Quality Assurance Guidelines for Testing Using Rapid HIV Antibody Tests Waived Under the Clinical Laboratory Improvement Amendments of 1988

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Introduction and Background

Purpose	This document provides guidance on quality assurance (QA) practices for sites using or planning to use rapid test kits to detect antibodies to the human immunodeficiency virus (HIV) waived under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations.
Definition: waived rapid HIV tests	Waived rapid HIV tests are test devices or kits cleared by the U.S. Food and Drug Administration (FDA) that are determined to meet the criteria for waiver under CLIA.[1] They are simple, single-use, disposable devices, using minimal reagents, that can provide results in less than 60 minutes and are designed for use with unprocessed specimens (whole blood or oral fluid specimens). Rapid HIV tests, when used with specimens that require processing, such as plasma or serum, are not waived under CLIA.
How rapid HIV tests are used	Rapid HIV tests are used as screening tests to detect antibodies to HIV as part of multi-test algorithms to aid in the diagnosis of infection with HIV. Positive (reactive) rapid HIV test results are preliminary and must be followed up with an approved confirmatory test.
Importance of a QA program	Although waived rapid HIV antibody tests are simple to use and can provide reliable results when the manufacturer's directions are followed, mistakes can occur at any point in the testing process. To reduce mistakes and to ensure that the FDA restrictions for sale of these tests are followed (see Appendix A for information on the FDA sales restrictions), the testing site must have a QA program in place before offering waived rapid HIV antibody testing. The guidelines in this document outline the basic elements of a QA program.
How to use these guidelines	These guidelines are intended to assist a range of providers in developing policies, processes and procedures to ensure high quality HIV testing services. The contents include a description of steps that should be taken to identify and prevent errors in the testing process. Because rapid HIV tests are used in many different settings, each site needs to decide how best to fit the various QA elements into its own operation. For example, the QA program in a large clinic or hospital where on-site laboratory support is available may be quite different from an outreach setting with fewer personnel and resources.
How this document is organized	This document and its appendices provide basic information that personnel who offer waived rapid HIV testing should know. It includes information on: ▪ Basic elements of a QA program ▪ An overview of government rules that apply to using waived rapid HIV tests. ▪ Examples of forms and checklists that can be used to record and monitor QA processes and procedures.

Basic Elements of a Quality Assurance Program

What is quality assurance?

Quality assurance (QA) refers to planned, step-by-step activities that let one know that testing is being carried out correctly, results are accurate, and mistakes are found and corrected to avoid adverse outcomes. Quality assurance is an ongoing set of activities that help to ensure that the test results provided are as accurate and reliable as possible for all persons being tested. These activities should be in place during the entire testing process, from the time a person agrees to be tested until after the test results are provided.

How does quality assurance differ from quality control?

As described above, QA is an overall program of activities throughout the entire testing process. Quality control (QC) is one part of the QA program. Here are definitions for both terms[2]:

Term	Definition and activities performed
Quality assurance	Planned and organized activities to help ensure that certain requirements for quality will be met.
Quality control	Operational techniques or tasks that are in place to find and correct problems that might occur.

Basic elements of a QA program for rapid HIV testing

Even though waived tests are simple to use, things can go wrong. To help find and prevent problems, the basic elements of a QA program should be in place before offering testing. More detail on these six elements is provided in this document. These basic elements are the building blocks of a QA program and are listed below.

1. Organization of the QA program
2. Testing personnel
3. Process control
    a. Before testing
    b. During testing
    c. After testing
4. External assessment
5. Documents and records
6. QA evaluation and troubleshooting

1. Organization of the QA Program

Establishing a QA program

A QA program, no matter how simple, requires resources.[3] Someone must oversee the program and ensure the necessary personnel and supplies are available. Each organization must:

- Identify the person(s) responsible for managing the QA program (this could be a senior staff member, outside consultant or a network of individuals who oversee different aspects of the QA program).
- Verify the testing process.
- Write site-specific procedures (step-by-step instructions) and make them available to all personnel involved in testing.
- Ensure personnel know how to perform each of the procedures.
- Create mechanisms for communication so that personnel are informed about problems when they are identified.
- Have a CLIA Certificate of Waiver if performing only waived rapid HIV antibody or other waived tests, or be included under an organization with a CLIA exception for limited public health or mobile testing. (See Appendix A for more information on regulatory requirements.)
- Develop and implement mechanisms to ensure the site meets all applicable Federal, State, and other regulatory requirements, including requirements for biohazard safety.

Verifying the testing process

Before offering the test to clients or patients, each site should make sure (verify) that the testing process works as planned. Verifying the process includes: ensuring that personnel have been trained and are able (competent) to perform their assigned tasks, the test kits work as expected (e.g., give accurate results for a referenced panel of nonreactive, weakly reactive, and reactive specimens), and that logistics are in place for providing confirmatory testing of preliminary positive test results and handling biohazardous waste.

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1. Organization of the QA Program, continued

Providing written testing instructions

Testing personnel must follow instructions provided by the manufacturer. It is strongly recommended that step-by-step, written instructions be made available to all personnel performing testing. The test kit package insert provides text that can be used as a procedure for steps in the testing process listed below:

Procedure	Describes how to...
Pretest information	provide required pretest information to test subject.
Materials and storage	maintain sufficient supplies of unexpired test and control kits and adhere to the manufacturer's temperature ranges for storage and testing areas.
Test performance	collect specimens, perform the test, interpret and report test results, resolve problems (troubleshoot) before reporting results.
Quality control	check performance of new test kit lots and shipments, frequency of routine QC testing, and actions to take if controls do not work.

Recommended site-specific written procedures

Site-specific procedures describing other operations should be written and available to help ensure personnel know how to perform additional QA tasks:

Procedure	Describes how to...
Personnel training and competency	train and assess competency of new employees; periodic competency assessment of all testing personnel.
Safety	use gloves and other personal protective equipment (PPE); safely dispose of biohazard waste, including used lancets or other sharps used for blood collection.
Reporting	report results including confirmatory results, if applicable.
Confirmatory testing	refer specimens or test subjects for confirmatory testing; manage test results.
Documentation	keep records and timelines for review, retain and destroy when outdated.

2. Testing Personnel

Overview

Having qualified, trained personnel who perform and supervise rapid HIV testing and the various activities in the QA program is one of the most important factors for ensuring accurate and reliable results. Key aspects of this element include:

- Qualifications
- Training
- Competency assessment (i.e., how well they are doing their job)

Personnel qualifications

There are no Federal requirements for who can perform waived tests; however, some States have specific requirements for testing personnel. Beyond any regulatory requirements, it is recommended that certain qualities be considered when selecting personnel to perform rapid HIV antibody testing. The following list of desirable qualities is based on practical considerations and expert opinion:

- *Sincerity and commitment* – A dedication to performing testing accurately, according to defined procedures.
- *Literacy* – The ability to read instructions and record results is critical.
- *Organizational skills* – The level of skill necessary will depend on the number and complexity of tasks an individual performs in the testing process. If test volume is high and the individual performing testing is doing several tests or managing several other tasks simultaneously, organizational skills can be critical.
- *Decision-making skills* – Testing personnel should be able to interpret results and be able to recognize and handle problems that might arise.
- *Communication skills* – If the person performing the test also is the one who shares results or other information with the person being tested, being able to communicate clearly is important.

Components of training

Training is crucial to ensuring quality testing.[4] Assurance that personnel who perform testing receive training information is required to purchase rapid HIV test kits (see Appendix A for the FDA sales restrictions). Personnel should be fully trained on how to perform their assigned tasks and responsibilities. Training should be documented for each individual; using training checklists is one way to handle this documentation (see Appendix B for an example checklist). The key components to include in a training program are:

- The importance of QA and the elements of the site's QA program
- How testing is integrated into the overall program
- How to perform the test, including procedures performed before, during, and after testing.
- The use and importance of blood and body fluid precautions and biohazard safety. (See Biohazard Safety/Universal or Standard Precautions.)

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2. Testing Personnel, continued

Training method

A training method should optimally include the following activities:

- Read the instructions for performing the test.
- Watch someone perform the test or view a video of someone performing the test.
- Practice performing the test with positive and negative control materials.
- Practice performing the venipuncture, finger-stick and/or oral fluid collection procedure.
- Review the procedures and forms on how to document testing.

Competency assessment

Before a trainee is permitted to perform testing alone for the first time, his or her ability to conduct the test should be demonstrated and documented. This assessment should also be carried out at periodic intervals after training, such as every six months or other interval as determined by the testing site. Competency assessment can be carried out in many ways, but regardless of the method, every task for which an individual is responsible should be evaluated. A supervisor or trainer should perform the assessment, using a combination of methods to determine competency. Examples of these methods are presented below.

Assessing performance of tasks done before testing

To assess task performance before testing, personnel should be observed as they:

- Check and record the temperatures of the testing and storage areas.
- Set up the testing area, label the test device and prepare control and test results log sheets.
- Run the external controls and record results.

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2. Testing Personnel, continued

Assessing performance of tasks done during testing

To assess personnel's ability to perform the test and interpret results:

- Observe personnel performing specimen collection and handling according to the manufacturer's instructions.
- Observe how the test is performed on a client/patient. If such observation will interfere with the actual client-provider interactions, observe test performance on a volunteer.
- Evaluate the use of Universal or Standard Precautions and procedures for biohazard and sharps (e.g., lancets, needles) waste disposal.
- Review results obtained from testing a panel of referenced specimens that show a range of results, such as five specimens that include nonreactive, weakly reactive, and reactive results. Control materials supplied by the manufacturer may be used as a source of specimens in the panel. In addition, specimens may be obtained from laboratories performing confirmatory testing or from other commercial sources.
- Appraise the individual's ability to interpret results. This might include using previously used test devices or pictures of devices that show nonreactive, weakly reactive, reactive, and invalid results.

Assessing performance of tasks done after testing

To assess task performance after testing:

- Review test records and quality control results for proper documentation.
- Observe oral reporting of results to a test subject (if trainee's responsibility).
- If confirmatory test specimens are collected on-site, observe the collection and handling of venous blood and/or oral fluid specimens for referral. If the frequency of reactive rapid test results is low, the trainee should be observed collecting blood and/or oral fluid from a volunteer staff member and demonstrate how it is processed for confirmatory testing.
- Verify that confidentiality is maintained.

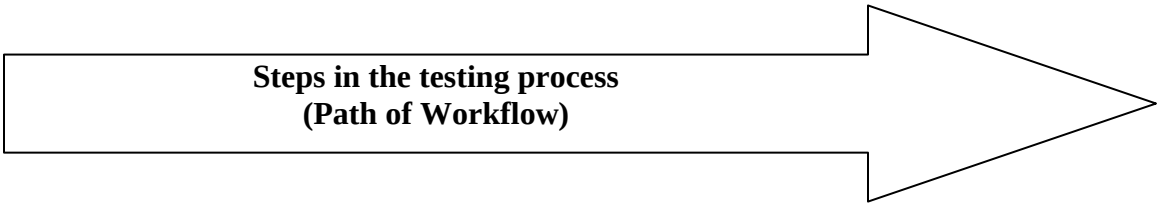
3. Process Control

What is process control?

Process control refers to the activities and techniques that are carried out to ensure that the testing procedures are performed correctly, the environment is suitable, and the test kit works as expected to produce accurate and reliable results.

Steps in the testing process

Steps in the testing process follow the path of workflow beginning with tasks before testing, followed by those conducted during and after testing. This path of workflow and the associated steps are shown in the table below. Detailed descriptions about each of the steps listed in this table are provided in the remainder of this document.



Before testing	During testing	After testing
▪ Check storage and room temperatures daily ▪ Check inventory and test kit lots, as needed ▪ Receive request for testing ▪ Provide HIV/AIDS test information to the test subject ▪ Set up test area, label test device ▪ Perform external QC according to the manufacture's and the site's instructions	▪ Follow biohazard safety precautions ▪ Collect the blood or oral fluid specimen ▪ Perform the test ▪ Interpret the results	▪ Document results ▪ Report results to test subject ▪ Collect, process, and transport confirmatory test specimens or refer clients/patients for follow-up ▪ Clean up and dispose of biohazardous waste ▪ Manage confirmatory test results ▪ Participate in periodic external quality assessment

3a. Before Testing

Overview	As shown in the table above, there are a number of steps that must be followed before testing a specimen. These activities are in place to ensure that the conditions at which the test kits and controls are stored and tests are performed are suitable, the test area and the test subject are prepared, and the test is working appropriately.
Temperature control: test and control kits storage	Test kits and controls must be stored within the temperature ranges specified by the manufacturer. These ranges vary with different test kits. Place thermometers in refrigerators and monitor areas where kits are stored. Check and record temperatures of the storage area on a log sheet each day testing is performed. An example temperature log is provided in Appendix C. NOTE: "Min-Max" thermometers maintain a record of the highest and lowest temperature recorded during the observation period and can be very helpful to monitor storage conditions.
Temperature control: testing area	The temperature in the area where the test will be performed must be within the range specified by the manufacturer. For testing carried out in the field (not on-site), monitor the temperature of the test and control kits in their portable storage containers and check the temperature where testing will be performed if it appears to be outside the specified range.
When temperatures are out of range	If the temperature falls outside of the specified range, take action as needed to adjust the temperature. If there are doubts about the testing area temperature or whether test kits have stayed within the appropriate temperature range, run external controls as described in the QC section below to ensure test devices are usable.
Inventory control	Procedures should be in place to ensure adequate supplies of unexpired test kits, controls, and other materials and should include: ▪ Rotating inventory to ensure the oldest kits are used first. ▪ Adhering to shelf life limitations defined by the manufacturer. o Test or control kits should never be used beyond their expiration dates. o Discard any test kits that are past their expiration date. o Once control vials are opened, their shelf life is reduced. It is helpful to record on the control vial the date it is opened and the date after which the opened control expires. NOTE: It is useful to document on a log sheet when test and control kits are received, their lot numbers and their expiration dates. (See Appendix D for an example log sheet of control results.)

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3a. Before Testing, continued

Setting up the testing area

The testing area should be prepared according to the specific site procedure, which should include directions for:

- Setting up the workspace and organizing supplies,
- Ensuring lighting is adequate to interpret rapid HIV test results. As a rule of thumb, lighting is sufficient if standard newsprint held next to the test device can be read without difficulty. (See page 12 for additional information on interpreting results.),
- Preparing the test kit components and controls,
- Completing report forms.

NOTE: If test kits are refrigerated, test devices, other kit components, and controls should be brought to room temperature before opening and performing the test, according to the manufacturer's instructions.

Specimen identification and labeling the test device

It is critical to correctly identify each person to be tested and to ensure that proper identification of the specimen is maintained throughout the testing process. Labeling is especially important when more than one test is being performed at the same time. Using preprinted labels improves the efficiency of performing this task. Label components of the test (e.g., vials of developer solution, test device, and test result logs) with the name or identifying number of the person being tested before collecting the specimen.

Providing information to test subjects

Manufacturers of rapid HIV tests provide a subject information pamphlet that must be given to each person prior to performing the HIV rapid test, in accordance with FDA sales restrictions. Each site may provide additional information. For further details, see the CDC website http://www.cdc.gov/hiv/pubs/rt-counseling.htm and applicable State or local rules.

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3a. Before Testing, continued

Quality control

Waived rapid HIV tests include two types of QC. These are described in the table below.

Type of quality control	Description of activity
Internal controls	Controls built into each testing device can verify the specimen was adequate and the solution flowed through the device as intended. Functions of internal controls vary by device.
External controls	Known reactive and nonreactive liquid samples (controls) are either provided in each test kit or purchased separately from the manufacturer. External controls are surrogate samples used to evaluate the integrity of the test system and whether the person conducting the test performs it correctly.

External quality control

To verify that test devices accurately detect antibodies to HIV, external positive and negative controls must be tested from time to time. The test kit manufacturer provides external controls containing HIV antibody-negative (nonreactive) and positive (reactive) human plasma compatible with its test system. Before using external controls from a different source, contact the test manufacturer to verify they are compatible with the specific test system being used and evaluate them in the testing site. Controls may be ordered separately from the test kit depending on the manufacturer.

Run external controls according to the manufacturer's instructions

Follow the manufacturer's instructions for when to run negative and positive controls. These instructions recommend running external controls under the following circumstances:

- By each new operator prior to performing testing on clients/patients for the first time,
- When opening a new test kit lot (a test kit lot is defined as boxes of test devices that have the same lot number label on the outside of the box),
- Whenever a new shipment of test kits is received (even if it is the same kit lot number in current use),
- If the temperature of the testing area falls outside of the range specified by the manufacturer, and
- At periodic intervals as determined by the testing facility.

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3a. Before Testing, continued

Frequency of running external controls	How often controls are run will depend on the number of tests performed by the site, how often new test kit shipments or lot numbers are received, changes in storage and testing area temperatures, and turnover of testing personnel. Sites testing large numbers of persons, and especially those offering anonymous testing, should plan to run controls more often than facilities conducting fewer tests. Each site needs to decide how often to run controls based on its own situation and testing practices. Control results should be documented. (See Appendix D for an example of a log for results of control testing.)
Incorrect control results	When external controls give incorrect results, none of the tests that were run since the last time control results were correct can be considered valid until troubleshooting is done to determine the source of the problem. If test kits are determined to be faulty, everyone who was tested since the last time control results were correct may need to be called back and retested (unless a confirmatory test was ordered). Results of client retesting should be documented along with steps taken to resolve problems.
Incorrect control results: troubleshooting	If external controls do not give the correct result, steps should be taken to determine the source of error by following the external control kit troubleshooting instructions. Troubleshooting steps help determine if the source of error is the test kit, the external controls, or operator technique. When necessary, contact the manufacturer for assistance and/or to report defective test system components. Document steps take to resolve the problem.

3b. During Testing

Overview	This phase of the testing process involves running the test and interpreting the results. Activities during testing include collecting the specimen, performing the test, interpreting the internal control and client/patient test results, and following biohazard safety guidelines.
Collecting the specimen	Follow the written procedure for whole blood or oral fluid specimen collection, labeling, and handling. Further information on collecting blood by skin puncture can be found in *Procedures and Devices for the collection of Diagnostic Capillary Blood Specimens; Approved Standard – Fifth Edition.*[5]

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3b. During Testing, continued

Performing the test and interpreting results	Follow the manufacturer's step-by-step instructions for performing the test and interpreting the results. Interpreting rapid HIV tests requires good eyesight and adequate lighting. The test should be read from a comfortable distance without manipulating the test device. If supplemental lighting, such as a flashlight, is necessary, care should be taken to avoid shadows or reflections that might lead to an incorrect interpretation of the test. (A flashlight should never be used to shine light through the test device to accentuate the test result.) Test results can be one of the following: ▪ *Nonreactive* (report as negative) ▪ *Reactive* (report as preliminary positive) ▪ *Invalid* (the test result is inconclusive and cannot be interpreted)
Internal controls	Each rapid test device includes a built-in (internal) control. Internal controls in test devices vary among test manufacturers, therefore, it is important to read and understand the manufacturer's explanation of the location and functioning of internal controls for the test being used.
Evaluating internal control results	Internal control results are evaluated with every test. If the internal control does not produce the expected result, the test result for the client/patient is invalid, cannot be reported, and the test must be repeated. If a second invalid result occurs, external controls should be evaluated as described below before repeating the test a third time.
Running external controls to troubleshoot invalid or suspicious results	If repeatedly invalid test results or an unexpectedly high number of reactive results are obtained during testing sessions, external controls should be run to help find out if problems are due to faulty test kits, improper testing procedures, or something to do with the patient specimen. It is important to run the positive and negative controls whenever two consecutive invalid test results are obtained on a person being tested. If the external control results are valid, the problem may be due to interfering substances in the client's/patient's specimen.

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3b. During Testing, continued

Biohazard safety/ Universal or Standard precautions

All specimens and materials contacting specimens must be handled as if they are capable of transmitting an infectious organism. As described in Appendix A, each site must ensure that the Occupational Safety and Health Administration (OSHA) bloodborne pathogens standards are met. Persons doing the testing must know how to safely handle potentially infectious specimens. Also, according to Universal Precautions, all human blood and certain body fluids should be treated as if know to be infectious for HIV, hepatitis B virus, hepatitis C virus, and other bloodborne pathogens. Sites must have available, and follow procedures for, biohazard safety to include instructions for the use of gloves, hand washing, sharps and biohazardous waste disposal, spill containment and disinfection. A different pair of gloves should be worn for collecting a specimen from each person being tested. Used gloves should be handled as biohazardous waste. For further details on these precautions see the manufacturer's package insert, OSHA regulations and guidelines on Universal and Standard Precautions.[2,6,7,8]

3c. After Testing

Overview

Quality assurance extends to those activities completed following the performance of the test. Each site should have established procedures for:

- Reporting and recording results,
- Referring specimens (or test subjects, if specimens are not collected on-site) for confirmatory testing,
- Managing confirmatory test results, and
- Conducting external quality assessment.

Reporting results

Reporting procedures should describe how results are provided to the person being tested (verbal and/or written results) and how results are documented in the person's chart and in the test result logs. (See Appendix E for an example of a test result log.)

Referral for confirmatory testing

Whenever a rapid HIV test result is reactive (preliminary positive), follow-up testing must be performed to confirm that the person being tested is infected with HIV. Therefore, each site must have established procedures for referral of either test specimens or persons being tested for confirmatory testing when rapid test results are reactive. Collecting confirmatory specimens on-site may improve follow-up, since some clients/patients may not go elsewhere for the testing or to obtain results. However, if the site is not able to collect confirmatory test specimens, a procedure must be in place for referring clients/patients to another site to obtain this testing.
NOTE: If the client/patient refuses confirmatory testing, this should be documented in the test results log.

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3c. After Testing, continued

Confirmatory specimen and results handling

If specimens are collected on-site, the site must establish procedures describing:

- How to collect, label, process, store, and document specimen transfer. Note: It should be indicated on the referral laboratory test requisition that the specimen is from an individual who has had a reactive rapid HIV test result. (See Appendix F for an example specimen transfer log.)
- Transportation of the confirmatory test specimens to the site(s) where they will be tested.
- How confirmatory results are obtained to give to the client/patient.
- How to report confirmed positive HIV results to your state health department, as required. Check with your State health department for specific requirements.

Confirmatory testing protocols for a reactive rapid HIV test

For confirmatory testing of reactive (preliminary positive) rapid test results, recommended testing algorithms are as follows:

- All reactive (preliminary positive) rapid test results must be followed up with an approved supplemental test, such as a Western blot, an immunofluorescent assay (IFA) or an RNA [9,10] test, for confirmation.
- Confirmatory testing can be done on blood (plasma, serum, or dried blood spots) or oral fluid specimens, though blood specimens have higher accuracy than oral fluid specimens. Urine should not be used for confirmatory testing because of its lower sensitivity.

Performing an enzyme immunoassay (EIA) screening test prior to a confirmatory test is optional. Even if the EIA is nonreactive, the specimen must proceed to confirmatory testing with a Western blot, IFA, or RNA.

Follow-up testing for a negative confirmatory result

Most confirmatory test results will be positive; however, some may be negative. A negative confirmatory test result indicates one of three possibilities: specimen mix-up, early seroconversion (too early for antibody detection by Western blot or IFA), or false positive rapid test result. If the initial confirmatory test is negative, it is recommended that:

- For blood specimens, a repeat confirmatory test with a new blood specimen should be done to rule out specimen mix-up or early infection.
- For oral fluid specimens, a repeat confirmatory test with a blood specimen should be done because the Western Blot test is less accurate with oral fluid than it is with blood.

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3c. After Testing, continued

Follow-up testing for an indeterminate confirmatory test result

Occasionally, confirmatory test results are indeterminate. If the Western blot or IFA is indeterminate, it is recommended that:

- If the initial confirmatory test was conducted on blood, the person should be advised to return for repeat confirmatory testing in one month or a test for HIV RNA may be performed.
- If the initial confirmatory test was conducted on oral fluid, a repeat confirmatory test (Western blot, IFA, or RNA) should be conducted using a blood specimen.

See CDC's Revised Guidelines for HIV Counseling, Testing and Referral found at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a1.htm

Handling confirmatory test result discrepancies

Procedures should describe how to handle result discrepancies when the rapid test result was reactive and the confirmatory test was negative or indeterminate. If the laboratory providing confirmatory testing performed an EIA test only and reported a nonreactive or negative result, the testing site should contact the confirmatory testing laboratory and request a Western blot, IFA, or RNA test. If the original specimen is not available, a new specimen will need to be collected to be used for confirmatory testing.

4. External Assessment

Overview

External assessment, an evaluation of the testing process by an impartial outside source, is a way to evaluate how well testing is being performed and whether it is being performed reliably. It can help to identify existing or potential problems. Moreover, information gathered can provide an educational tool to improve performance. Although not required by Federal (CLIA) regulations for waived testing sites, some form of external assessment is highly recommended.

Methods for external assessment

Every reactive test is externally assessed by a second, confirmatory test. However, if there is a low prevalence of HIV infection in the population being tested, these assessments may be rare and will not provide an external check for the majority of the results, i.e., those that are nonreactive. Other ways to assess performance may be needed. Some external assessment mechanisms include:

- Comparing the reactive results with the confirmatory test results.
- Arranging for someone outside the organization to observe testing.
- Participating in a proficiency testing (PT) or external performance evaluation program. (For more information on these programs, see Appendix G.)

5. Documents and Records

Overview

One of the hallmarks of an adequate QA program is comprehensive documentation. Sites using waived rapid HIV tests should have policies and procedures describing what QA records are required and how and when they are reviewed, stored, and destroyed. Having a supervisor review records periodically is recommended. State regulations or other governmental or accrediting agencies may require facilities to have specific record retention policies. QA records include the following:

- Training documentation (Appendix B)
- Temperature logs (Appendix C)
- External control result logs (Appendix D)
- Test result logs (Appendix E)
- Specimen transfer logs (Appendix F)

Temperature logs

Temperature logs should include a daily record of the refrigerator and/or room temperature where test kits and external controls are stored and the temperature of the testing area. Thermometers should be placed in each location. Laboratory grade thermometers, which can be purchased from medical or laboratory supply houses, are recommended and their accuracy checked periodically (e.g., every six months) by comparison with another thermometer.

External control result logs

External control records should include the date and time of control testing, lot number and expiration date of the test kit, lot number and expiration date of the controls, control results, and corrective action taken if control results are unacceptable. Control records should be kept in the order in which they were completed so they can be easily compared with the test records. This will help find answers if there are questions about testing performed within a specific time frame.

Test result logs

Test result records should include the date and time of testing, an identifier for the person being tested, a test kit lot number and expiration date, test result, action taken if the result was invalid, identification of the person who performed the test, whether confirmatory testing was requested, including the type of specimen sent for confirmation (e.g., oral fluid, blood), and the confirmatory test results when they are available. If more than one person is conducting testing, there should be a mechanism to chronologically link the test record log sheets to detect problems, such as invalid results occurring repeatedly with the same test kit lot number.

6. QA Monitoring and Troubleshooting

Overview

Each site should have protocols to identify key QA measures that are routinely monitored and evaluated and have corresponding troubleshooting procedures to resolve problems that may occur. Significant problems, especially those concerning the accuracy of the rapid HIV test in use should be immediately reported to the QA manager or appropriate supervisory personnel. The local or state HIV test coordinator and the manufacturer should be notified when appropriate.

QA monitoring

QA managers should routinely monitor and evaluate QA measures. Some suggested measures include the following:

- Number of tests or external control materials that expired before use or occurrences of expired tests used for diagnostic or QC purposes
- Number of days tests or QC materials were stored or used outside of temperature specifications
- Frequency of external QC testing compared with test site procedure
- Frequency of invalid or incorrect results for external control testing or patient/client testing
- Proportion of negative and preliminary positive patient/client results
- Proportion of reactive rapid test results confirmed positive of all reactive rapid test results

Troubleshooting

Troubleshooting procedures should be available to all testing personnel and include the following:

- When to discontinue testing, for example, when the external control results are unacceptable as described in the package insert
- How to take corrective action, or an action taken in response to a problem, such as contacting the manufacturer when the external control results are unacceptable and following the advice provided
- How to document problems and actions taken, such as a logbook where problems and corrective actions can be recorded
- How to verify the corrective actions taken addressed the problem

NOTE: In accordance with Federal regulations, manufacturers of diagnostic devices must monitor, investigate, and report to the FDA complaints about device performance.

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6. QA Monitoring and Troubleshooting, continued

Expired tests or QC materials	When tests or external controls expire before they can be used for testing, QA managers should consider evaluating the following: ▪ Inventory management, ordering, and storage procedures, to ensure materials have a reasonable shelf life ▪ The use of test and control materials ▪ If needed, adjust ordering procedures, revise QA protocols, or retrain staff.
Tests or QC materials stored or used when temperatures are outside of specifications	When tests or external controls are used or stored outside of the manufacturer's temperature specifications, QA managers should consider the following actions: ▪ Determine the cause for out-of-range temperature(s) and ensure corrective measures have been taken. ▪ Confirm whether tests were used in out-of-range temperatures, if procedures were followed, and if testing personnel were aware of temperature conditions. ▪ Determine whether external QC tests were performed to verify the test could be performed and correctly interpreted. ▪ If needed, modify procedures and retrain staff on temperature control specifications.
Excessive External QC tests	Because of the costs associated with rapid tests, QA managers should monitor the ratio of tests used for diagnostic purposes to tests used for external QC purposes. If the ratio is less than 20 patient/client tests for each set (positive and negative) of external controls tested, then the number of tests used for external QC may be excessive. (Twenty tests is the smallest number of CLIA-waived rapid tests manufacturers provide per kit.[11-13]) If external QC testing is excessive because of the interval defined by the specific test site procedure (e.g., daily), consider adjusting the frequency of QC testing (e.g., from daily to weekly, bi-weekly, or monthly) to a more appropriate interval.

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6. QA Monitoring and Troubleshooting, continued

Incorrect or invalid QC test results

QA managers should consider the following procedures when incorrect or invalid QC test results are observed:

- Evaluate procedures for testing external controls and review records of control results.
- Perform troubleshooting procedures in accordance with the manufacturer's control kit instructions to determine the source of the incorrect or invalid result.
- If test devices used with valid external control materials provide invalid or incorrect results, discontinue testing and contact the manufacturer.
- Resume testing only after tests on external control materials provide correct results and document corrective actions.
- If needed, modify the QA protocol and/or retrain staff on appropriate testing of external controls.

Invalid patient/client test results

QA managers should consider the following actions when excessive invalid client test results are observed:

- If possible, observe specimen collection, testing, and result interpretation to confirm test procedures are performed correctly.
- Confirm the test device(s) used had not expired.
- Review documentation of testing to ensure procedures are being followed.
- Determine whether external controls were tested after the second invalid test result and if troubleshooting procedures were followed. If not, perform external QC testing using test devices from the same kit or lot to determine proper functioning of the test device.
- Perform troubleshooting procedures according to the manufacturer's instructions.
- If test results using valid external control materials provide invalid results, testing should be discontinued.
- If the test kit/lot is determined to be faulty, notify the manufacturer.
- Resume testing only after tests on external controls provide correct results and document corrective actions.
- If needed, retrain staff on appropriate testing procedures.
- If appropriate, notify local or state health department HIV test manager.

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6. QA Monitoring and Troubleshooting, continued

Excessive false-positive patient/client test results

QA managers should periodically compare the total number of reactive rapid test results with the number of confirmed positive results. If the resulting ratio of false-positive rapid test results suggests the test is not performing according to the manufacturer's specifications (refer to the product insert for population prevalence and performance data), QA managers should consider the following actions:

- Evaluate the expiration dates of test kits and temperatures of the storage and testing areas for test kit lots that produced, and did not produce, false positive test results.
- Review records of external control testing for test devices of the same lot and subjected to the same temperature conditions.
- Perform additional troubleshooting procedures in accordance with the manufacturer's instructions.
- Evaluate facility testing procedures and, if appropriate, modify the QA protocol and/or retrain staff on appropriate testing procedures.
- If necessary, inform the manufacturer and appropriate local or state health department HIV test managers. If appropriate, consider discontinuation of testing or changing to another waived test vendor.

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Glossary

AIDS:

Acquired immunodeficiency syndrome, caused by the human immunodeficiency virus (HIV), can affect the immune and central nervous systems and can result in neurological problems, opportunistic infections, or cancers.

CLIA-waived test:

A test system, assay, or examination that has been cleared by the FDA for home use, or has been determined by the FDA to meet the CLIA criteria of being a simple test with an insignificant risk for an erroneous result.

Confidentiality:

Pertains to the disclosure of personal information in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the original disclosure. Confidentiality must be maintained for persons who are recommended and/or who receive HIV counseling, testing, and referral (CTR) services.

Confirmatory test:

A highly specific test designed to confirm the results of an earlier (screening) test. For HIV testing, a Western blot, an immunofluorescence assay (IFA), or an RNA is used as a confirmatory test. The person is considered HIV-positive only if the confirmatory test result is positive.

EIA:

Enzyme immunoassay, sometimes referred to as ELISA, is a commonly used screening test to detect antibodies to HIV.

False negative:

A negative test result for a person who is actually infected.

False positive:

A positive test result for a person who is actually not infected.

HIV:

Human immunodeficiency virus, which causes AIDS. Several types of HIV exist, with HIV-1 being the most common in the United States.

Indeterminate test result:

A possible result for a Western blot, which might represent a recent HIV infection or a false-positive.

Nucleic acid amplification testing:

A type of testing that identifies viral genes (e.g., specific sequences of nucleic acids) using gene amplification technologies such as polymerase chain reaction (PCR).

Glossary, continued

Preliminary positive test:
For rapid HIV testing, a test result that is reactive by a rapid HIV test and not yet confirmed positive by a Western blot, IFA, or approved RNA supplemental test.

Rapid HIV test:
A test to detect antibodies to HIV that can be collected and processed within a short interval of time (e.g., approximately 10 to 60 minutes).

Referral laboratory:
An external laboratory to which a sample is submitted for a supplementary or confirmatory examination procedure and report.

RNA test:
A test used to detect HIV-1 in plasma using nucleic acid amplification. The test may be used as a confirmatory test for a reactive rapid HIV test result to aid in the diagnosis of infection with the virus.

Screening test:
An initial test, usually designed to be sensitive, to identify all persons with a given condition or infection.

Seroconversion:
Initial development of detectable antibodies specific to a particular antigen; the change of a serologic test result from negative to positive as a result of antibodies induced by the introduction of antigens or microorganisms into the host.

Western blot:
A laboratory test that detects specific antibodies to components of a virus. Chiefly used to confirm HIV antibodies in specimens found to be reactive using a screening test.