Rapid HIV testing guidance

April 2024

Utah Department of
Health & Human
Services

Introduction

This document provides guidance when using rapid testing technology. This guidance was designed for Utah Department of Health and Human Services (DHHS) funded agencies but may be used by any site that conducts rapid HIV testing. Visit our provider resource page periodically to review updates and find other resources such as required logs (https://epi.utah.gov/ptc-hiv/).

Direct questions or comments to:

Kim Farley
HIV prevention coordinator
Utah Department of Health and Human Services
Division of Population Health
PO Box 142104
Salt Lake City, UT 84114-2104
(801) 538-6287
kimfarley@utah.gov
OR
HIVandMe@utah.gov

List of abbreviations

Ab	antibody
Ag	antigen
Ag/Ab	antigen/antibody
AIDS	acquired immune deficiency syndrome
CDC	Centers for Disease Control and Prevention
CLIA	Clinical Laboratory Improvement Amendments
DHHS	Utah Department of Health and Human Services
FDA	U.S. Food and Drug Administration
HCV	hepatitis C virus
HIV	human immunodeficiency virus
IA	immunoassay
STD	sexually transmitted disease

Table of contents

General information

Test site administrator

Each test site should assign a rapid test site administrator who is a point person at the test site as well as the person who is responsible for and overseeing the following:

- Maintain trained and quality counselors and lab techs
- Maintain CLIA waiver
- Make sure blood-borne pathogen/universal precautions measures are followed
- Perform regular quality control measures
- Report problems promptly
- Maintain proper records
- Keep client information confidential
- Maintain test kits, controls, supplies
- Ensure compliance with Communicable Disease Rule
- Ensure compliance with all applicable local, state, and federal policies, protocols, procedures, guidance, and standards

Establishing policies and procedures

When establishing a site for rapid testing, program policies, and procedures must address:

- Confidentiality
- Staff training and proficiency
- Quality assurance
- HIV counseling
- Record keeping
- Reporting preliminary positive results
- Appropriate referrals and referral tracking to other HIV prevention services, partner services, HIV medical care, treatment, and other supportive services

Before conducting rapid testing, verify the following items:

- Staff and volunteers have been trained to perform their assigned tasks
- Test kits work as expected
- Logistics for providing confirmatory testing are in place
- Arrangements for biohazard waste handling and disposal are in place

- Detailed procedures are distributed to staff and volunteers (or they know where to access them)

Additional information on the above recommendations/documents is available from DHHS. An agency may establish its policies and procedures but its standards must align with DHHS guidelines.

Approved test devices

The term rapid test refers to the test devices listed below throughout this document. As of the revision date listed on the title page, no other test devices are approved for use at publicly-funded HIV test sites in the state of Utah without prior approval from the HIV prevention coordinator.

Approval to use a different FDA-approved HIV rapid testing technology

DHHS-funded HIV testing providers prefer to use the Determine™ HIV-1/2 Ag/Ab Combo 4th Generation Test for HIV rapid testing.
However, if the provider would like to use a different FDA-approved HIV rapid testing technology that is not the Determine™ HIV-1/2 Ag/Ab Combo 4th Generation, OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test, or OraQuick® In-Home HIV Test, the provider must submit in writing a request to the HIV prevention coordinator which indicates the following:

- what testing technology is preferred
- why a different testing technology is preferred
- the protocol for administering the test (describe any changes to the procedures used to maintain confidentiality, provide pre-and post-test counseling, linkage to care, and data collection for EvaluationWeb® if required)
- what is the estimated duration for testing with this technology

In addition, the provider must indicate rapid lab technicians have been trained on the use of the proposed technology. If training is required on an alternative device, note this in the request. This request must be approved by the HIV prevention coordinator before the purchase or use of any test technology that is not the Determine™ HIV-1/2 Ag/Ab Combo, OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test, or OraQuick® In-Home HIV Test.

Purchasing test kits and external controls

Provider may purchase test kits and external controls directly from each manufacturer listed below:

Abbott
150 S Saunders Road
Lake Forest, IL 60045
(877) 441-7440
www.abbott.com

Mary Haight
Senior specialist, Public Health
(719) 641-0992
Mary.haight@abbott.com

Determine™ HIV-1/2 Ag/Ab Combo
https://www.globalpointofcare.abbott/en/product-details/determine-1-2-ag-ab-combo.html

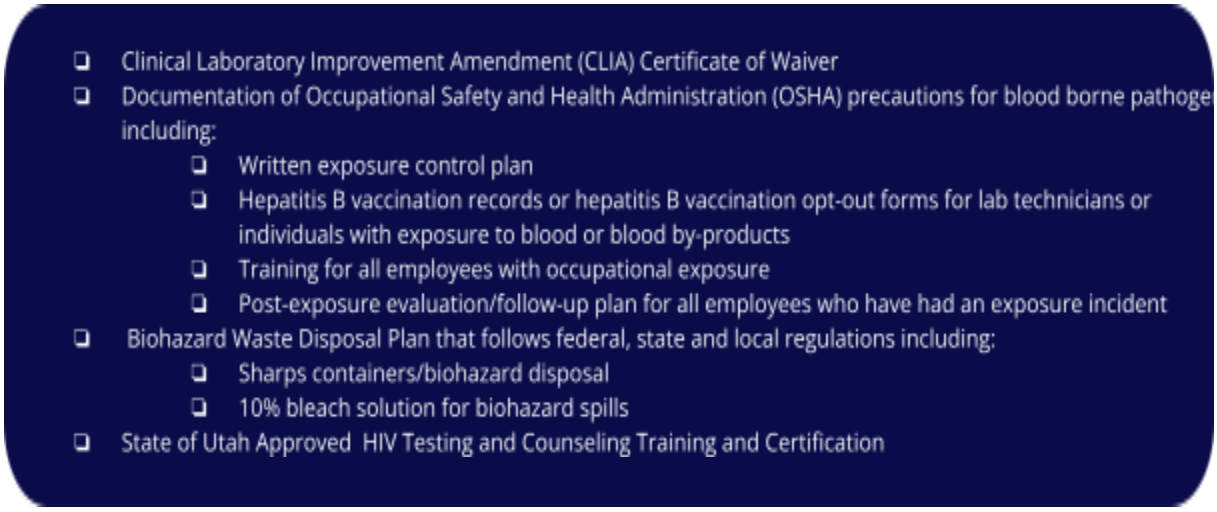
OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015-1360
(800)-ORASURE (1-800-672-7873)
www.orasure.com
customercare@orasure.com

Laurie Kops
National sales support
(484) 460-6471
lkops@orasure.com

OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test
https://www.orasure.com/products-infectious/OraQuick-Advance-HIV.html
OraQuick® In-Home HIV Test
https://www.orasure.com/products-infectious/OraQuick-OTC.html

Start-up requirements

Before any site may initiate rapid testing, the following items are to be completed and appropriate documentation kept.



CLIA certificate of waiver

Laboratory certificate requirements for HIV testing in nonclinical settings
CLIA outlines quality standards for laboratory testing—including rapid HIV testing—to ensure the accuracy, reliability, and timeliness of patient test results.
Nonclinical HIV testing sites using waived rapid HIV tests must either obtain their own certificate of waiver CLIA or establish an agreement to work under the CLIA certificate of an existing laboratory.

- Current waiver must be present at every testing activity including outreach
- Valid for two years, $150
- Lab director specification
- http://www.cms.hhs.gov/clia (for requirements and to apply for a certificate)

Blood-borne pathogens

Users of these tests and individuals who collect blood specimens, or who may encounter an occupational exposure to potentially infectious materials, should follow:

- Perspectives in Disease Prevention and Health Promotion Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings

- Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV Recommendations for Postexposure Prophylaxis
- The U.S. Department of Labor Occupational Health and Safety Administration (OSHA) standards for blood-borne pathogens: https://www.osha.gov/SLTC/bloodbornepathogens/index.html

Universal precautions

Treat all human blood as if it is known to be infectious with HIV, hepatitis B or C virus, and other blood-borne pathogens. Sites must follow procedures for biohazard safety including:

- **ALWAYS** wear gloves when handling blood or body fluids.
- Thoroughly wash hands with soap and water after any contact with blood or body fluids.
- Prior to testing, discuss with a supervisor about any cuts, abrasions, or skin rashes on hands or lower arms that may allow for easier transmission of infection.
- Dispose of gloves, absorbent work surfaces, and used testing materials in biohazard waste bags.
- **AVOID** personal activities like eating, drinking, texting, applying make-up, and touching faces or eyes in a workspace where specimen collection and testing occur.
- For additional safety precautions, refer to the manufacturer's recommendations and specifications packet.

Fluid exposure

Use universal precautions in all instances of fluid exposure.

Exposure of mucous membranes

- Rinse mucous membranes (nose or mouth) or eyes with large amounts of water or saline solution for at least 10 minutes.
- If running water is not readily available, use another source of water to rinse.

Puncture of skin

- Wash the puncture with soap and water while encouraging the puncture to bleed (through squeezing if necessary) for at least 10 minutes.
- Bandage the puncture when finished.

Report exposure

- Report any exposures to those responsible for managing exposures (occupational health, infection control, management).
- Post-exposure treatment may be recommended and will need to be started as soon as possible.
- Determine if the exposure was from a reactive rapid HIV test specimen.
- Discuss the possible risks of acquiring HBV, HCV, and HIV and the need for post-exposure treatment with the provider who manages your care.

Cleaning biohazard spills

- Wear protective equipment when cleaning a spill
- Clean up blood spills or body fluids immediately with absorbent towels
- Clean the area with a 10% bleach and 90% water solution (1 part bleach, 9 parts water)
- Wipe up any spills with absorbent towels
- Disinfect the area again with the bleach solution and let air dry
- Throw away all contaminated materials in a biohazard waste container

Hepatitis B vaccination record or opt-out form

All people who certify as lab technicians need to have documentation in their personnel or volunteer file of either hepatitis B vaccination or an opt-out form. Vaccination records can usually be obtained from private doctors, public clinics, or state agencies, and opt-out forms can be created at an agency or retrieved online.
https://www.osha.gov/sites/default/files/enforcement/directives/CPL_2-2_69.pdf

It is important to note that even with proper lab set-up, any technician can come into contact with infectious bodily fluids. Hepatitis B vaccination protects against hepatitis B virus. Signing an opt-out form acknowledges the individual chooses not to have the hepatitis B vaccination and accepts responsibility for possible infection of hepatitis B and future treatment.

Testing guidelines

DHHS complies with national and state testing guidelines. Refer to the resources below to make sure your agency complies with all updated guidelines.

National HIV Testing Guidelines
Utah HIV Testing Guidelines

Data collection and reporting

All DHHS funded contractors are required to gather unidentified client-level data and laboratory records of each client tested.

Client-level data is collected using DHHS EvaluationWeb® HIV Testing Form and reported according to the instructions provided with the form. Forms must be maintained for at least 18 months by the reporting agency or DHHS.

Laboratory records, such as the day of test logs and temperature logs (tests kits and external controls) are to be maintained by the agency for 18 months and made available to DHHS reviews upon request. See Appendix A—Resources.

Quality assurance

Quality assurance (QA) is the foundation of a successful testing program. QA standards ensure the accuracy of the test and results, as well as the quality of service agencies deliver.

Although waived rapid tests are easy to use, mistakes can occur at any point during the testing process. To reduce mistakes and make sure FDA restrictions are followed, the testing site must have a QA program in place before waived rapid antibody testing can be offered. CDC Quality Assurance Guidelines for testing using Rapid HIV Antibody tests waived under CLIA. and Developing an IQCP—A Step-by-Step Guide.

The basic elements of a QA program for rapid testing include:

- maintain accurate inventory and sufficient supply of unexpired test devices and control kits
- maintain and document the temperature of the room where testing is performed as well as where test kits and controls are stored
- conduct external quality assessment as needed
- review, store, and destroy records as they become outdated
- troubleshoot and take corrective action when things go wrong
- documentation and record-keeping

- QA evaluation and troubleshooting

Agencies should review the rapid test documents each day after testing ends or each week for internal assessment. A regular review process allows timely feedback to rapid testing staff and provides coaching when needed. DHHS EvaluationWeb® HIV Test Forms, test kit storage logs, control kit storage logs, and day of test logs should be retained for 18 months.

Electronic copies of the day of test log, test kit storage log, and control kit storage logs are available at: https://epi.utah.gov/ptc-hiv/ or refer to Appendix A of this document.

HIV testing and counseling training

Agencies funded by the Utah Department of Health and Human Services to conduct HIV testing are required to attend and pass DHHS-sponsored training.

Rapid lab technician training and certification

Rapid lab technician involves:

- Overview of rapid HIV testing technologies
- Demonstration of how to run a rapid lab and conduct rapid HIV tests
- Test result interpretation
- Paperwork completion and quality assurance

Rapid lab tech certification involves:

- 2.5 hour training
- Knowledge assessment
- Skills assessment

HIV prevention counseling

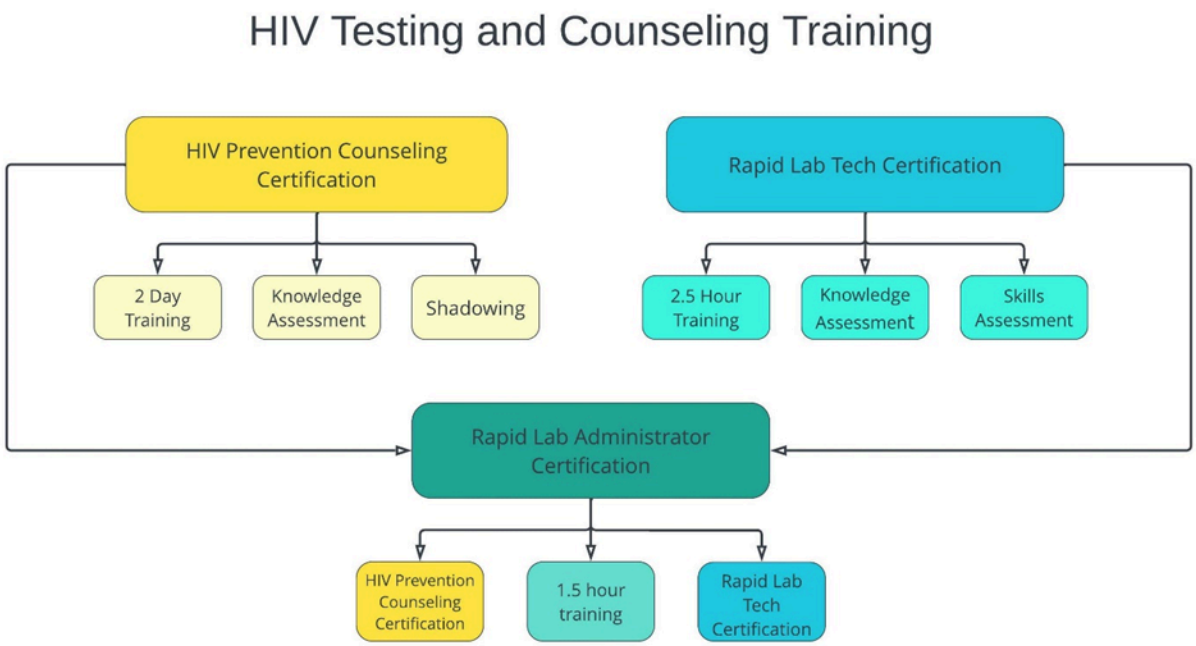
Prevention counseling involves:

- Explaining the testing process and possible results
- Identifying a person's unique risk factors for acquiring HIV
- Providing client-centered education and referrals to reduce risk
- Delivering test results

Prevention counseling certification involves:

- 2-day training
- Knowledge assessment
- Shadowing

Training tracks



For more information on training visit: https://epi.utah.gov/hiv-training/,

HIV external controls

Control kits

Each manufacturer produces external controls to validate the correct operation of each test device. Controls are specifically formulated and manufactured to ensure the performance of the test and are also used to verify the user's ability to properly perform the test and interpret the results.

External controls evaluate:

- if the testing device is functioning properly

- if the entire testing process is performed correctly
- if the control results are in the expected ranges or values as found in the manufacturer's instructions

The controls are unique to each test device and each manufacturer. The exchange of controls and test devices within or between manufacturers is not permitted and the result may not indicate whether the test device is operating within the manufacturer's specification. For example, OraQuick® ADVANCE controls cannot be run on Determine™ HIV tests. Exchanging external controls and test devices between manufacturers is a violation of CLIA guidelines.

Determine™ HIV- ½ Ag/Ab Combo HIV Controls

Determine™ HIV-1/2 Ag/Ab Combo Controls are human, plasma-based reagents. The HIV-1 and HIV-2 Reactive Controls will produce a reactive test result and have been manufactured to produce a visible test "Ab" line. The HIV-1 p24 Antigen Control will produce a reactive test result and has been manufactured to produce a visible test "Ag'' line. The non-reactive control will produce a non-reactive test result.

OraQuick® ADVANCE HIV Antibody Test Controls

The OraQuick® ADVANCE HIV Antibody Test control kits each include one vial of negative fluid and one vial of HIV-positive fluid (positive fluids are deactivated and do not pose a contamination risk). The HIV Positive Control will produce a reactive reddish-purple line at the test zone. The HIV Negative Control will generate a non-reactive test result (no reddish-purple line).

Control kit storage and monitoring

Refrigerate and maintain control kits at a consistent temperature. Monitor the temperature every business day on the control kit temperature Log (See Appendix A).

Control kit type	Frequency	Temperature range
Determine™ HIV-1/2 Ag/Ab Combo	Monitor every business day	36 to 46°F or 2 to 8°C
OraQuick® ADVANCE HIV Antibody Tests	Monitor every business day	35 to 46°F or 2 to 8°C

Control kit expiration

If the controls are expired, dispose of them in a biohazard waste container. Similarly, if the fluid in the vials is cloudy or discolored, immediately discard them in a biohazard waste container and open a new box of controls.

Control kit type	Stable period—SEALED	Stable period—OPEN
Determine™ HIV-1/2 Ag/Ab Combo	Expiration date printed on vial	Expiration date printed on vial
OraQuick® ADVANCE HIV Antibody Tests	Expiration date printed on vial	Eight weeks after the first use

Controls during testing events

- Controls must be stored in refrigerator-type temperatures and must not be expired or compromised.
- Controls must be accessible and available at every testing event.
- Controls can be stored in an insulated bag or cooler for up to 4 hours for outreach events.
    - The best practice is to transport 2 sets of controls in a hard-sided, well-insulated, portable cooler that maintains a consistent temperature.
    - Temperature should be monitored every 30 minutes.
    - 'Blue Ice' or similar frozen packs should be used to help maintain temperature.
    - If the temperature inside the cooler falls outside of 36 to 46°F or 2 to 8°C, the controls must be discarded.

Running controls

Use a methodical approach when running controls, such as introducing the negative reagent into one test device/developer vial before introducing the positive reagent in the second test device/developer vial. This will minimize errors with duplicate reagents.
The controls should have expected results for specific testing devices. This indicates the test device is operating correctly and client testing may begin. Client testing should not take place before the control run is finished and the desired results interpreted.

Determine™ HIV- ½ Ag/Ab Combo HIV Controls

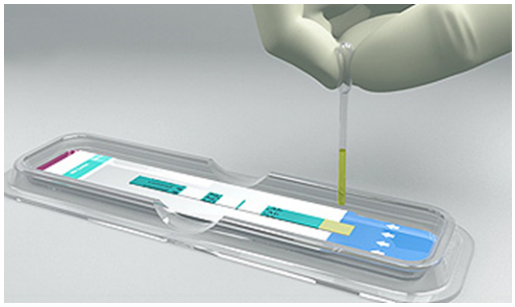
Click here for a demonstration video on running controls.

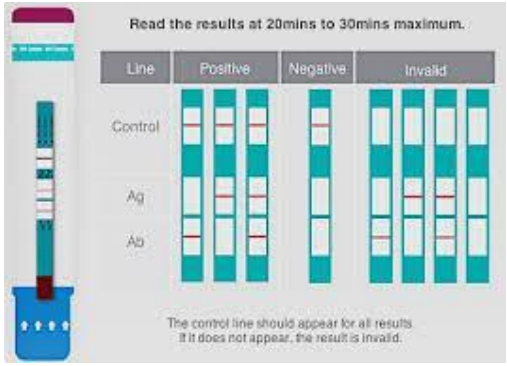
Control kit materials provided

- Each kit control box contains a package insert
- 40 disposable pipettes (not the same as specimen collection pipettes)
- Four vials:
    - HIV-1 Ab reactive control
    - HIV-2 Ab reactive control
    - HIV-1 p24 antigen control
    - Nonreactive control

Using controls with the Determine™ HIV Combo Assay:

1. External control material stored at refrigerated temperatures must be brought to room temperature (15 to 30°C; 59 to 86°F) prior to testing.
2. Remove 4 (one for each control reagent) test units from the test card by bending and tearing at the perforation.
3. Remove the protective foil cover from each test and place it on a flat surface or in the workstation.
4. Label the test device or write on the surface cover with the control name (negative, Ag +, Ab1, Ab2)
5. Open a control vial containing the control reagent.
6. Fill the pipette by inserting it into the control vial, squeezing the bulb, and releasing it to fill the pipette with the control reagent.
7. Apply 1 large drop of control to the sample pad by squeezing the bulb of the pipette. Do NOT touch the tip of the disposable pipette to the sample pad.
8. Return leftover control into the vial. Reseal and restore vial.
9. Record the start time for each control on the day of test log at the time the control reagent is added to the sample pad. Do not add chase buffer when running external controls.
10. Repeat with the other 3 vials. Use a new pipette with each new control.



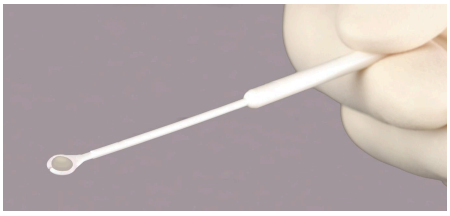


11. Read the test result between 20 and 30 minutes and record the read time and result on the day of test log.
12. Discard the used test device and any other test materials into a biohazard waste container.
13. Report any unexpected results to DHHS.

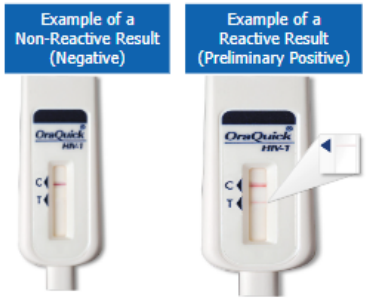
OraQuick® ADVANCE HIV Antibody Test controls

[See the training video and package insert for more instruction]

1. Open a kit control vial containing the control reagent.
2. Insert the round end of an unused specimen collection loop into the vial of the control reagent. Use separate unused specimen collection loops for each control reagent.
   NOTE: The kit control reagents are clear to straw-colored. Do not use it if the reagent appears visually cloudy or discolored.
3. Immediately immerse the control-reagent-filled specimen collection in the developer solution inside the developer solution vial.



4. Use the loop to stir the contents.
5. Discard the loop in a biohazard waste container.
6. Insert the flat pad of the device down into the developer vial.
7. Start timing the test.
8. Pink fluid will appear and travel up the result window. Gradually this will disappear as the test develops.
9. Read the results after 20 minutes but not more than 60 minutes in a fully lighted area.
   - The negative control will produce a non-reactive test result. A line should be present at the “C” triangle in the result window.
   - The positive control will produce a reactive test result that has been manufactured to produce a very faint test “T” line. Lines should appear at the “C” and “T” triangles in the result window.



If any other result than what is expected is present, repeat the control run with new test

kits. If the second control run still results in unexpected results, contact the manufacturer and/or DHHS for guidance and technical assistance.

When to run controls for HIV test kits

ALL testing locations: • Each new lab operator • First-time lab set-up at the main facility • Each new lot of test kits • Each new shipment of test kits • The temperature of the specimen collection area and/or lab exceeds the temperature window (specific to each test) • The temperature of the test storage area exceeds the temperature window (specific to each test) • At periodic intervals as indicated by the user facility • Whenever the number of preliminary positive results exceeds 1% of the site's historical incident rate The best practice is to maintain 2 sets of unexpired controls at the testing location under cold storage.	**OUTREACH testing locations**: • Each new lab operator • When test kits are transported to an outreach location and the travel time is more than 30 minutes where temperature is not monitored or maintained • Each new lot of test kits • Each new shipment of test kits • The temperature of the specimen collection area and/or lab exceeds the temperature window (specific to each test) • The temperature of the test storage area exceeds the temperature window (specific for each test) • Whenever the number of preliminary positive results exceeds 1% of the site's historical incident rate The best practice is to maintain 2 sets of unexpired controls at the testing location and store them in a portable cooler where the temperature range can be maintained and verified.

HIV test kits

Test kit temperature and monitoring

All Determine™ HIV-1/2 Ag/Ab Combo test cards and chase buffer and OraQuick® ADVANCE HIV Antibody Tests **must be stored at 36 to 86°F (2 to 30°C),** with the temperature of the storage area monitored and recorded each business day. If test kits/cards and chase buffer are refrigerated, bring them to room temperature (between 59-86°F, 15-30°C) prior to testing (approximately 30 minutes).

Test kit disposal—expired or compromised

Expiration dates are noted on the box and each test kit or test card and chase buffer. DO NOT USE test kit components beyond the expiration date printed on the label. Expired or compromised kits may provide an incorrect test result. Always check the expiration date prior to testing.

Compromised Determine™ HIV-1/2 Ag/Ab test cards

- If the desiccant package is missing, DO NOT USE. Discard test cards (all test units) and use a new test card.
- Do not use any test units from the test cards if the pouch has been perforated.
- Each test unit and disposable capillary tube, used for collection and transfer of fingerstick samples, are for single use only.

Compromised OraQuick® ADVANCE HIV Antibody Test kits:

- The developer vial is empty.
- The foil pouch is pierced.
- A shake of the test kit pouch produces no rattle sound (indicating the absence of a desiccant packet).
- The test device has been removed from the foil pouch and dropped.
- The test device has been compromised by being exposed to extreme temperatures above/below the manufacturer's specifications and recommendations.

You may elect to retain a limited number of test devices to be used for training and education exercises. Mark 'TRAINING' or 'DEMO" on the outside of each test kit pouch/box and store it in a different location from the unexpired test kits.

Rapid lab setup

Supply list

The following is a comprehensive list of recommended supplies to help run an efficient lab. Rapid testing requires unique supplies, and each manufacturer may require different materials. Refer to each manufacturer's recommendations for specific details.

Determine™ HIV-1/2 Ag/Ab Test

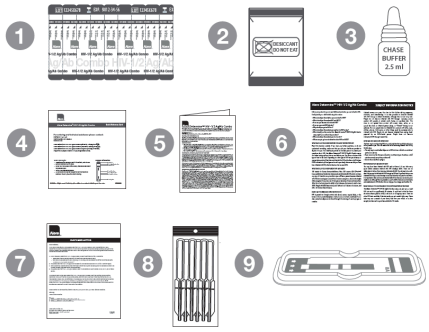
- ❑ All materials provided in the Determine™ HIV-1/2 Ag/Ab Combo box
- ❑ Determine™ HIV-1/2 Ag/Ab Combo Controls
- ❑ Sterile lancets capable of producing 50 µL of blood

OraQuick® ADVANCE HIV Antibody Test

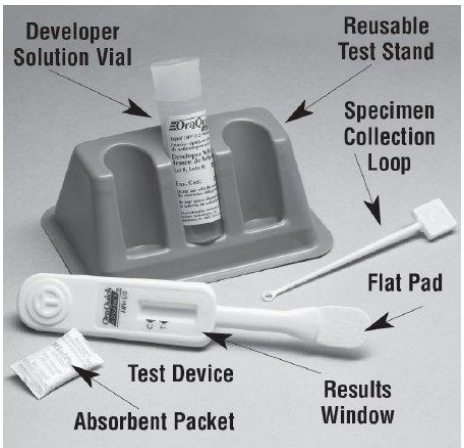
- ❑ OraQuick® ADVANCE HIV Antibody Test kits
- ❑ Controls
- ❑ Test stands
- ❑ Collection loops

General supplies

- ❑ Day of test log, intake form and other paperwork
- ❑ Disposable Gloves (multiple sizes)
- ❑ Sterile Lancet
- ❑ Timer or Watch
- ❑ Thermometer
- ❑ Antiseptic Wipe/Alcohol pad
- ❑ Sterile Gauze Pads or cotton balls
- ❑ Band-aids
- ❑ Biohazard Waste Container
- ❑ Disposable, Absorbent Workspace Cover
- ❑ Bleach solution
- ❑ Pen, stapler, paperclips, clipboards, etc
- ❑ Educational materials
- ❑ Portable cooler and frozen packs (for off-site or outreach testing)



1. Determine™ HIV-1/2 Ag/Ab Combo Test Cards
2. Desiccant Package
3. Chase Buffer
4. Quick Reference Card
5. Package Insert
6. Subject Information Notices
7. Customer Letter
8. Disposable Capillary Tubes
9. Disposable Workstations



Lab site

Whether at a main test site or conducting outreach testing, consider the following when selecting the best lab location:

- A dedicated area exclusively to run and monitor tests
- Sufficient level counter space to run and monitor tests
- Consistent room temperature
- Sufficient lighting to read the test window
- Sufficient area to store supplies
- Ability to lock room or limit access
- Ability to maintain client confidentiality
- Ability to maintain client files in a secure manner

Lab temperature range

Lab temperature requirements are specific to each type of rapid test. The temperature of the specimen collection area must fall within a defined range. Whenever the temperature falls outside the minimum or maximum operating temperature, NO new clients may be tested until the temperature is once again within range. Any tests running are allowed to run their time and be interpreted as usual.

Once the temperature is within range, run one negative external control and one external positive control to verify the test kits are operating per the manufacturer's design. Only after controls have run their full time and have been interpreted correctly (one negative and one positive) can client testing commence or resume.

Test kit type	Lab temperature range
Determine™ HIV-1/2 Ag/Ab Combo	59 to 86°F or 15 to 30°C
OraQuick® ADVANCE HIV Antibody Test	59 to 99°F or 15 to 37°C

General testing

Testing capacity

Direct observation and staff interviews have determined one lab technician can efficiently administer and monitor up to 5 tests in one 60-minute period. Whenever more than 5 tests are administered in one 60-minute period, it is strongly suggested one person perform specimen collection and another person monitor tests and lab paperwork. Only certified lab technicians are qualified to interpret test results, and/or sign off as a conferring opinion.

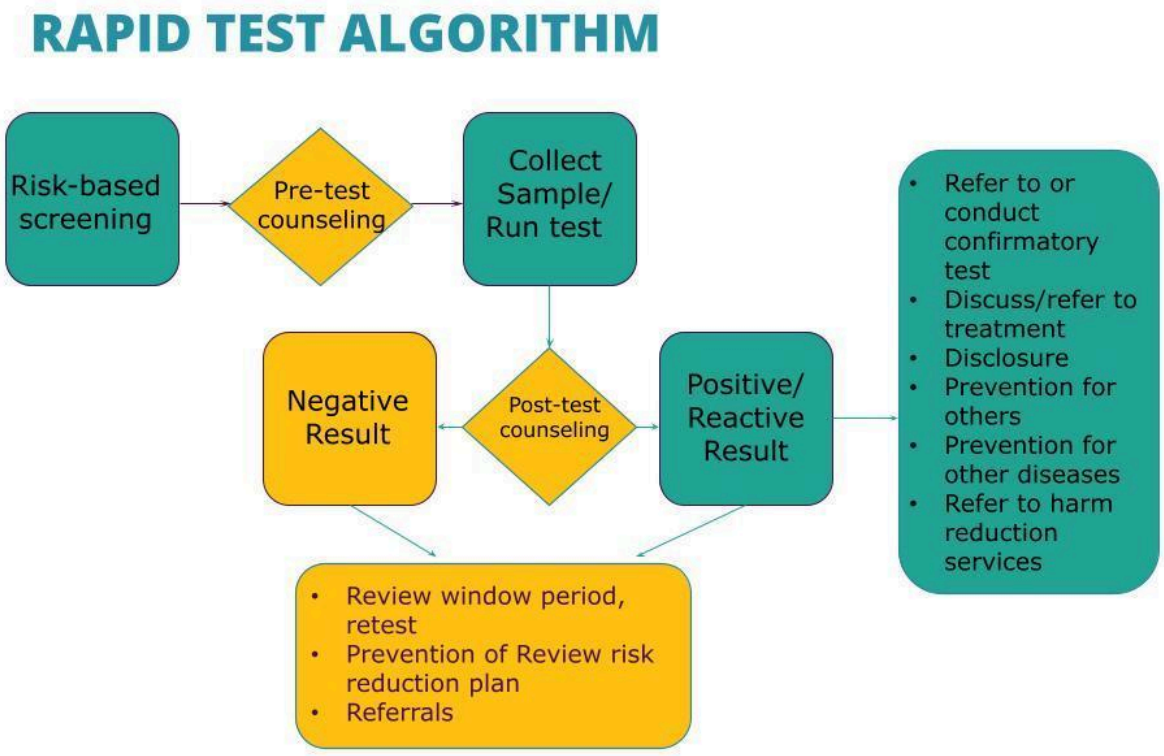
For rapid HIV testing: At least one staff member who is certified to give preliminary positive results must be present at all times while rapid HIV testing is being conducted.

High-volume testing can require increased capacity and resources. To ensure quality testing and accurate results, consideration can be given to partnering with trained staff at other agencies. Contact DHHS for more information.

Before testing starts

Verify you can ensure:

- A flat surface, well-lit area, and plenty of room to work
- The ability to keep client confidentiality and supplies clean and safe
- All supplies are present, including unexpired test kits and controls, fingerstick and biohazard supplies, day of test logs, and any other paperwork
- Disinfect the area prior to use
- Cover the workspace with a clean, absorbent pad
- Set up rapid lab station and make sure all required items are present
- Arrange supplies to be sterile and accessible, including biohazard and sharps containers
- Complete the top portion of the day of test log and run controls if necessary



Conducting HIV rapid tests

Fingerstick procedure

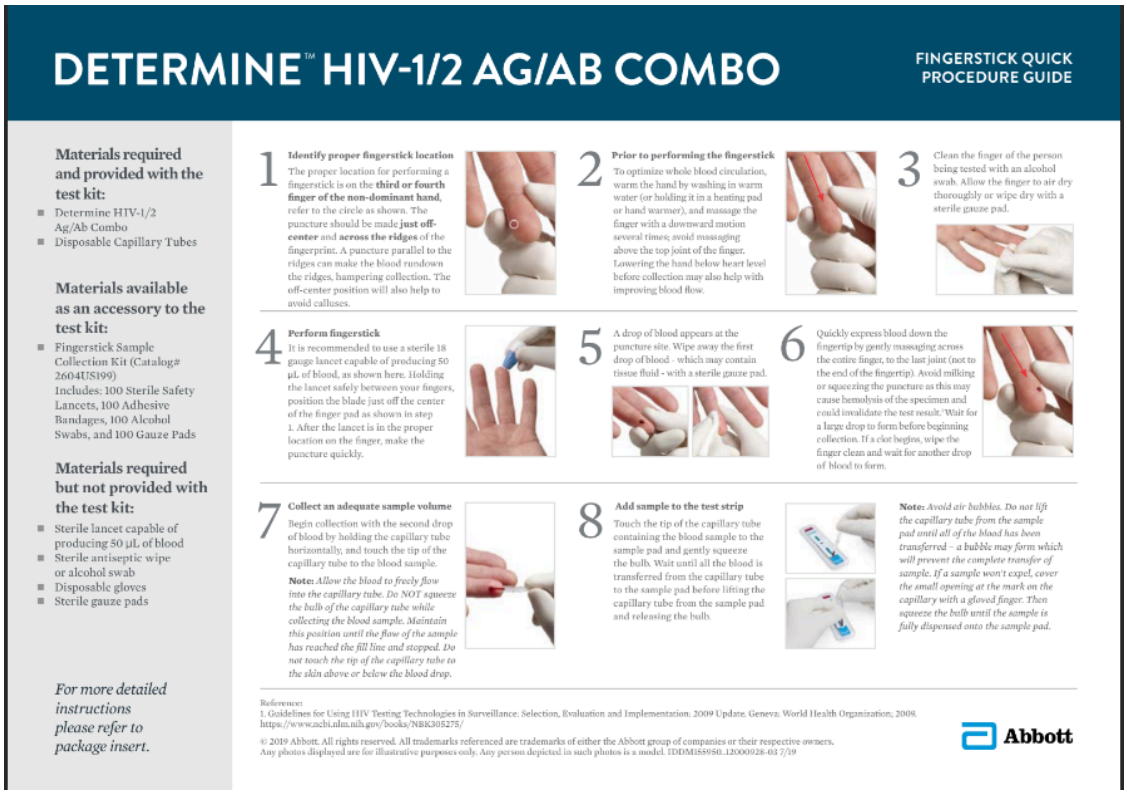
- Put on gloves
- Label test device and day of test log with client ID
- Prepare test device
- Wipe the client's finger with an alcohol pad and let it dry
- Stick pad of clean finger with a lancet, dispose lancet in a sharps container
- Wipe away the first drop of blood and discard gauze in biohazard
- Collect blood—see each test type for specimen collection specifics
    - Determine™ HIV-1/2 Ag/Ab Combo
    - OraQuick® ADVANCE HIV Antibody Test
- Start timer and record start time on the day of test log
- Place cotton or gauze on the wound and give the client a Band-Aid
- Remove and dispose of gloves and prepare for the next client

Determine™ HIV-1/2 Ag/Ab Combo

Online resources—fingerstick video, fingerstick guide, quick reference card.

1. Collect the second drop of blood by holding the capillary tube HORIZONTALLY, and touch the tip of the capillary tube to the bubble of blood. *NOTE: Filling of the capillary is automatic—do NOT squeeze the bulb while sampling.* Maintain this position until the flow of the sample has reached the fill line and stopped.
2. Hold the capillary tube vertically and touch the tip of the capillary tube containing the blood sample to the sample pad (marked by the arrow symbol) and gently squeeze the bulb. Do not lift the capillary tube from the sample pad before all the blood has been transferred.
3. When all of the blood is transferred to the sample pad, wait one minute to make sure the chase buffer does not overflow the sample pad.
4. Add one drop of chase buffer to the sample pad
5. Read the test result between 20 and 30 minutes after the addition of the chase buffer. Do not read test results after 30 minutes.

NOTE: Discard the used capillary tubes, test units, and any other test materials into a biohazard waste container.



DETERMINE™ HIV-1/2 AG/AB COMBO

FINGERSTICK QUICK PROCEDURE GUIDE

Materials required and provided with the test kit:

- Determine HIV-1/2 Ag/Ab Combo
- Disposable Capillary Tubes

Materials available as an accessory to the test kit:

- Fingerstick Sample Collection Kit (Catalog# 2604USI99) Includes: 100 Sterile Safety Lancets, 100 Adhesive Bandages, 100 Alcohol Swabs, and 100 Gauze Pads

Materials required but not provided with the test kit:

- Sterile lancet capable of producing 50 µL of blood
- Sterile antiseptic wipe or alcohol swab
- Disposable gloves
- Sterile gauze pads

For more detailed instructions please refer to package insert.

1 **Identify proper fingerstick location**
The proper location for performing a fingerstick is on the **third or fourth finger of the non-dominant hand**, refer to the circle as shown. The puncture should be made **just off-center** and **across the ridges** of the fingerprint. A puncture parallel to the ridges can make the blood rundown the ridges, hampering collection. The off-center position will also help to avoid calluses.

2 **Prior to performing the fingerstick**
To optimize whole blood circulation, warm the hand by washing in warm water (or holding it in a heating pad or hand warmer), and massage the finger with a downward motion several times; avoid massaging above the top joint of the finger. Lowering the hand below heart level before collection may also help with improving blood flow.

3 Clean the finger of the person being tested with an alcohol swab. Allow the finger to air dry thoroughly or wipe dry with a sterile gauze pad.

4 **Perform fingerstick**
It is recommended to use a sterile 18 gauge lancet capable of producing 50 µL of blood, as shown here. Holding the lancet safely between your fingers, position the blade just off the center of the finger pad as shown in step 1. After the lancet is in the proper location on the finger, make the puncture quickly.

5 A drop of blood appears at the puncture site. Wipe away the first drop of blood - which may contain tissue fluid - with a sterile gauze pad.

6 Quickly express blood down the fingertip by gently massaging across the entire finger, to the last joint (not to the end of the fingertip). Avoid milking or squeezing the puncture as this may cause hemolysis of the specimen and could invalidate the test result.[1] Wait for a large drop to form before beginning collection. If a clot begins, wipe the finger clean and wait for another drop of blood to form.

7 **Collect an adequate sample volume**
Begin collection with the second drop of blood by holding the capillary tube horizontally, and touch the tip of the capillary tube to the blood sample.
Note: *Allow the blood to freely flow into the capillary tube. Do NOT squeeze the bulb of the capillary tube while collecting the blood sample. Maintain this position until the flow of the sample has reached the fill line and stopped. Do not touch the tip of the capillary tube to the skin above or below the blood drop.*

8 **Add sample to the test strip**
Touch the tip of the capillary tube containing the blood sample to the sample pad and gently squeeze the bulb. Wait until all the blood is transferred from the capillary tube to the sample pad before lifting the capillary tube from the sample pad and releasing the bulb.

Note: *Avoid air bubbles. Do not lift the capillary tube from the sample pad until all of the blood has been transferred – a bubble may form which will prevent the complete transfer of sample. If a sample won't expel, cover the small opening at the mark on the capillary with a gloved finger. Then squeeze the bulb until the sample is fully dispensed onto the sample pad.*

Reference:
1. Guidelines for Using HIV Testing Technologies in Surveillance: Selection, Evaluation and Implementation: 2009 Update. Geneva: World Health Organization; 2009. https://www.ncbi.nlm.nih.gov/books/NBK305275/

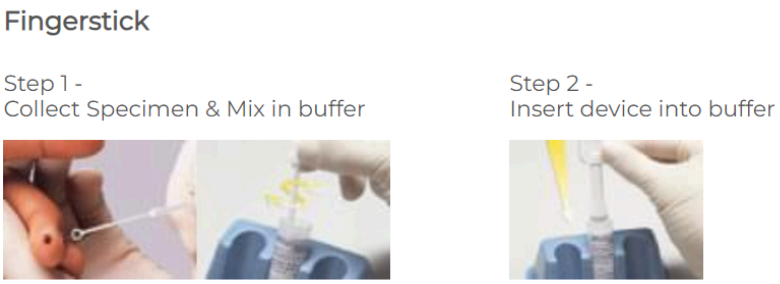
Abbott

OraQuick® ADVANCE HIV Antibody Test

[Online training with instructions, video, and other resources]

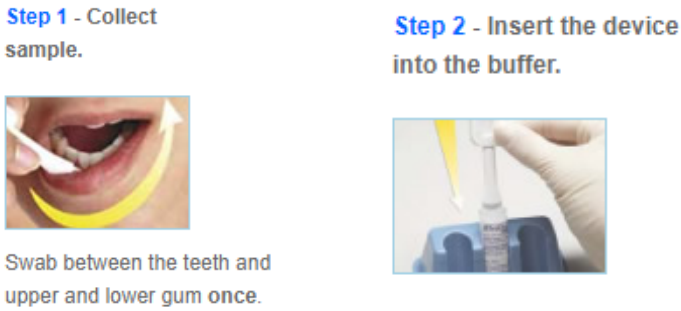
Whole blood collection Instructions:

1. Collect blood drop with the collection loop making sure the blood fills the loop from side to side.
2. Place the loop with the sample in the buffer and mix it with the developer solution.
3. Remove the loop and insert the test device into the buffer solution vial.
4. Read the test result between 20 and 40 minutes after the test device is inserted into the test vial. Do not read the test results after 40 minutes.



Oral fluid collection instructions:

1. Make sure the client has not had anything to eat or drink or chewed gum for at least 15 minutes.
2. Have the client remove the test device from the pouch. DO NOT touch the flat pad.
3. Have the client place the flat pad between the lip and gum above the teeth and gently swab ONCE across the top of the mouth then repeat ONCE across the bottom.
4. Have the client return the test device to the pouch, ensuring the flat pad is not touched by anyone's hands and inserted completely.
5. Have the client hand the pouch back to the lab technician.
6. Remove the test device from the pouch and insert it into the testing vial.
7. Read the test result between 20 and 40 minutes after the test device is inserted into the test vial. Do not read test results after 40 minutes.



Interpreting test results

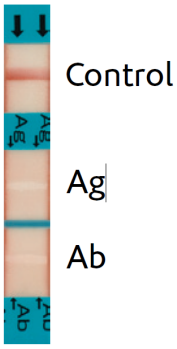
The result windows of both test devices are different. Refer to the summary information below and/or to each manufacturer's information packet.

Determine™ HIV-1/2 Ag/Ab Combo interpretation of results

NOTE: When testing whole blood samples, a faint pink background may be visible on the test membrane.

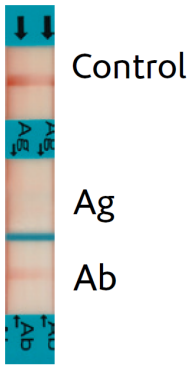
NONREACTIVE (One line—control line)

A PINK/RED control line appears in the control area of the test unit, and no PINK/RED Ab or Ag line appears in the lower test area and the upper test area of the test unit, respectively. This means HIV-1 or HIV-2 antibodies and HIV-1 p24 Ag were not detected in the specimen. A nonreactive result does not preclude the possibility of exposure to HIV or infection with HIV. However, no further testing is required for specimens that are nonreactive on the initial immunoassay.



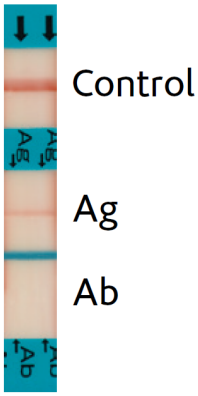
ANTIBODY REACTIVE (Two lines—control and Ab line)

A PINK/RED control line appears in the control area AND a PINK/RED Ab line must appear in the lower test area of the test unit. The intensity of the Ab and control lines may vary. Any visible PINK/RED color in both the control and lower test areas, regardless of intensity, is considered REACTIVE. A reactive test result means HIV-1 and/or HIV-2 antibodies have been detected in the specimen. The test result is interpreted as PRELIMINARY POSITIVE for HIV-1 and/or HIV-2 antibodies.

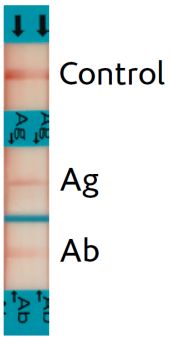


ANTIGEN (HIV-1 p24) REACTIVE (Two lines—control line and Ag line)

A PINK/RED control line appears in the control area AND a PINK/RED Ag line must appear in the upper test area of the test unit. The intensity of the Ag and control lines may vary. Any visible PINK/RED color in both the control and upper test areas, regardless of intensity, is considered REACTIVE. A reactive test result means HIV-1 p24 antigen has been detected in the specimen. The test result is interpreted as PRELIMINARY POSITIVE for HIV-1 p24 antigen.

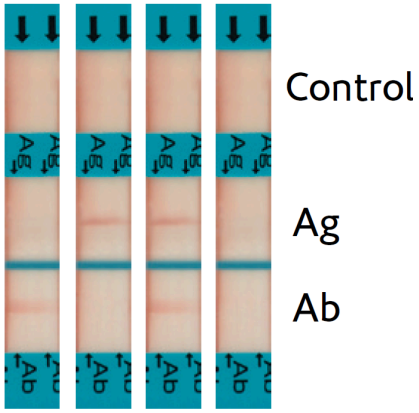


ANTIBODY REACTIVE AND ANTIGEN (HIV-1 p24) REACTIVE (Three lines—control, Ab and Ag lines)



A PINK/RED control line appears in the control area AND a PINK/RED Ab line must appear in the lower test area AND a PINK/RED Ag line appears in the upper test area of the test unit. The intensity of the Ab, Ag, and control lines may vary. Any visible PINK/RED color in the control area, the lower test area, and the upper test area, regardless of intensity, is considered REACTIVE. The test result is interpreted as PRELIMINARY POSITIVE for HIV-1 and/or HIV-2 antibodies and HIV-1 p24 antigen.

INVALID (No control line)



If there is no PINK/RED control line in the control area of the test unit, even if a PINK/RED line appears in the lower test area or the upper test area of the test unit, the result is INVALID and the test should be repeated.

DO NOT interpret an invalid test result. An invalid test occurs when there was either a problem running the test or a problem related to the device, or the testing procedure. Record the lot number and report to DHHS and test the client with a new test device.

OraQuick® ADVANCE HIV Antibody Test interpretation of results

NON-REACTIVE (one line)

- A reddish-purple line appears next to the triangle labeled “C” and no line appears next to the triangle labeled “T.”
- A non-reactive test result means HIV-1 antibodies were not detected in the specimen. The test result is interpreted as NEGATIVE for HIV-1 antibodies.

REACTIVE (two lines)

- A reddish-purple line appears next to the triangle labeled “C” and a reddish-purple line appears next to the triangle labeled “T.” Lines may vary in intensity.
    - NOTE: The test is reactive if any reddish-purple line appears next to the “T” triangle and next to the “C” triangle, no matter how faint these lines are.

- A reactive test result means HIV-1 antibodies have been detected in the specimen. The test result is interpreted as PRELIMINARY POSITIVE for HIV-1 antibodies.

INVALID (no line or lines in incorrect places, etc.)

- No reddish-purple lines appear next to the triangle labeled “C.”
- A red background in the results window makes it difficult to read the result after 20 minutes.
- If any of the lines are NOT inside the “C” or “T” triangle areas.
- An invalid test result means there was a problem running the test, either related to the specimen or to the device. IT CANNOT BE INTERPRETED. Repeat the test with a new pouch and new fingerstick blood sample.

Preliminary positive results

Reporting preliminary positive results

All positive HIV tests, including reactive rapid tests, must be reported by official reporting channels. Do not wait for a confirmatory test to report a preliminary positive result. It is possible a client will be lost prior to completion of confirmatory testing and reporting allows the appropriate local health departments to follow-up with the client.

Utah law mandates HIV to be reported to the local health department or DHHS within three (3) working days.

Reports can be submitted by:

1. Fax: (801) 538-9923
2. Email: reporting@utah.gov (do not use if you do not have secure email)
3. Phone: 1-888-EPI-UTAH
4. Online: Online reporting form
5. Local health department: List of local health departments

It is important to collect as much contact information about the client as possible. Phone numbers, preferred language, addresses, emails, any contact information that can help the local health department reach out to the client is vital.

Confirmatory testing

All reactive or preliminary positive results must be confirmed with an appropriate diagnostic test. Rapid HIV tests are screening tests, not diagnostic tests, so preliminary positive rapid test results must be confirmed with an appropriate diagnostic test such as an FDA-approved antigen/antibody combination (4th generation) immunoassay that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen to screen for established infection with HIV-1 or HIV-2 and acute HIV-1 infection. AIDS-related conditions are clinical syndromes, and their diagnosis can only be established clinically.

It is recommended you identify locations to refer people for confirmatory testing prior to instituting rapid HIV testing. This may be your location if you are a medical provider or have phlebotomists available. If not, other medical clinics, urgent cares, or local health departments are good options.

Utah's Rapid HIV Testing Algorithm using the Determine™ HIV-1/2 Ag/Ab Combo test allows for appropriate active referrals. Under this algorithm, all clients who test preliminary positive for HIV can be directly referred to care and partner services for appropriate follow-up.

Medical providers should refer to the CDC Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens to confirm the preliminary positive results.

Partner services

Local health departments are the typical providers of partner services. Partner services are a broad array of services that should be offered to persons with HIV or other sexually transmitted diseases (such as, syphilis, gonorrhea, chlamydial infections) and their sexual or needle-sharing partners.

Partner services programs can offer substantial benefits by identifying persons infected with HIV, interviewing them to gather information about their sexual and needle sharing partners, confidentially notifying their partners of their possible exposure, and by providing persons infected with HIV and their partners a range of medical, prevention, and psychosocial services including testing and linkage to care. Partner services are always voluntary, confidential, client-centered, and free.

Appendix

Appendix A—Resources

CDC

- CDC HIV Testing
- CDC HIV Testing in Non-Clinical Settings
- CDC's Rapid HIV Testing Online Training Course
- Fact Sheet: HIV Testing 101

CLIA

- CDC CLIA home page
- CDC CLIA of Certificate Waiver Fact Sheet
- State agency & regional office CLIA contacts
- How to establish an Individualized Quality Control Plan (IQCP) for HIV-CLIA waived testing
- Additional resources for setting up a nonclinical testing site

HIV testing technologies

- Fact Sheet: False Positive HIV Test Results
- CLIA-waived rapid HIV tests
- Guidance for nonclinical HIV testing sites use a laboratory-based algorithm

Utah resources

- Utah HIV Testing Guidelines
- DHHS HIV Case Report Form
- Utah Testing & Treatment Guide
- HIVandMe
- DHHS HIV Prevention

Recommendations and guidelines

- Partner Services Providers Quick Guide
- Planning and Implementing HIV Testing and Linkage Programs in Nonclinical Settings: A Guide for Program Managers,
- Evaluation Guide for HIV Testing and Linkage Programs in Nonclinical Settings
- HIV recommendations and guidelines
- STD & HIV Screening Recommendations
- hepatitis C Virus testing information
- Recommendations for Partner Services Programs for HIV Infection, Syphilis, Gonorrhea, and Chlamydial Infection

DHHS rapid testing paperwork

- Rapid Lab Supply Checklist
- Day of Test Log
- Test Kit Temperature Log
- Lab Results Sheet
- Intake Form
- EvaluationWeb® positive result form