied to the sample port, followed by two drops of wash buffer and allowed to react. Antibodies to any immunoglobulin class, specific to the synthetic HIV-1 or HIV-2 peptides, will react with the colloidal gold–linked antigens. The antibody peptide–colloidal gold complex moves chromatographically along the membrane through the test and control regions of the test device.

A positive reaction is visualized by a pink or red band in the test region of the device.

A negative reaction occurs in the absence of human immunoglobulin antibodies to HIV in the analysed specimen. Consequently, no visually detectable band develops in the test region of the device.

Excess conjugate forms a second pink or red band in the control region of the device. The appearance of this band indicates proper performance of the reagents in the device.

Kit contents

- XX number of test devices

Each test device contains colloidal gold labelled with synthetic HIV peptides, synthetic HIV peptides as test zone and a control line.

- Wash reagents (4 ml)
- 20 disposable pipettes
- Package insert

Materials required but not provided with the kit:

- Timer or stopwatch
- Blood collection and application devices (lancets, capillary tubes and test tubes)

Storage and stability

The XXX HIV test devices can be stored at 2–30°C. No kit components should be used after the kit expiry date.

Precautions

- The XXX HIV test is intended for in vitro use.
- Do not use the kit past the expiration date.
- Do not smoke, eat or drink in areas in which specimens are handled.
- Dispose of all specimens, used devices and pipettes as capable of transmitting infection. The preferred methods of disposal are by autoclaving at 121°C for a minimum of 60 minutes or by incineration.

All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.

Use a separate disposable pipette and device for each specimen tested.

Controls, where supplied, have been certified virus free. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to the testing algorithm.

Specimen collection and storage

Whole blood, serum or plasma may be used.

Whole blood: If finger-stick whole blood is used, drops of blood produced should be taken up from the finger-tip by the pipette, capillary, or loop supplied and applied onto the device. Blood droplets should not be dropped directly from the fingertip onto the device as their size may vary. Whole blood specimens should be used within ten minutes of collection for optimum performance.

If a specimen has started to clot, do not remix before testing. In such instances, the clear serum should be pipetted off the clotted specimen and used for analysis. If an anticoagulant has been used in the blood sample, whole blood can be used directly on the device using the pipette supplied. If testing is not to be carried out immediately, samples should be stored at

2–8°C for up to three days, or preferably, the sample should be centrifuged and the plasma retained for future testing.

Serum or plasma: Serum or plasma may be kept for seven days at 2–8°C. Samples should be frozen for longer storage. Avoid repeated freezing and thawing of samples.

Quality control

Good laboratory practice necessitates using control specimens to ensure proper device performance at least once daily.

A built in procedural control on the test device indicates that the test is functioning correctly. A pink or red band should always appear at the control window.

Internal and external controls should be run daily before analysing patient or client specimens. The results should be recorded on the quality control log. The results are reported only if the quality control results are acceptable.

Test procedure

1. If any reagent or samples have been refrigerated, remove and allow to stand for 20 minutes to reach room temperature.

2. Remove the required number of test devices from their protective wrappers.

3. Label each test with the appropriate patient identification.

4. Using one of the disposable pipettes (loop or capillary) supplied, fill with sample (serum, plasma or whole blood).

5. Hold the pipette over the sample port and add the recommended volume of sample.

6. Add two drops of the recommended volume of the appropriate wash reagent to the sample port.

7. Allow 10 minutes for reaction to occur. The result should be read at the end of the 10-minute incubation time. The results are stable for at least 20 minutes after adding the sample to the device.

Interpreting test results

- One line of any intensity only in the control window is reported as negative or non-reactive.

- Two lines of any intensity in both the patient and control window are reported as positive or reactive.

- No line in the control window, irrespective of the presence or absence of a test line, is reported as invalid.

Limitations

The HIV test procedure and interpretation of results must be followed closely when testing for the presence of HIV antibodies in serum, plasma or whole blood.

Immunosuppressed or immunocompromised individuals infected with HIV-1 or HIV-2 may not produce antibodies to the virus.

Testing with any kit designed to detect antibodies may give negative results and would not be a reliable test method for such people.

Infants may receive antibodies from an infected mother or they may not produce antibodies in response to an infection. Therefore, it is necessary to exercise great care in interpreting their results.

AIDS and AIDS-related complex are clinical syndromes, and their diagnosis can only be established clinically. HIV test results alone cannot be used to diagnose AIDS. A negative result does not preclude the possibility of exposure to or infection with HIV.

B. Example of a job aid for HIV rapid diagnostic testing

- Check the kit before use. Use only items that have not expired or been damaged.

- Bring the kit and previously stored specimens to room temperature before use.

- Always use universal safety precautions when handling specimens. Keep work areas clean and organized.

This outline is not intended to replace the product insert or your standard operating procedure.

1. Collect test items and other necessary lab supplies.

2. Use one strip per test, and be sure to preserve the lot number on the remaining packet of strips.

3. Label the test strip with the client identification number.

4. Pull off the protective foil cover.

5. Collect 50 µl of specimen using either a Pasteur or precision pipette.

6. Apply the specimen to the absorbent pad on the strip.

7. For whole blood only: add 1 drop of chase buffer to the specimen pad.

8. Wait 15 minutes (but no longer than 60 minutes) before reading the results.

9. Read and record the results and other pertinent information on the worksheet.

10. Reactive: two lines of any intensity appear in both the control and patient areas.

11. Non-reactive: one line appears in the control area and no line in the patient area.

12. Invalid: no line appears in the control area. Do not report invalid results. Repeat the test with a new test device even if a line appears in the patient area.

C. Example of a job aid for HIV point-of-care CD4 testing

How To Do the *Simu* POC CD4 System

for the enumeration of CD4 cells in whole blood

Collect:
A   NEW unopened test packet
B   NEW unopened alcohol swab
C   NEW unopened lancet
D   NEW pair of disposable gloves
E   Sharps box
F   Marker pen
G   Specimen Transfer Device
H   SIMU POC Reader

A Test packet   B Alcohol swab   C Lancet   D Disposable gloves   F Marker pen   G Specimen transfer device   H Simu POC Reader

READ THESE INSTRUCTIONS CAREFULLY BEFORE YOU BEGIN.

1   Check the expiry date on the test packet. *Expiry date*

2   Put on the gloves. Use new gloves for each patient.

3   Open the packet and remove the *Simu* POC CD4 Cartridge.

4   Ensure there is no purple colouring in the sachet. Discard *Simu* POC CD4 Cartridge if any beads have turned purple. DO NOT USE if any beads are purple.

5   Write the patient's name on the test.

6   Open the alcohol swab. Grasp the 4th finger on the patient's left hand. Clean the finger with the alcohol swab. Allow the finger to dry before pricking. Keep the hand below the heart level of the patient.

7   Open the lancet. Prick patient's finger to get a drop of blood. Do not allow the tip of the lancet to touch anything before pricking the patient's finger.

8   Discard the lancet in the Sharps Box immediately after pricking finger. Do not set the lancet down before discarding it.

9   Use the specimen transfer device to collect the drop of blood. Do not transfer blood directly from the finger tip.

10   Use the specimen transfer device tube to put the drop of blood into the slot marked "A."

11   Discard the specimen transfer device tube in the Sharps Box.

12   INSERT *SIMU* POC CD4 CARTRIDGE INTO SIMU POC SYSTEM READER.

This will activate the reader. Follow the instructions on the display.

13   A result will be displayed 15 minutes after insertion of the Cartridge into the Simu POC System Reader. Record results or transmit as required.

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14   Dispose of the cartridge, gloves, alcohol, desiccant sachet and packaging in a non-sharps waste container.

Each test can be used **ONLY ONE TIME.**
Do not try to use the test more than once.

THE MANUFACTURING COMPANY – SIMU POC CD4 SYSTEM

1. Turn on the analyser.

2. Select a site for the finger-stick.

3. Wipe the tip of the selected finger with alcohol and allow the alcohol to air dry.

4. Remove the test cartridge from its pouch.

5. Open the cartridge cap to expose the sample collector.

6. Use sterile lancets to make a skin puncture just off the centre of the finger pad.

7. Ensure a steady blood flow without applying pressure to the site. Wipe away the first drops of blood. Position the capillary in contact with the blood drop. Fill the capillary, angled upward at a 45-degree angle. Once the sample collector is full, stop blood collection.

8. Keeping the cartridge upright, look at the control window until it turns red and is filled. Once the control window is completely full, the sample collector can be removed.

9. Remove the sample collector in one, continuous upwards motion. Do not leave the sample collector on the cartridge.

10. Be sure to close the cartridge cap completely before inserting the closed cartridge into the analyser.

11. Press the "OK" button on the analyser. Insert the cartridge in the direction indicated by the arrow on the cartridge label.

12. Enter the operator and sample ID.

13. Remove cartridge once prompted by the analyser.

14. The test result will be displayed on the screen. A test report can be printed.

Annex 9. Use of quality control samples and proficiency testing

This standard operating procedure has been provided to illustrate the kinds of information that need to be captured and followed to ensure accurate performance and interpretation of test procedure. The site in which testing is performed may have specific requirements that will need to be incorporated in this standard operating procedure and other collective documents.

Quality control samples

HIV rapid diagnostic tests

The XXX HIV test is a single reagent assay for detecting antibodies to HIV types 1 and 2 in serum, plasma or whole blood.

Quality control samples for HIV rapid diagnostic tests comprise two or three well characterized samples (HIV positive and negative and sometimes a weakly reactive positive sample). When cold-chain transport of quality control samples is not feasible, a dried tube specimen may be used. Internal quality control samples for rapid diagnostic tests can be procured commercially or, preferably, can also be prepared within the country by the national reference or referral laboratory. It is recommended that internal quality control samples be distributed with the test kits, assuring that each site has sufficient internal quality control samples for use with the kits. Use of the internal quality control samples should be clearly explained during training, including practical exercises using real internal quality control samples for testers to gain competence in both internal quality control procedures and documentation. The use of internal quality control samples should also be outlined on both standard operating procedures and job aids.

The preparation of internal quality control samples in country requires considerable laboratory coordination, planning and resources (human, infrastructure and access to patient samples). Laboratories should prepare internal quality control samples by using a standardized protocol. Ideal specimens for such applications can be acquired from the local blood banks in bulk volume, processed, aliquotted and stored frozen for the long term. They should be well characterized by multiple tests before being used for internal quality control (or proficiency testing panels).

CD4

Quality control samples for point-of-care CD4 testing are not currently commercially available. Since whole blood is required for CD4 testing at the point of care, it is less feasible to implement a comprehensive CD4 quality control sample programme that can reach remote sites. However, local district-based laboratory CD4 testing sites may be able to support point-of-care CD4 testing sites by providing fresh quality control samples regularly. Samples could be tested at the laboratory first and then shared with the point-of-care CD4 testing site for comparing results. For instrument-based CD4 testing, however, real-time data collection for quality assurance ensures a good degree of quality assurance, and quality control samples and retesting for point-of-care CD4 is therefore not considered necessary.

Viral load and early infant diagnosis

Quality control samples (usually dried tube specimens) for point-of-care viral load plasma testing should consist of

well characterized negative, low positive and high positive samples and can be purchased or provided by the United States Centers for Disease Control and Prevention.

Proficiency testing

Proficiency testing enables an external laboratory or national quality assurance programme to evaluate the performance of a testing site regularly. Proficiency testing is designed to identify sites and testers needing assistance. At regular intervals (at least three times a year), panels of well characterized samples are distributed to proficiency testing programme participants for blind testing. Participants test the specimens and return results to the reference laboratory. The data are analysed and information is provided back to the participating testing sites. Proficiency testing panels can be procured and in some cases obtained free of charge or prepared in country as part of a national proficiency testing programme.

Programmes must allocate resources at the national and regional levels to implement proficiency testing programmes. Proficiency testing programmes should be implemented stepwise to ensure that scale-up is sustainable and includes the complete cycle of returning results, analysing data and providing feedback to sites. An effective proficiency testing programme has to provide timely corrective action and is not useful if data are not collected and analysed in a timely manner or if sites are not provided with appropriate feedback, corrective measures and recognition of performance.

During training, testing personnel should understand the benefits and positive nature of full participation in proficiency testing to improve and monitor testing performance. They should be reassured that they will not be penalized for incorrect results but provided with resources and assistance to overcome the challenges that may arise in their testing quality. However, participation must be mandatory for all sites. If an agreed level of participation in a year (such as 80%) is not achieved, then measures to rectify the poor participation must be implemented, and if no improvement is observed, the testing at the site should be stopped since the quality of the results they are achieving may not be accurate.

Proficiency testing panel distribution and return of results can be combined with site supervision for point-of-care testing and clinical site supervision to facilitate the logistics of site visits.

HIV rapid diagnostic tests

Because of the large number of testing sites and testers, a large volume of specimens will be used for a proficiency testing programme (>100 ml per specimen). The best source of these bulk volume specimens is from local blood

banks, which routinely discard HIV- or hepatitis-positive specimens. After sourcing the specimens and ensuring that the quality has not been compromised, they should be fully characterized with respect to HIV status and then can be used to prepare the panels. Proficiency testing panels for HIV rapid diagnostic testing should be prepared in country by coordinating with accredited national and/or regional reference laboratories. Annexes 10A–D outline the processes and requirement for setting up a national proficiency testing programme for HIV rapid diagnostic tests.

CD4

Proficiency testing for CD4 point-of-care testing is only advisable by procuring panels from international agencies that produce CD4 proficiency testing panels. The technical skill and resources required to produce proficiency testing panels is prohibitive for most countries.

The following programmes provide CD4 proficiency testing programmes (others may exist).

- QASI (quality assessment and standardization for immunological measures relevant to HIV/AIDS, https://qasi-lymphosite.ca/default.asp) is an international quality assurance programme for CD4– T cell enumeration providing services to resource-limited countries at no charge. The programme distributes panels of two samples three times per year. Samples are stabilized whole-blood specimens with normal and low CD4 counts. The programme assesses absolute and percentage CD4 counts.

- United Kingdom National External Quality Assessment Service (http://www.uknPTs.org.uk) is a not-for-profit organization that offers a fully accredited immune monitoring programme to testing facilities in the United Kingdom and elsewhere. The programme distributes panels of two samples 4–6 times per year. The samples are stabilized whole-blood specimens with normal and low CD4 counts. The programme assesses absolute and percentage CD4 counts.

Viral load

- The WHO HIV viral load proficiency testing programme in the African Region provides services to 46 countries. The programme includes distribution of panels of samples six times a year.

- United States Centers for Disease Control and Prevention.

- QCMD (Quality Control for Molecular Diagnostics, http://www.qcmd.org) offers proficiency testing programmes for viral load and early infant diagnosis. The service is open to all laboratories.

Early infant diagnosis

Current proficiency testing samples that are available for early infant diagnosis such as those supplied by the United States Centers for Disease Control and Prevention comprise dried blood spots and therefore may not be suitable for new point-of-care early infant diagnosis technologies that use whole blood from finger prick, heel prick or EDTA tube. Therefore, it may be necessary to change the external quality assessment strategy and perform blinded retesting of a proportion of samples at a referral early infant diagnosis laboratory to provide an additional measure of quality assurance. Point-of-care early infant diagnosis testing using equipment, however, provides real-time connectivity, which can be used to assess the quality assurance of the point-of-care early infant diagnosis testing sites.

Annex 10. Standardized protocols for preparing proficiency testing samples at a national laboratory

A. Standard operating procedures: proficiency testing programme using dried tube specimens

HIV rapid diagnostic tests

1.0 Purpose
The purpose of this procedure is to provide guidance to setup a proficiency testing programme using dried tube specimens to ensure the quality of HIV testing.

2.0 Equipment
Biosafety cabinet
Vacuum pump unit

3.0 Supplies
- 2.0-ml conical bottom tubes
- Green food colouring dye
- Pipettes that are capable of multi-dispensing pipette tips
- Disposable transfer pipettes
- Freezer boxes
- Tube racks
- Cryo labels
- Storage bottles
- Zipper storage bags
- Labels
- Disposable filter unit 0.2 µl

4.0 Special safety precautions
4.1 Wear protective clothing while handling dried tube specimens.
4.2 Handle dried tube specimens as if they are capable of transmitting an infectious agent.
4.3 Do not interchange vial caps; this will lead to cross-contamination of specimens.
4.4 Leave the dried tube specimens in the biosafety cabinet for overnight drying of the specimen.

5.0 Procedure
5.1 Obtain rejected plasma units from the local blood bank of different HIV reactivity, including some HIV negatives. Initially acquire >10 units to build specimen inventory.
5.2 Transfer plasma from the bag to a clean storage bottle. Store plasma at 4°C until further testing has been conducted.
5.3 Regardless of the status given by the blood bank, the laboratory that is responsible for providing the proficiency testing panel should verify the specimen reactivity.
5.4 Plasma specimens should be characterized with respect to their HIV status by all HIV rapid tests, ELISA and Western blot (if available) based on a country-specific algorithm.
    5.4.1 Rapid test: test plasma specimens with all commonly used HIV rapid tests in the country.
    5.4.2 ELISA: test all samples on all ELISA procedures used in the country.
    5.4.3 Western blot: if available, the Western blot banding pattern should also be established for HIV-positive specimens.

5.5 Preparing proficiency testing buffer (phosphate-buffered saline (PBS)/Tween-20)
    5.5.1 PBS with Tween-20 pouches can be commercially purchased from Sigma (catalogue no. 3563).
    5.5.2 Dissolve one foil pouch of PBS with Tween-20, pH 7.4, in 1 litre of deionized water. It will yield 0.01 M PBS; NaCl 0.138 M; KCl 0.0027 M; Tween 20 – 0.05%; pH 7.4.
    5.5.3 Filter it through a 0.2-µm filter flask.
    5.5.4 Prepare 1.8-ml aliquots in prelabelled 2-ml screw-capped tubes.
    5.5.5 The label on tube should include the following:
        5.5.5.1 Identify the tube as "proficiency testing buffer".
        5.5.5.2 Set an expiration date of one year after you prepare.

5.6 Preparing dried tube specimens
    5.6.1 Create a panel of six samples from the characterized specimens with a combination of negative and positive reactivity for HIV.
    5.6.2 Carefully blind the panel, assigning a new ID to each of the six-member panel. For example, dried tube specimens A1 to dried tube specimens A6. Ensure that the original ID and new ID are linked.
    5.6.3 Label each tube with an appropriate new ID.
    5.6.4 Depending on the number of laboratories enrolled in the proficiency testing programme, prepare 10–20 extra sets.
    5.6.5 Prepare a 1:1001 dilution of green dye to specimen. For example, add 1 µl of dye (food colouring) to 1 ml of specimen. Vortex the specimen to mix the dye.
    5.6.6 Prepare dried tube specimens by transferring 20 µl of coloured serum or plasma specimen to tube.
    5.6.7 Ensure that each specimen is aliquotted in properly labelled tubes. Aliquot only one specimen at a time to avoid any possibility of mixing.
    5.6.8 Leave the tubes uncapped in a biosafety cabinet and let it dry overnight at room temperature. Make sure different specimens are kept in separate racks in a biosafety cabinet.
    5.6.9 The following day, ensure that the specimens have dried completely before capping each tube.
    5.6.10 A visible coloured pellet is formed towards the bottom of the tube.
    5.6.11 Capped dried tube specimens are kept at 4°C until ready for shipment to the participating laboratories.

5.7 Packaging proficiency testing panels
    5.7.1 Prepare proficiency testing panels for shipments to include the following:
        5.7.1.1 One member of each panel
        5.7.1.2 One vial of proficiency testing buffer
        5.7.1.3 Two plastic transfer pipettes (dropper)
        5.7.1.4 One page of instruction sheet or handout
        5.7.1.5 One page of reporting forms each (for rapid diagnostic tests and enzyme immunoassays)
    5.7.2 Put all the contents in labelled zippered storage bags.
    5.7.3 The bagged proficiency testing panels can be stored at 4°C until shipment or delivery to testing sites.

Reconstitution of dried tube specimens

5.7.4 Tap the tube gently to ensure that the coloured pellet falls to the bottom of the tube.

5.7.5 Antibodies are reconstituted one day before testing.

5.7.6 Using the dropper provided, add 7 drops of proficiency testing buffer to each dried tube specimen to be tested. Cover the tube, tap gently and incubate overnight at room temperature.

5.7.7 The next day, mix the specimen by gently tapping the tube.

5.7.8 Test the reconstituted dried tube specimens with the appropriate HIV rapid or enzyme immunoassay tests.

5.7.9 Report the results using the report form before the deadline.

5.8 Result analysis

5.8.1 Collect reports from all participating laboratories.

5.8.2 Enter data in the appropriate spreadsheet.

5.8.3 Analyse the data using the proficiency testing spreadsheet.

5.8.4 Send the final report to all the participating laboratories.

5.8.5 Follow up with a supervisor for the laboratories that do not receive a 100% passing grade.

B. Visual instructions for testing with dried tube specimens

DTS Testing Instructions

Six PT specimens (A1 to A6)
(ensure green pellet is at the bottom of the tube)
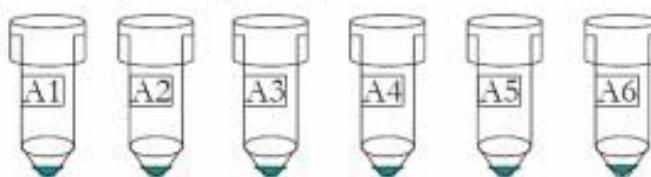
1 vial of PT buffer

Add exactly 7 drops of PT Buffer to each tube
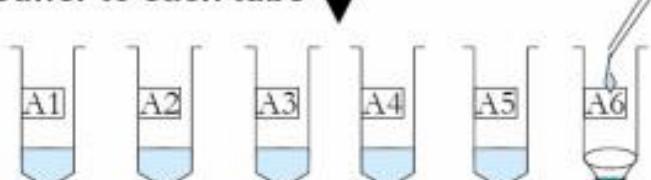
Cap the tubes, tap few times to mix well and Incubate at room temperature overnight
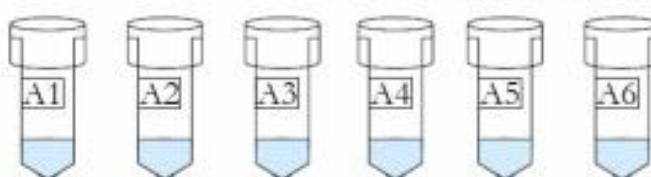
Next day, tap to mix the contents and perform RT as per algorithm

Source:

Source: Parekh B, Kalou M, Alemnji G, Ou C, Gershy-Damet G, Nkengasong J. Scaling up HIV rapid testing in developing countries: comprehensive approach for implementing quality assurance. Am J Clin Pathol. 2010;134:573–84.

C. Reporting form for results for dried tube specimens

Dried tube specimens for HIV serology – results form

Name of site:

District: (Laboratory/non-laboratory) Circle one

Second tester name (if applicable):

Date dried tube specimens samples were received: / /

Date samples are eluted: / /

Date testing performed: / /

Sample buffer present YES / NO

Type of test HIV – rapid tests

	Test 1	Test 2	Test 3
Name of test			
Lot number			
Expiration date			

Sample ID	Test 1 results	Test 2 results	Test 3 results	Final status	Comments

Tester: Date / /

Laboratory supervisor: Date / /

Date sent results: / /

D. Example of a Gannt chart work plan for setting up a national proficiency testing programme by a coordinating laboratory

Activities	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dic
Plan for EQAS Implementation			■	■								
Write SOP				■	■							
Recruit NEQAS staff			■	■	■							
Procurement of lab equipment/Consumables				■	■							
Lab set up				■	■	■						
Validation						■	■					
Paricipant Assessment				■	■							
Serum Bank set up					■	■						
Training for Provider (CPHL)						■						
Workshops for Partecipants (Provincial labs)							■					
Prepare & Distribute at least first panel							■	■	■			

Note: Each month is subdivided into weeks 1, 2, 3, 4. The shaded cells indicate the scheduled period for each activity.

Annex 11. Standardized logbook for HIV rapid diagnostic testing and point-of-care CD4 testing

A. Standardized logbook for HIV rapid diagnostic testing (This logbook is not intended or likely to be in electronic format)

Serial No.	Client or Specimen ID	Age (Yrs)	Sex	Date Tested	Test 1 Kit Name_____ Lot No._____ Exp. Date_____	Test 2 Kit Name_____ Lot No._____ Exp. Date_____	Test 3 Kit Name_____ Lot No._____ Exp. Date_____	Final results	Operaton Name / Initials	Sent for further QA Testing	Date sent	Final QA Results	Date Received	Comments
1			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
2			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
3			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
4			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
5			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
6			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
7			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
8			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
9			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
10			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
11			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
12			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
13			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
14			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
15			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
16			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
17			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
18			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
19			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		
20			M F		R RN I	R RN I	R RN I	P N I		☐		P N I		

PAGE TOTAL

	Test 1	Test 2	Test 3	Final results	Sent for further QA Testing	Final QA Results
Total Tested						
Total Reactive/Positive						
Total Non-Reactive/Negative						
Total Invalid (or Indeterminate)						

R=Reactive, NR=Nonreactive and I=Invalid
P=Positive, N=Negative and I=Indeterminate

B. Logbook for point-of-care CD4 testing

Machine serial number: _____

CD4 log form: _____

Site/location: _____

	Date and time collected	Date and time tested	Patient ID or quality control low/ normal	Age and sex	Kit and lot	Kit expiry date	Daily quality control beads pass/fail	Reading result		Corrective actions taken and comments	Clinical decision made	Operator signature
								CD4	Error code			
1												
2												
3												
4												
5												
6												
7												
8												
9												
10												

Annex 12. Test reporting forms

Monthly CD4 data collection sheet							
Month		**Date of completing this form:**				**Lab/clinic name:**	
Year		**Data of reporting this form:**				**Province:**	
Type of CD4 analyser used (please circle): BD FACSCount PARTEC CYFlow PIMA							
	Age group	Total no. of HIV patients who received CD4 test for the month		No. of CD4 tests repeated due to error or results check		Total no. of daily CD4 controls run for the month	Total no. of CD4 samples run for QASI proficiency testing
		CD4 test		CD4 test		CD4 test	CD4 test
		M	F	M	F		
Infants	0–6 months						
	7–12 months						
Children	1–2 years						
	2–4 years						
	5–9 years						
	10–14 years						
Adults	15–19 years						
	20–24 years						
	25–29 years						
	30–49 years						
	50+ years						
	Total						
Comments							

Instructions to fill out form

Month: Enter month for which data is being reported

Year: Enter year of month being reported

Date of completing this form: Enter the date the form is being completed

Date of reporting this form: Enter the date the form is being faxed or mailed or delivered

Lab name: Enter the name of your laboratory

Province: Enter the province name

Type of CD4 analyser used: Circle the analyzer used at your site

Total no. of HIV patients who received CD4 test for the month: Enter the total number of HIV patients for whom a CD4 test was done. Enter data based on patient age and sex.

No. of CD4 tests repeated due to error or results check: Enter the total no. of CD4 tests that were repeated due to error or to recheck a result or if a sample needed to be diluted if the result was outside the limit of detection. Enter data based on patient age and sex.:

Total no. of daily CD4 controls run for the month: Enter the total no. of controls that were run during the month. NOTE: To ensure quality results, controls must be run daily with each batch of samples.

Total no. of CD4 samples run for QASI proficiency testing: Enter the total no. of CD4 samples run for QASI proficiency. NOTE: Three QASI rounds should be received by your laboratory each year. Each round contains two samples to be run.

Comments: Enter any additional comments you wish to convey to the National CD4 Testing Programme

Annex 13. Example of a performance report for point-of-care CD4 testing

Clinic PIMA™ CD4 Analyser Performance Review

Site(s):_____
Province:_____

Period of Review: December 2012 – April 2013
Operating PIMA™ Serial #:_____

Observations

Quality Control
- ☐ PIMA™ CD4 Analyser is operating within control according to Levey-Jennings Chart (Figure 1)
- ☐ Consistent performance of PIMA beads prior to testing!

CD4 Testing
- ☐ Consistent PIMA CD4 testing
- ☐ 131 Successful patient tests
- ☐ Error rate of 12%
- ☐ Excellent input of correct operator ID's and sample ID's for CD4 tests and quality control
- ☐ High frequency of 850 errors (Figure 2)

Recommendations

- ☐ ALWAYS adequately mix/invert sample within the EDTA tube prior to testing, as per the SOP's pg.5-6
- ☐ Ensure that test cartridge cap is closed firmly as per the SOP's p.g. 7 before insertion into the analyser.
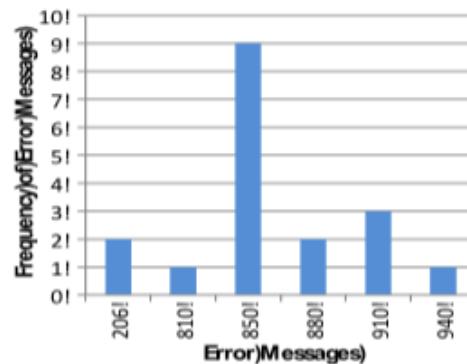
Figure 2. Frequency of error messages reported from PIMA™ D-003965 currently operating in _____ Clinic, _____over the period of Nov12 – Apr 13. The highest frequency of error messages are exposure control errors (850), image errors (910) followed by gaiting errors (940), cell movement control (880) and manual abort (206).
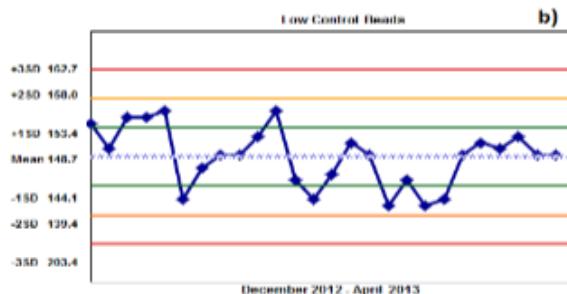
Figure 1. Quality control data for PIMA™ D-003965 currently operating in Tininga Clinic over the period of Dec12 – Apr13 (a) Normal control beads data fluctuates between ±1 - ±2 SD this indicates that PIMA™ D-003965 is functioning normally (b) Low control beads data fluctuates close to the mean and between ±1 - ±SD this also indicates that PIMA™ D-003965 is functioning normally.
SD=!Standard!Deviation!!

_____
Manager
Central Public Health Laboratory

PH:
FAX _____

Annex 14. Standard operating procedure: verifying new kit lots

Principle

New reagent lots are tested in parallel with old lots before or concurrently with being placed in service to ensure that the new lot of reagent behaves consistently with older lots currently in use with patient specimens.

Clinical significance

Consistent reagent performance reduces the likelihood of misinterpretation of patient data caused by shifts in test kit performance.

Procedure

At least two known patients (at least one positive and one negative, plus ideally one weak positive) are analysed with an established lot of reagent and are retested in parallel using a new lot of reagent. The results of the tests are compared and evaluated as specified below.

Alternatively, available proficiency testing specimens (external quality assessment panels) can be used. As a last resort, external controls covering the reportable range (or prepared using serial dilutions) can be assessed side by side with new and old lots to determine relative performance.

Reporting requirements

1. Develop a new log sheet for verifying kit lots electronically or as a hard copy.

2. Complete entry of the appropriate identifying information in a new log for kit lot verification. The information being collected currently includes:
   • kit manufacturer;
   • kit name;
   • verification date;
   • kit lot number and the lot number of any other testing components if separate;
   • expiration date of the kit and of any other components;
   • lot comparison method used – patient specimens, proficiency specimens, external controls, serial dilution;
   • comparison lot number;
   • outcome of the comparison (pass/fail); and
   • operator name and signature.

3. Print out the new lot verification log and maintain in a binder. Write the accession number of the two samples and the date the study is being performed. Alternatively, store this information in a database electronically.

Sources:

Adapted from: Reagent lot verification using parallel testing. Baltimore: Johns Hopkins University; 2013 (http://www.google.com/url?url=http://resources.psmile.org/resources/process-control/parallel-testing/copy_of_reagent-lot-verification-using-parallel-testing&rct=j&frm=1&q=&esrc=s&sa=U&ei=SBLiU92ODcnG0QWS1oGICw&ved=0CCUQFjAD&usg=AFQjCNGZd65FExZMbkwvmRIBmYY_BUvEsg, accessed 9 November 2015).

Parekh B, Kalou M, Alemnji G, Ou C, Gershy-Damet G, Nkengasong J. Scaling up HIV rapid testing in developing countries: comprehensive approach for implementing quality assurance. Am J Clin Pathol. 2010;134:573–84.

Clinical laboratory technical procedure manual. 3rd ed. Wayne (PA): NCCLS; 1996 (NCCLS document GP2-A3).

Annex 15. Examples of monitoring and evaluation indicators for the quality of point-of-care CD4 testing

Indicator name	Indicator type	Data collection method	Related programme area
Number of individuals receiving point-of-care testing services and results			
Test result: positive or negative	Output	Routine programme	Laboratories, HIV testing and counselling settings
Test result: above or below threshold	Output	Routine programme	Laboratories
Service delivery point: antenatal clinics, labour and delivery, under-5 clinic, maternal and child health clinic, tuberculosis, sexually transmitted infections, outpatient department, inpatient, HIV care and treatment clinic, voluntary counselling and testing co-located, voluntary counselling and testing stand-alone, mobile, home-based, other	Output	Routine programme	Laboratories, HIV testing and counselling settings
Geographical area: district, region, province, other	Output	Routine programme	Laboratories, HIV testing and counselling settings
Previously tested during the reporting period: yes, no	Output	Routine programme	Laboratories, HIV testing and counselling settings
Type of counselling and testing: individual, couple, index client	Output	Routine programme	Laboratories, HIV testing and counselling settings
Specific populations: adults, pregnant and breastfeeding women, couples, adolescents, infants and children, key populations	Output	Routine programme	Laboratories, HIV testing and counselling settings
Key population: most-at-risk populations (sex workers, men who have sex with men, transgender people, people who inject drugs) and vulnerable populations	Output	Routine programme	Laboratories, HIV testing and counselling settings
Percentage of point-of-care testing sites that meet national service quality standards			
Service delivery point: antenatal clinics, labour and delivery, under-5 clinic, maternal and child health clinic, tuberculosis, sexually transmitted infections, outpatient department, inpatient, HIV care and treatment clinic, voluntary counselling and testing co-located, voluntary counselling and testing stand-alone, mobile, home-based	Output	Special studies or facility assessment	
Geographical area: district, region, province, other	Output	Special studies or facility assessment	
Number of health facilities that provide point-of-care testing services per 100 000 population	Output	Special studies or facility assessments	Health system strengthening
Number of individuals trained in point-of-care testing	Output	Special studies or facility assessments	Health system strengthening
Number of individuals who in the past 12 months received competency-based certificate, or higher-level training to (1) conduct or support HIV point-of-care testing (testers, master trainers, certified trainers, laboratory managers) and (2) audit point-of-care testing facilities	Output	Routine programme	Human resources for health
Percentage of sites with documented routine supportive supervision visits that address point-of-care testing HIV programmes	Process	Routine programme	Laboratories, HIV testing and counselling settings
Percentage of sited with documented routine quality measures and quality improvement initiatives that address point-of-care testing HIV programmes	Process	Routine programme	Laboratories, HIV testing and counselling settings
Proportion of HIV point-of-care testing facilities participating in an external quality assessment programme	Outcome	Supervisory visits, programme review	Capacity-building
HIV programme monitoring tools are updated to include the variables needed to monitor HIV point-of-care testing activities	Output	National programme review	Capacity-building

Indicator name	Indicator type	Data collection method	Related programme area
Number of individuals receiving point-of-care testing services and results			
Proportion of HIV point-of-care testing facilities receiving capacity-building on updated monitoring tools that capture variables needed to monitor HIV point-of-care testing activities	Outcome	Supervisory visits, programme review	Capacity-building
Are appropriate policies in place for the delivery of high-quality HIV point-of-care testing services? (aligned with WHO)	Outcome	Policy tracking table (one per priority policy)	Prevention, care, treatment
Are the aforementioned appropriate policies for the delivery of quality HIV services being implemented?	Input	Policy tracking table (one per priority policy)	Prevention, care, treatment
Supply chain and essential medicines			
Commodities stocked according to plan: number of facilities at a given level of the system with one or more tracer commodities between the minimum and maximum levels during a given period over the total number of facilities			
Commodity: rapid test kits, supplies and reagents for instrument-based HIV point-of-care testing diagnostic technologies, supplies for quality control	Outcome		HIV testing and counselling
System level: central, regional and district if included in the system as a supplying entity			HIV testing and counselling
Order fulfilment rate			
By: central to regional, regional to district and if possible, district to point-of-care testing facility	Outcome		Health system strengthening
On-time delivery rate			
By: central to regional, regional to district and if possible, district to facility	Outcome		HIV testing and counselling Health system strengthening
Percentage of facilities submitting inventory control reports on time and complete			
By: regional and district (if the district supplies facilities) and reports submitted on time but incomplete, and reports submitted late, but complete.	Outcome		HIV testing and counselling
Percentage of total stock lost in previous reporting period			
Cause (such as theft, expiry, damage) from each system level	Outcome		All
National supply chain plan in place and updated annually	Output		All
Are there inventory management and storage standard operating procedures? Are the standard operating procedures being used?			
Level of the system: central, regional, district, point-of-care testing facility	Output		HIV testing and counselling Health system strengthening
Standard operating procedures present and being used, and standard operating procedures present but not being used	Output		HIV testing and counselling Health system strengthening
Percentage of supply chain personnel who are trained in supply chain			
Level of the system, central, regional, district, point-of-care testing facility	Output		Human resources for health
			Health system strengthening

Enhanced monitoring indicator: HIV rapid test proficiency testing

Testing and counselling

Indicator name	Percentage of HIV rapid testing sites that participate in and successfully pass an HIV rapid test proficiency testing programme[a]
	[a]HIV rapid test proficiency testing programmes can use liquid or dried tube specimens to create their proficiency panels.
Purpose	The main purpose of this indicator is to monitor and improve the quality of HIV rapid testing. This indicator will:
	demonstrate that the sites are participating in a HIV rapid test proficiency testing programme; and
	demonstrate that the sites participating in the HIV rapid test proficiency testing programme have successfully passed proficiency testing during the reporting period or proficiency testing round.[b]
	[b]Successfully passing requires 100% reporting accuracy on the proficiency test panel by the site. All staff members that perform HIV rapid tests at a site should undergo proficiency testing to assess the individual competence of each tester. A site can report 100% score only if each tester has 100% reporting accuracy on the proficiency panel.
	% of sites participating in the HIV rapid test proficiency testing programme = $(P/N) \times 100$
	% of sites passing the HIV rapid test proficiency testing programme = $(S/P) \times 100$
	N: number of sites performing HIV rapid testing
	P: number of sites participating in the HIV rapid test proficiency testing programme during the reporting period or proficiency testing round (receive panels and return the results)
	S: number of HIV testing sites passing the HIV rapid test proficiency testing programme during the reporting period or proficiency testing round (accurately report 100% of the results on the proficiency panel)
Numerator	For the % of sites participating in HIV rapid test proficiency testing programme:
	P: number of HIV testing sites participating in the HIV rapid test proficiency testing programme.
	For the % of sites passing the HIV rapid test proficiency testing programme:
	S: number of HIV testing sites passing the HIV rapid test proficiency testing programme.
Denominator	For the % of sites participating in HIV rapid test proficiency testing programme:
	N: number of sites performing HIV rapid testing
	For the % of sites passing the HIV rapid test proficiency testing programme:
	P: number of HIV testing sites participating in the HIV rapid test proficiency testing programme
Disaggregation(s)	None
Data collection tool	Data should be available from the national reference laboratory or similar body implementing proficiency testing programmes in the country
Data collection frequency	Quarterly or after every proficiency testing round which falls during the reporting period

Method of measurement

This indicator measures the percentage of sites that participated in and successfully passed HIV rapid test proficiency testing.

Explanation of numerator

Number of HIV rapid testing sites that participate in and pass a national HIV rapid test proficiency testing programme

Explanation of denominator

Number of HIV rapid testing sites with the capacity to perform HIV rapid testing

Interpretation

This indicator measures the coverage of the HIV rapid test proficiency programme and the quality of HIV rapid testing in sites participating in the programme. Calculating the percentage of sites participating in the HIV rapid test proficiency testing programme provides information about the coverage of the proficiency testing programme and the progress towards the goal of 100% participation of testing sites. Calculating the percentage of sites passing the HIV rapid test proficiency testing programme provides critical information about the quality of rapid testing. The percentage of HIV testing sites passing the HIV rapid test proficiency programme will reach 100% when all participating HIV testing sites accurately report all results on the proficiency panel. Any site with a score of <100% on proficiency testing requires immediate technical assistance (site supervision) to review testing practices and implement corrective actions.

Site level proficiency testing indicates the quality of test site operations. Only by providing the proficiency panel to every tester in the site can the quality of individual personnel performance be assessed. Proficiency testing for every staff member performing HIV rapid tests should be conducted.

Proposed indicators for enhanced monitoring of sites implementing lifelong treatment

Indicator	
Percentage of HIV rapid testing sites that participate in and successfully pass an HIV rapid test proficiency testing programme	The implications of inaccurate HIV rapid test results at the individual and programme level requires testing sites to regularly participate in and successfully pass HIV rapid test proficiency testing.

Enhanced monitoring indicators 1: rapid test quality assurance

Robust quality assurance systems are essential to ensure that HIV rapid tests are performed properly, the testing algorithm is followed correctly and the results are recorded accurately. As part of a multi-step quality assurance system, the participation in and passing of HIV rapid test proficiency testing will improve the reliability and accuracy of HIV rapid testing and prevent misdiagnosis.

Indicator name	Percentage of HIV rapid testing sites using a standardized HIV rapid test logbook[a] to monitor the quality of HIV rapid testing
	[a]Or incorporating key quality assurance elements into existing HIV registers or HIV rapid test logbooks.
Purpose	The main purpose of this indicator is to monitor and improve the quality of HIV rapid testing. This indicator will:
	1. demonstrate that the testing sites have effectively implemented the standardized HIV rapid test logbook as an ongoing quality assurance monitoring tool; and
	2. demonstrate that the sites using the HIV rapid test logbook have acceptable testing performance during the reporting period.[b]
	[b]Demonstrating acceptable testing performance requires each site to have:
	• >98% agreement between the first rapid test and the second rapid test in the testing algorithm; and/or
	• <1% of HIV rapid tests performed have invalid results.
Numerator	% of sites using a standardized HIV rapid test logbook as an ongoing quality assurance monitoring tool = (L/N) X 100
	% of sites with acceptable testing performance using logbook data = (P/L) X 100
	% of invalid results for each test used in the algorithm = (IN1/T) X 100 or (IN2/T) X 100
	% agreement between test 1 and test 2 for serial algorithm = (CS/R) X 100
	% agreement between test 1 and test 2 for parallel algorithm $$= \frac{R - [(NG1 - NG2) + (PO1 - PO2)]}{R} \times 100$$
	N: number of sites that perform HIV rapid testing
	L; number of HIV testing sites that have implemented the standardized HIV rapid test logbook as an ongoing quality assurance monitoring tool
	P: number of HIV testing sites with acceptable testing performance using logbook data during the reporting period (have >98% agreement between the two rapid tests used in the testing algorithm and/or <1% invalid test results
Denominator	CS: number of concordant results between test 1 and test 2 for a serial algorithm (positive and negative)
	R: number of people tested (positive results + negative results; all invalid results excluded)
	T: number of HIV rapid tests performed (positive + negative + invalid)
	IN1: number of invalid test1 results during the reporting period
	IN2: number of invalid test2 results during the reporting period
	NG1: number of negative test1 results during the reporting period
	NG2: number of negative test2 results during the reporting period
	PO1: number of positive test1 results during the reporting period
	PO2: number of positive test2 results during the reporting period

Indicator name	**Percentage of HIV rapid testing sites using a standardized HIV rapid test logbook[a] to monitor the quality of HIV rapid testing**
	[a]Or incorporating key quality assurance elements into existing HIV registers or HIV rapid test logbooks.
Numerator	For % of sites using standardized HIV rapid test logbook as an ongoing quality assurance monitoring tool
	L: number of HIV testing sites that have implemented the rapid test quality assurance logbook
	For % of sites with acceptable testing performance using logbook data:
	P: number of HIV testing sites demonstrating acceptable testing performance using logbook data during the reporting period (have <1% invalid test results and/or >98% agreement between the two rapid tests used in the testing algorithm)
Denominator	For % of sites using the standardized HIV rapid test logbook as an ongoing quality assurance monitoring tool:
	N: number of sites that perform HIV rapid testing
	For % of sites demonstrating acceptable testing performance using logbook data:
	L: number of HIV testing sites that have implemented the standardized rapid test logbook
Disaggregation(s)	None
Data collection tool	The rapid test logbook monthly summary data sheets
Data collection frequency	Monthly

Method of measurement

This indicator measures the percentage of sites that have implemented the standardized HIV rapid test quality assurance logbook as an ongoing quality assurance monitoring tool and the percentage of sites with acceptable testing performance using logbook data during the reporting period.

Explanation of numerator

Number of sites that use the standardized HIV rapid test quality assurance logbook as an ongoing quality assurance monitoring tool and have acceptable testing performance demonstrated by logbook data

Explanation of denominator

Number of HIV rapid testing sites with capacity to perform HIV rapid testing

Interpretation

This indicator measures the uptake of the standardized HIV rapid test quality assurance logbook as an ongoing quality assurance monitoring tool and the monitors the accuracy of HIV testing. Calculating the percentage of sites using a standardized HIV Rapid Test logbook provides information about the uptake of the standardized logbook and progress towards the goal of 100% coverage of testing sites using the logbook. Calculating the percentage of sites with acceptable testing performance using logbook data provides critical information about the quality of rapid testing. The percentage of HIV testing sites with acceptable testing performance will reach 100% when all HIV testing sites have >98% agreement between the two rapid tests used in the testing algorithm and/or <1% invalid test results. Any site with testing performance with <98% agreement between test 1 and test 2 and/or >1% invalid test results requires immediate site supervision to review testing practices and implement corrective actions. All sites should be trained on how to conduct their own routine standardized logbook reviews to identify any problems with test kits or individual personnel performance.

Proposed indicators for enhanced monitoring of sites implementing lifelong treatment

Indicator	Rationale
Percentage of HIV rapid testing sites utilizing a standardized HIV rapid test quality assurance logbook as an ongoing quality assurance monitoring tool and demonstrating improvement in the testing performance using the logbook	The implications of inaccurate HIV rapid test results at the individual and programme level requires testing sites to regularly use and review a standardized rapid test logbook.

Enhanced monitoring indicators 2: HIV rapid test logbook

In addition to a proficiency testing programme, a comprehensive HIV rapid test quality assurance cycle includes the use of a standardized rapid test logbook as an ongoing quality assurance monitoring tool (or revising existing registers to include key rapid test quality assurance elements), ongoing training and retraining of testing personnel and periodic site supervision, which includes a thorough review of the rapid test quality assurance logbook and corrective actions. As part of a comprehensive quality assurance cycle, the effective use of the logbook and demonstrated improvement in the testing performance using the logbook will improve the accuracy of HIV rapid testing, ensure the reliability of the rapid test results and prevent misdiagnosis.

Annex 16. Special considerations

A. Special considerations for point-of-care testing for hepatitis

Area	Considerations for programmes
Point-of-care testing currently used or in the pipeline for this programme	**Hepatitis C** • Anti-HCV rapid diagnostic tests of immunochromatographic format. • There are no known anti-Ab/HCV Ag rapid diagnostic tests (exist for enzyme immunoassays and chemiluminescent immunoassays only). • HCV in vitro diagnostic medical devices undergoing WHO prequalification: • http://www.who.int/diagnostics_laboratory/140409_hcv.pdf?ua=1 • Some known manufacturers of anti-HCV rapid diagnostic tests: • Guangzhou Wondfo, InTec Products, NewScen Coast Bio-Pharmaceuticals, Core Technologies, Standard Diagnostics, Bioland, MedMira, Premier Medical Corporation, Span Diagnostics, Beijing Wantai, OraSure Technologies, EY Laboratories, Shanghai Kehua, Green Cross Medical Corporation, J Mitra & Co, LumniQuick Diagnostics • Possible future manufacturers of HCV serology for point-of-care testing: Chembio, MBio • Possible future manufacturers of qualitative HCV nucleic acid testing for point-of-care testing: Daktari, Mbio, EOSCAPE from Wave80 Biosciences. All are very far from market launch. • Possible future manufacturers of quantitative HCV nucleic acid testing for point-of-care testing: Alere, Daktari, Roche (IQuum), Wave 80 Biosciences, Cepheid, Hologic Gen-probe. All are very far from market launch. **Hepatitis B** • HBsAg rapid diagnostic tests of immunochromatographic format. • Some rapid diagnostic tests available for other HBV markers (anti-HBc total [IgM +IgG], anti-HBc IgM, HBeAg, anti-HBe, anti-HBs) • HBsAg in vitro diagnostic medical devices undergoing WHO prequalification: • http://www.who.int/diagnostics_laboratory/140409_hbv.pdf?ua=1 • Some known manufacturers of HBsAg rapid diagnostic tests: • Abon Biopharm, Alere Medical Japan, Standard Diagnostics, Guangzhou Wondfo, InTec Products, LumniQuick Diagnostics, Bio Focus, other Chinese suppliers with unknown manufacturers • Some known manufacturers of anti-HBc rapid diagnostic tests: Acon, MedMira, LumniQuick Diagnostics, other Chinese suppliers with unknown manufacturers • Some known manufacturers of HBeAg rapid diagnostic tests: CTK Biotech, Binax Alere, AssureTech, Blue Cross bio-Medical, LumniQuick Diagnostics, Creative Diagnostics, Medinostics International, other Chinese suppliers with unknown manufacturers • Some known manufacturers of anti-HBs rapid diagnostic tests: Bio Focus, LumniQuick Diagnostics, Fortress Diagnostics, other Chinese suppliers with unknown manufacturers • Some known manufacturers of laboratory-based qualitative and/or quantitative HBV DNA nucleic acid testing: Roche, Abbott, Siemens. • Possible future manufacturers of quantitative HBV nucleic acid testing for point-of-care testing: LAMP format?

Area	Considerations for programmes
Settings in which point-of-care testing are used and operators in this programme	**Settings** • Currently rapid diagnostic tests for point-of-care testing are not as widely used as those for HIV rapid diagnostic tests. Screening and diagnosis of viral hepatitis is usually through blood donor screening or when clinical signs and symptoms arise and are referred to a hepatologist or infectious disease physician for care and treatment. These are usually services that are based in hospitals/facilities where there are laboratory services available. • Theoretically, there is nothing about the format of anti-HCV or HBsAg rapid diagnostic tests and HCV or HBV nucleic acid testing for point-of-care testing that would preclude these products from being used in non-laboratory settings since they generally have the same properties as their HIV equivalents. • The only differences are that some brands of anti-HCV and HBsAg rapid diagnostic tests have not been validated for fingerstick whole blood and may require cold-chain storage. This is usually because the manufacturer has not performed the validation or has not considered this potential intended use in their design of the product. It could be done if it was requested and evidence of validation is required. **User** • There is nothing to limit the operation of rapid diagnostic tests for viral hepatitis by non-laboratory but trained personnel. The test result can be interpreted; however, the serostatus report might require clinician intervention, for example, if more than one HBV marker were to be tested. • Who can perform the test is one thing; whoever can decide on the HBV status report might need to have more laboratory training. Potentially easier for HCV, if Ab result only required.
Challenges associated with point-of-care testing in this programme	• Does not follow the typical testing service delivery model that has been well established for HIV. Less emphasis on non-laboratory testing services as the care and treatment of viral hepatitis is very medicalized, unlike for HIV. Also, countries in the WHO Eastern Mediterranean, South-East Asia and Western Pacific Regions are much more affected by viral hepatitis than countries in the WHO African Region; there has been less update of non-laboratory HIV testing services (rapid diagnostic tests, community-based, non-laboratory users, etc.) in these settings. • For HCV, rapid diagnostic tests only detect antibodies and do not indicate viraemic state. This means that rapid diagnostic tests will detect both active (and transmissible) and past resolved or treated infections. It is highly unlikely that the coming nucleic acid testing for point-of-care testing of HCV RNA will be used down to the same level as rapid diagnostic testing for anti-HCV, so you will always need to refer for confirmation of viraemic status. If same-day diagnosis is the goal, then to put rapid diagnostic tests and nucleic acid testing in the same place makes sense. If the goal is to screen all for anti-HCV, then you can expand the deployment of rapid diagnostic tests below where nucleic acid testing would be available. Examples include people who inject drugs, who do not generally like to come in for traditional health services.
Specific quality assurance issues relevant to point-of-care testing in this programme	Same as for HIV.
Key strategies to strengthen quality assurance for point-of-care testing for this programme	Same as for HIV.

B. Special considerations for point-of-care testing for HIV testing and counselling

Area	Considerations for programmes
Point-of-care testing currently used or in the pipeline for this programme	HIV rapid diagnostic tests List of common rapid diagnostic tests currently approved and used by countries can be found via the following links: List of products eligible for WHO procurement: http://www.who.int/diagnostics_laboratory/procurement/140514_v12_pqed_products_eligible_for_procur_2014.pdf?ua=1 USAID Waiver List: http://www.usaid.gov/sites/default/files/documents/1864/hiv_tests.pdf CD4 instruments for point-of-care testing are also used to determine CD4 counts for HIV-seropositive people and facilitate the initiation of antiretroviral therapy and linkage to care In the pipeline, device-free point-of-care CD4 tests for point-of-care testing, point-of-care viral load testing for point-of-care testing or near to point-of-care testing

Settings in which point-of-care testing are used and operators in this programme	Point-of-care testing is used in facility-based settings including antenatal care, TB and sexually transmitted infection clinics, outpatient departments and inpatient wards and co-located and stand-alone HIV testing and counselling sites.
	Point-of-care testing is also used in a wide range of community-based settings including mobile units, tents, workplace, homes, schools, etc.
	HIV rapid diagnostic tests are conducted by laboratory professionals, trained health care providers, and lay counsellors.
	Several countries are developing policies for HIV self-testing. Currently over the counter rapid diagnostic tests in the private sector, for the purpose of self-testing, are available in many countries, as well as ongoing research-based programmes examining HIV self-testing in the public sector.
Challenges associated with point-of-care testing in this programme	Adequate training including refresher training for staff performing HIV rapid diagnostic tests
	Adequate mentoring for new staff and ongoing supervision for all staff to monitor and ensure the quality of testing
	Proper documentation incorporated into HIV testing and counselling or stand-alone registers for monitoring performance of tests kits and the individual performing them.
	Focus on quantity (number of people tested) instead of quality (did the individual receive the correct result?).
	Adequate quality assurance procedures, including proficiency testing to monitor skills of tester, retesting of seropositive patients to ensure correct test result before initiating treatment, post-marketing surveillance to identify problems with test kits and follow-up at test sites performing poorly with corrective action to improve the quality of testing.
	Back-up testing algorithms and functioning supply chain management systems to deal with and prevent stock-outs of test kits and supplies
	Providers adhering to standard operating procedures (particularly reading times) in settings with limited human resources and high patient volume
	National policies to support the implementation of quality assurance efforts for HIV rapid diagnostic testing.
Specific quality assurance issues relevant to point-of-care testing in this programme	Use of standardized logbook for monitoring the performance of test kits and individuals conducting point-of-care tests
	Supervision and refresher trainings for staff conducting testing at point-of-care.
	Retesting of people who test positive before initiating antiretroviral therapy to ensure that their initial testing was conducted correctly and that they have received the correct test result.
	Test for triage approach, using a single rapid HIV test in community-based settings and then onward referral and linkage to a facility to confirm test results could be considered to improve quality testing.
	Personal identifier: to monitor the retesting cases and know not only the number of tests done but also the number of people tested to meet the 90–90–90 target.
	Proficiency testing to monitor the skills of individuals tasked with conducting testing at the point of care, including HIV rapid diagnostic tests.
	Implementing quality assurance and quality improvement methods including indicators to monitor quality at all levels of the health system
	HIV self-testing is not a diagnosis. Reactive (positive) self-test results need to be confirmed in a facility using a national algorithm. Important that health workers start the algorithm from scratch. Quality assurance systems need to ensure that they can address or acknowledge HIV self-testing and that self-test results are not used for diagnosis or as first-line screening tests.
Key strategies to strengthen quality assurance for point-of-care testing for this programme	Implementing key variables into HIV testing and counselling registers or using a stand-alone standardized logbook for monitoring HIV rapid diagnostic test performance.
	Strengthening training curricula and refresher training for providers of HIV rapid diagnostic tests.
	Implement retesting procedures using a different tester or a more specific algorithm for individuals who receive an HIV-positive test result to ensure that they have received a correct diagnosis.
	Implement proficiency testing programmes to monitor the skills of point-of-care testing providers and ensure that corrective measures are taken to improve quality at sites performing poorly.
	Training programme managers and providers on quality assurance and quality improvement approaches for point-of-care using HIV rapid diagnostic tests.
	Developing national quality assurance indicators for point-of-care testing using HIV rapid diagnostic test and indicators to track the uptake of WHO serial algorithms.
	Conduct site monitoring visits and observations to determine whether providers are following standard operating procedures for point-of-care testing using HIV rapid diagnostic tests and other quality assurance procedures.
	Ensure the cold chain from the time the rapid diagnostic tests are ordered until they are used.

C. Special considerations for point-of-care testing for children

Area	Considerations for programmes
Point-of-care testing currently used or in the pipeline for this programme	HIV rapid testing is recommended for children greater than 18 months of age (and as an initial screening test for infants 9–18 months of age), and many point-of-care tests are available. Infant testing using virological methods such as DNA/RNA amplification or p24 antigen detection is recommended for diagnosing HIV in children younger than 18 months of age, but no point-of-care tests are available. CD4 testing is recommended for determining eligibility for antiretroviral therapy among children older than 5 years of age and monitoring treatment response where viral load is not available, and at least two point-of-care CD4 tests are currently available. Viral load testing is recommended for all children receiving antiretroviral therapy, but no point-of-care tests are available.
Settings in which point-of-care testing are used and operators in this programme	There is significant overlap with the considerations for preventing the mother-to-child transmission of HIV. HIV rapid testing for children is currently performed by nurses and lay counsellors in multiple entry points, including HIV testing and counselling sites, paediatric clinics and hospitals, antiretroviral therapy clinics, immunization clinics and anywhere children are seen for care. Testing algorithms usually comply with country-specific recommendations. Point-of-care infant testing, when it becomes available, will likely be performed by nurses, laboratory assistants, laboratory technicians, and in some cases lay counsellors at all the same entry points where sample collection for laboratory-based infant testing is currently conducted, including antenatal care clinics, paediatric clinics and hospitals, antiretroviral therapy clinics and immunization clinics. It should ultimately be available anywhere children are seen for care, at facilities with and without a laboratory. As infant testing expands to testing at birth, it will also be needed at maternity wards. Point-of-care CD4 testing for children is currently performed by nurses, laboratory assistants, laboratory technicians, and in some cases lay counsellors, in multiple entry points, including HIV testing and counselling sites, paediatric clinics and hospitals and antiretroviral therapy clinics, at facilities with and without a laboratory. Point-of-care viral load testing for children, when it becomes available, will likely be performed by nurses, laboratory assistants, laboratory technicians, and in some cases lay counsellors at facilities where antiretroviral therapy is provided, including paediatric clinics and hospitals, at facilities with and without a laboratory.
Challenges associated with point-of-care testing in this programme	Large number of sites where testing is needed, with low testing volumes at many sites, particularly for infant testing. HIV rapid diagnostic test, point-of-care CD4 and point-of-care viral load testing for children will be able to piggyback on adult testing programmes. Infant testing may be in the form of a separate test that is not required for adults (although some point-of-care technologies may perform both viral load and infant testing). Point-of-care CD4 and viral load will likely be performed primarily at sites where antiretroviral therapy is provided. Laboratory-based infant testing uses sample referral networks from a vast number of collection sites, many more than the number of sites currently providing point-of-care CD4 or antiretroviral therapy. The added urgency of receiving an infant test result and initiating antiretroviral therapy, due to the high infant mortality in the first 3–4 months of life, gives infant testing the strongest argument for providing point-of-care testing to as many testing sites as possible. Testing may even be needed at multiple locations within a single site, for example at the maternity ward and the immunization clinic within a hospital, either using multiple point-of-care devices or multiple sample collection points for the same point-of-care device. Infant testing volumes at each site will likely be very low, leading to a high cost per person of providing testing and implementing quality assurance systems. Expanding access will require training large numbers of health-care workers on new technologies and testing procedures, including lower-level health-care workers Distributing testing supplies to large numbers of sites Implementing quality assurance systems to large numbers of sites Procuring expensive equipment for large numbers of sites Providing service and maintenance for large fleets of equipment New point-of-care technologies may not perform as well for children as they do for adults. For example, some viral load technologies may be semi-quantitative, giving a result as either above or below a specific clinical threshold, but these results may not be applicable or accurate for children. Similarly, some point-of-care viral load technologies may be able to diagnose HIV in infants, but exposure to antiretroviral drugs may reduce sensitivity. Technologies specifically designed for children may be needed. Measuring the sensitivity and specificity of point-of-care rapid testing for infants and young children requires distinct evaluation, since physiological differences surrounding perinatal infection may alter the performance of the assays in this population. Any point-of-care testing among children, particularly those involving the collection of whole blood rather than dried blood spot specimens, must consider the volume of required blood in the protocols, since this can be a barrier for collecting samples among children.

Area	Considerations for programmes
Specific quality assurance issues relevant to point-of-care testing in this programme	Providing quality assurance for large numbers of testing sites, particularly for infant testing, will be especially challenging and will require stand-alone strategies to accommodate infant testing programmes: Training large numbers of health-care workers, including lower-level workers, on standard operating procedures for testing, internal quality controls and external quality assessment Distributing proficiency testing panels for external quality assessment and collecting and analysing results from large numbers of sites Monitoring testing using connectivity at extremely remote sites that may have limited network coverage
Key strategies to strengthen quality assurance for point-of-care testing for this programme	There is significant overlap with considerations for preventing the mother-to-child transmission of HIV. Rapid testing, point-of-care CD4 and point-of-care viral load testing for children should leverage adult testing and quality assurance programmes. Some form of quality assurance is needed in every testing site. However, the large number of testing sites, particularly for infant testing, requires giving priority to quality assurance activities. The initial focus should be on operator training, retraining and certifying every testing site. Proficiency testing programmes should give priority to high-volume testing sites first. Site selection for point-of-care infant testing should also give priority to sites with the highest potential testing volumes and those where it will be most feasible to implement quality assurance systems and to maximize access, patient impact, testing quality and cost efficiency.

D. Special considerations for point-of-care testing for preventing the mother-to child transmission of HIV

Area	Considerations for programmes
Point-of-care testing currently used or in the pipeline for this programme	• HIV rapid diagnostic tests • CD4 • Viral load (pipeline) • Infant testing (see the considerations for children) • Chemistry, haematology, sexually transmitted infections (see considerations for sexually transmitted infections)

Settings in which point-of-care testing are used and operators in this programme	• HIV rapid diagnostic tests
	  ◦ Nurses and lay counsellors perform HIV rapid diagnostic testing in maternal, newborn and child health settings
	  ◦ Multiple locations in maternal, newborn and child health settings where HIV rapid diagnostic testing occurs (antenatal care, labour and delivery, infant follow-up clinic, paediatric outpatient department, paediatric ward)
	• CD4
	  ◦ Nurses or other trained staff perform CD4 in facilities without a laboratory
	  ◦ CD4 is needed for clinical monitoring postpartum and is performed in maternal, newborn and child health facilities without a laboratory
	• Viral load
	  ◦ Likely to be performed by a laboratory professional, nurse or other trained staff in facilities without a laboratory
	  ◦ When used for clinical monitoring, this will likely be performed in maternal, newborn and child health facilities without a laboratory

Challenges associated with point-of-care testing in this programme	• Training
	  ◦ Different types of health-care workers performing HIV rapid diagnostic testing and other point-of-care testing
	  ◦ Multiple locations for HIV rapid diagnostic testing in the same facility
	• HIV rapid diagnostic testing and point-of-care testing quality assurance logbook
	  ◦ Multiple registers already used in maternal, newborn and child health settings
	  ◦ High workload of maternal, newborn and child health staff
	  ◦ Staff not used to implementing quality assurance activities
	• Dried tube specimens proficiency testing
	  ◦ Logistics for dried tube specimens proficiency testing panel distribution and results return in numerous decentralized sites with multiple testers per site in different locations in a facility
	  ◦ Logistics for following up unsatisfactory proficiency testing results in numerous decentralized sites

Area	Considerations for programmes
Specific quality assurance issues relevant to point-of-care testing in this programme	• As HIV testing and counselling services offered in maternal, newborn and child health settings are scaled up through the implementation of testing and treatment for pregnant and breastfeeding women living with HIV (option B+), there is an increased need to ensure the quality of HIV rapid diagnostic testing. In particular, it is important that HIV-seronegative women not mistakenly be initiated on lifelong antiretroviral therapy. • Maternal, newborn and child health settings implementing option B+ should be given priority for implementing quality assurance activities for HIV rapid diagnostic testing since antiretroviral therapy initiation is solely based on the results of the HIV rapid diagnostic testing without additional immunological (CD4 count) or virological (viral load) testing before initiation.
Key strategies to strengthen quality assurance for point-of-care testing for this programme	• Quality assurance is required in every site. • Having large number of sites requires giving priority to quality assurance activities. • Focus should be on HIV rapid diagnostic testing and point-of-care testing training, retraining and certification and the use and analysis of a HIV rapid diagnostic testing and point-of-care testing quality assurance logbook at every site. • The proficiency testing programme should focus on high-volume testing sites. • A dried tube specimen proficiency testing programme (including panel distribution, results return and feedback) can be combined with clinical site supervision in maternal, newborn and child health settings and settings for preventing the mother-to-child transmission of HIV and site supervision for point-of-care testing to facilitate logistics • Implement repeat and confirmatory testing of all HIV-positive people before initiating antiretroviral therapy as a strategy in the quality assurance process (additional data are needed to determine whether this strategy reduces misdiagnosis and is cost-effective) • See Annex 1 for the HIV rapid testing quality assurance checklist for maternal, newborn and child health settings

E. Special considerations for point-of-care testing in sexually transmitted infections

Area	Considerations for programmes
Point-of-care testing currently used or in the pipeline for this programme	• Point-of-care tests for syphilis, *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis* and human papillomavirus are commercially available. • Most tests are immunochromatographic in strip or cassette format. • There are several commercially available combined HIV and syphilis rapid diagnostic tests that are undergoing WHO prequalification • There is a reasonably robust pipeline for point-of-care testing (or near-point-of-care) diagnostics for dual HIV and syphilis testing as well as nucleic acid amplification assays for *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Chlamydia trachomatis/Neisseria gonorrhoeae*, *Trichomonas vaginalis* and human papillomavirus screening.
Settings in which point-of-care testing are used and operators in this programme	• Most are used in small sexually transmitted infection clinics by nurses or laboratory staff. • Some point-of-care tests are used in outreach settings by community health care workers. • The combined HIV syphilis assays are also used in antenatal care clinics.
Challenges associated with point-of-care testing	• Point-of-care tests for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* are expensive, require 7–14 steps and have low sensitivity.
Specific quality assurance issues relevant to point-of-care testing in this programme	• None of the marketed point-of-care tests have internal controls, and external quality assurance or proficiency testing is rarely carried out. • Materials for quality assurance are not commercially available. • Dried tube specimens may be prepared from blood for antibody detection tests. • Except for the WHO Syphilis Serology Proficiency Programme run by the United States Centers for Disease Control and Prevention, external quality assessment programmes for sexually transmitted infection testing are expensive and hence out of reach of most sexually transmitted infection programmes in low- and middle-income countries.
Key strategies to strengthen quality assurance for point-of-care testing for this programme	• Develop national quality assurance systems for point-of-care tests, with each national reference laboratory generating proficiency panels for distribution to point-of-care testing sites around the country. • For instrument-based point-of-care tests, the quality of testing may be determined by transmitting a picture of the test result to a central database for checks by a supervisor.

F. Special considerations for tuberculosis point-of-care testing

Area	Considerations for programmes

Point-of-care testing currently used or in the pipeline for this programme	• Currently available and WHO endorsed:
	  • Smear microscopy
	  • Xpert MTB/RIF
	
	• Pipeline or not yet WHO endorsed: (http://www.unitaid.eu/images/marketdynamics/publications/UNITAID-TB_Dx_Landscape-Update_Dec%202013.pdf; http://www.unitaid.eu/images/marketdynamics/publications/TB-Dx-Landscape_1-Jul-2013.pdf)
	
	• Determine TB-LAM, Eiken Loopamp MTBC Detection, Epistem Genedrive Mycobacterium ID, Molbio Truelab TB, Ustar EasyNAT TB, Alere Q, QuantuMDx Q-TB, Wave80 EOSCAPE TB, NWGHF

Settings in which point-of-care testing are used and operators in this programme	• Peripheral and intermediate laboratories • Testing by laboratory staff • Health facilities (limited use) • Testing by nurses and other healthcare workers
Challenges associated with point-of-care testing in this programme	• Currently, there is no true point-of-care test available for detection of TB disease that is both sensitive and specific. • Although conducted at point-of-care in select settings, Xpert MTB/RIF is instrument-based and requires stable electricity, temperature-controlled environments for testing and kit storage. • Same-day diagnosis and treatment initiation are limited.
Specific quality assurance issues relevant to point-of-care testing in this programme	• Numerous types or errors and uninterpretable results requires significant end-user training • Aggregate data collection for performance monitoring not easily accessible • Proficiency testing panel distribution and corrective action limited due to the number of testing sites and lack of global consensus on appropriate approaches • On-site supervisory visits costly
Key strategies to strengthen quality assurance for point-of-care testing for this programme	• Development of consensus standardized, customizable training materials (such as http://www.stoptb.org/wg/gli/TrainingPackage_XPERT_MTB_RIF.asp) • Remote monitoring software (diagnostic manufacturer or third party) for routine, centralized analysis of performance indicators • Expanded availability of proficiency testing panels, including technology transfer to regional or national laboratories • Integrated supervisory visits using standardized checklists

Annex 17. HIV rapid testing quality assurance checklist for maternal, newborn and child health settings

Background

The past decade has seen rapid global scale-up of HIV testing and counselling, the vast majority using HIV rapid tests. The relative simplicity of HIV rapid diagnostic testing has expanded the accessibility of HIV testing in areas with limited laboratory facilities and no formal laboratory-trained staff, thereby significantly increasing the number of people who learn their HIV status. As more countries implement revised WHO guidelines that recommend early treatment for all pregnant and breastfeeding women and for all children younger than 5 years of age (option B+), there is an increased need to ensure the quality of rapid HIV testing and address common service delivery issues regarding HIV testing in maternal, newborn and child health clinics.

Purpose and intended use of the tool

The purpose of this checklist is to facilitate the process of thinking through key HIV rapid test quality assurance[1] and programmatic issues needed to improve HIV rapid testing in maternal, newborn and child health settings. This document expands on the option B/B+ readiness assessment checklist and offers more detailed recommendations on specific HIV testing activities.

Audience

This checklist will be useful for public health authorities, programme managers and laboratory technicians at the central, regional and district levels when planning for and establishing minimum standards and requirements for the quality assurance of HIV rapid testing in maternal, newborn and child health programmes.

Introduction

The 2013 WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection recommended providing antiretroviral therapy for all children living with HIV younger than 5 years of age and for pregnant and breastfeeding women living with HIV. Consequently, antiretroviral therapy initiation is based solely on the result of the HIV rapid test for pregnant and breastfeeding women and for children aged 18 months to 5 years (children younger than 18 months have PCR as their diagnostic HIV test). HIV rapid tests can be misclassified (false positive or false negative) due to use of expired test kits, lack of quality assurance procedures, deviation from the national testing algorithm and not using WHO-recommended serial algorithms (including a screening test, confirmatory test and tiebreaker), any deviation from the HIV rapid testing standard operating procedures, lack of adequate training or supervision or inherent limitations of the HIV rapid tests. Responsible programming requires implementing quality assurance systems to ensure the accuracy of HIV test results. In particular, it is important that HIV-negative women and children not mistakenly be initiated on lifelong antiretroviral therapy and that women and children living with HIV not miss opportunities for services for preventing the mother-to-child transmission of HIV and for antiretroviral therapy due to misdiagnosis.

The following areas need to be addressed to assure the quality of HIV rapid tests: (1) a national policy for HIV rapid test quality assurance; (2) standardized HIV rapid test training and national certification programme for testers and provide ongoing supervision;[2] (3) regular use and review of standardized HIV rapid test logbooks including quality assurance;[3] (4) implementation of a national HIV rapid test external quality assessment programme;[4,5] (5) the routine use of quality control samples for monitoring and evaluation; and (6) logistics and stock management strengthening, to avoid stock-outs. It is critical that all maternal, newborn and child health sites adopt these policy and quality assurance activities to ensure the accuracy of HIV test results.

1 Parekh BS et al. Scaling up HIV rapid testing in developing countries: comprehensive approach for implementing quality assurance. Am J Clin Pathol. 2010;4:573–84.

2 http://whqlibdoc.who.int/publications/2005/9241593563_eng.pdf?ua=1

3 A Handbook for Assuring and Improving Quality of HIV Testing and Counselling http://whqlibdoc.who.int/publications/2010/9789241500463_eng.pdf?ua=1

4 Parekh BS, et al. Dried tube specimens: a simple and cost-effective method for preparation of HIV proficiency testing panels and quality control materials for use in resource-limited settings. J Virol Methods. 2010 Feb;163(2): 295-300

5 Benzaken AS et al. External quality assurance with dried tube specimens (dried tube specimens) for point-of-care syphilis and HIV tests: experience in an indigenous populations screening programme in the Brazilian Amazon. Sex Transm Infect. 2014 Feb;90(1):14-8.

HIV rapid test quality assurance checklist for maternal, newborn and child health settings

Recommended timing

Before implementation

Early in implementation

During implementation

	Completed	In process	Not yet started
Policy engagement			
National guideline for laboratory quality assurance in HIV rapid testing			
Costing and budget allocation for quality assurance activities			
National technical working group including stakeholders from maternal, newborn and child health, services for preventing the mother-to-child transmission of HIV, provider-initiated HIV testing and counselling, HIV treatment and laboratory to review HIV testing strategies and ensure that the national HIV testing algorithm follows WHO guidance			
Implement mechanisms to address rapid test kit stock-outs, expired test kits and recalls			
Include rapid test quality assurance monitoring in all site supervision visits			
Policy decision on the treatment of discordant couples			
Training and certification			
National policy requiring training, periodic re-training (every two years) and certification of HIV testing personnel			
Quality-assured HIV testing training curricula incorporated into all preservice and in-service antiretroviral therapy and services for preventing the mother-to-child transmission of HIV (maternal, newborn and child health) training; job aids, standard operating procedures and DVDs provided			
Use of standardized logbooks			
Standardized HIV logbook or register used to capture key HIV testing data (such as kit names, lot number, expiration dates, the result of each test in the algorithm, results of regular internal quality control and external quality assessment)[a]			
HIV testing logbooks or registers harmonized across programmes and used at all sites (such as HIV testing and counselling, services for preventing the mother-to-child transmission of HIV, inpatient, etc.)			
Ensure that clinical site staff and site supervisors review standardized logbook data and perform corrective actions as needed (data compiled as monthly reports for centralized analysis with reports fed back to sites, including performance in external quality assessment)			
Proficiency testing and quality control			
External proficiency testing and an internal quality control programme are in place to monitor the competence of all testing personnel and sites with dried tube specimens or plasma or serum			
Proficiency testing programme data are used to provide timely feedback and corrective actions to the testing sites			
Service delivery			
Strategy for repeat testing during pregnancy, labour and delivery and in the breastfeeding period			
Strategy for HIV testing for older children of pregnant and breastfeeding women living with HIV			
Partner testing and disclosure assistance services for all pregnant and breastfeeding women			
Strategy to provide antiretroviral therapy to male partners living with HIV			
Implementing universal HIV screening at immunization clinics in settings with high burden of HIV infection			

[a]Revising existing registers to include key HIV rapid testing quality assurance elements is an acceptable alternative.

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