Rapid HIV and HCV Testing Guidance

FOR

Determine™ HIV-1/2 Ag/Ab Combo

OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test

AND

OraQuick® HCV Rapid Antibody Test

May 2020

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.

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
BOE	Bureau of Epidemiology
STD	sexually transmitted disease

Table of Contents

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 without prior approval from the HIV Prevention Specialist.

1.2 Approval to use a different FDA Approved HIV Rapid Testing Technology

For HIV Rapid Testing, UDOH funded HIV testing providers are preferred to use the Determine™ HIV-1/2 Ag/Ab Combo 4th Generation Test. However, if the provider would like to use a different FDA approved HIV rapid testing technology, the provider must submit in writing a request to the HIV Prevention Specialist indicating the following: what testing technology is preferred, why is a different testing technology preferred, what is the protocol for administering the test (please describe any changes to the procedures used to maintain confidentiality, obtain and record Utah residency, provide pre- and post-test counseling, linkage to care, and data collection for EvaluationWeb) and what is the estimated duration for testing with this technology. In addition, provider must indicate that rapid Lab Technicians have been trained on the use of the proposed technology. If training is required on alternative device, note this in the request. This request must be approved by the HIV Prevention Specialist before the purchase or use of any test technology that is not the Determine™ HIV-1/2 Ag/Ab Combo 4th Generation Test.

1.3 Purchasing Test kits and External Controls

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

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

Determine™ HIV-1/2 Ag/Ab Combo
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
1-800-ORASURE (1-800-672-7873)
customercare@orasure.com

Laurie Kops
National Sales Support

OraSure Technologies, Inc.
484-460-6471
lkops@orasure.com

OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test
https://www.orasure.com/products-infectious/products-infectious-oraquick.asp
www.knowyourstatustoday.com
OraQuick® Rapid HCV Antibody Test
https://www.orasure.com/products-infectious/products-infectious-oraquick-hcv.asp
www.TestHepC.com
OraQuick® In-Home HIV Test
http://www.oraquick.com/

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

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 BOE. An agency may establish their own policies and procedures but their standards must meet UDOH guidelines.

2.7 Testing Guidelines

UDOH complies with national and state testing guidelines. Please refer to the resources below to ensure your agency is complying with all updated guidelines.

National HIV Testing Guidelines: https://www.cdc.gov/hiv/guidelines/testing.html
Utah HIV Testing Guidelines: see Appendix B

National Hepatitis C Testing Guidelines: https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm

3. Training

3.1 Lab Technician Training and Certification

Prospective lab technicians must attend Basic HIV, HCV and STD Facts training and the Rapid Lab Technician Certification, complete a knowledge assessment and pass a supervised observation.

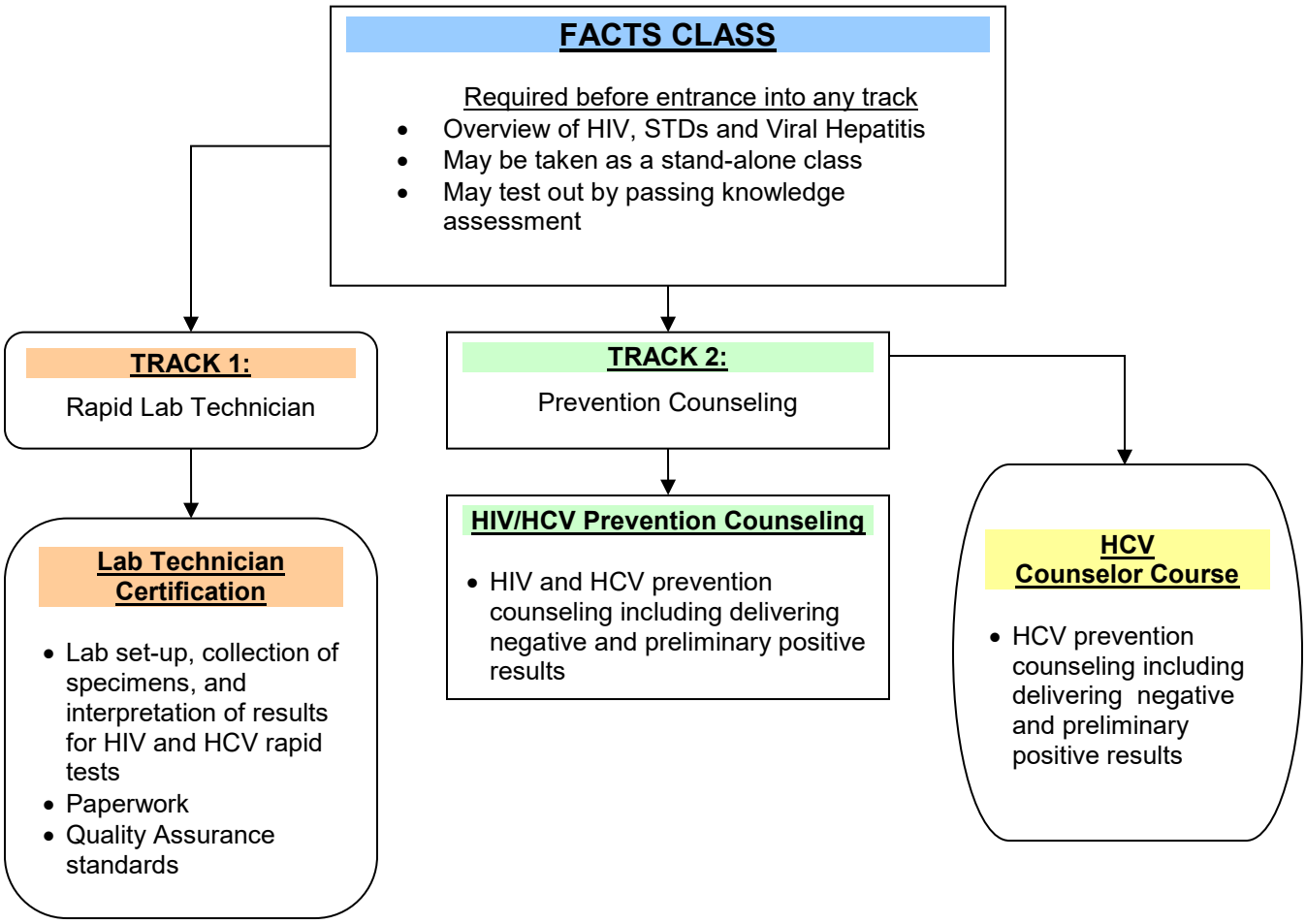
Prospective lab technicians are not required to attend HIV/HCV Prevention Counseling Course, unless they will also provide counseling activities.

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 HCV controls cannot be run on Determine™ HIV tests or for OraQuick Advance HIV 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
Determine™ HIV-1/2 Ag/Ab Combo	Monitor every business day	36°- 46°F or 2°- 8°C
OraQuick® Advance HIV tests	Monitor every business day	35°- 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
Determine™ HIV-1/2 Ag/Ab Combo	Expiration date printed on vial	Expiration date printed on vial
OraQuick® Advance HIV tests	Expiration date printed on vial	**Eight weeks after first use**
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 Determine™ HIV-1/2 Ag/Ab Combo Test Cards and Chase Buffer, OraQuick® Advance HIV test and OraQuick® HCV Rapid Antibody Test must be stored at 36°- 86°F or 2°- 30°C and monitored 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/Cards Disposal – Expired or Compromised
Expiration dates are noted on the box and each test kit or test card & chase buffer.
DO NOT USE test kit components beyond the expiration date printed on label. Always check expiration date prior to testing.

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.

OraQuick® HCV or OraQuick ADVANCE® HIV Test kits are 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.

Determine™ HIV-1/2 Ag/Ab:

- All materials provided in the Determine™ HIV-1/2 Ag/Ab Combo (Please refer to manufacturer's package insert.
- 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 and OraQuick ADVANCE® HIV Test

- Test kits
- Controls
- Test stands
- Collection loops
- 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

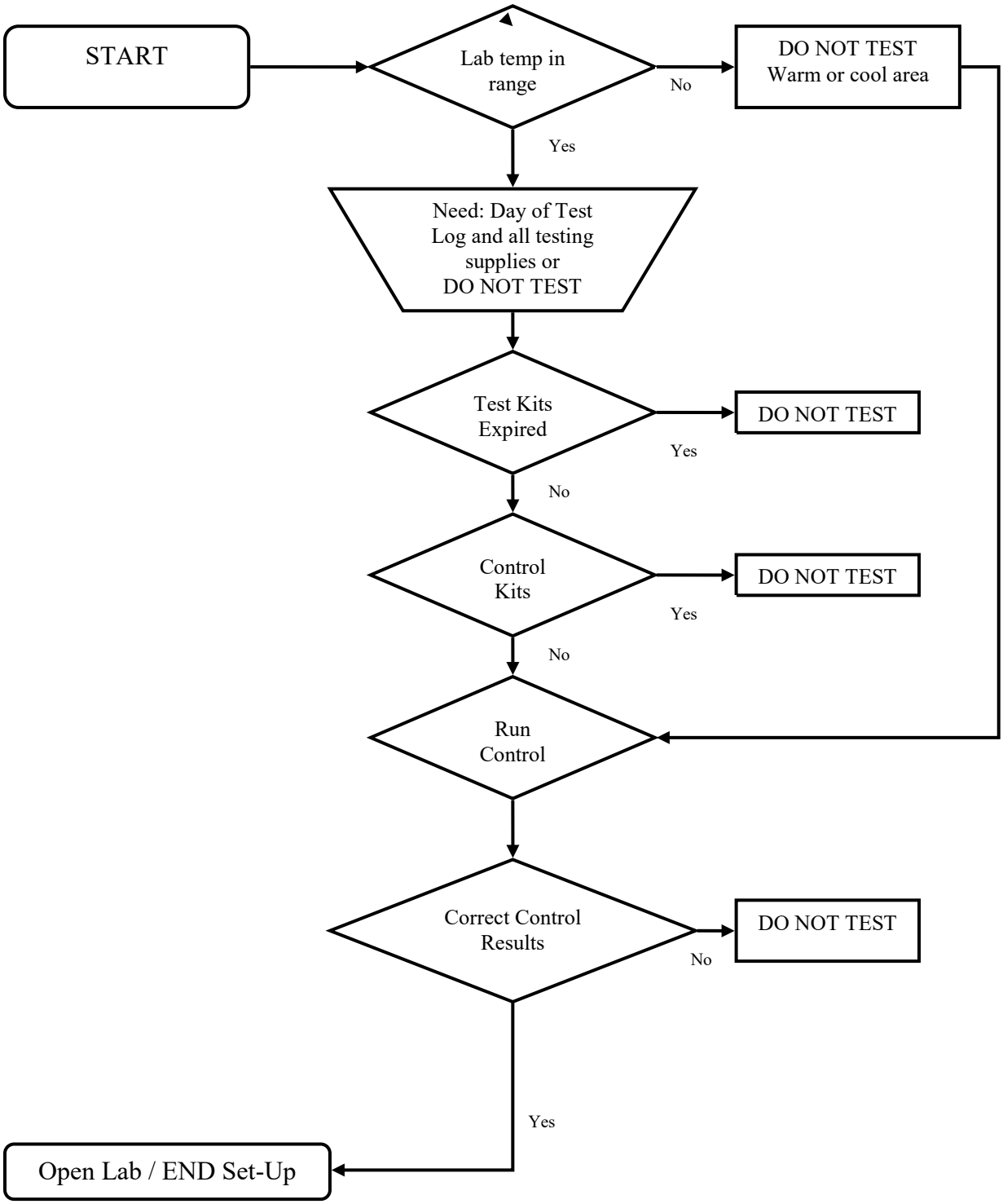
Lab temperature requirements are specific to each type of rapid test. The temperature of the specimen collection area must fall within a defined range. Whenever the temperature falls outside the minimum or maximum operating temperature, NO new clients may be tested until the temperature is once again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

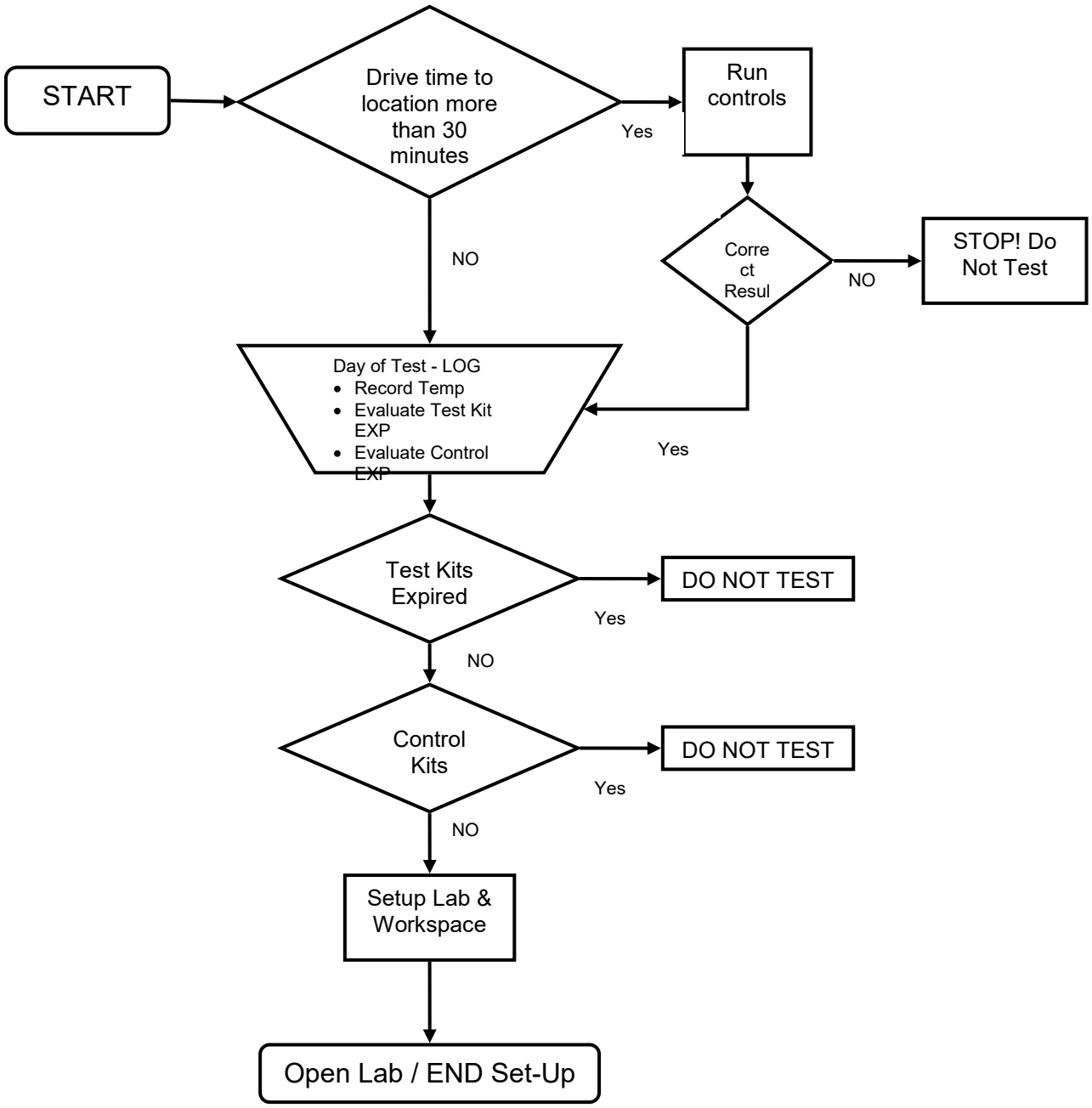
Test Kit Type	Lab Temperature Range
Determine™ HIV-1/2 Ag/Ab Combo	59-86°F, 15-30°C
OraQuick ADVANCE® HIV Test and OraQuick® HCV	59° - 99°F or 15° - 37°C

1. 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

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 OraQuick ADVANCE HIV Test and Ora Quick HCV Test Controls

The OraQuick ADVANCE® HIV Test and OraQuick® HCV control kits each include one vial of negative fluid and one vial of HIV or HCV positive fluid (positive fluids are deactivated and do not pose a contamination risk). The HIV or HCV Positive Control will produce a reactive reddish-purple line at the Test Zone. The HIV or 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	
ALL testing locations: • 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 Best practice is to maintain two 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 • 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 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.

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 rest. 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 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 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 Determine™ HIV-1/2 Ag/Ab Combo at: http://www.alerehiv.com/ww/home/hiv-screening/alere-hiv-combo/procedure.html

10.2 OraQuick ADVANCE® HIV Test - specimen collection

Detailed Manufacturer Instructions:
https://www.orasure.com/docs/pdfs/products/oraquick_advance/OraQuick_ADVANCE_PI-US_EN.pdf

Instructional Video: https://www.youtube.com/watch?v=5FBWORY91J4&t=59s

Whole Blood Collection Instructions:

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

Oral Fluid Collection Instructions:

1. Remove the testing vile from the one side of the testing pouch and slide into test stand and remove cap.
2. Ensure client has not had anything to eat or drink or chewed gum for at least 15 minutes.
3. Have the client remove the test device from the pouch, DO NOT touch the flat pad.
4. Place the flat pad between the lip and gum above the teeth and gently swab across the top of the mouth then repeat across the bottom
5. Have the client return the test device to the pouch, ensuring flat pad is not touched and inserted completely
6. Have client hand pouch back to Lab Technician.
7. Remove test device from pouch and insert into testing vile.
8. Read the test result between 20 and 40 minutes after the test device is inserted into the test vile. Do not read Test Results after 40 minutes.

10.3 OraQuick® HCV - specimen collection

Please note, OraQuick Rapid HCV Antibody test is ONLY approved for whole blood collection

Whole Blood Collection Instructions:

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

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 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.

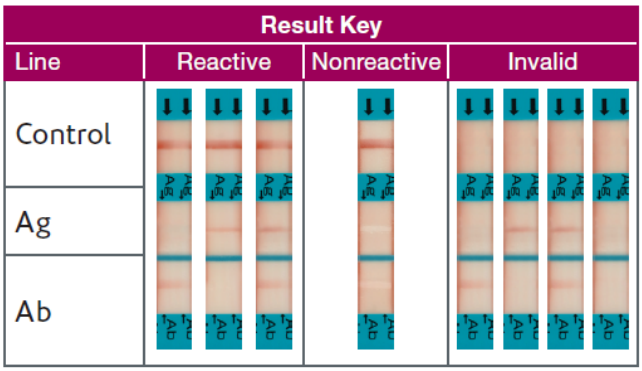
11.1.2 NONREACTIVE:

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.



11.2 OraQuick ADVANCE® HIV Test and OraQuick® HCV

11.2.1 Reactive or Preliminary Positive

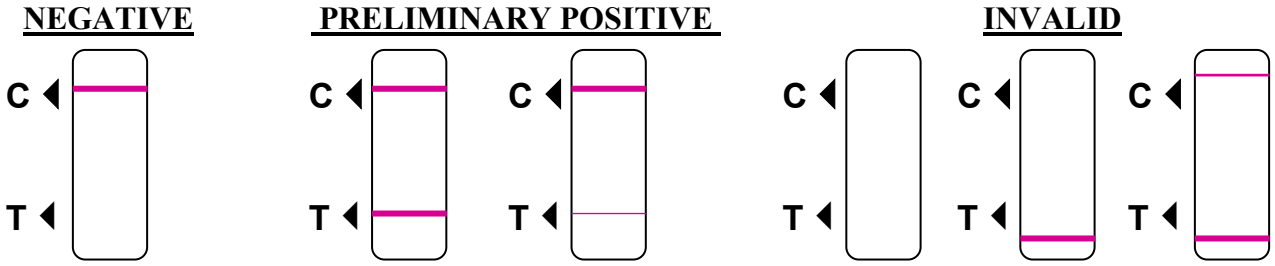
Two pink/purple lines appear; one in the "C" triangle or top 1/3 of the read window and one in the "T" triangle or bottom 1/3 of the read window indicating a preliminary positive test result. Intensities of the two lines may vary. A preliminary positive result means antibodies were detected in the specimen. 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 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. 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 Rapid HIV Testing Algorithm using the 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 Determine™ HIV-1/2 Ag/Ab Combo test. Please see the Updated Recommendations for Laboratory Testing for the Diagnosis of HIV Infection at: https://www.cdc.gov/hiv/guidelines/testing.html

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. See CDC Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection: https://www.cdc.gov/hepatitis/hcv/pdfs/hcv_flow.pdf

Refer to UDOH for more information on confirmatory HCV testing.

Test Sequence	Result	Next Step
Rapid HCV Antibody	(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. See Appendix A: Rapid Testing Forms and Logs

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_Guidlines.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: Rapid HIV/HCV Testing Forms and Logs

Most recent version of forms can be found here: http://health.utah.gov/epi/prevention/providerResource.html

RAPID HIV/HCV Day of Test Log
RAPID HIV/HCV Test Kit Temperature Storage Log
RAPID HIV/HCV Control Kit Temperature Storage Log
UDOH EvaluationWeb® HIV Test Form

Appendix B: Utah HIV Testing Guidelines – Published 10/1/2019

Utah HIV Screening Guidelines

HIV Screening: An Important Tool for Healthy Utahns

Medical providers and public health professionals have the tools to end the HIV epidemic in Utah. Individuals with HIV who receive antiretroviral therapy (ART) and achieve and maintain an undetectable viral load cannot sexually transmit HIV to others.[1] **Appropriate screening is crucial to eliminate new HIV infections.** In 2017, there were 2,988 people living with HIV in Utah, and approximately 120 new HIV infections are identified in Utah every year.[2]

Development of the Utah HIV Screening Guidelines

In 2019, the Utah Department of Health recognized the need for state-specific HIV screening guidelines and organized an HIV Screening Guidelines Workgroup. The Workgroup consisted of HIV experts from local health departments, the University of Utah School of Medicine, University of Utah Health hospitals and clinics, and Intermountain Healthcare. The Workgroup utilized national HIV screening guidelines and recommendations from the American College of Obstetrics and Gynecology, Centers for Disease Control and Prevention (CDC), National Institutes of Health, U.S. Preventative Services Task Force, and World Health Organization to develop the Utah-specific guidelines. These guidelines will help improve the healthcare Utahns receive, especially for those who are at high risk for HIV infection.

Utah HIV Testing Strategy

- Include HIV screening as a standard of care and reduce sexual health stigma in Utah.
- Utilize FDA approved, 4th generation testing technologies recommended by the CDC and Association of Public Health Laboratories (APHL).
- Identify acute and early HIV infection as soon as possible to reduce the risk of HIV transmission from person-to-person.
- Initiate antiretroviral treatment (ART) for all individuals the same day they test positive for HIV.[3]

Other Considerations

Taking a Sexual History

Sexual health is an integral part of overall health. Providing appropriate clinical services depends on an accurate sexual history. Guidance for taking a sexual history may be found at https://bit.ly/2HTT30B (CDC, A Guide to Taking a Sexual History) or https://bit.ly/2DsEHUa (Act Against AIDS, Taking a Sexual History).

Sexually Transmitted Infection (STI) screening

The same behaviors and circumstances that put an individual at risk for HIV can also put them at risk for acquiring a sexually transmitted infection (STI). Additionally, people who have STIs are more likely to acquire HIV due to biological and behavioral factors when compared to people who do not have STIs.[4] It is imperative HIV and STI screening be conducted simultaneously. It is also important to conduct site-specific testing to account for all anatomical sites that may have been exposed to an STI.[4] The CDC STI screening guidelines may be found at www.cdc.gov/std/tg2015/specialpops.htm.

Pre-exposure Prophylaxis (PrEP)

Pre-exposure prophylaxis, or PrEP, is a pill taken daily to decrease an HIV-negative individual's chances of acquiring HIV. When taken as directed, PrEP reduces the risk of HIV transmission from sex by more than 99% and by more than 72% from injection drug use.[5] Guidance for PrEP may be found at www.cdc.gov/hiv/basics/prep.html.

Indications for PrEP:

- Men who have sex with men and:
  - Have an HIV-positive partner
  - Have multiple partners, a partner with multiple partners, or a partner whose HIV status is unknown and also:
    - Have anal sex without a condom, or
    - Recently had a sexually transmitted infection
- Heterosexuals who:
  - Have an HIV-positive partner
  - Have multiple partners, a partner with multiple partners, or a partner whose HIV status is unknown, and also:
    - Don't always use a condom for sex with people who inject drugs, or
    - Women who have sex with men who have sex with other men and don't always use a condom
- Persons who inject drugs and:
  - Share needles or equipment to inject drugs
  - Are at risk for getting HIV from sex

Non-occupational Post-exposure Prophylaxis (nPEP)

Non-occupational post-exposure prophylaxis (nPEP) is a highly effective HIV prevention tool for individuals believed to have been exposed to HIV due to sexual, injection drug use, or other non-occupational means. nPEP must be administered within 72 hours of a potential exposure. It can decrease the odds of HIV transmission by 81%.[9] nPEP is prescribed as a 28-day course of a 3-drug antiretroviral regimen.

nPEP should only be given to those believed to be at substantial risk for HIV acquisition, including:

- Receptive and insertive anal intercourse*
- Receptive and insertive vaginal intercourse*
- Needle sharing*

*Risk increases if exposure is from a known HIV-positive individual.

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Who Should be Screened for HIV in Utah

Population	Guideline

Adults & Adolescents	• Screen once per lifetime:
	  ○ Aged 15-64, or earlier, depending on sexual debut and other risk factors
	  ○ Routinely conduct sexual history, repeating testing as risk determines[3, 6, 7]
	• Screen people seeking STI treatment [3, 5]
	• Screen people initiating TB treatment [3]

Increased Behavioral Risk Factors	● Screen annually: ○ Gay, bisexual, and men who have sex with men[3, 4, 5, 6] ○ Women who have sex with men who have sex with other men[5] ○ Sex partners of HIV-infected persons[3, 6] ○ Persons who use drugs and their sex partners[3, 6] ○ Persons exchanging sex for money or drugs[3, 6] ○ Heterosexual persons with more than one partner since their last HIV test[3, 6]
Pregnant Women	● Routine prenatal screening panel; this should be opt-out[3, 4, 5, 6, 7] ● Repeat 3rd trimester for women who are at higher risk for HIV[3, 7] ● Screen in labor/postpartum/newborn if HIV status is unknown [3, 5, 7]
Incarcerated	● All adults and adolescents upon admission into a correctional facility, unless tested within the last three months[6]

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