

Rapid HIV and HCV Testing Guidance

For

Alere Determine™ HIV-1/2 Ag/Ab

Combo

OraQuick® HCV Rapid Antibody Test

Effective Date April 1, 2016

Introduction

The purpose of this document is to provide guidance when using rapid testing technology. This guidance was designed for Utah Department of Health (UDOH) funded agencies, but may be used by any site that conducts rapid HIV or Hepatitis C (HCV) testing. Visit our provider resource page periodically to review updates.

Please direct questions or comments to the people listed below:

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Resources

Rapid testing guidance and other resources, such as required logs, are located on the Utah Department of Health, Bureau of Epidemiology, HIV/HCV Prevention Provider Resources page. To access the webpage visit: <http://health.utah.gov/epi/prevention/providerResource.html>

Disclaimer

The Utah Department of Health does not endorse specific products or brands. The use of a brand/product name is for demonstration purposes only.

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1. General Information

1.1 Approved Test Devices

Throughout this document, the term ‘rapid test’ refers to the test devices listed below. As of the revision date listed on the title page, no other test devices are approved for use at publicly funded HIV and HCV test sites in the State of Utah. Test kits and external controls may be purchased directly from each manufacturer listed below:

Alere North America

51 Sawyer Road, Suite 200
Waltham, MA 02453-3448
(877) 441-7440
www.alere.com

Product name: **Alere Determine™ HIV-1/2 Ag/Ab Combo**
Product Code: 7D2648
External Controls Code: 7D92112
Product website: <http://www.alere.com/en/home/product-details/determine-1-2-ag-ab-combo.html>

OraSure Technologies, Inc.

220 East First Street
Bethlehem, PA 18015-1360
www.orasure.com
800/672-7873

Product name: **OraQuick® Rapid HCV Antibody Test**
Product number: 1001-0180 (100 count)
Product number: 1001-0181 (25 count)
OraQuick® ADVANCE Rapid HCV Control number: 1001-0182
Product website: <http://www.orasure.com/products-infectious/products-infectious-oraquick-hcv.asp>

2. General Start-up Requirements

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

- Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver**
- Documentation of Occupational Safety and Health Administration (OSHA) precautions for blood borne pathogens including:**
 - Written exposure control plan
 - Hepatitis B vaccination records or hepatitis B vaccination opt-out forms for lab technicians or individuals with exposure to blood or blood by-products
 - Training for all employees with occupational exposure
 - Post-exposure evaluation/follow-up plan for all employees who have had an exposure incident
- Biohazard Waste Disposal Plan that follows federal, state and local regulations including:**
 - Sharps containers/biohazard disposal
 - 10% bleach solution for biohazard spills
- State of Utah Training and Certification**
 - HIV, STD and, Viral Hepatitis FACTS Class
 - Rapid Lab Technician Training and Certification
 - 2009 - CDC Fundamentals of HIV Prevention Counseling

Clinical Laboratory Improvement Amendment (CLIA) Regulations

2.1 CLIA Certificate of Waiver

The rapid HIV and HCV tests approved for use in the State of Utah are classified as “waived” under Federal regulations for the Clinical Laboratory Improvement Amendment of 1988.

Visit <http://www.cms.hhs.gov/clia> for a full listing of certification requirements and to apply for a certificate of waiver.

2.2 Blood Borne Pathogens

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

- Universal Precautions for Preventing Transmission of Bloodborne Infections
<http://www.cdc.gov/niosh/topics/bbp/universal.html>
- “Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV Recommendations for Postexposure Prophylaxis”
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm>

- meet 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>

2.3 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 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, please refer to the manufacturer's recommendations and specifications packet

2.4 Cleaning Up 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 water solution (1 part bleach, 9 parts water)
- Wipe up spill with absorbent towels
- Disinfect the area again with the 10% bleach solution and let air dry
- Throw away all contaminated materials in a biohazard waste container

2.5 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, visit:

<https://www.osha.gov/SLTC/etools/hospital/hazards/bbp/declination.html> for more information.

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 that the individual chooses not to have the hepatitis B vaccination and accepts responsibility of possible infection of hepatitis B and future treatment.

2.6 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 and HCV counseling

- Record keeping
- Appropriate referrals and referral tracking to other HIV prevention services, Partner Services, HIV medical care and HCV diagnostic testing, treatment and other supportive services

Additional information to the above recommendations/documents, are available from UDOH PTCP. An agency may establish their own policies and procedures but their standards must meet UDOH guidelines.

3. Training

3.1 Lab Technician Training and Certification

Prospective lab technicians must attend the FACTS training and the lab technician certification course. Before testing clients and interpreting results the prospective lab technicians must attend the two training courses reference above, complete a knowledge assessment and pass a supervised observation.

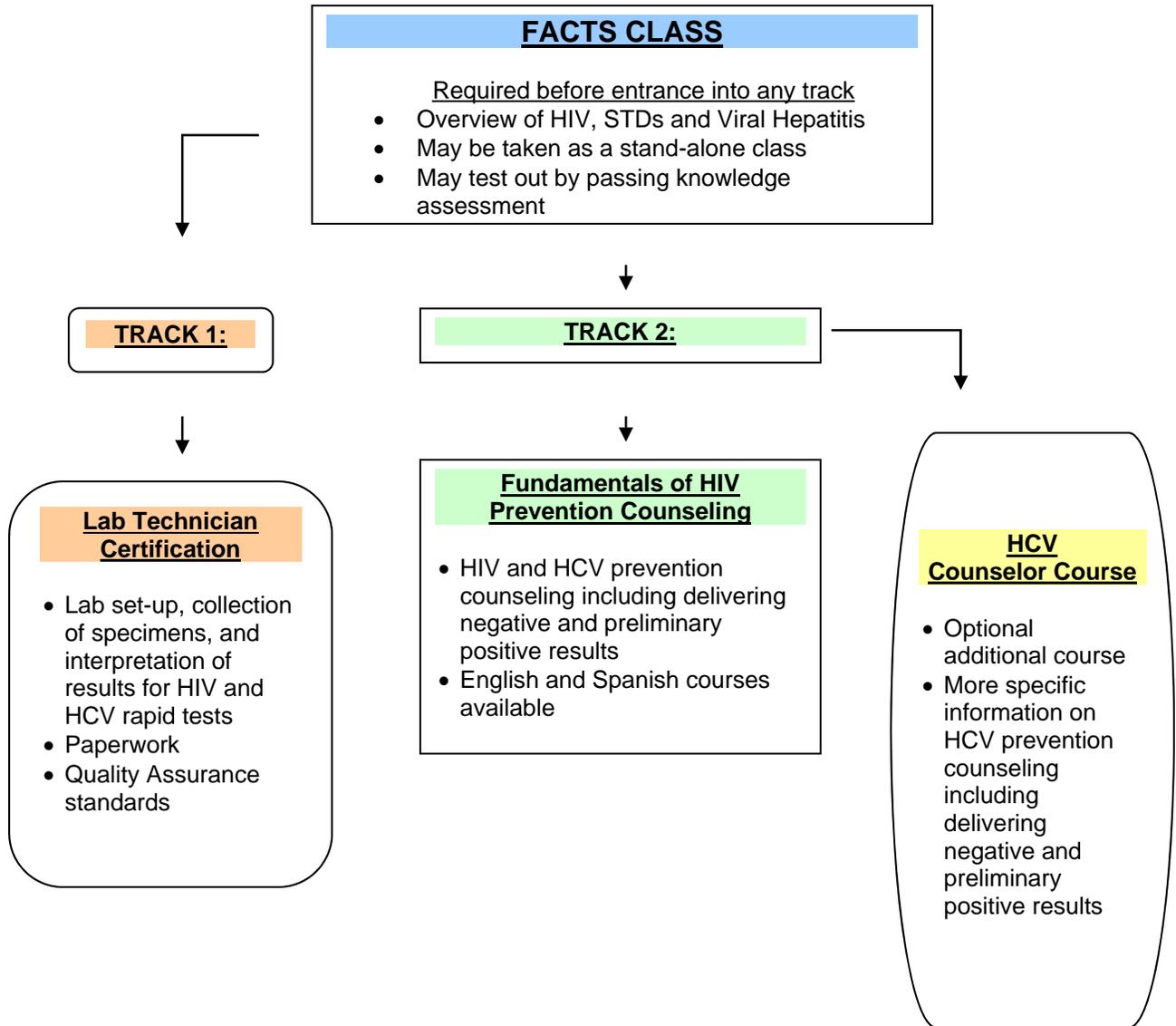
Prospective lab technicians are not required to attend the Fundamentals of HIV Prevention Counseling course or Issues of Clients who test Positive course, unless they will also provide counseling activities.

For more information on the training schedule please visit: <http://health.utah.gov/epi/prevention/>

3.2 HIV and HCV Prevention Counselor Training

Agencies funded by the Utah Department of Health to conduct HIV/HCV testing are required to attend and pass State of Utah-sponsored training. The following diagram identifies the training tracks audiences.

Training Tracks



4. Control Kits and Test Kits

4.1 Control Kits

Each manufacturer produces external controls to validate the correct operation of each test device. 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 controls cannot be run on Alere Determine™ tests.

Control Kit Storage Temperature and Monitoring:

Refrigerate and maintain control kits at a consistent temperature. No warm-up is required before use.

Control Kit Type	Frequency	Temperature Range
Alere Determine™ HIV-1/2 Ag/Ab Combo	Monitor every business day	36°- 46°F or 2°- 8°C
OraQuick® HCV Rapid Antibody Test	Monitor every business day	35°- 46°F or 2°- 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
Alere Determine™ HIV-1/2 Ag/Ab Combo	Expiration date printed on vial	Expiration date printed on vial
OraQuick® HCV Rapid Antibody Test	Expiration date printed on vial	Eight weeks after first use

4.1.1 Storage during Outreach Events

When conducting off-site/outreach testing it will be necessary to transport controls from the main facility to the off-site/outreach location. Best practice is to transport two 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°- 46°F or 2°- 8°C, the controls must be discarded.

4.2 Test Kits/Cards and Chase Buffer

All Alere Determine™ HIV-1/2 Ag/Ab Combo Test Cards and Chase Buffer and OraQuick® HCV Rapid Antibody Test must be stored at 36°- 86°F or 2°- 30°C. 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/Cards and Chase Buffer Storage Temperature and Monitoring:

Test Kit Type	Frequency	Temperature Range
Alere Determine™ HIV-1/2 Ag/Ab Combo	Monitor every business day	36°- 86°F or 2°-30°C
OraQuick® HCV Rapid Antibody Test	Monitor every business day	36°- 86°F or 2°-30°C

Test Kit/Cards and Chase Buffer Expiration:

Test Kit Type	Expiration Date
Alere Determine™ HIV-1/2 Ag/Ab Combo	Printed on box and on each test card & chase buffer
OraQuick® HCV Rapid Antibody Test	Printed on box and on each test kit

Test Kit/Cards Disposal – Expired or Compromised

DO NOT USE test kit components beyond the expiration date printed on label. Always check expiration date prior to testing.

Alere Determine™ HIV-1/2 Ag/Ab test cards are compromised:

- If the dissecant 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, lancet and disposable capillary tube for collection and transfer of fingerstick samples is for single use only.

- An OraQuick® HCV test kit is compromised if: the developer vial is empty,
- the foil pouch is pierced,
- a shake of the test kit pouch produces no rattle sound,
- the test device has been removed from the foil pouch and dropped, or
- the test device has been compromised by being exposed to extreme temperatures above/below 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/Cards and store in a different location from the unexpired kits.

NOTE: Expired or compromised kits may provide an incorrect test result.

5. Lab 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. Please refer to each manufacturer's recommendations for specific details.

Alere Determine™ HIV-1/2 Ag/Ab:

- All materials provided in the Alere Determine™ HIV-1/2 Ag/Ab Combo (Please refer to manufacturer's package insert.
- Alere Determine™ HIV-1/2 Ag/Ab Combo Controls
- Precision pipette capable of delivering 50 µL of sample with disposable tips, to be used in lieu of the Disposable Capillary Tubes supplied with the kit (for other than fingerstick whole blood specimens)
- Sterile lancets capable of producing 50 µL of blood

OraQuick® HCV

- Test kits – rapid HCV
- Controls – rapid HCV
- Test stands
- Collection loops
- Rapid HCV product insert

General supplies

- Day of test log
- Temperature logs – test kits and controls
- Finger stick and lab supplies (alcohol swabs, cotton balls, sharps container, finger bandages, exam gloves, absorbent surface pads, biohazard bags, etc.)
- Scientific thermometer
- Timer or clock
- 10% bleach solution
- Portable cooler and frozen packs (for off-site or outreach testing)

6. Selecting the Lab Site

Whether at a main test site or when 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 confidentiality of clients
- Ability to maintain client files in a secure manner

6.1 Lab Temperature Range

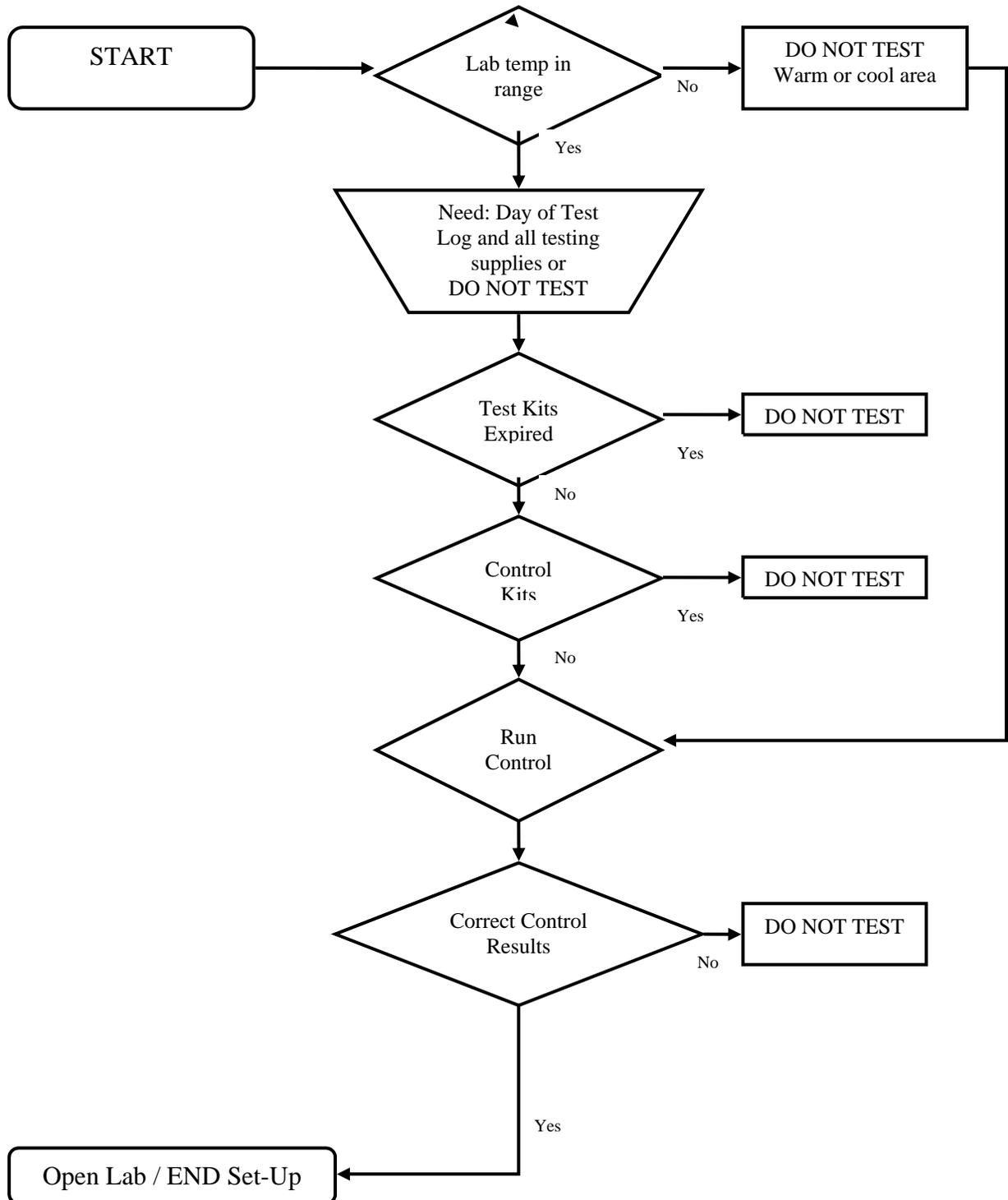
Lab temperature requirements are specific to each type of rapid test. The temperature of the specimen collection area must fall within a defined range. Whenever the temperature falls outside the minimum or maximum operating temperature, NO new clients may be tested until the temperature is once again 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 that test kits are operating in accordance with 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.

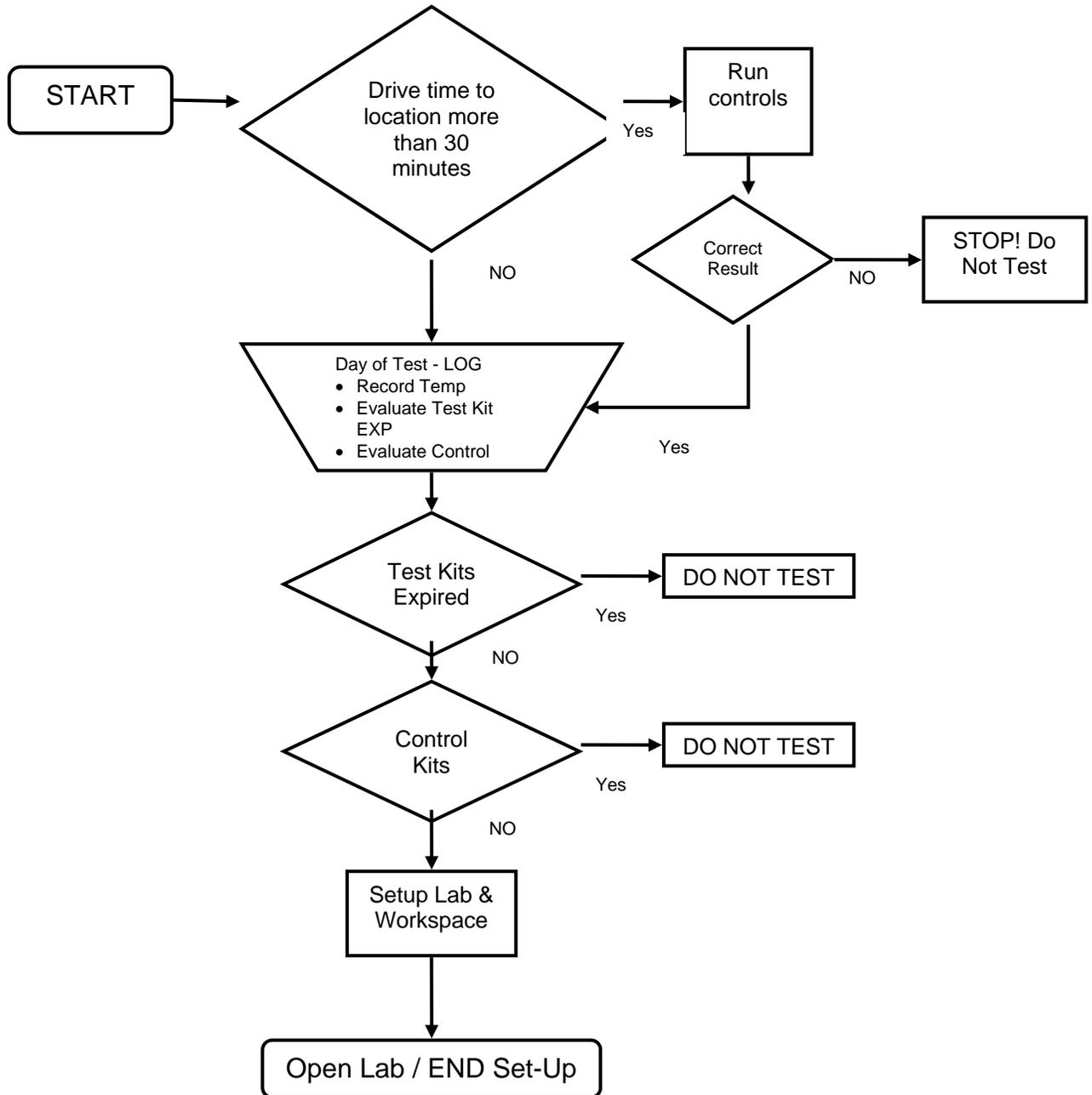
Test Kit Type	Lab Temperature Range
Alere Determine™ HIV-1/2 Ag/Ab Combo	59-86°F, 15-30°C
OraQuick® HCV	59° - 99°F or 15° - 37°C

7. Lab Set-up Flow Charts

7.1 Lab Set-up Flowchart (Clinic or On-Site Testing)



7.2 Lab Set-up Flowchart (Outreach Settings)



8. HIV and HCV External Control Reagents

HIV and HCV controls kits are different and specific to each infection. The exchange of external controls and test devices within or between manufacturers is not permitted and violates CLIA guidelines.

8.1 HIV Controls

Alere Determine™ HIV-1/2 Ag/Ab Combo Controls are human, plasma-based reagents. The Controls are specifically formulated and manufactured to ensure performance of the test, and are used to verify the user's ability to properly perform the test and interpret the results.

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 Nonreactive Control will produce a Nonreactive test result.

8.2 HCV Controls

The HCV control kit includes one vial of negative fluid and one vial of HCV positive fluid (positive fluids are deactivated and do not pose a contamination risk). The HCV Positive Control will produce a reactive reddish-purple line at the Test Zone. The HCV Negative Control will generate a non-reactive test result (no reddish-purple line).

If the external controls do not produce expected results, client testing should not be performed. Contact OraSure Technologies' Customer Service if the Kit Control reagents do not produce the expected results.

When to Run Controls for HIV and HCV	
<p><u>ALL testing locations:</u></p> <ul style="list-style-type: none"> • Each new lab operator • First time lab set-up at main facility • Each new lot of test kits • Each new shipment of test kits • Temperature of specimen collection area and/or lab exceeds the temperature window (specific to each test) • 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 result exceeds 1% of the sites historical incident rate <p>Best practice is to maintain two sets of unexpired controls at the testing location under cold storage.</p>	<p><u>OUTREACH testing locations:</u></p> <ul style="list-style-type: none"> • Each new lab operator • When test kits are transported to an outreach location and the travel time is than 30 minutes • Each new lot of test kits • Each new shipment of test kits • Temperature of specimen collection area and/or lab exceeds the temperature window (specific to each test) • Temperature of the test storage area exceeds the temperature window (specific for each test) • Whenever the number of preliminary positive result exceeds 1% of the sites historical incident rate <p>Best practice is to maintain two sets of unexpired controls at the testing location and stored in a portable cooler where the temperature range can be maintained and verified.</p>

It is the responsibility of each laboratory using these products to establish an adequate quality assurance program to ensure the performance of these devices under its specific locations and conditions of use.

8.3 Running External 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. For additional support, refer to the customer letter/product insert/package insert included in the box of controls for operating procedures.

The desired result is one HIV-1 negative and one HIV-1 positive test result. This indicates that the test device is operating correctly and client testing may begin. Client testing should not take place before the control run is finished and desired results interpreted.

If any other result is present, repeat the control run with two new test kits. If the second control run result differs from one negative and one positive, contact the UDOH for guidance and technical assistance.

9. General Testing

9.1 Testing Capacity

Direct observation and staff interviews have determined that one lab technician can efficiently administer and monitor up to five tests in one 60-minute period. Whenever more than five tests are administered in one 60-minute period, it is strongly suggested that 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.

For rapid HCV testing: At least one HCV prevention counselor, who has been certified to give reactive results and provide appropriate referrals, must be present at all times while rapid HCV testing is being conducted.

9.2 High Volume Testing

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 the UDOH for more information (page 2).

10. Conducting HIV and HCV Rapid Tests

10.1 Alere Determine™ HIV-1/2 Ag/Ab Combo – fingerstick whole blood collection

Brief Instructions:

- Clean finger with alcohol pad
- Let air dry or dry with sterile cotton/gauze (do not blow on the finger)
- Massage the finger with a downward motion several times before performing the fingerstick.
- Perform the fingerstick
- Wipe away the first drop of blood with a cotton ball/sterile gauze
- Avoid squeezing the finger to accelerate bleeding
- Collect the second drop of blood by holding the capillary tube HORIZONTALLY, and touch the tip of the 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.*
- 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.
- When all of the blood is transferred to the Sample Pad, wait one minute to ensure the Chase Buffer does not overflow the Sample Pad.
- Add one drop of Chase Buffer to the Sample Pad
- 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.

When using venous whole blood, remove the cap from the vial and collect 50 µL of blood from the inside of the blood tube.

For more information on collecting whole blood specimens refer to the package insert or visit the Alere Determine™ HIV-1/2 Ag/Ab Combo at:
<http://www.alerehiv.com/wv/home/hiv-screening/alere-hiv-combo/procedure.html>

10.2 OraQuick® HCV – whole blood collection

Brief Instructions:

- Wipe finger with alcohol pad.
- Let air dry or dry with sterile cotton/gauze (do not blow on the finger).
- Massage the finger with a downward motion several times before performing the fingerstick.
- Perform the fingerstick.
- Wipe away the first drop of blood with a cotton ball/sterile gauze.
- Avoid squeezing the finger to accelerate bleeding.
- Collect blood drop with the collection loop making sure the blood completely fills the loop from side to side.
- Place the loop with sample in the buffer and mix with the developer solution.
- Remove loop and insert test device into the buffer solution vial.
- Read the test result between 20 and 40 minutes after the addition of the Chase Buffer. Do not read Test Results after 40 minutes.

For more information on collecting whole blood specimens refer to the package insert or visit the OraQuick® HCV Rapid Antibody test: <http://www.orasure.com/products-infectious/products-infectious-oraquick-hcv.asp>

11. Interpreting Test Results

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

11.1 Alere Determine™ HIV-1/2 Ag/Ab Combo

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

11.1.1 **REACTIVE:**

a) **ANTIBODY REACTIVE (Two lines – Control & Ab Line)**

If a **PINK/RED** Control line appears in the Control Area AND a **PINK/RED** Ab line appears in the Lower Test Area of the Test Device, the test is considered antibody REACTIVE. This indicates that HIV-1 or HIV-2 antibodies were detected in the specimen and this result is interpreted as **PRELIMINARY POSITIVE** for HIV-1 or HIV-2 antibodies.

b) ANTIGEN (HIV-1 p24) REACTIVE (Two Lines – Control and Ag Line)

(If a **PINK/RED** Control line appears in the Control Area AND a **PINK/RED** Ag line appears in the Lower Test Area of the Test Device, the test is considered antigen REACTIVE. This indicates that HIV-1 p24 antigen was detected in the specimen and this result is interpreted as **PRELIMINARY POSITIVE** for HIV-1 p24 antigen.

c) ANTIBODY REACTIVE AND ANTIGEN (HIV-1 p24) REACTIVE (Three Lines – Control, Ab and Ag Lines)

If a **PINK/RED** Control line appears in the Control Area AND a **PINK/RED** Ab line appears in the Lower Test Area AND a **PINK/RED** Ag line appears in the Upper Test Area of the Test Device, the test is considered antibody and antigen (HIV-1 p24) REACTIVE. This indicates that HIV-1 and/or HIV-2 antibodies and HIV-1 p24 antigen was detected in the specimen and this result is interpreted as **PRELIMINARY POSITIVE** for HIV-1 and/or HIV-2 antibodies and HIV-1 p24 antigen.

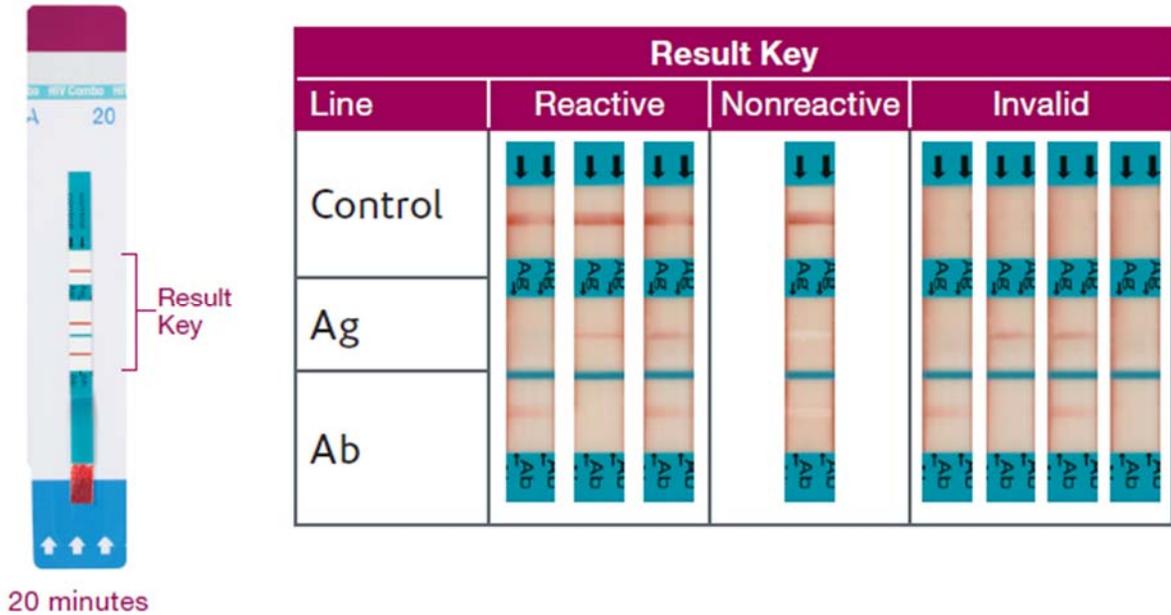
11.1.2 NONREACTIVE:

a) If a **PINK/RED** Control line appears in the Control Area of the Test Device, and no **PINK/RED** Ab or Ag line appears in the Lower Test Area and the Upper Test Area of the Test Device, respectively, this is a **NONREACTIVE** test result. This means that 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. **End here - client is negative.**

11.1.3 INVALID:

a) **INVALID (No Control Line)** If there is no **PINK/RED** Control line in the Control Area of the Test Device, even if a **PINK/RED** line appears in the Lower Test Area or the Upper Test Area of the Test Device, 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 UDOH and tested the client with a new test device.



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11.2 OraQuick® HCV Rapid Antibody Test

11.2.1 Reactive or Preliminary Positive

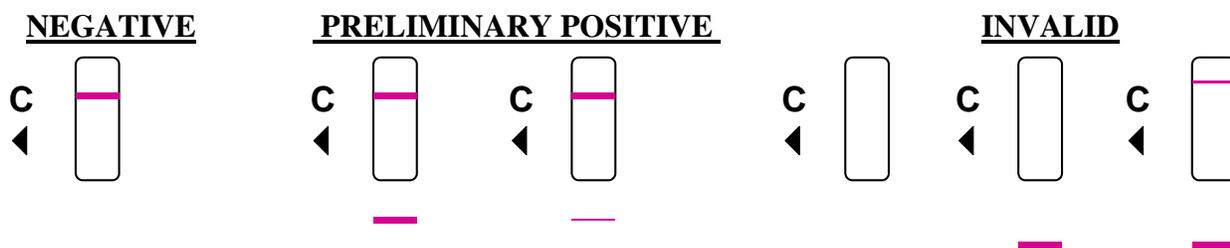
Two pink/purple lines appear; one in the “C” triangle or top 1/3 of the read window and one in the “T” triangle or bottom 1/3 of the read window indicating a preliminary positive test result. Intensities of the two lines may vary. A preliminary positive result means antibodies were detected in the specimen. Preliminary positive results need to be validated by two trained staff members.

11.2.2 Non-reactive or Negative

One pink/purple line appears; one line next to the “C” triangle or top 1/3 of the read window and no line next to the “T” triangle or bottom 1/3 of the read window indicates a negative result. A negative result means no antibodies were detected in the specimen.

11.2.3 Invalid Result

An invalid result occurs when no pink/purple lines appear in the read window, no pink/purple line appears next to the “C” triangle or in the top 1/3 of the read window or lines appear around the side of the “C” triangle and “T” triangle or top and bottom 1/3 of the read window



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

12. Preliminary Positive Results and Confirmatory Testing

All Rapid HIV or HCV Reactive or Preliminary positive results must be confirmed with an appropriate diagnostic test.

12.1 HIV

A reactive/preliminary positive test result using Alere Determine™ HIV-1/2 Ag/Ab Combo suggests the presence of HIV-1 p24 antigen and/or antibodies to HIV-1 and/or HIV-2 in the sample.

The Reactive result is interpreted as PRELIMINARY POSITIVE for HIV-1 p24 antigen and/or antibodies to HIV-1 and/or HIV-2. Alere Determine™ HIV-1/2 Ag/Ab Combo is intended as an aid in the diagnosis of infection with HIV-1/2 and its reactive results must be confirmed by a medical provider with 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 for acute HIV-1 infection. AIDS-related conditions are clinical syndromes, and their diagnosis can only be established clinically.

Utah's One-Rapid HIV Testing Algorithm using the Alere Determine™ HIV-1/2 Ag/Ab Combo test allows for appropriate active referrals. Under this algorithm, all clients testing 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 of the Alere Determine™ HIV-1/2 Ag/Ab Combo test. Please see the Updated Recommendations for Laboratory Testing for the Diagnosis of HIV Infection at:

<http://www.cdc.gov/hiv/pdf/hivtestingalgorithmrecommendation-final.pdf>

12.2 HCV

The OraQuick® HCV rapid test is a screening test which detects HCV antibodies, therefore it cannot determine if someone is actively infected with HCV. In order to determine if someone is actively infected with HCV, additional testing must be done. This testing may include HCV RNA testing by PCR. Refer to UDOH for more information on confirmatory HCV testing.

Test Sequence	Result	Next Step
Rapid HCV (Test 1)	(N) HCV Negative	STOP
	(PP) HCV Preliminary Positive	Refer to local health department or medical provider for confirmatory testing

13. Data Collection and Reporting

All funded UDOH contractors are required to gather unidentified client-level data and laboratory records.

Client level data is collected using the UDOH EvaluationWeb HIV Testing Form and reported according to the instructions provided with the form.

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 UDOH reviews upon request.

14. 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 that agencies deliver.

Although waived rapid tests are easy to use, mistakes can occur at any point during the testing process. To reduce mistakes the testing site must have a QA program in place before waived rapid antibody testing can be offered. The basic elements of a QA program for rapid testing include:

- Organization of the QA program
- Personnel who will conduct testing
- Process control
 - before, during and after testing
- External assessment
- Documentation and record-keeping
- QA evaluation and troubleshooting

More information on how to establish a QA program can be found at:

http://www.cdc.gov/hiv/pdf/testing_QA_Guidelines.pdf

For internal assessment, agencies should review the rapid test documents each day after testing ends or at the conclusion of each week. A regular review process allows timely feedback to rapid testing staff and provides coaching when needed. UDOH 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: <http://health.utah.gov/epi/prevention/providerResource.html> or refer to Appendix A of this document.

Appendix A

Required Forms and Sample Logs

1. Day of Test Log

HIV and HCV Day of Test LOG

Test Site: _____ Date: _____
 Site Type Main Site Outreach Lab Technician: _____
 Test Kit LOT# HIV-DC _____ HCV _____
 Test Kit EXP Date HIV-DC ____/____/____ HCV ____/____/____

Client Log									
Test Type	Client Label or Client ID	Lab Temperature (Limits: 15° - 30°C or 59° - 86°F)	Start Time	Read Time	Read result HIV: 20-30 min. HCV: 20-40 min. YES - test next CLT NO - retest this CLT	Result (✓ one)			Done by: (Initials)
						N	R	I	
C HIV DC	Control DC (-)				[]Yes []No				
C HIV DC	Control DC (Ag+)				[]Yes []No				
C HIV DC	Control DC (Ab+)				[]Yes []No				
C HCV	Control HCV (-)				[]Yes []No				
C HCV	Control HCV (+)				[]Yes []No				
1	[] HIV [] HCV				[]Yes []No				
2	[] HIV [] HCV				[]Yes []No				
3	[] HIV [] HCV				[]Yes []No				
4	[] HIV [] HCV				[]Yes []No				
5	[] HIV [] HCV				[]Yes []No				
6	[] HIV [] HCV				[]Yes []No				
7	[] HIV [] HCV				[]Yes []No				
8	[] HIV [] HCV				[]Yes []No				
9	[] HIV [] HCV				[]Yes []No				
10	[] HIV [] HCV				[]Yes []No				
RESULT = (N) Negative, (R) Reactive, (I) Invalid						TOTAL - N			
NOTE: For HIV DC - Indicate if Antigen (Ag) or Antibody (Ab) in appropriate result column						TOTAL - PP			
NOTES _____						TOTAL - I			

HIV and HCV Day of Test LOG

HIV and HCV Day of Test LOG - Page 2

Test Site _____ Date _____
Site Type Main Site Outreach Lab Technician _____

Client Log									
Test Type	Client Label or Client ID	Lab Temperature (Limits: 15° - 30°C or 59° - 86°F)	Start Time	Read Time	Read result HIV: 20-30 min. HCV: 20-40 min. YES - test next CLT NO - retest this CLT	Result * (✓ one)			Done by: (Initials)
						N	R	I	
1	<input type="checkbox"/> HIV <input type="checkbox"/> HCV				<input type="checkbox"/> Yes <input type="checkbox"/> No				
2	<input type="checkbox"/> HIV <input type="checkbox"/> HCV				<input type="checkbox"/> Yes <input type="checkbox"/> No				
3	<input type="checkbox"/> HIV <input type="checkbox"/> HCV				<input type="checkbox"/> Yes <input type="checkbox"/> No				
4	<input type="checkbox"/> HIV <input type="checkbox"/> HCV				<input type="checkbox"/> Yes <input type="checkbox"/> No				
5	<input type="checkbox"/> HIV <input type="checkbox"/> HCV				<input type="checkbox"/> Yes <input type="checkbox"/> No				
6	<input type="checkbox"/> HIV <input type="checkbox"/> HCV				<input type="checkbox"/> Yes <input type="checkbox"/> No				
7	<input type="checkbox"/> HIV <input type="checkbox"/> HCV				<input type="checkbox"/> Yes <input type="checkbox"/> No				
8	<input type="checkbox"/> HIV <input type="checkbox"/> HCV				<input type="checkbox"/> Yes <input type="checkbox"/> No				
9	<input type="checkbox"/> HIV <input type="checkbox"/> HCV				<input type="checkbox"/> Yes <input type="checkbox"/> No				
10	<input type="checkbox"/> HIV <input type="checkbox"/> HCV				<input type="checkbox"/> Yes <input type="checkbox"/> No				
11	<input type="checkbox"/> HIV <input type="checkbox"/> HCV				<input type="checkbox"/> Yes <input type="checkbox"/> No				
12	<input type="checkbox"/> HIV <input type="checkbox"/> HCV				<input type="checkbox"/> Yes <input type="checkbox"/> No				
13	<input type="checkbox"/> HIV <input type="checkbox"/> HCV				<input type="checkbox"/> Yes <input type="checkbox"/> No				
14	<input type="checkbox"/> HIV <input type="checkbox"/> HCV				<input type="checkbox"/> Yes <input type="checkbox"/> No				

*RESULT = (N) Negative, (PP) Preliminary Positive, (I) Invalid

NOTE: For HIV DC - Indicate if Antigen (Ag) or Antibody (Ab) in appropriate result column

TOTAL - N	
TOTAL- PP	
TOTAL - I	

HIV and HCV Day of Test LOG - Page 2

2a. Test Kit Temperature Storage Log (Celsius)

HIV and HCV Rapid TEST Kit Storage
Daily Temperature Log

Agency _____
Month / Year _____

Temperature Range: 2°- 30°C

Place an x or tick the recorded temperature

Day	Time	AM PM	Staff Initials	<1	2-4	5-7	8-10	11- 13	14- 16	17- 19	20- 22	23- 25	26- 27	28- 30	≥31
1		AM PM													
2		AM PM													
3		AM PM													
4		AM PM													
5		AM PM													
6		AM PM													
7		AM PM													
8		AM PM													
9		AM PM													
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Rapid HIV/HCV TEST Kit - storage

3. Control Kit Temperature Storage Log (Fahrenheit)

HIV and HCV Rapid **CONTROL** Kit Storage

Daily Temperature Log

Agency _____

Month / Year _____

Refrigerator temperature range 36°- 46°F

Day	Time	AM PM	Staff Initials	≤32	33	34	36	37	38	39	40	41	42	43	44	45	46	47	48	≥49
1																				
2																				
3																				
4																				
5																				
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Rapid HIV/HCV CONTROL Kit - storage

3a. Control Kit Temperature Storage Log (Celsius)

HIV and HCV Rapid CONTROL Kit Storage

Daily Temperature Log

Agency _____

Month / Year _____

Refrigerator temperature range 2°- 8°C

Day	Time	AM PM	Staff Initials	-1	0	1	2	3	4	5	6	7	8	9	10	≥11
1		AM PM														
2		AM PM														
3		AM PM														
4		AM PM														
5		AM PM														
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Rapid HIV/HCV CONTROL Kit - storage

Appendix B

UDOH EvaluationWeb® HIV Test Form

UDOH EVALUATIONWEB® HIV TEST FORM

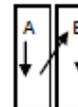
General instructions for completing the UDOH EvaluationWeb HIV Test Form

This HIV testing data collection form is provided to assist Local Health Departments and HIV Prevention grantees in collecting Utah HIV Testing data to report it as part of the State HIV Prevention Program Monitoring and Evaluation. This form is a mandated state form for use in the field.

- Part ONE—for all UDOH-funded testing events
- Part TWO—for recording linkage and referral data on all preliminary and confirmed HIV-positive clients

This form is specifically designed for direct HIV data entry into EvaluationWeb. The form follows the EvaluationWeb direct data entry screens beginning from top upper left column A to bottom left, then to upper right column B to bottom right.

Detailed instructions for completing the EvaluationWeb HIV Test Template



- The fields on this form reflect data requirements as described in the most current NHME Data Variable Set. Please note that all questions must be answered to fulfill CDC reporting requirements.
- Six data fields are mandatory(*) for a valid testing event: Form ID, Session Date, Program Announcement, Agency ID or CBO agency ID as applicable, Jurisdiction (populated automatically in EvaluationWeb) and Site ID.
- Write in the Form Identification (ID) number or adhere a sticker with the Form ID Number to each data entry page.
- There are three different response formats that you will use to record data: (1) text boxes, (2) check boxes and (3) fill-in ovals. Text boxes are used to write in information (codes and dates). Check boxes and fill-in ovals are used to select only one response, unless otherwise indicated on the template.
- Write in either the name OR the identification number for the Agency and Site. Do not write both.
- Write in the Site Type for this event. Page 3 lists codes for Site Type, Other Risk Factor(s), and Other Session Activities. Please refer to these codes for entry in Part One.
- For agencies directly entering data into EvaluationWeb, it may not be necessary to complete the fields Agency ID, Site Type, Site County and Site ZIP code as they will be pre-loaded by the system administrator. Except, when the form needs to be turned in to UDOH due to a preliminary positive result.
- For client county of residence, report the three-digit FIPS code for the county, not the county name.

For assistance with data reporting and submissions

- To add new local sites to your Agency, contact the UDOH EvaluationWeb Coordinator, Rob Sonoda at 801-538-6987 at rsonoda@utah.gov
- For questions about EvaluationWeb, contact the HELP DESK at Luther Consulting (help@lutherconsulting.com or 1-866-517-6570 option #1).
- Do not enter HCV data into EvaluationWeb. For questions about reporting and submitting HCV data, please contact, the UDOH HCV Coordinator, Heather Bush at 801-538-6194 at hbush@utah.gov

CDC assurance of confidentiality

The CDC Assurance of Confidentiality statement assures clients and agency staff that data collected and recorded on templates will be handled securely and confidentially. All CDC grantees are encouraged to include the CDC Assurance of Confidentiality statement on all HIV prevention program data collection templates.

Assurance of Confidentiality Statement:

The information in this report to the Centers for Disease Control and Prevention (CDC) is collected under the authority of Sections 304 and 306 of the Public Health Service Act, 42 USC 242b and 242k. Your cooperation is necessary for evaluation of the interventions being done to understand and control HIV/AIDS. Information in CDC's HIV/AIDS National HIV Prevention Program Monitoring and Evaluation (NHME) system that would permit identification of any individual on whom a record is maintained, or any health care provider collecting NHME information, or any institution with which that health care provider is associated will be protected under Section 308(d) of the Public Health Service Act. This protection for the NHME information includes a guarantee that the information will be held in confidence, will be used only for the purposes stated in the Assurance of Confidentiality on file at CDC, and will not otherwise be disclosed or released without the consent of the individual, health care provider, or institution described herein in accordance with Section 308(d) of the Public Health Service Act (42 USC 242m(d)).

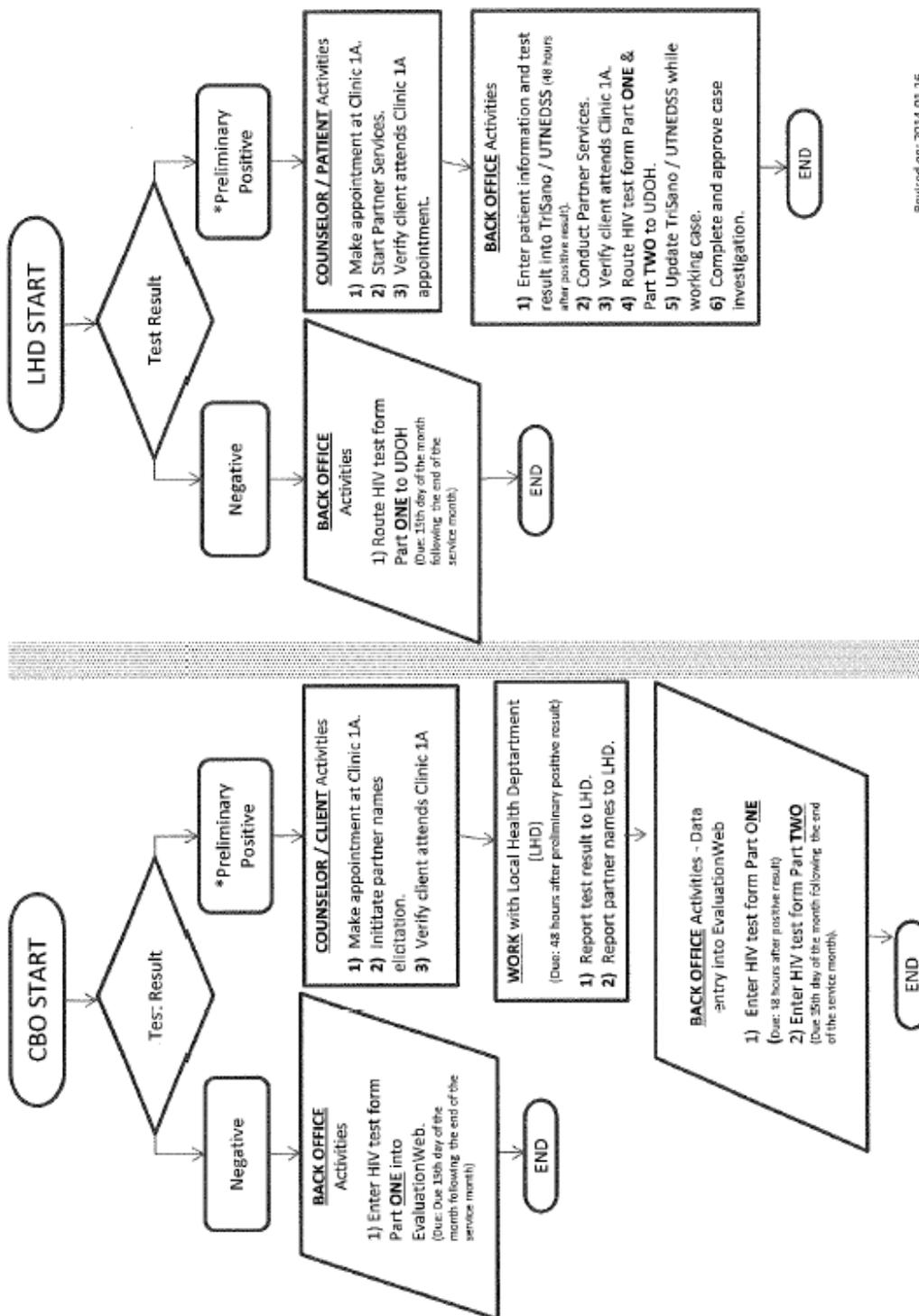
Form Approved: OMB No. 0920-0696, Exp. Date 3/31/2016

Public reporting burden of this collection of information is estimated to average 8 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB Control Number. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-79, Atlanta, Georgia, 30333, ATTN: PRA 0920-0696, CDC 50.135b(1),10/2007

Revised by UDOH 04/01/2014. Page 1

UDOH EVALUATIONWEB® HIV TEST FORM

HIV Counseling and Testing
HIV Test Form Data Entry and Positive Result Flowchart



Revised on: 2014.01.16

* All rapid HIV preliminary positive test results must be confirmed. Please refer to UDOH Rapid Testing Guidance.

UDOH EVALUATIONWEB® HIV TEST FORM

PART ONE

Enter or adhere form ID *												Sample Date																																																																											
Session Date *												M M D D Y Y Y Y				M M D D Y Y Y Y				M M D D Y Y Y Y																																																																			
Program Announcement (select only one)*												HIV Test 1				HIV Test 2				HCV Test																																																																			
<input type="checkbox"/> PS12-1201 Category A <input type="checkbox"/> PS12-1201 Category C <input type="checkbox"/> UDOH HCV Project <input type="checkbox"/> Independent Site <input type="checkbox"/> Other: _____												Worker ID																																																																											
Agency ID Name/Number*												Test Election				Test Election				Test Election																																																																			
Site Name/ID Number *												<input type="checkbox"/> Anonymously <input type="checkbox"/> Confidentially <input type="checkbox"/> Test Not Offered <input type="checkbox"/> Declined Testing				<input type="checkbox"/> Anonymously <input type="checkbox"/> Confidentially <input type="checkbox"/> Test Not Offered <input type="checkbox"/> Declined Testing				<input type="checkbox"/> Anonymously <input type="checkbox"/> Confidentially <input type="checkbox"/> Test Not Offered <input type="checkbox"/> Declined Testing																																																																			
Site Type (enter type code from page 3)												Test Technology				Test Technology				Test Technology																																																																			
Site ZIP Code												<input type="checkbox"/> Conventional <input type="checkbox"/> Rapid				<input type="checkbox"/> Conventional <input type="checkbox"/> Rapid				<input type="checkbox"/> Conventional <input type="checkbox"/> Rapid																																																																			
Site County (enter 3-digit FIPS code)												Test Result				Test Result				Test Result																																																																			
Client ID												<input type="checkbox"/> Positive/Reactive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate <input type="checkbox"/> Invalid <input type="checkbox"/> No Result				<input type="checkbox"/> Positive/Reactive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate <input type="checkbox"/> Invalid <input type="checkbox"/> No Result				<input type="checkbox"/> Positive/Reactive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate <input type="checkbox"/> Invalid <input type="checkbox"/> No Result																																																																			
(Description on back)												Result Provided				Result Provided				Result Provided																																																																			
Date of Birth (enter 01/01/1800 if unknown)												<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Yes, client obtained results from another agency				<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Yes, client obtained results from another agency				<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Yes, client obtained results from another agency																																																																			
Client State (use USPS abbreviation)												If Results NOT provided, why?				If Results NOT provided, why?				If Results NOT provided, why?																																																																			
Client County												<input type="checkbox"/> Declined Notification <input type="checkbox"/> Did Not Return/ Could Not Locate <input type="checkbox"/> Other				<input type="checkbox"/> Declined Notification <input type="checkbox"/> Did Not Return/ Could Not Locate <input type="checkbox"/> Other				<input type="checkbox"/> Declined Notification <input type="checkbox"/> Did Not Return/ Could Not Locate <input type="checkbox"/> Other																																																																			
Client ZIP Code												Choose status of collection of behavioral risk profile																																																																											
Client Ethnicity												<input type="checkbox"/> Client completed a behavioral risk profile <input type="checkbox"/> Client was not asked about behavioral risk <input type="checkbox"/> Client was asked, but no behavioral risks identified <input type="checkbox"/> Client declined to discuss behavioral risk factors																																																																											
Client Race (check all that apply)												For clients completing a risk profile, did the client report the following behaviors in the past 12 months? (select all that apply)																																																																											
<input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Don't Know <input type="checkbox"/> Declined <input type="checkbox"/> Not Asked												<table border="1"> <thead> <tr> <th></th> <th>No</th> <th>Yes</th> <th>Client doesn't know</th> </tr> </thead> <tbody> <tr> <td>Vaginal or Anal Sex with a male</td> <td></td> <td></td> <td></td> </tr> <tr> <td> With a male without using a condom</td> <td></td> <td></td> <td></td> </tr> <tr> <td> With a male who is IDU</td> <td></td> <td></td> <td></td> </tr> <tr> <td> With a male who is HIV +</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Vaginal or Anal Sex with a female</td> <td></td> <td></td> <td></td> </tr> <tr> <td> With a female without using a condom</td> <td></td> <td></td> <td></td> </tr> <tr> <td> With a female who is IDU</td> <td></td> <td></td> <td></td> </tr> <tr> <td> With a female who is HIV +</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Vaginal or Anal Sex with a transgender person</td> <td></td> <td></td> <td></td> </tr> <tr> <td> With a transgender without using a condom</td> <td></td> <td></td> <td></td> </tr> <tr> <td> With a transgender who is IDU</td> <td></td> <td></td> <td></td> </tr> <tr> <td> With a transgender who is HIV +</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Injection drug use</td> <td></td> <td></td> <td></td> </tr> <tr> <td> Share drug injection equipment?</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Vaginal or Anal Sex with MSM (female only)</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>													No	Yes	Client doesn't know	Vaginal or Anal Sex with a male				With a male without using a condom				With a male who is IDU				With a male who is HIV +				Vaginal or Anal Sex with a female				With a female without using a condom				With a female who is IDU				With a female who is HIV +				Vaginal or Anal Sex with a transgender person				With a transgender without using a condom				With a transgender who is IDU				With a transgender who is HIV +				Injection drug use				Share drug injection equipment?				Vaginal or Anal Sex with MSM (female only)			
	No	Yes	Client doesn't know																																																																																				
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With a transgender without using a condom																																																																																							
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Client Assigned Sex at Birth												Additional Risk Factors (enter two-digit code from page 4)																																																																											
<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Declined <input type="checkbox"/> Not Asked <input type="checkbox"/> Transgender MTF <input type="checkbox"/> Transgender FTM <input type="checkbox"/> Transgender Unspecified Additional (specify): _____												<table border="1"> <thead> <tr> <th></th> <th>1</th> <th>#</th> <th>#</th> <th>2</th> <th>#</th> <th>#</th> <th>3</th> <th>#</th> <th>#</th> <th>4</th> <th>#</th> <th>#</th> </tr> </thead> <tbody> <tr> <td>Session Activities (enter codes from page 4)</td> <td>1</td> <td>#</td> <td>#</td> <td>.</td> <td>#</td> <td>#</td> <td>3</td> <td>#</td> <td>#</td> <td>.</td> <td>#</td> <td>#</td> </tr> <tr> <td>Local Use Fields</td> <td>L1</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>L3</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> </tr> <tr> <td></td> <td>L2</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>L4</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> </tr> </tbody> </table>													1	#	#	2	#	#	3	#	#	4	#	#	Session Activities (enter codes from page 4)	1	#	#	.	#	#	3	#	#	.	#	#	Local Use Fields	L1	#	#	#	#	#	L3	#	#	#	#	#		L2	#	#	#	#	#	L4	#	#	#	#	#												
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<input type="checkbox"/> No <input type="checkbox"/> Yes → If Yes, what is the client's self-reported result? <input type="checkbox"/> Don't know <input type="checkbox"/> Declined <input type="checkbox"/> Not Asked <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Preliminary Positive <input type="checkbox"/> Indeterminate <input type="checkbox"/> Don't Know <input type="checkbox"/> Declined <input type="checkbox"/> Not Asked												<table border="1"> <thead> <tr> <th></th> <th>1</th> <th>#</th> <th>#</th> <th>.</th> <th>#</th> <th>#</th> <th>2</th> <th>#</th> <th>#</th> <th>.</th> <th>#</th> <th>#</th> </tr> </thead> <tbody> <tr> <td>Local Use Fields</td> <td>L1</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>L3</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> </tr> <tr> <td></td> <td>L2</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>L4</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> </tr> </tbody> </table>													1	#	#	.	#	#	2	#	#	.	#	#	Local Use Fields	L1	#	#	#	#	#	L3	#	#	#	#	#		L2	#	#	#	#	#	L4	#	#	#	#	#																									
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Revised by UDOH 04/01/2014. Page 3

UDOH EVALUATIONWEB® HIV TEST FORM

Client ID (8 digits)	First and third initial of first name (F1, F3), first and third initial of last name (L1, L3) and two digit month and two digit day of DOB. i.e. John Smith 12/11/1980 = jhsi1211	
Codes for Site Type: CLINICAL	Codes for Site Type: NON-CLINICAL	
F01.01 Clinical - Inpatient hospital F02.12 Clinical - TB clinic F02.19 Clinical - Substance abuse treatment facility F02.51 Clinical - Community health center F03 Clinical - Emergency department F08 Clinical - Primary care clinic (other than CHC) F09 Clinical - Pharmacy or other retail-based clinic F10 Clinical - STD clinic F11 Clinical - Dental clinic F12 Clinical - Correctional facility clinic F13 Clinical - Other	F04.05 Non-clinical - HIV testing site F06.02 Non-clinical - Community setting - School/educational facility F06.03 Non-clinical - Community setting - Church/mosque/synagogue/temple F06.04 Non-clinical - Community setting - Shelter/transitional housing F06.05 Non-clinical - Community setting - Commercial facility F06.07 Non-clinical - Community setting - Bar/club/adult entertainment F06.08 Non-clinical - Community setting - Public area F06.12 Non-clinical - Community setting - Individual residence F06.88 Non-clinical - Community setting - Other F07 Non-clinical - Correctional facility - Non-healthcare F14 Non-clinical - Health department - Field visit F15 Non-clinical - Community setting - Syringe exchange program F88 Non-clinical - Other	
Codes for Additional Risk Factor(s)		
01 Exchange vaginal/anal sex for drugs/money/or something they needed 02 Vaginal/anal sex while intoxicated and/or high on drugs 05 Vaginal/anal sex with person of unknown HIV status 06 Vaginal/anal sex with person who exchanges sex for drugs/money	08 Vaginal/anal sex with anonymous partner 12 Diagnosed with a sexually transmitted disease (STD) 13 Sex with multiple partners 14 Oral sex 15 Unprotected vaginal/anal sex with a person who is an IDU	16 Unprotected vaginal/anal sex with a person who is HIV positive 17 Unprotected vaginal/anal sex in exchange for drugs/money/or something they needed 18 Unprotected vaginal/anal sex with person who exchanges sex for drugs/money 19 Unprotected sex with multiple partners
Codes for Session Activities		
04.00 Referral 05.00 Personalized risk assessment 06.00 Elicit partners 07.00 Notification of exposure 08.01 Information - HIV/AIDS transmission 08.02 Information - Abstinence/postpone sexual activity 08.03 Information - Other sexually transmitted diseases 08.04 Information - Viral hepatitis 08.05 Information - Availability of HIV/STD counseling and testing 08.06 Information - Availability of partner notification and referral services 08.07 Information - Living with HIV/AIDS 08.08 Information - Availability of social services 08.09 Information - Availability of medical services 08.10 Information - Sexual risk reduction 08.11 Information - IDU risk reduction 08.12 Information - IDU risk-free behavior 08.13 Information - Condom/barrier use 08.14 Information - Negotiation/Communication 08.15 Information - Decision making 08.16 Information - Disclosure of HIV status 08.17 Information - Providing prevention services 08.18 Information - HIV testing 08.19 Information - Partner notification 08.20 Information - HIV medication therapy adherence 08.21 Information - Alcohol and drug use prevention 08.22 Information - Sexual health 08.23 Information - TB testing 08.88 Information - Other 09.01 Demonstration - Condom/barrier use 09.02 Demonstration - IDU risk reduction	09.03 Demonstration - Negotiation/communication 09.04 Demonstration - Decision making 09.05 Demonstration - Disclosure of HIV status 09.06 Demonstration - Providing prevention services 09.07 Demonstration - Partner notification 09.88 Demonstration - Other 10.01 Practice - Condom/barrier use 10.02 Practice - IDU risk reduction 10.03 Practice - Negotiation/Communication 10.04 Practice - Decision making 10.05 Practice - Disclosure of HIV status 10.06 Practice - Providing prevention services 10.07 Practice - Partner notification 10.88 Practice - Other 11.01 Discussion - Sexual risk reduction 11.02 Discussion - IDU risk reduction 11.03 Discussion - HIV testing 11.04 Discussion - Other sexually transmitted diseases 11.05 Discussion - Disclosure of HIV status 11.06 Discussion - Partner notification 11.07 Discussion - HIV medication therapy adherence 11.08 Discussion - Abstinence/postpone sexual activity 11.09 Discussion - IDU risk free behavior 11.10 Discussion - HIV/AIDS transmission 11.11 Discussion - Viral hepatitis 11.12 Discussion - Living with HIV/AIDS 11.13 Discussion - Availability of HIV/AIDS counseling & testing 11.14 Discussion - Availability of partner notification and referral services	11.15 Discussion - Availability of social services 11.16 Discussion - Availability of medical services 11.17 Discussion - Condom/barrier use 11.18 Discussion - Negotiation/communication 11.19 Discussion - Decision making 11.20 Discussion - Providing prevention services 11.21 Discussion - Alcohol and drug use prevention 11.22 Discussion - Sexual health 11.23 Discussion - TB testing 11.24 Discussion - Stage-based encounter 11.88 Discussion - Other 12.01 Other testing - Pregnancy 12.02 Other testing - STD 12.03 Other testing - Viral hepatitis 12.04 Other testing - TB 13.01 Distribution - Male condoms 13.02 Distribution - Female condoms 13.03 Distribution - Safe sex kits 13.04 Distribution - Safer injection/bleach kits 13.05 Distribution - Lubricants 13.06 Distribution - Education materials 13.07 Distribution - Referral lists 13.08 Distribution - Role model stories 13.09 Distribution - Dental dams 13.88 Distribution - Other 14.01 Post-intervention follow-up 14.02 Post-intervention booster session 15.00 HIV testing history survey 16.00 Risk reduction counseling 17.00 Personalized cognitive counseling 88 Other

Appendix C

Utah's One-Rapid HIV Testing Algorithm

Utah Department of Health Prevention, Treatment and Care Program (PTCP)

Utah's One-Rapid HIV Testing Algorithm

The following description and algorithm describes the test method the Prevention, Treatment and Care Program (PTCP) of the Utah Department of Health recommends for its grantees, local health departments and other agencies, as a guide on how to use HIV rapid testing technology for the early detection of HIV infection to prevent further transmission of the disease. Additionally, this document describes how to appropriately link those individuals with preliminary positive results to medical care, partner services and HIV Prevention Services.

The PTCP recommends that Alere Determine™ HIV-1/2 Ag/Ab Combo be used as a point-of-care immunoassay for the simultaneous detection HIV-1 p24 antigen (Ag) and antibodies (Ab) to HIV-1 and HIV-2 in human serum, plasma, capillary (fingerstick) whole blood or venipuncture (venous) whole blood.

Alere Determine™ HIV-1/2 Ag/Ab Combo is not intended for newborn screening or for use with cord blood specimens or specimens from individuals less than 12 years of age.

Alere Determine™ HIV-1/2 Ag/Ab Combo is not intended for use in screening blood, plasma, cell, or tissue donors.

The recommended test device and algorithm have several advantages over previous recommendations, including

- CLIA-waived for fingerstick whole blood
- it is a 4th generation rapid point-of-care that detects both HIV-1/2 antibodies and free HIV-p24 antigen on a single test strip.
- detects HIV earlier than 3rd generation antibody-only tests
- allows for speedy and seamless linkage to care
- reduces referral burden for clients and counselors

A reactive test result using Alere Determine™ HIV-1/2 Ag/Ab Combo suggests the presence of HIV-1 p24 antigen and/or antibodies to HIV-1 and/or HIV-2 in the sample. The reactive result is interpreted as PRELIMINARY POSITIVE for HIV-1 p24 antigen and/or antibodies to HIV-1 and/or HIV-2. Alere Determine™ HIV-1/2 Ag/Ab Combo is intended as an aid in the diagnosis of infection with HIV-1/2 and its reactive results must be confirmed by a medical provider with 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 for acute HIV-1 infection. AIDS-related conditions are clinical syndromes, and their diagnosis can only be established clinically.

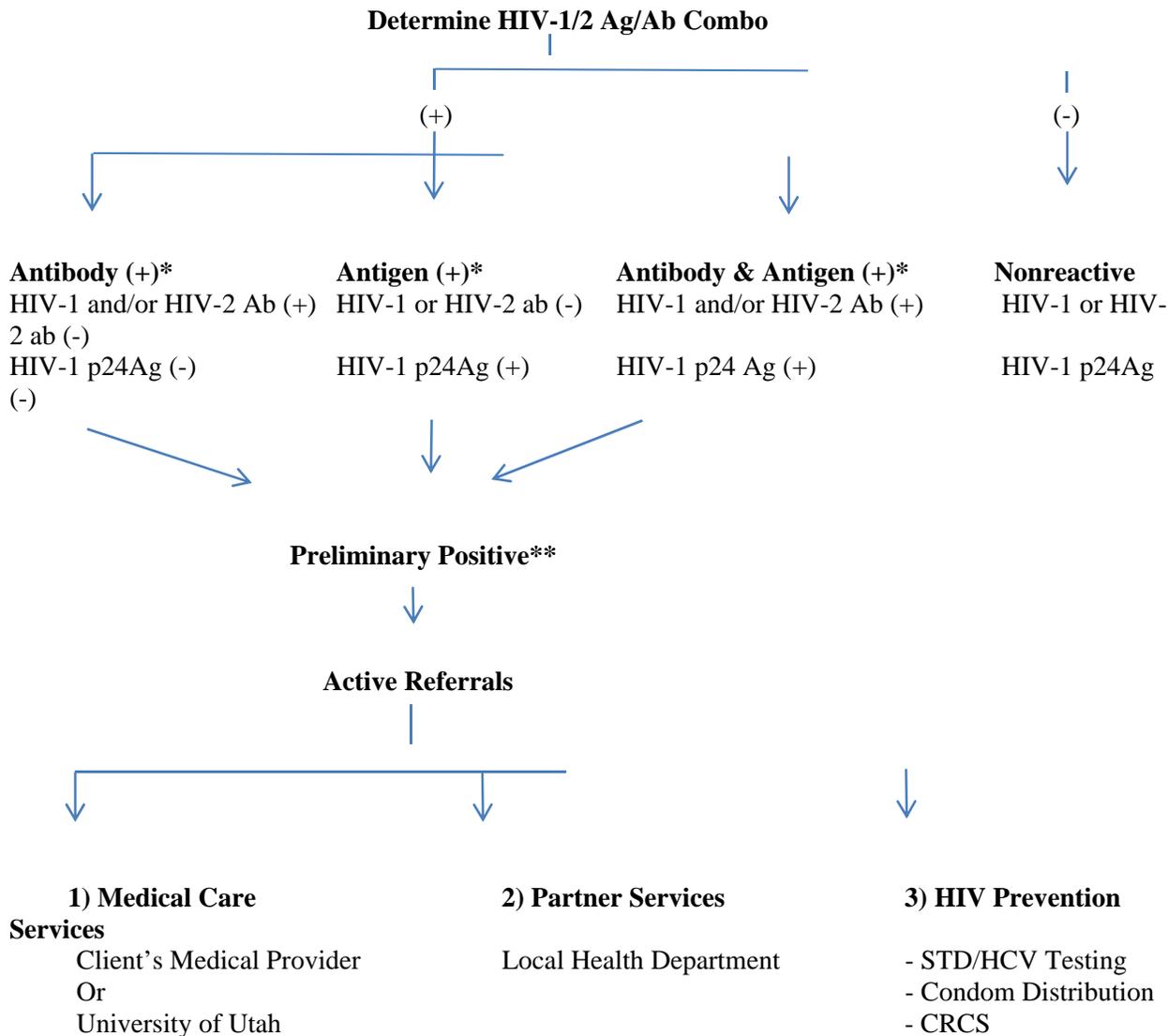
Medical providers should refer to the CDC Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens to confirm the preliminary positive results of the Alere Determine™ HIV-1/2 Ag/Ab Combo test. Please see the Updated Recommendations for Laboratory Testing for the Diagnosis of HIV Infection at:

<http://www.cdc.gov/hiv/pdf/hivtestingalgorithmrecommendation-final.pdf>

For specific information on the above test and pertinent guidance on how to use rapid testing technology, please refer to the Utah Department of Health, Prevention, Treatment and Care Program Rapid HIV and HCV Testing Guidance. A copy of this guidance can be accessed at:

http://health.utah.gov/epi/testing/resources/Rapid_Testing_Guidance.pdf

Figure 1: Recommended Rapid HIV Testing Algorithm for serum, plasma, and capillary (fingerstick) whole blood or venipuncture (venous) whole blood.



(+) Indicates reactive test result

(-) Indicates non-reactive test result

STD means Sexually Transmitted Disease

HCV means Hepatitis C Virus

CRCS means Comprehensive Risk Counseling & Services

* Result is reportable

** Rapid reactive results must be confirmed

Interpretation of Test Results

2) **REACTIVE:**

a) **ANTIBODY REACTIVE (Two lines – Control & Ab Line)**

If a **PINK/RED** Control line appears in the Control Area AND a **PINK/RED** Ab line appears in the Lower Test Area of the Test Device, the test is considered antibody REACTIVE. This indicates that HIV-1 or HIV-2 antibodies were detected in the specimen and this result is interpreted as **PRELIMINARY POSITIVE** for HIV-1 or HIV-2 antibodies.

b) **ANTIGEN (HIV-1 p24) REACTIVE (Two Lines – Control and Ag Line)**

(If a **PINK/RED** Control line appears in the Control Area AND a **PINK/RED** Ag line appears in the Lower Test Area of the Test Device, the test is considered antigen REACTIVE. This indicates that HIV-1 p24 antigen was detected in the specimen and this result is interpreted as **PRELIMINARY POSITIVE** for HIV-1 p24 antigen.

c) **ANTIBODY REACTIVE AND ANTIGEN (HIV-1 p24) REACTIVE (Three Lines – Control, Ab and Ag Lines)**

If a **PINK/RED** Control line appears in the Control Area AND a **PINK/RED** Ab line appears in the Lower Test Area AND a **PINK/RED** Ag line appears in the Upper Test Area of the Test Device, the test is considered antibody and antigen (HIV-1 p24) REACTIVE. This indicates that HIV-1 and/or HIV-2 antibodies and HIV-1 p24 antigen was detected in the specimen and this result is interpreted as **PRELIMINARY POSITIVE** for HIV-1 and/or HIV-2 antibodies and HIV-1 p24 antigen.

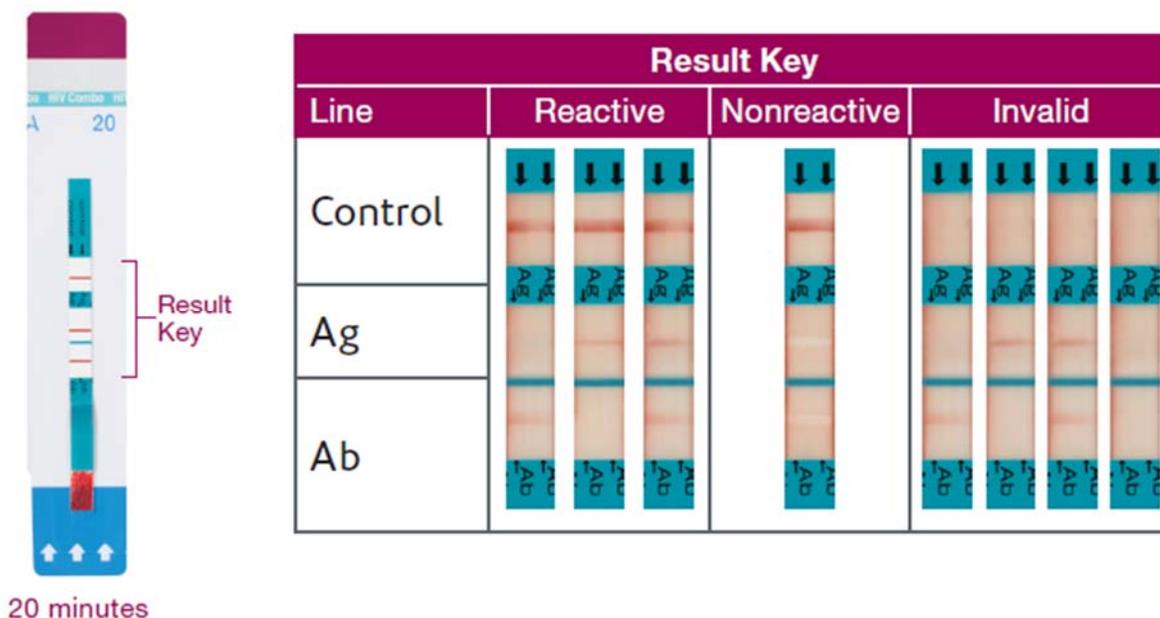
3) **NONREACTIVE:**

- a) If a **PINK/RED** Control line appears in the Control Area of the Test Device, and no **PINK/RED** Ab or Ag line appears in the Lower Test Area and the Upper Test Area of the Test Device, respectively, this is a **NONREACTIVE** test result. This means that 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. **End here - client is negative.**

4) **INVALID:**

a) **INVALID (No Control Line)**

If there is no **PINK/RED** Control line in the Control Area of the Test Device, even if a **PINK/RED** line appears in the Lower Test Area or the Upper Test Area of the Test Device, the result is INVALID and the test should be repeated.



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Active Referrals for Preliminary Positive Clients

Clients, whose test results are Reactive are considered to be Preliminary Positive for HIV and their immediate needs for care and supportive services must be prioritized and clients must be provided with assistance in accessing services. An **active referral** includes calling the referral site to make an appointment for the client while client is present and/or assisting with transportation. All active referrals must be supported with appointment reminders and confirmation of linkage to medical care, HIV partner services, and HIV prevention services.

1. Medical Care Referral

Preliminary Positive clients need to be immediately linked with HIV care providers and case managers to help ensure that the HIV medical needs of the client are addressed. HIV-infected patients who are not receiving medical care should be referred or directly linked to medical care or to case managers who can then link them to care services.

Counselors should actively link a client, whose result is preliminary positive, to their own medical provider or to the University of Utah Infectious Disease Clinic by calling 801-585-2031. Counselor must ensure linkage is made and a successful first appointment is completed.

2. Partner Services Referral

Partner services are a broad array of services that should be offered to persons with HIV or other STDs and their sexual or needle sharing partners. By identifying infected persons and their partners, a range of medical, prevention, and psychosocial services can improve the health not only of individuals, but of communities as well.

Partner Services in Utah are provided by the Disease Investigation Section (DIS) of the local health departments in various locations throughout the state. Counselors at non-clinical settings can start partner elicitation (names of partners) during the first interview with their client, and are required to schedule a re-interview appointment with the DIS worker of the corresponding local health department. Counselor must ensure linkage is made and a successful first appointment is completed.

3. HIV Prevention Services Referral

Utah HIV prevention services comprises of 3 different but very important services:

- 1) referral to testing, such as HIV, STD or HCV,
- 2) condom distribution, and
- 3) Comprehensive Risk Counseling and Services.

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 of 1988
CRCS	Comprehensive Risk Counseling & Services
HCV	Hepatitis C Virus
HIV	human immunodeficiency virus
IA	immunoassay
PTCP	Prevention, Treatment and Care Program
STD	sexually transmitted disease