

Technical series on HIV comprehensive care with
public health approach (CC-VIH)

Guidelines *for the Implementation of* *Reliable and Efficient diagnostic* HIV Testing

R E G I O N O F T H E A M E R I C A S



**Pan American
Health
Organization**

Regional Office of the
World Health Organization

GUIDELINES FOR THE IMPLEMENTATION OF RELIABLE AND EFFICIENT DIAGNOSTIC HIV TESTING

Region of the Americas

FCH

Family and Community Health

HIV/AIDS (AI)

Child and Adolescent Health (CA)

Women and Maternal Health (WM)

&

THS

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Essential Medicines, Vaccines and Health Technologies (EV)

2008

Pan American Health Organization

“Guidelines for the implementation of Reliable and Efficient Diagnostic HIV Testing, Region of the Americas”

Washington, D.C.: PAHO, © 2008

(Technical Documents. Policies. THS/EV-2008/001)

ISBN 978 92 7 512904 3

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3. IMMUNOLOGIC TESTS
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5. INVESTIGATIVE TECHNIQUES
6. QUALITY CONTROL
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(NLM WC 503.4)

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EXECUTIVE SUMMARY

Testing and counseling for human immunodeficiency virus (HIV) is now recognized as a priority in national HIV programs because it is the gateway to HIV/AIDS prevention, care, treatment, and support interventions. In order to ensure access to HIV testing for large populations and to facilitate access to antiretroviral treatment in the context of the World Health Organization's universal access strategy, radical scaling up of HIV testing and counseling services is urgently required.

The use of HIV rapid tests will facilitate this in many settings, particularly in services in which the people most likely to benefit from knowing their HIV status can be reached. These settings include diagnostic and treatment services for tuberculosis and sexually transmitted infections; services linked to the prevention of mother-to-child transmission of HIV; the management of occupational and non-occupational exposures to HIV; at voluntary counseling and testing (VCT) sites; in remote areas where the creation and maintenance of a laboratory infrastructure is not possible; and where hard-to-reach populations have access to HIV testing.

The practical advantages of introducing HIV rapid testing and counseling include the following: more people benefit from knowing their HIV status, results are communicated directly to the individuals tested, test results are obtained quickly, and less reliance is placed on centralized laboratory services for obtaining the results. HIV rapid tests are increasing the acceptance of point-of-care diagnostics by health care consumers.

The Algorithm. These guidelines describe a process for implementing government-approved, same-visit HIV testing in the Region of the Americas. Upon completion of this protocol, same-visit HIV test results will be reported using an algorithm encompassing HIV rapid testing and standard diagnostic procedures. These tests are performed at two levels: the local or community level, and the reference level. A positive diagnostic test result will be the entry point to access to HIV care and treatment services in country and will be accepted nationwide.

The Challenges. There are many challenges associated with scaling up same-visit HIV testing. The issue of quality assurance (QA) is paramount. QA depends on several critical factors, including the characteristics of the test itself, test-kit procurement, algo-

rithm selection and validation, training of personnel, continuous competency testing, and extensive monitoring of the entire testing process to ensure that the quality of testing is uniformly accurate at all testing locations. One characteristic that affects the quality of testing is the quality of the testing devices themselves; thus, tests must be nationally licensed and validated. HIV rapid tests are readily available and easy to use, even by non-laboratory personnel; however the interpretation of the rapid-test result is subjective. Therefore, Ministry of Health (MOH) certification of same-visit HIV testing will include MOH-approved training for each person who provides testing on its behalf. In order to ensure that testing is accurate, a training program and QA mechanisms must be implemented. Finally, the MOH should establish a mechanism for periodical reporting of rapid-test results to permit the monitoring and evaluation of rapid tests as a tool in the diagnosis of HIV infection.

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ACRONYMS

AIDS	acquired immune deficiency syndrome
CDC	United States Centers for Disease Control and Prevention
EIA	enzyme immunoassays
EQA	external quality assessment
HIV	human immunodeficiency virus
IQC	internal quality control
PAHO	Pan American Health Organization
PITC	provider-initiated testing and counseling
PMTCT	prevention of mother-to-child transmission
QA	quality assurance
SOP	standard operating procedure
VCT	voluntary counseling and testing
WHO	World Health Organization

1. OVERVIEW

THE ROLE OF HIV TESTING

Testing plays an essential role in evidence-based prevention of HIV transmission and in the expansion of access to higher-quality care and antiretroviral treatment. Since the beginning of the HIV/AIDS epidemic, surveillance testing to detect HIV infection has been widely used to monitor its trend. As the HIV epidemic has grown, the need for *individuals* to know their HIV status has become apparent. This need has fostered the development of diagnostic HIV testing. Despite significant progress, the vast majority of HIV-infected people are unaware of their status, making HIV testing and counseling a pivotal element of HIV prevention, care, and treatment services. The spread of HIV would be reduced if infected people became aware of their status as soon as possible after infection and received assistance to avoid exposing others to the virus.

In some places, diagnostic HIV test results also are used to provide surveillance information. These can be stripped of information connecting them to specific individuals and used to compile surveillance data about HIV in populations. Because diagnostic HIV testing can provide HIV-infection status information for both *individuals* and *populations*, the trend in HIV testing is toward diagnostic testing (1). An early indication of this trend was observed in 1999, when the U.S. Centers for Disease Control and Prevention (CDC) issued guidelines recommending the addition of individual HIV-case reports to surveillance data (2). The guidelines also included recommendations for ensuring the confidentiality of patient information in the reporting process.

To achieve universal access, HIV testing and counseling must be implemented on a broader and larger scale within clinical care settings and, at the same time, traditional, client-initiated voluntary counseling and testing (VCT) services that rely upon individuals to seek HIV testing must also be increased in number. Access to VCT services with same-visit HIV test results has greatly increased the number of people who know their HIV status (3, 4).

In addition, access to HIV testing and counseling has expanded within prenatal services, sexual and reproductive health services, tuberculosis (TB) clinics, and other clinical settings. In provider-initiated testing and counseling (PITC), individuals attending

health care facilities who might benefit from knowing their HIV status are routinely offered HIV testing and counseling, with the option to decline testing and thus “opt out.” In the PITC approach, every encounter between a patient and a health care provider is seen as:

- An opportunity for someone who has never known his or her HIV status to learn it
- An opportunity for someone who previously tested HIV-negative to consider taking another test and determine his current status (with reasonable frequency)
- An opportunity for the patient to live his life and make choices for himself and his family according to his HIV status
- An opportunity for health care workers to provide the best care and prevention services possible according to the patient’s HIV status

Routine testing with the right to decline refers to confidential HIV testing for patients who do not have HIV-related signs or symptoms yet are at risk for HIV infection and could benefit from knowing their HIV status. When patients with medical conditions or symptoms suggestive of HIV infection or AIDS seek medical attention, HIV testing is strongly recommended, as knowing a patient’s status is crucial for the provision of adequate medical care.

In many settings, there are important advantages to integrating HIV testing and counseling with services provided within the normal course of clinical care. More patients accept testing when it is offered routinely to everyone rather than only to high-risk groups. Normalizing HIV testing will very likely reduce the stigma associated with HIV infection. Progressively expanding access to treatment and prophylaxis for opportunistic infections and to antiretroviral therapy (ART) increases the incentive for people to know their HIV status. These interventions delay the onset of HIV-related illnesses, influence their course, and prolong life. HIV-positive people can also benefit from psychosocial and nutritional support as well as advice on how to “live positively” with the virus.

Similar to other medical conditions, such as hypertension and cervical cancer, HIV infection meets the criteria used to decide whether testing asymptomatic people for treatable conditions is justified. In clinical settings with concentrated epidemics (HIV prevalence greater than 5% in defined subpopulations), routine HIV testing and counseling with the possibility to opt out should be offered to all patients attending clinical services. On the other hand, routine HIV testing and counseling with the right to decline may not be a cost-effective strategy for many settings with low-prevalence HIV epidemics.

The way in which reliable and efficient HIV testing will be best implemented depends on several factors, including HIV prevalence, the level of the health care facilities (e.g., availability of a laboratory), the need for same-day results, and the availability and expertise of health staff. Strategies must be simplified, standardized, and adapted to the existing health care system to make the process more convenient for both patients/clients and providers.

Diagnostic HIV testing will be the entry point to all publicly funded HIV/AIDS care and treatment services.

2. PURPOSE OF THE GUIDELINES

These guidelines aim to help countries to expand testing and counseling services by taking advantage of opportunities presented during encounters between health care providers and the public. They describe the actions that need to be taken to deliver HIV testing in VCT settings (client-initiated testing) and in clinical settings (provider-initiated testing). This document emphasizes approaches that are most likely to have a broad public health impact while focusing on the implementation of reliable and cost-efficient HIV testing in existing health care settings.

The guidelines present simple and standardized testing strategies to be used as an entry point for HIV care, treatment, and prevention services in the Region of the Americas. This approach will facilitate the development of appropriate national HIV testing algorithms for laboratory and non-conventional laboratory sites.

3. OBJECTIVES

OVERALL OBJECTIVES

- To support universal access to HIV prevention, care, and treatment services by expanding HIV testing and counseling within VCT and clinical settings
- To provide guidance for countries to assess key issues for scaling up VCT and PITC tailored to local conditions, and to develop effective strategies and programs
- To promote a standardized approach to VCT and provider-initiated HIV testing and counseling in clinical settings

SPECIFIC OBJECTIVES

- To ensure reliable HIV testing in VCT and clinical settings through the implementation of quality systems
- To describe the different HIV testing strategies
- To describe procedures for the appropriate selection of HIV test kits and for the validation of the HIV test algorithms

4. QUALITY SYSTEM GUIDELINES¹

INTRODUCTION

Implementation of a quality system is critical to ensuring reliable testing results. Ensuring the quality of laboratory services requires a focus on all the components of laboratory operations, including organizational structure, documentation of policies and procedures, resource mobilization and management, management of laboratory data, internal and external quality control systems, preventive maintenance, procurement, inventory management, and safety.

The implementation of quality systems in both laboratory and non-conventional laboratory environments is indispensable. The training program for those performing HIV tests must be competency- and performance-based and must include a focus on good laboratory practice, laboratory safety, specimen collection and handling, recording and transcription management, reporting and data management, and quality control.

All testing algorithms must be validated in the country *prior* to implementation. Quality control specimens must be used to monitor the correct performance of HIV testing. Quality control traditionally involves the testing of specimens of a known value using the same reagents and equipment that are used for the specimens being measured. Since rapid/simple HIV test kits are single-use devices, this approach is not possible. Quality control specimens must therefore be used in a manner that monitors the correct performance of the test by the tester and the ability of the test kits to work properly. While it is not possible to test each kit, quality control specimens can be used to detect damage to an entire batch or lot of kits due to improper storage or handling, or through manufacturing defects.

¹ Section 4, Quality System Guidelines, is based largely on the guidelines presented in *Guidelines for Assuring the Accuracy and Reliability of HIV Rapid Testing: Applying a Quality System Approach* (5), published by the World Health Organization. The Pan American Health Organization is grateful for the permission to reproduce and modify the material.

ORGANIZATION AND MANAGEMENT

A strong commitment from top-level managers is essential for the success of the overall quality program. However, such commitment is important at all levels, and national laboratory leaders will need to provide strong leadership and motivate and help laboratory managers and HIV rapid-testing site officers throughout the country to understand the quality system and commit to its success.

Responsibilities at the National Level

Establishing a Laboratory Quality System

Implementing a quality system for laboratory diagnosis requires commitment from the top levels of management. The Ministry of Health, including national laboratory leaders with appropriate government authority, should establish a national quality system that includes:

- A national quality assurance or quality management office
- Appointment of a national quality manager
- Appointment of a multisectoral working team in order to extend the quality system to all aspects of testing practices and to avoid vertical decisions and assessments

The quality system should be extended to all tiers of the laboratory network (central, regional, district, point of service), and involve all service providers at all levels. It also should be extended to all laboratory testing, including HIV serologic testing.

Planning for HIV Test Management, including Rapid Tests

There must be an overall, nationwide plan for the management of HIV testing that clearly defines the role of HIV conventional testing versus rapid testing in the national program. The following steps are necessary to establish this plan:

- National policies must be established for the use of HIV conventional and rapid tests. Issues to be addressed include:
 - Use of rapid testing as an alternative to enzyme-immunoassays (EIA). When and where is this appropriate?
 - Personnel issues. Who will be allowed to perform HIV rapid testing, and what training and certification will be required? How will appropriate supervision be provided?

- Legal requirements that might apply to testing, such as national certification requirements for existing personnel as well as existing national laboratory and safety standards
- Evaluation and selection of HIV conventional and rapid test kits to be used in the country and establishment of algorithms to be used for testing
- Definition of a procedure for confirmation of HIV infection
- Development of a standard operating procedure (SOP) to be used in all testing sites
- Confidentiality of patient information
- Requirements for corrective or remedial action
- A strategic plan for implementing HIV conventional and rapid testing should be developed. This plan should include provisions for training of personnel and for continuous monitoring and improvement of the testing process. It is important to establish timelines as well as processes to address the implementation of the quality system's many elements.
- Performance monitoring processes that can identify problems and confirm that the system is working should be established. There must be a plan for solving problems, and a record of corrective actions taken must be kept.

RESPONSIBILITIES AT THE TESTING SITE

At the laboratory or point-of-care facility where conventional and/or rapid testing is being conducted, such as VCT and PITC settings, there must be assigned responsibility for testing oversight, for ensuring that the necessary staff and supplies are available, and for ensuring that confidential record systems are established and maintained. Steps towards achieving this should include the following:

- Responsibility for the management and coordination of the HIV testing quality system program at each site must be assigned to one person, who may be designated the quality or site officer/coordinator (hereafter referred to as the site officer). This responsibility should be assigned to someone with the authority to make and implement decisions; sound, in-depth knowledge of HIV testing procedures; and a complete understanding of the quality system essentials that need to be addressed. In some settings, one site officer might serve several sites. The site officer should have a clear channel of communication to the Ministry of Health, hospi-

tal authority, or other policy-making body, as well as to all staff who are performing testing, so that any changes in procedure or other important information can be shared in a timely fashion.

- An SOP must be available at each site. This step-by-step set of instructions outlining all the processes for conducting testing, including on-site rapid tests, must be accessible to everyone who performs tests.
- The site officer must ensure that all testing is performed by staff who are trained and certified according to the approved national requirements. The site officer must also have a plan for evaluating the competency of personnel who carry out testing, both initially and on an ongoing basis at appropriate intervals.
- Oversight of the record-keeping system must be provided.
- The site officer should ensure that all other components of the quality system are in place before testing is initiated at a site. No diagnostic testing should be conducted or results released until the site can be demonstrated to be properly prepared according to criteria defined in the SOP.

PERSONNEL

The most important resource in any health care setting is its staff. The selection criteria for personnel who will conduct testing should be developed by program managers. It is essential that this valuable resource be given the tools needed to perform testing so that accurate and reliable test results are obtained. Direct support for the testing staff will include initial training for testing and some means of periodically evaluating each person. This periodic evaluation is conducted to ensure that all protocols, including SOPs, are being followed and that testing continues to be performed accurately. Unlike other laboratory testing, HIV rapid tests will frequently be performed by individuals who have no training in laboratory technology. Thus, while training is critical for all testing staff at all levels of the health system, very careful attention must be given to the training provided for non-laboratory personnel (6).

Training for Persons Who Will Be Performing HIV Conventional and Rapid Testing

Training Programs for Testers

Frequently, training of large numbers of staff will be accomplished when testing is broadly implemented, for example in the establishment of a new group of VCTs or the

expansion of PITC in clinical settings such as TB clinics, sexually transmitted infection clinics, or PMTCT programs. A standardized training program for non-laboratory staff should be developed in close collaboration with national reference laboratory personnel and implemented at all levels of service delivery. An appropriate course of training must be conducted. A competency-based approach to training should be followed to ensure that trainees are adequately prepared to provide reliable testing. Training for test performance is usually integrated into a program that covers all aspects of counseling and testing, including:

- Good laboratory practice
- Effective communication and customer service
- Troubleshooting approaches
- Review of recording formats
- Instruction in test performance, including all parts of the process, from specimen collection to the reading, interpretation, recording, and reporting of results, as well as the proper use of external control materials
- Hands-on practice, with all participants actually carrying out specimen collection and testing procedures
- An explanation of how the test is used in the program at the site
- The importance of quality assurance
- The importance of biohazard safety procedures, including waste disposal
- An assessment of the participant's ability to safely and accurately perform the testing

In the period immediately following training, when newly trained staff first begin to test clients, continuous supervision and mentoring are important.

Plan for Ongoing Training of New Staff

The national training plan must provide for the training of new staff as they are hired. This will be critical to the maintenance of quality and reliable testing, and may sometimes be a challenge, as training may have to be conducted for only one or two people. However, all new staff should receive the same training as staff who attended the initial training.

Training for Supervisors and Site Officers

Training for Supervisors and Monitors

In many settings, oversight and monitoring of the quality of HIV testing will be performed by local laboratory staff. When choosing personnel to provide oversight and monitoring, consideration should be given to good communication skills, an ability to organize and carry out these tasks, an ability to motivate, a track record of reliability, and proven problem-solving skills. Additionally, oversight and monitoring require a set of skills and knowledge not always included in the initial laboratory technology training, thus training must be provided in monitoring, performing on-site evaluations, and advising and assisting testing personnel.

Training for Trainers

Training plans should include training for the trainers themselves. Also, it is important to make available training for program staff who may not be performing the testing but who need to know how the tests are conducted and how they work.

Proof of Competency and Early Monitoring of Performance

The government or its delegated authority should develop a program for the exclusive certification of non-laboratory staff as proof of achieving competency in HIV rapid testing. An important first step is to establish criteria for the successful completion of a standardized training program, including a written examination on material presented during the training and a demonstration of competency to conduct HIV rapid tests by testing a proficiency panel. This competency check could be conducted in the following manner: Before assignment to a new test site, testers perform an internship at an established site under direct supervision, where they are observed by experienced and trained personnel during the testing of at least 50 specimens, or until the individual has demonstrated competency based on the site checklist.

In the first few months following training, new staff should be closely supervised. On-site monitoring visits should be frequent, since these provide opportunities to help new staff improve skills and recognize problems when they occur. New staff will need to know how to seek help from laboratory professionals to solve the problems they identify.

Persons without formal laboratory training who are not certified through an official program should not be allowed to perform HIV rapid tests.

Continuous Competency Evaluation

A method for continuous monitoring of personnel competency must be developed. Evaluation of both newly trained personnel and those staff who have been performing testing should include the following important elements:

- Verification that personnel can set up a testing environment consistent with that described in the SOP, including compliance with operating temperatures and storage conditions, labeling and recording formats, and safety considerations
- Direct observation of testing to ensure that all steps are performed correctly and that the correct result on known specimen(s) can be obtained
- Provision of known samples for analysis by staff who perform testing to ensure that the correct result can be obtained
- Evaluation of the tester's ability to interpret quality controls and test results, including the ability to interpret HIV status based on the established testing algorithm
- Verification that personnel can properly follow all record-keeping procedures
- Assessment of interpersonal communications and interaction with clients
- Assessment of compliance with confidentiality standards
- Assessment of compliance with good laboratory practice and safety standards

Initial and ongoing competency evaluation is required for all staff who conduct testing. There should also be a mechanism for correcting any problems or deficiencies identified during the monitoring visits. The site visit can also be used to identify training needs and provide important refresher training.

EQUIPMENT

One of the great advantages of using rapid, simple technology for HIV testing is that little or no equipment is required. However, in some settings the use of whole blood or serum may require a centrifuge and pipetting devices. Equipment for conventional HIV tests, such as ELISA plate incubators, washers, and readers must be maintained appropriately. In this case, a calibration and maintenance plan should be developed. If refrigeration is required for storing HIV conventional and rapid test reagents or specimens, a plan for conducting and documenting temperature checks and for maintaining equipment must be in place.

PURCHASING AND INVENTORY

The availability of dependable and reliable test kits and supplies is essential. This requires a national plan for procurement and distribution, as well as careful management of supplies and reagents at the testing site.

Responsibilities at the National Level

Many countries use a tendering process to procure reagents and supplies for all laboratories and testing sites managed through the Ministry of Health. It is important that supplies and reagents be carefully selected, that they are ordered in sufficient quantity, and that deliveries are carefully planned to avoid stock shortages or waste due to expired reagents. Good procurement and supply management includes forecasting.

Purchased kits must have a sufficiently distant expiration date to allow for efficient use and to prevent waste. A policy of “first to expire, first used” (e.g., kits with the earliest expiration date must be used before kits that expire later) helps to assure minimum waste.

The Ministry of Health/national reference laboratory must have some means of assessing the quality of the kits, reagents, and supplies as they are received by the central purchasing body to ensure that standards and specifications are met. Each lot number should be checked by the national reference laboratory before distribution.

A distribution plan that allows these reagents and supplies to reach all testing sites within the appropriate time frame and prior to expiration is needed. The plan also must take into account unexpected or emergency needs.

Responsibilities at the Testing Site

Each site should maintain an inventory record for kits and supplies, and determine reorder levels for each stock item based on workload and usage. This allows for timely ordering so that the testing site always has the necessary reagents and supplies in stock and no interruptions in testing occur.

Upon receipt of new supplies and reagents, the inventory record should be updated and all of the new material should be stored under the appropriate environmental conditions.

To avoid waste, sites should follow the concept of “first to expire, first used.”

PROCESS CONTROL

Process control refers to the activities undertaken and techniques used to ensure that the testing process is correctly performed, that the environment is suitable for reliable testing, and that the test kit works as expected to produce accurate and reliable results. Steps in the testing process follow the “path of workflow”: pre-analytic (steps performed prior to testing), analytic (steps performed during testing), and post-analytic (steps that follow testing). When using HIV test kits, a number of steps in the path of workflow are essential to ensuring accurate and reliable test results.

Evaluation of Methods

The evaluation of HIV test kits should be performed by the national reference laboratory or other appropriate body. In order to assure a sufficient supply of kits for testing, each country should validate and approve a variety of HIV test kits for use. The Ministry of Health should establish a national policy regarding appropriate tests to use and an approved algorithm for testing.

Standard Operating Procedures

Each country must develop standard operating procedures that provide detailed instructions on all aspects of testing, including specimen collection, management, and transport; storage and inventory requirements and procedures; test request and performance procedures; environmental requirements; quality control; test interpretation; reporting and recording of results; appropriate use of the testing algorithm, and any external quality assessment requirements. Each test kit will require its own SOP. A written SOP should be available at each testing site and should always be followed when conducting tests. A chart showing a simplified version of the procedural steps (work instructions) is very useful and should be provided at the point of testing. The test site must have written guidelines on all policies and procedures relating to testing, personnel training and requirements for the certification of competency, competency checks, confidentiality policies, and safety.

Work instructions should outline all steps to be taken during the work process, including the path of workflow. An example of a path of workflow might be:

Pre-analytic:

1. Check storage and room temperatures daily.
2. Check inventory and test kit lots as needed.
3. Receive requests for testing.
4. Set up test area.
5. Record all needed data, such as kit lot number and operator identity.

Analytic:

1. Follow biohazard safety precautions.
2. Perform quality control according to SOP.
3. Correctly identify person to be tested if pre-counseled by someone else. Ensure that pre-counseling has taken place.
4. Collect the specimen, including specimen for confirmation testing if required.
5. Perform the test as directed by the manufacturer.
6. Interpret the test results.

Post-analytic:

1. Re-check patient identifier and report results to the counselor.
2. Clean up and dispose of biohazardous waste.
3. Package and transport re-test specimens for external quality control to referral laboratory, or appropriately store until next shipment to referral laboratory, if needed.

Quality Control

Quality control procedures are essential to ensure that the testing process has been carried out properly and that the kit reagents are performing as intended.

Quality Control Materials

In most cases, an internal control is built into the testing device and will always be a part of the testing process. In some kits, these controls may be in the form of a control band on the devices (most HIV rapid tests) or may be provided as separate material (e.g., HIV-positive or negative control samples, such as with most EIAs). These kit controls provided by the manufacturer usually do not check the entire testing process.

In addition to the kit controls, independent internal quality control (IQC) samples should be used with each conventional EIA test. IQC samples cannot be used with each HIV rapid test, and thus must be used with them periodically (once a day or at least once a week) in order to assure that the HIV rapid test kits are accurately detecting HIV antibodies.

Frequency of Use of Internal Quality Control

The Ministry of Health should establish a policy stating how and when internal quality control samples should be used, and should describe it in the quality system guidelines.

The frequency of use of IQC samples for HIV rapid tests depends on several factors. The condition of all kits should be evaluated over time. In areas where environmental conditions are sometimes extreme, difficult to control, and where transportation can be challenging, the integrity of kits may be affected. It will thus be important to check kits fairly often in such environments.

When running controls for HIV rapid testing, it is important to use both a negative and a positive control. Whenever possible, a weakly reactive positive control that has been validated to yield weakly reactive results on all HIV rapid test kits used should be included.

Recording and Monitoring Internal Quality Control Sample Results

The national policy should provide guidance on recording and monitoring IQC sample results. Standardized record-keeping methods make it easier to compile data, monitor performance of the IQC samples, and monitor test performance. Information and materials provided to the testing sites should include:

- A standard worksheet, with space for recording IQC sample results
- A separate register for IQC sample results, to which information will be transferred from the worksheet. This allows for quick review of IQC sample data.
- A flow chart for corrective action, showing steps to follow when the IQC sample results do not read as expected. This should include information on how to refer problems back to the reference laboratory.

All quality control data should be regularly reviewed by the site officer.

Sources of Internal Quality Control Samples

Quality control samples are available commercially. They can also be prepared in country, usually by the national reference laboratory. In some countries, the capability and capacity for preparing IQC samples may be present in regional or provincial laboratories.

External Quality Assessment

Through external quality assessment (EQA), the performance of a testing site can be evaluated from outside the laboratory or the site itself. Methods for EQA include traditional proficiency testing and careful on-site monitoring using a checklist and knowledgeable assessors.

On-site Monitoring

EQA can be accomplished by careful on-site observation of the testing processes and procedures, conducted by a knowledgeable person or team. A checklist that allows for assessment of all parts of the quality system is an important tool for such an on-site visit. The following are recommendations for on-site monitoring:

- The EQA plan should place major emphasis on on-site monitoring. In low-volume sites, this may be the only EQA tool available.
- On-site monitoring should encompass all aspects of the quality system, including personnel competency and training, equipment policies, inventory control, quality control practices, records and document control, and facilities and safety.
- If other testing is performed at an HIV rapid testing site, an integrated approach to on-site visits should be taken to assess all aspects of testing practices.
- The site visit should include observation of testing with specimens of known reactivity (proficiency panels).
- When possible, direct observation of interaction with a client is useful. Other means of assessing performance of testing personnel could include exit interviews with clients and use of “mystery clients” (persons with known serostatus who present anonymously).
- A standard checklist must be used for all visits.
- On-site assessments should occur at least twice a year in established sites, and at least quarterly for new sites or sites with new personnel. Frequency should be based on initial findings and need for corrective action.

- On-site visits should be educational and provide a mentoring experience.

The experience should not be punitive.

A plan must be established for corrective action related to findings during the on-site visit. All problems should be discussed immediately with on-site staff, and any necessary follow-up activities, including training, should be undertaken in a timely manner.

Re-testing of Specimens

Re-testing of specimens is generally not recommended because it is very often not a statistically valid approach. Usually, large numbers of specimens need to be retested to identify errors, making it a costly exercise. In addition, retesting may not occur immediately, making timely feedback, corrective action, and identification of the source of error difficult, if not impossible.

Proficiency Testing

Traditional proficiency testing is organized and conducted by international EQA scheme providers, or by a reference laboratory or center at the national level. At regular intervals, a panel of specimens with known reactivity is sent to all participants, who test the specimens and return their results to the EQA scheme provider. The data is analyzed and information is sent back to the participating testing sites.

Recognizing that proficiency testing can be a useful tool when combined with on-site monitoring, it is recommended that testing sites participate in and demonstrate acceptable concordance (>90%) with a proficiency testing panel circulated by a central laboratory. For testing sites using rapid/simple tests and blood specimens obtained from finger sticks, a dried blood spot (DBS) panel may be more appropriate than a plasma/sera panel.

DOCUMENTS AND RECORDS

Standardized documents and recording formats should be developed at the national level in order to assure conformity to national standards and to facilitate national data collection. Documents and records must be maintained in such a way as to be always up-to-date, accurate, readily accessible by laboratory staff, and protected from damage and deterioration. Retention times for documents and records should be established. Policies should be developed to ensure confidentiality when appropriate.

Document Management

Documents should be consistent with national policy to assure uniformity and adequacy of data. All documents must be managed with a tracking system to assure that all testing sites have the most current information on hand and that outdated documents are archived, and ultimately discarded, to avoid confusion at the worksite.

Records

Recording formats for HIV testing sites should be standardized and distributed from the national level. At minimum, worksheets should include space for the date and time of the test, client identifiers, name of the person performing the test, name and lot number of the kit used, and kit controls and internal quality control sample results. A separate quality control chart should be maintained to allow for analysis and quick review of IQC sample results. Personnel records on training, competency evaluation, and work injury should be kept. All adverse occurrences, including any corrective action taken, should be recorded.

INFORMATION MANAGEMENT

Records may be kept manually but computerized record-keeping is preferred. When computer systems are available, laboratories are afforded many useful tools for managing client data as well as quality control and EQA information. For example, a system for tracking specimens (serum or DBS) collected for EQA purposes would make it much easier to manage this aspect of the quality system function. If there is nationwide networking, the ability to correlate an individual's clinical data and laboratory results country-wide is very useful.

When computerized information management systems are available:

- Processes to ensure the accuracy and reliability of data, and to protect it from damage and loss, must be put in place.
- Privacy and confidentiality of data must be strictly observed.
- Staff will need training to develop competency in the use of computer tools, including the use of a laboratory information system and word processing, spreadsheet, and database software.

INCIDENT MANAGEMENT

Errors and problems occur in the most carefully conducted and monitored testing environments. The purpose of a quality system is to reduce and minimize errors in the entire testing process. In order to meet this goal, each testing site should have a method to detect and resolve problems. It is important to understand root causes and to take corrective action.

The following steps are important when adverse incidents, errors, and problems occur:

- Investigate the error or problem to determine its cause.
- Take action to address the cause of the problem. Corrective actions may result in changes in policy or procedures to help ensure that the error will not recur.
- Communicate appropriately with all those affected by the error or problem, for example, the nursing staff, physician, and/or client.
- Keep a record of all circumstances related to the error or problem, including corrective action taken and any communications with affected persons. This information is useful for those monitoring the testing, for any internal audits, for informing staff who may encounter these problems in the future, and for use in the event of further inquiries from patients or physicians.

The site officer is responsible for ensuring that this process is followed and that all appropriate corrective actions are taken.

ASSESSMENT

The key to a successful quality system is continuous improvement, and an essential component of this process is assessment. Formal assessments may be external, performed by persons outside the laboratory or testing site, or they may be conducted by staff at the site and be internally managed. External assessment of testing sites in this model will be conducted as site visits.

The regular performance of internal quality assessments or audits can yield much important information about how well the laboratory or testing site is following its quality policies and procedures, and can help to identify problem areas. Information on internal audit processes is widely available, and the International Organization for Standar-

dization (ISO) describes an internal audit process that is useful in laboratories. Smaller testing sites could use a more informal process.

PROCESS IMPROVEMENT

Process improvement is part of the continuous effort identify problems and take action to resolve them in order to better operational procedures. Process improvement is the action of revising a process based on information gathered. As used in this model, it involves identifying an area to study, collecting and evaluating information, and taking corrective action based on the findings. For example, a testing site might decide to study its turnaround time; this would require collecting data for a period of time, analyzing it, evaluating whether the turnaround time is sufficiently short, and if not, implementing steps to reduce it.

All these efforts should be the responsibility of the site officer, who should manage all processes related to assessment and process improvement and communicate project results to both the site staff and to appropriate higher-level management.

SERVICE AND SATISFACTION

In diagnostic testing, customers include both the providers who order the tests and the patients/clients who will eventually receive care based on the test results. Methods to evaluate how well the testing site is serving the needs of its customers should be put in place to measure and assure quality of service, satisfaction, and fulfillment of program goals.

Policies and procedures should be established for responding to customer suggestions and complaints.

FACILITIES AND SAFETY

Facilities

Each site where HIV conventional and/or rapid testing is performed must have facilities appropriate for carrying out testing, including:

- An adequate working surface that can be easily cleaned and maintained
- Assurance of an ambient temperature that does not exceed that required by the test kits
- Refrigeration, if necessary
- Required equipment
- Facilities for hand washing and cleaning

Safety

Sites must have available, and personnel must follow, procedures to safely handle biohazardous material. To ensure safety:

- Instructions on the use of gloves, closed footwear, hand washing, handling and disposing of sharps, and spill containment and disinfection must be provided.
- Basic safety procedures should be clearly posted or visibly available in the laboratory.
- General policies, such as those prohibiting eating, drinking, smoking, or entrance of unauthorized persons in the testing area, must be enforced.
- Procedures for the safe disposal of all specimens and materials used in testing must be available and followed at each site. This is essential to protect those who perform the tests as well as others who might be exposed to discarded materials. All specimens and materials must be treated as infectious.
- A procedure must be developed for workers to follow in the event of an accidental staff exposure to biohazardous material. This procedure and an emergency contact list must be readily accessible to all staff in the facility. It is recommended that all persons performing HIV rapid tests know their own serostatus.

Full safety requirements for testing HIV specimens are very detailed. Any site performing testing should have available a complete set of guidelines used in the country. ISO, WHO, and CDC all are useful sources for biosafety guidelines and information.

5. HIV TESTING STRATEGIES AND ALGORITHM GUIDELINES

GENERAL CONCEPTS OF HIV TESTING STRATEGIES

The choice of a testing strategy, and the selection of the most appropriate tests or combination of tests to use, depends on four criteria:

1. The aim of the test
2. The sensitivity and specificity of the test(s) used
3. The prevalence of HIV infection in the population being tested
4. The costs involved

The three main objectives of HIV testing are:

1. **Diagnosis of HIV infection:** Assessment and testing in VCT and PITC settings of asymptomatic individuals or persons with clinical signs suggestive of HIV infection or AIDS
2. **Surveillance:** Unlinked and anonymous testing of serum and second-generation surveillance to monitor the prevalence of and trends in HIV infection over time in a given population
3. **Transfusion safety:** Screening of blood and blood products

Note: *PAHO does not recommend the use of HIV rapid tests for blood-donor screening purposes.*

While a testing strategy describes a generic testing approach for specific needs (e.g., surveillance; VCT and PITC services, as well as PMTCT programs that take into consideration the HIV prevalence in the population and the intrinsic quality of the HIV test kits in terms of their sensitivity and specificity), an algorithm is a combination and sequence of specific tests employed in a given strategy.

DIAGNOSTIC ALGORITHMS USING CONVENTIONAL ENZYME IMMUNOASSAYS AND RAPID HIV TESTS

The WHO 3 by 5 Initiative (7) defined diagnostic HIV testing as the entry point to HIV care and treatment, including antiretroviral therapy. This definition is more valid than ever under the strategic plan for universal access.

The introduction of diagnostic HIV rapid testing significantly impacts delivery of HIV services (8). Such testing is an especially attractive option in VCT services (9–11), PMTCT programs (12, 13), the management of occupational and non-occupational exposures to HIV, geographically remote places, and hard-to-reach populations.

Various combinations of tests can be used: combinations of HIV EIAs; combinations of rapid tests; or an EIA in conjunction with rapid tests. The choice of strategy and of HIV tests should be determined by the quality of the tests and by the practicality of their implementation, logistics, and the cost-benefit analysis.

Sensitivity and specificity are two important factors that determine a test's accuracy in distinguishing between HIV-infected and uninfected individuals. It is crucial that the HIV tests used in the algorithms all have a sensitivity of at least 99% and a specificity of at least 98%. There are commercially available HIV EIAs and HIV rapid tests that meet these criteria.

When selecting HIV tests to be used in combination, it is important to select tests that do not share the same false positive and same false negative results. This information can be obtained from comparative evaluation studies of HIV test kits, such as those published in international scientific publications and in WHO reports. It is recommended that such comparative evaluations of a select number of HIV test kits be conducted at the national and/or regional level prior to the establishment of the national HIV test algorithms. These principles apply to both conventional HIV EIA and HIV rapid tests. The national reference laboratory should validate a select number of test kits for use in the national HIV testing algorithms.

Specific implementation requirements must be considered when selecting tests kits and algorithms. For example, will testing be performed in a laboratory setting, or in a VCT or clinical setting without extensive laboratory facilities? In settings without extensive laboratory facilities or where clients do not return for follow-up visits, algorithms using only rapid tests are preferred. In situations in which patients return at regular intervals (e.g., TB clinics) or in prenatal clinics where blood specimens are taken for other

testing purposes, the set-up may allow for HIV EIA-based algorithms or algorithms combining EIA and rapid tests.

Another factor determining the most cost-efficient approach is the volume of specimens to be processed daily or weekly. An EIA test is half the price of a rapid test, so if a particular setting processes 40 specimens a day and the laboratory has the required equipment, it is more cost effective to use EIAs than rapid tests. It is important that the HIV tests and algorithms be chosen carefully and with the aim of optimal integration into the existing health care facilities, minimizing the potential to disrupt their operations or unnecessarily overburden staff.

CHOOSING A TESTING STRATEGY AND ALGORITHM

There are many strategies for HIV testing (14–21). WHO, CDC, and the Association of Public Health Laboratories have jointly developed one of the most useful references for HIV testing algorithms, *Guidelines for Appropriate Evaluations of HIV Testing Technologies in Africa* (22).

Testing strategies can be divided into two approaches: serial (or sequential) testing and parallel testing.

Sequential Testing Strategy

In a sequential testing strategy, samples are initially tested with only one, highly sensitive assay. Samples that are reactive in the first assay are then re-tested using a second, highly specific assay. A third test may be performed, depending on the result of the second assay and the objective of the testing. Both the selection of and the order in which the assays are used are of the utmost importance for the final outcome of the tests. If test combinations are not carefully selected, individuals may be incorrectly diagnosed.

WHO recommends sequential testing in most settings because it is more economical, as the second test is required only when the initial test result is positive.

Parallel Testing Strategy

In a parallel testing strategy, samples are tested using two different assays simultaneously. This approach is rather expensive, as it virtually doubles the cost of testing in low-prevalence settings by requiring two tests at the outset. As with sequential testing,

a third test may be performed (preferably at the secondary level, where laboratory facilities and experienced staff are available), depending on the result of the assays and the objective of the testing.

Therefore, the parallel testing strategy is recommended only in situations in which it can add value. Prenatal clinics provide one such example: A woman's first visit to the clinic may be to deliver her child, thus requiring a rapid decision whether an intervention to prevent mother-to-child transmission of HIV is needed. Other emergency situations, such as work accidents, sexual violence, and discordant couples also would benefit from this strategy. In these cases, two rapid tests using whole-blood finger-stick specimens in parallel will provide the answer in just 10–15 minutes. HIV rapid tests using whole-blood finger-stick specimens have great potential in situations where results need to be known quickly, or where taking a conventional venous sample is difficult.

The selection of a national algorithm is the responsibility of the country's Ministry of Health (see Annex for algorithm options). The choice of sequential or parallel testing should be made after a thorough analysis of the scientific evidence, logistics, test performance requirements, and cost/affordability of the various algorithms. The selection process should include test licensing and validation using samples from the local environment, as well as assessment of the tests' affordability, continuous long-term availability, storage specifications, and shelf life.

The selection of tests for the chosen algorithm is important, as a high degree of accuracy of the results must be ensured. Each country should evaluate the sensitivity and specificity parameters as well as the operational characteristics of candidate tests. Test validation is usually done by the national reference laboratory, but if this is not possible test selection should be based on evaluations performed by an independent, non-commercial entity.

The WHO reports, *HIV Simple/Rapid Assays* (23–24), are an excellent source of reference data for the selection of HIV algorithms.

ALGORITHM DESIGN

An HIV algorithm may be composed of a combination of rapid and/or conventional tests. The accuracy of test results depends on the characteristics of the tests, the skill of the tester, the algorithm, and most of all on the degree of compliance with the quality assurance requirements. For definitive laboratory diagnosis of HIV, a two-level system will be adopted. The third level (national reference laboratory) will be responsible for

laboratory monitoring of the efficiency of antiretroviral therapy and characterization of virus strains. In these guidelines, sequential algorithms with two tests at the first level and confirmation at the second level (laboratory) have been proposed for low-prevalence settings (Option 1) and for targeted higher-risk populations (Option 2). A parallel, though more expensive algorithm, has been proposed for emergency situations, using rapid tests with whole-blood finger-stick specimens (e.g., for women in labor and for occupational- and non-occupational-exposure accidents). The three different options for these algorithms can be adopted and applied in the rapid testing sites as well as in the laboratory sites. Regardless of the algorithm chosen, all tests should be highly sensitive and specific, with the first test having the highest sensitivity. A recent WHO report provides a full explanation of this process (14).

Option 1 uses a flow chart to depict a sequential algorithm with two tests at the first level and confirmation at the second level, providing a same-visit HIV presumptive diagnosis in low-prevalence settings (<5%) (Figure 1).

Level 1

1. At the local level, the first step is to initiate testing of the specimen (whole blood obtained from a finger stick) with the first, highly sensitive rapid test (R1).
 - 1a. If the result of R1 is negative, the result is final and can be reported to the individual tested.
 - 1b. If the result of R1 is positive, the second, highly specific rapid test (R2) should be performed.
2. Another sample is tested using R2.
 - 2a. If the result of R2 is negative, the final result is negative .
 - 2b. If the result of R2 is positive, a venous blood specimen should be drawn and sent for confirmation by the second-level laboratory. The result reported is strongly indicative of HIV positive, awaiting confirmation.”
3. Testing at the second level will be performed according to the national algorithm. Results will be returned within a few days (at maximum, one week) to the counselor.
 - 3a. If the result of the secondary laboratory test is negative, the counselor will report this result to the individual tested.
 - 3b. If the result of secondary laboratory test is positive, the result is final and can be reported to the individual tested. No further confirmatory assay is needed. A case notification to the local or national health authority should follow.

Option 2 uses a flow chart to depict a sequential algorithm with two tests at the first level and confirmation at the second level, providing a same-visit HIV presumptive diagnosis, for targeted populations at increased risk and in settings with a prevalence of 5% or higher (Figure 2).

Level 1

1. At the local level, the first step of an algorithm is testing of the specimen (whole blood obtained from a finger stick) with the first, highly sensitive test (R1).
 - 1a. If the result of R1 is negative, the result is final and can be reported to the individual tested.
 - 1b. If the result of R1 is positive, the second, highly specific rapid test (R2) should be performed.
2. Another sample is tested using R2.
 - 2a. If the result of R2 is negative, the individual will be asked to return for retesting after two weeks (to cover the “window period” of potential seroconversion).*
 - 2b. If the result of R2 is positive, a venous blood specimen should be drawn and sent for confirmation by the second-level laboratory. The result reported is strongly indicative of HIV positive, awaiting confirmation.
3. Testing at the second level will be performed according to the national algorithm. Results will be returned within a few days (at maximum, one week) to the counselor.
 - 3a. If the result of the secondary laboratory test is negative, the counselor will report this result to the client.
 - 3b. If the result of the secondary laboratory test is positive, then this result is final and can be reported to the client. No further confirmatory assay is needed. A case notification to the local or national health authority should follow.

* If the result remains R1+/R2-, after two weeks a venous blood sample is drawn and sent to the secondary level for confirmation.

Option 3 uses a flow chart to depict a parallel algorithm with two tests at level 1 and confirmatory testing at level 2 for same-visit HIV diagnosis (Figure 3).

Level 1

1. At the local level, the first step is to initiate testing of the specimen (whole blood obtained from a finger stick) with two rapid tests (R1 and R2) at the same time. One finger prick is sufficient for both tests.

- 1a. If the results of both R1 and R2 are negative, the result is final and can be reported to the client.
- 1b. If the result of R1 is positive and R2 is negative, or if the R1 result is negative and R2 is positive, the final result is inconclusive and two actions can be taken:
 - 1b1. The client is referred for a new testing cycle at the center two weeks later.
 - 1b2. A venous blood sample is collected and sent to the second-level laboratory for confirmation.
- 1c. If the result of both R1 and R2 are positive, then the prophylactic intervention is made, and a venous blood specimen should be drawn and sent to second-level laboratory for confirmation. The result reported is strongly indicative of HIV positive, awaiting confirmation.
2. Testing at the second level will be performed according to the national algorithm. Results will be returned with in a few days (at maximum, one week) to the counselor.
 - 2a. If the result of the secondary laboratory test is negative, the counselor will report this result to the client and the prophylactic intervention will be stopped.
 - 2b. If the result of the secondary laboratory test is positive, then the result is final and can be reported to the client. No further confirmatory assay is needed, and the prophylactic intervention is continued. A case notification to the local or national health authority should follow.

CHOICES OF SPECIMENS TO BE USED IN TESTING

When deciding which type of specimens will be used for same-day diagnostic rapid tests, it must be kept in mind that specimen collection should be compatible with a non-laboratory setting where rapid testing is most useful. Further, sample processing should be avoided in order to speed up the testing result.

Whole Blood Finger-stick Specimens

Most of the assays available on the market can use whole blood collected by finger stick. This specimen is easy to obtain, requires no equipment, and can be performed by appropriately trained personnel. In addition, this method of specimen collection

reduces the risk of infection for staff as no needles are used and there is minimal waste disposal. However, depending on the algorithm used, more than one finger stick may be necessary to complete the testing required by the algorithm.

Serum and Plasma Specimens

Serum or plasma specimens can be used with rapid tests as well as with conventional HIV tests (EIA and confirmation tests), but requires that venous blood be drawn by means of syringes and collection tubes (e.g., Vacutainers®). In addition, whole blood must be centrifuged to separate the serum/plasma from the red blood cells.

Oral and Other Fluids

Tests using saliva or oral fluids also are available and may be a non-invasive and convenient method for screening.

GUIDING PRINCIPLES OF EXPANDED HIV TESTING AND COUNSELING

WHO recommends that the following guiding principles be observed in all HIV testing and counseling services (9):

- In order to enable the largest number of individuals to benefit from increasingly better care of and treatment for HIV it is recommended that HIV testing be offered as a standard service in all areas (9).
- In order to preserve the individual's right to health and privacy, it is unethical for HIV testing to be mandatory. Informed consent and privacy must be maintained in counseling and testing activities related to HIV. The following are principles for obtaining informed consent:
 1. Provide information on the purpose of the test.
 2. Ascertain that the client understands the information provided prior to testing, namely the purpose of testing, as well as information about support available once the test result is known.
 3. Respect the individual's right to decide whether or not to have the test (9).
- In the best interest of the individual's health, he or she should be informed immediately of his or her test results and should receive post-test counseling. HIV-positive individuals should be referred to support services.

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Figure 1. Two-test Sequential Algorithm–Option 1
Prevalence < 5%

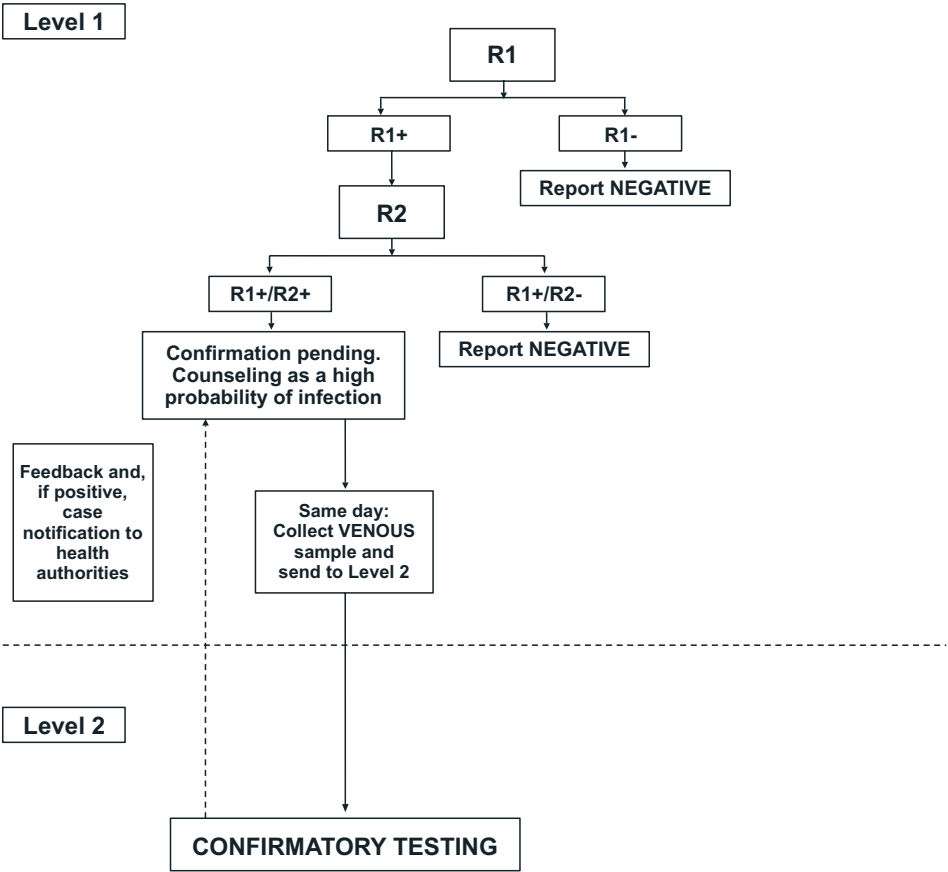


Figure 2. Two-test Sequential Algorithm–Option 2
Prevalence ≥ 5%

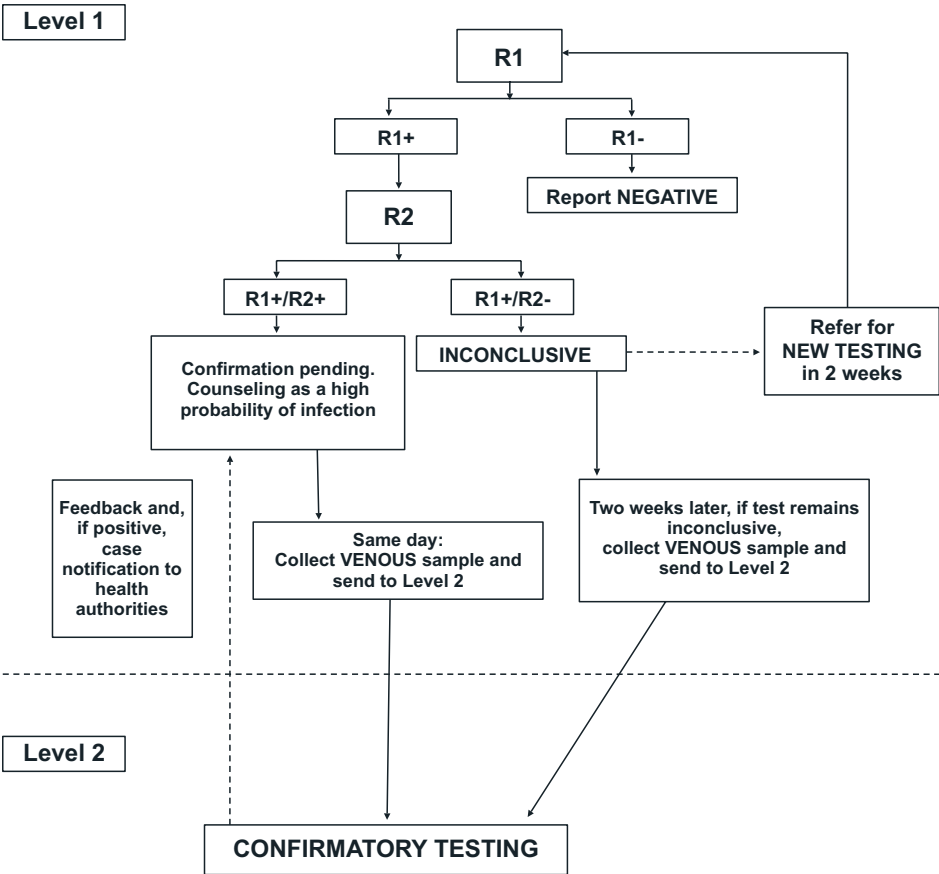


Figure 3. Two-test Parallel Algorithm–Option 3

