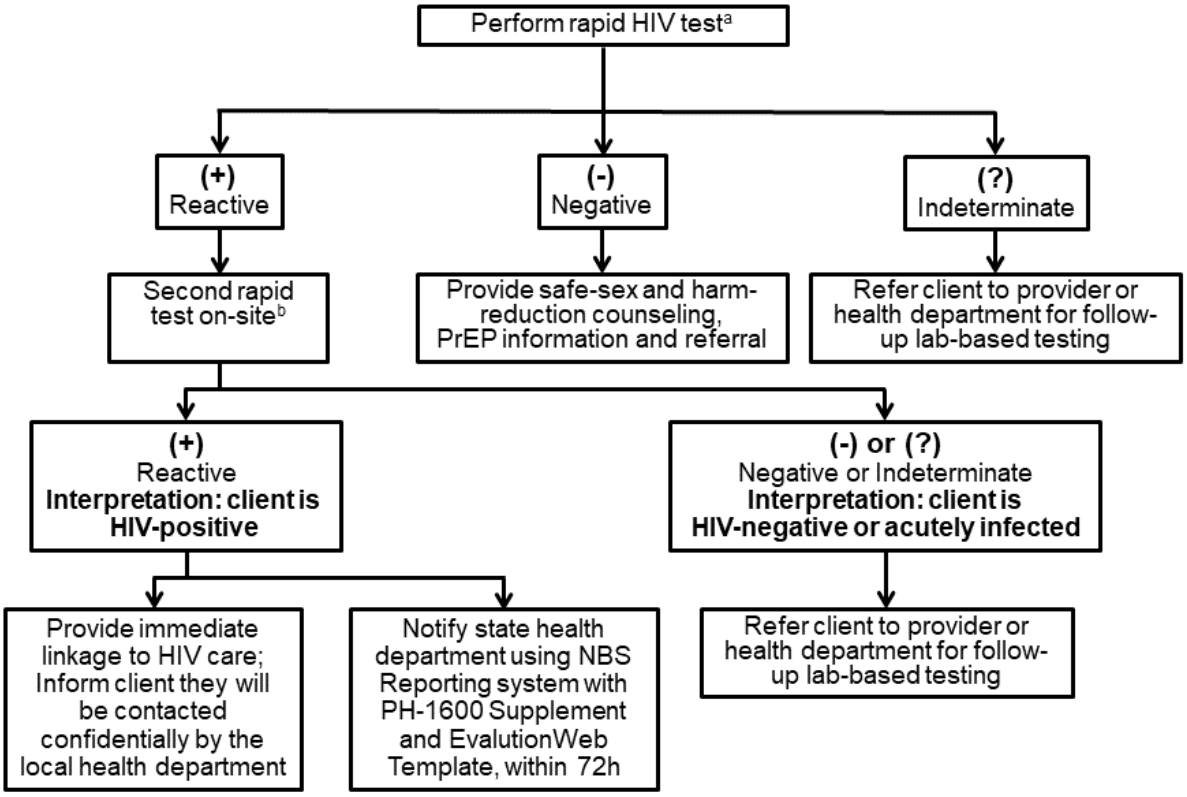
Double Rapid HIV Testing Guidelines

Tennessee Department of Health| HIV/STD/Viral Hepatitis | October 2019

Point-of-Care Double Rapid HIV Testing Algorithm



[a] TDH recommends OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test or INSTI® HIV-1/HIV-2 Rapid Antibody Test using finger stick (whole blood) sample. Do not use oral fluid (exceptions are made for limited settings [e.g., prisons/jails]).
[b] Confirm results using a different test and a second finger stick sample. TDH recommends INSTI® HIV-1/HIV-2 Rapid Antibody Test, OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test, or Chembio DPP® HIV 1/2 Assay Rapid HIV. Do not use oral fluid.

Note: if preliminary test result is indeterminate, followed by a subsequent indeterminate test result, TDH recommends running the control test and retest using a test kit from a different lot number, if available.

Reporting Process:

(1) Within 72 hours of receiving or testing a new or previously known HIV+ client, notify the Tennessee Department of Health using the online **National Electronic Disease Surveillance System (NEDSS) Base System (NBS).*** Attach the **PH-1600 Supplement for Reporting New HIV Infections via Rapid/Rapid HIV Tests** (Appendix A) and the **EvaluationWeb Positive Test Template** (Appendix B) online via NBS.

(2) Submit monthly testing counts to Tennessee Department of Health via TNCloud using the revised **All HIV Testing Spreadsheet** (Appendix C) due by the 15th day of the following month.

Questions? Contact:

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HIV Prevention Program Director
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*Request an NBS account at https://redcap.health.tn.gov/redcap/surveys/?s=8L7CMWHN4M or via email at CEDS.Informatics@tn.gov.

Point-of-Care Double Rapid HIV Testing

Rapid HIV screening tests are designed to provide quick results, typically within 20 minutes or less. They are intended to increase access to HIV testing in high prevalence areas by decreasing barriers associated with traditional laboratory methods of testing, and are especially useful for clients who are unable to maintain stable medical care or are unlikely to return for test results. Tests can be performed in community-based settings by trained personnel using whole blood (or oral fluid in limited settings), in addition to a laboratory using serum or plasma.

The accuracy of rapid tests is very high (>99% sensitive and specific) when testing clients with chronic infection. However, one study completed by the CDC showed approximately 12% of acute infections (typically 2-8 weeks after infection, before HIV antibodies are formed) can be missed by a single rapid antibody test.[1] Additionally, rapid HIV testing on oral secretions is less sensitive than using finger stick testing,[2] with one study showing 233 repeated false negative results using oral fluid in 80 of 237 (34%) HIV positive individuals.[3] HIV testing remains a critical element of the HIV care continuum and rapid HIV testing plays a crucial role in targeted testing in nonclinical, community-based settings.[4]

While rapid testing has many benefits, it may not be appropriate for all clients. Initiation of rapid HIV screening programs at community-based organizations *must* be accompanied by plans for client confidentiality and appropriate counseling for all post-test results. Clients should be made aware that rapid HIV tests provide a result in minutes; if they are not emotionally prepared to receive results, referral to their local health department or a clinical provider for a screening blood test may be more appropriate. Clients should additionally be provided with thorough counseling for harm reduction in all settings, such as clean needle use for persons who inject drugs, and consistent use of barrier protection. Referral for HIV pre-exposure prophylaxis (PrEP) should also be undertaken when appropriate.

If a patient tests positive for HIV, it is essential that they are referred to care without delay and instructed that they will be contacted confidentially by a Disease Investigation Specialist (DIS) from their local health department or the TN Department of Health (TDH) due to the reportable status of HIV, and to help identify partners that may benefit from further testing.

Policies and Legal Considerations

All agencies including community-based organizations and health departments using rapid HIV testing must comply with the following:

- Nonclinical HIV testing sites using rapid HIV testing must obtain a certificate of waiver under CLIA (the Clinical Laboratory Improvement Amendments of 1988), or establish an agreement to work under the CLIA certificate of an existing laboratory. More information about CLIA certification and CLIA waived laboratory tests can be found on CDC's HIV/AIDS website (http://www.cdc.gov/hiv/testing/lab/clia/). Agencies should contact their state or local health department for more information, including how to apply for a CLIA waiver. Technical assistance on how to apply is offered by the TDH HIV Prevention Testing Program Director. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html

- The State Medical Lab Board requires that those who perform rapid HIV testing have a color blind test administered via the internet at http://www.toledo-bend.com/colorblind/Ishihara.html. After completion of this test, a confirmation page should be printed and kept on file. All applicable documents should be maintained by the agency for annual site visits and audits.

- Testers working at agencies that receive funds and/or test kits from TDH are required to attend TDH HIV counseling and testing "I Know" training, prior to conducting testing. Successful completion of each training component will be assessed by the TDH HIV Prevention Testing Program Director or the TDH Public Health Educator. Counselors may only provide services corresponding to the training component completed. Please note that private medical providers are only accountable to their respective quality assurance policies.

- Only qualified staff may train new staff on the OraQuick ADVANCE ® Rapid HIV-1/2 Antibody Test, INSTI® HIV-1/HIV-2 Rapid Antibody Test, and Chembio DPP® HIV 1/2 Assay Rapid HIV Test, which include Central Office staff, certified "I Know" trainers, or a device company representative. The TDH Public Health Educator will make every effort to ensure that device training is provided in a timely manner.

- Proficiency testing for all qualified individuals performing testing and running quality controls will be conducted once per year, or per site-specific policy, and documentation maintained. In addition, temperature logs should be maintained daily on both the storage area and the testing area.

Quality Assurance

To ensure quality control, please refer to the steps outlined below:

a. OraSure Technologies, Inc. recommends that a control should be run under the following circumstances:
    1. When opening a new test kit lot
    2. Whenever a new shipment of test kits is received
    3. If the temperature of the test kit storage area falls outside of the 2-27ºC (35-80ºF)
    4. If the temperature of the testing area falls outside of 15-37ºC (59-99ºF)
    5. At periodic intervals as dictated by the user facility
    6. Each new operator prior to performing testing on patient specimens

b. INSTI HIV-1 controls should be run under the following circumstances:
    1. For new INSTI operator verification prior to performing testing on patient specimens
    2. When switching to a new lot number of INSTI test kits
    3. Whenever a new shipment of kits is received
    4. When the temperature during storage of the kit falls outside of 15-30ºC (59-86ºF)
    5. When the temperature of the test area falls outside of 15-30ºC (59-86ºF)
    6. At regular intervals as determined by the user facility

c. ChemBIO DPP controls should be run under the following circumstances:
    1. Each new operator prior to performing tests on patient specimens
    2. When opening a new test kit lot
    3. Whenever a new shipment of test kits are received
    4. If the temperature of the test storage area falls outside of 2 to 30ºC (36-86ºF)
    5. If the temperature of the testing area falls outside of 18-30ºC (64-86ºF)
    6. At periodic intervals as indicated by the user facility

For all tests: if the test result for either the negative control or the HIV-1 positive control or the HIV-2 positive control is not as expected, the test should be repeated using a new test device, developer solution vial, and control specimen.

If you are unable to obtain a valid test result upon repeat testing, contact the following:

Chembio Diagnostic Systems Customer Service: 1-800-327-3635
INSTI Biolytical Laboratories Technical Support: 1-866-674-6784
Orasure Technologies, Inc. Customer Service: 1-800-869-3538

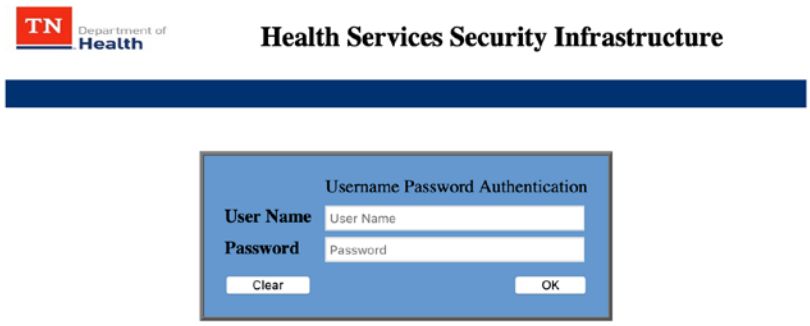
Reporting Requirements for HIV Testing Results

Report reactive (i.e. positive) results to the local health department immediately.[1] The **PH-1600 Reporting Form** (Appendix D) and **PH-1600 Supplement for Reporting New HIV Infections via Rapid/Rapid HIV Tests** (Appendix A) may be securely faxed or emailed directly to the local or regional health office at https://www.tn.gov/health/health-program areas/localdepartments.html.

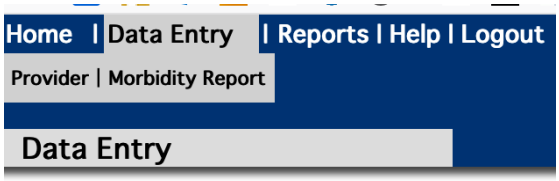
Within 72 hours of a positive HIV test result, notify TDH via the National Electronic Disease Surveillance System Base System (NBS). Instructions on reporting to TDH are outlined below.

To report online:

1. Request an NBS account at: https://redcap.health.tn.gov/redcap/surveys/?s=8L7CMWHN4M or via email at CEDS.Informatics@tn.gov.
2. Log into NBS using the following link: https://hssi.tn.gov/auth/login.



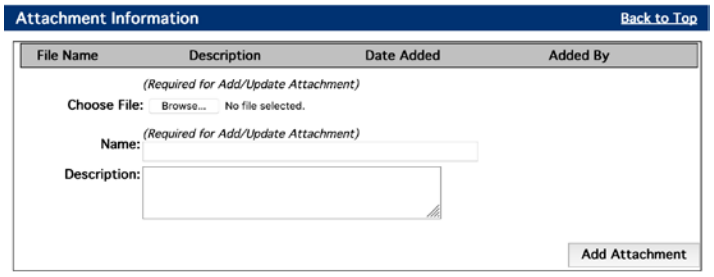
3. Select “NBS Production” followed by “Data Entry” and “Morbidity Report” on the NBS Production Dashboard. This will enable you to directly input patient information.



4. Enter patient demographics on the “Patient” tab, and additional information on the “Report Information” tab.
5. Do not enter information in the lab or treatment information boxes.
6. Upload **PH-1600 Supplement for Reporting New HIV Infections via Rapid/Rapid HIV Tests** (Appendix A) using the ‘Attachment Information’ section.

[1] Per State of Tennessee statute, T.C.A. 68-10-101.

7. Upload **EvaluationWeb Positive Test Template** (Appendix B) using the 'Attachment Information' section.



To report via fax:

Only if the online option is not available, the **PH-1600 Reporting Form** (Appendix D) may be securely faxed or emailed directly to the Communicable and Environmental Diseases and Emergency Preparedness (CEDEP) Division at the Tennessee Department of Health (TDH) at (615) 741-3857.

1. Mark the lab report section on the PH-1600 Form as 'Report Unavailable.'
2. Fax the **PH-1600 Reporting Form** (Appendix D), **PH-1600 Supplement for Reporting New HIV Infections via Rapid/Rapid HIV Tests** (Appendix A), and **EvaluationWeb Positive Test Template** (Appendix B).

Report		
	Disease/Event:	**Date of Report:** ___/____/_____
	Reporter Name:	**Phone:** ( )
	Lab Report: ☐ Attached ☐ Not Tested ☐ Report Unavailable	

Note: with patient permission, the **PH-1600 Supplement for Reporting New HIV Infections via Rapid/Rapid HIV Tests** can be sent to providers to communicate that this diagnostic method can be used to identify and confirm new HIV cases, per CDC HIV case definition.

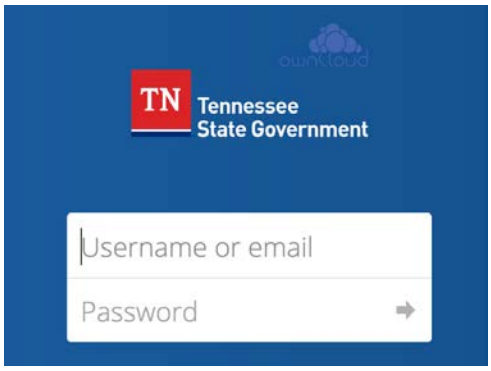
Required Monthly Reporting:

Community based organizations are required to submit monthly testing reports to Central Office.

The **All HIV Testing Spreadsheet** (Appendix C) provided by Central Office is intended to document all tests completed during the month, and should be submitted by the fifteenth (15th) day of the following month via TNcloud. These reports should contain:

a. Number of valid tests conducted
b. Number of HIV positive tests identified, including:
    1. Number of persons who test positive who receive their test results
    2. Number of persons who previously tested positive for HIV infection

Each CBO will be provided a unique link and password for TNcloud, a secure online method to upload this document electronically rather than mailing them. The TNcloud log-in site appears as follows:



Frequently Asked Questions: HIV rapid testing and the double rapid algorithm

Can the rapid tests be stored in a refrigerator?

- Yes, but you have to bring them to room temperature before testing. Use could result in a discrepant result if the tests are utilized before "thawing."

For the controls, which expiration date is the one we record? The date on the shipping package or the date on the controls?

- Neither, the controls expire eight weeks after the first use. So if you run controls on the 1st of January, they expire on the 26th of February. For administrative purposes, record the date on the control package.

Can a child under the age of 13 be tested with TDH-provided test kits?

- The OraQuick, INSTI, and ChemBio DPP are FDA approved for individuals aged 13 and older. However, some sites use the test in a pediatric setting; in these settings, the test must be validated for use in the facility.

I've heard that HIV antibodies or virus can't be transmitted in someone's saliva. If that's true, why do you test saliva when using an oral swab?

- The sample tested isn't saliva, its mucosa transudate which is good source of antibodies.

Why are we moving away from oral fluid testing to finger stick based testing?

- Finger stick samples are more sensitive than oral fluid (99.6% vs. 99.9%). Oral fluid tests have also been shown to detect HIV antibodies up to 30 days later than blood-based samples.
- The CDC has recommended for years that Tennessee move away from oral fluid testing.

If we draw blood for STI testing (e.g., syphilis), can we draw the blood from the vial to use for the INSTI test (50µl) or the OraQuick test (5µl), or do we still have to perform a finger stick?

- Yes, you can draw blood from the vial. Note, for the INSTI a calibrated 50 microliter laboratory pipette should be used.

What are the expiration dates for both the OraQuick, INSTI, and ChemBio tests?

- Oraquick – two years from date of manufacture.
- INSTI – 18 months from date of manufacture.
- ChemBio – 24 months from date of manufacture.

Why do we recommend the use of OraQuick as the screening test for batch testing? Why not use the INSTI as the screening test since it's so much faster?

- In a non-clinical outreach setting in which you are testing more than one client at a time, screening with INSTI can be more difficult to manage because of the fast read time (1-5 minutes). OraQuick allows the user to "batch" the tests (test more than one client at a time). The amount of blood required for the INSTI is another factor to consider (50µl for INSTI vs. 5µl for OraQuick). However, in other settings, the INSTI may be considered a more appropriate or convenient test (syringe services programs, clinical setting). If you have questions or seek additional guidance on which test to use as the screening test, please discuss with the TDH HIV Prevention Program Director and TDH HIV Testing Program Director.

What is a "false positive?" What might cause a "false positive?"

- A false positive occurs when the screening test returns a "preliminary reactive" result and the confirmatory result is negative.
- Several factors may cause a false positive:
  - With the oral swab OraQuick, over-collection of the oral sample may trigger a false positive.
  - Administrative factors such as storage area spikes over the recommended temperature or using expired tests.
  - Biological factors such as multiple pregnancies, infection with mononucleosis or any condition that may affect the client's immune system.

What should we do in the case of a false positive?

- Run controls.
- Re-test: ensure that the client understands that there is something wrong with the test itself, not the client.
- Report result to the TDH HIV Testing Director.

A client comes in for testing and self-reports as have never tested for HIV or never received a positive test result. However, after conducting the screening test, the client receives a preliminary reactive test result and then discloses that they in fact knew that they were HIV positive and needed a test for linkage to care or other personal reasons. What are our next steps? Should we run a confirmatory test? Should we report the client in NBS?

- Yes, run a confirmatory test; per CDC, two different tests are required to meet HIV case definition, which is then documented on the PH1600 Supplemental and serves as the lab report.
- Yes, report the client in NBS per the reporting requirements for positive HIV test results.
- Report the client as a "previous positive"

As an organization, we're interested in offering HIV testing. How do I apply for TDH HIV test kits?

- Please contact Kimberly Truss, TDH HIV Prevention Director (615-532-5744; Kimberly.truss@tn.gov), for more information.

References

1. Peters PJ, Westheimer E, Cohen S, et al. Screening Yield of HIV Antigen/Antibody Combination and Pooled HIV RNA Testing for Acute HIV Infection in a High-Prevalence Population. JAMA 2016;315:682-90.

2. Jaspard M, Le Moal G, Saberan-Roncato M, et al. Finger-stick whole blood HIV-1/-2 home-use tests are more sensitive than oral fluid-based in-home HIV tests. PLoS One 2014;9:e101148.

3. Curlin ME, Gvetadze R, Leelawiwat W, et al. Analysis of False-Negative Human Immunodeficiency Virus Rapid Tests Performed on Oral Fluid in 3 International Clinical Research Studies. Clin Infect Dis 2017;64:1663-9.

4. U.S. Centers for Disease Control and Prevention DoHAP, Capacity Building Branch. Implementing HIV Testing in Nonclinical Settings: A Guide for HIV Testing Providers. 2016.

List of Appendices

PH-1600 Supplement for Reporting New HIV Infections via Rapid/Rapid HIV Tests

INSTRUCTIONS

This form is to be completed by Community Based Organizations (CBOs) using Tennessee Department of Health (TDH)-provided rapid HIV test kits. Please complete this form for all positive tests* and submit with PH-1600 (TDH Case Report Form). Submit the PH-1600 form online here (https://is.gd/TNReportableDiseases) and attach this supplement to the online form under 'Upload additional documents'.

You may also choose to provide a copy of this form to your client for provider referral.

*Per CDC's revised surveillance case definition for HIV infection (2014), criteria for confirmed cases include a multi-test algorithm consisting of:
— A positive (reactive) result from an initial HIV antibody or combination antigen/antibody test, and
— An accompanying or subsequent positive result from a supplemental HIV test different from the initial test.

For more information: https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm

AGENCY INFORMATION

Agency name: _____

Person completing form:

Name: _____ Signature: _____

Phone number: (_____) _____ Date: _____

PATIENT INFORMATION

First Name: _____ Last Name: _____

DOB (MM/DD/YY): ____/____/____ Social Security Number: _____ _____ _____

Sex at birth: □ Male □ Female Current gender identity: □ Male □ Female □ Transgender

Transmission risk (check all that apply):

Male
□ Male-to-male sexual contact
□ Heterosexual contact
□ Injection drug use (IDU)
□ Other_____

Female
□ Heterosexual contact
□ Injection drug use (IDU)
□ Other_____

Transgender
□ Any sexual contact
□ Injection drug use (IDU)
□ Other_____

TEST #1

☐ OraQuick Advance Rapid HIV test
☐ ChemBIO DPP oral fluid
☐ ChemBIO DPP finger stick
☐ INSTI finger stick

Result:
☐ Reactive (positive)
☐ Non-Reactive
☐ Indeterminate/invalid

Test date (MM/DD/YY): ___/___/___

TEST #2

☐ OraQuick Advance Rapid HIV test
☐ ChemBIO DPP oral fluid
☐ ChemBIO DPP finger stick
☐ INSTI finger stick

Result:
☐ Reactive (positive)
☐ Non-Reactive
☐ Indeterminate/invalid

Test date (MM/DD/YY): ___/___/___

TEST #3

☐ OraQuick Advance Rapid HIV test
☐ ChemBIO DPP oral fluid
☐ ChemBIO DPP finger stick
☐ INSTI finger stick

Result:
☐ Reactive (positive)
☐ Non-Reactive
☐ Indeterminate/invalid

Test date (MM/DD/YY): ____/____/____

REFERRALS

□ Local health department/DIS Health department location:_____ Date of referral (MM/DD/YY): __/__/_

□ HIV Care Provider Provider name:_____ Date of referral (MM/DD/YY): __/__/_

□ STI testing performed by CBO

□ STI testing recommended

□ Other: _____

Client Name:_____

CLIENT SIGNATURE: _____ **Date:** _____

EvaluationWeb® 2018 HIV Test Template

Complete section 1-5 for ALL persons

Form ID	First Name	Last Name

1 | Agency and Client Information

Session Date (mm/dd/yyyy)

Program Announcement ○PS18-1802 ○SSP

Agency Name

Site Name

Local Client ID *(optional)*

Client Date of Birth

Client County

Client State

Client ZIP Code

Client Ethnicity
○Hispanic or Latino ○Don't know
○Not Hispanic or Latino ○Declined

Client Race *(select all that apply)*
☐ American Indian/Alaska Native ☐ White
☐ Asian ☐ Not Specified
☐ Black/African American ☐ Declined to Answer
☐ Native Hawaiian/Pacific Islander ☐ Don't Know

Client Assigned Sex at Birth
○Male ○Female ○Declined to Answer

Client Current Gender Identity
○Male ○Transgender Unspecified
○Female ○Declined to Answer
○Transgender Male to Female ○Another Gender
○Transgender Female to Male

Has the client ever previously been tested for HIV?
○No ○Yes ○Don't Know

2 | PrEP Awareness and Use

Has the client ever heard of PrEP (Pre-Exposure Prophylaxis)?
○No ○Yes

Has the Client used PrEP anytime in the last 12 months?
○No ○Yes

Is the client currently taking daily PrEP medication?
○No ○Yes

3 | Priority Populations

In the past **five** years, has the client

had sex with a ***male?***	○No	○Yes
had Sex with a ***female?***	○No	○Yes
had sex with a ***transgender person?***	○No	○Yes
injected drugs or substances?	○No	○Yes

4 | HIV Final Test Information

HIV Test Election
○Confidential ○Test Not Done

Test Type *(select one only)*
○CLIA-waived point-of-care **(POC) Rapid Test(s)** ○Laboratory-based Test

POC Rapid Test Result	Laboratory-based Tests
○Preliminary Positive	○HIV-1 Positive
○Positive	○HIV-1 Positive, possibly acute
○Negative	○HIV-2 Positive
○Discordant	○HIV Positive, undifferentiated
○Invalid	○HIV-1 Negative, HIV-2 Inconclusive
	○HIV-1 Negative
	○HIV Negative
	○Inconclusive, further testing needed

Result provided to client?
○No ○Yes ○Yes, client obtained the results from another agency

5 | Additional Tests

Was the client tested for co-infections?
○**No** (*finished with section 5)* ○**Yes** (*complete below*)

Syphilis	Gonorrhea	Chlamydia	Hepatitis C
○No ○Yes	○No ○Yes	○No ○Yes	○No ○Yes
If Yes, Test Result			
○ Newly identified infection ○ Not infected ○ Not known	○Positive ○Negative ○Not known	○Positive ○Negative ○Not known	○Positive ○Negative ○Not known

Complete Sections 6-8 for persons testing NEGATIVE for HIV **Sections 9-10 for POSITIVE**

Form ID	First Name	Last Name

6 | Risk Assessment

Is the client at risk for HIV infection?

○No ○Yes ○Risk Not Known

7 | PrEP Eligibility and Referral

Was the client screened for PrEP eligibility?

○No ○Yes ○Not Assessed

Is the client eligible for PrEP referral?

○No ○Yes, by CDC criteria ○Yes, by local criteria

Was the client given a referral to a PrEP provider?

○No ○Yes

Was the client provided navigation or linkage services to assist with linkage to a PrEP provider?

○No ○Yes

8 | Essential Support Services

	Screened for need	Need determined	Provided or referred
Health benefits navigation and enrollment	○No ○Yes	○No ○Yes	○No ○Yes
Evidence-based risk reduction intervention	○No ○Yes	○No ○Yes	○No ○Yes
Behavioral health services	○No ○Yes	○No ○Yes	○No ○Yes
Social services	○No ○Yes	○No ○Yes	○No ○Yes

9 | Essential Support Services (Positive only)

	Screened for need	Need determined	Provided or referred
Navigation services for linkage to HIV medical care	○ No ○Yes	○ No ○Yes	○ No ○Yes
Linkage services to HIV medical care	○ No ○Yes	○ No ○Yes	○ No ○Yes
Medication adherence support	○ No ○Yes	○ No ○Yes	○ No ○Yes

10 | Positive Test Result

Did the client attend an HIV medical care appointment after this positive test?

○Yes, confirmed ○No

○Yes, client/patient self-report ○Don't Know

→ Date attended

Has the client ever had a positive HIV test?

○No ○Yes ○Don't Know

→ Date of first positive HIV test

Was the client provided with individualized behavioral risk-reduction counseling?

○No ○Yes

Was the client's contact information provided to the health department for Partner Services?

○No ○Yes

What was the client's most severe housing status in the last 12 months?

○Literally homeless ○Not asked

○Unstably housed or at risk of losing housing ○Declined to Answer

○Don't know

○Stably housed

If the client is female, is she pregnant?

○No ○Declined to Answer

○Yes ○Don't know

→ Is the client in prenatal care?

○No ○Not asked ○Don't know

○Yes ○Declined to Answer

→ Was the client screened for need of perinatal HIV service coordination?

○No ○Yes

→ Does the client need perinatal HIV service coordination?

○No ○Yes

→ Was the client referred for perinatal HIV service coordination?

○No ○Yes

Appendix C: All HIV Testing Spreadsheet

TDH Monthly Data Report - HIV Testing

{AGENCY NAME}					
Month	**# total tests performed**	**# positive**	**% positive**	**# previous diagnoses (self-report)**	**# new diagnoses**
Jan-19					
Feb-19					
Mar-19					
Apr-19					
May-19					
Jun-19					
Jul-19					
Aug-19					
Sep-19					
Oct-19					
Nov-19					
Dec-19					

*new diagnoses = total # positive (column C) - # self reported previous diagnoses (column E)

TN Department of Health

This form may be completed online at https://hssi.tn.gov/auth/login or faxed to the Division of Communicable and Environmental Diseases and Emergency Preparedness (CEDEP) at Tennessee Department of Health (TDH) at (615) 741-3857. To fax directly to the local or regional health office, refer to http://tn.gov/health/topic/localdepartments. For questions, contact CEDEP at (615) 741-7247 or (800) 404-3006. For more specific details, refer to the TDH Reportable Diseases website at https://apps.health.tn.gov/ReportableDiseases.

Directions for Providers:

- ☑ All of the information on this form is required to report, if available. Public Health will follow-up with the reporter for the patient demographics and lab report, if missing.
- ☑ The provider information, patient demographics, and clinical information may be provided on this form, or attached (e.g., patient cover sheet, notifiable diseases report, relevant medical records).
- ☑ Provide the contact information for the provider for Public Health follow-up. If the primary place of work for the provider is a private practice, provide the name, phone, and fax for that facility rather than the hospital.
- ☑ Attach the associated laboratory report to this form.
- ☑ Provide the county of the provider facility or practice to aid in assignment of the case to a public health jurisdiction.
- ☑ *If patient's "Date of Birth" is unavailable, report the patient's age in years. If the patient is < 1 year of age, please mark the box for "Months." If the patient is < 1 month of age, please list "0" and mark the box for "Months."
- ☑ Patient address is used to assign public health jurisdiction for the investigation.
- ☑ [H] Hepatitis symptoms include: fever, malaise, vomiting, fatigue, anorexia, diarrhea, abdominal pain, jaundice, headache, nausea.
- ☑ [T] Reportable tickborne diseases such as Ehrlichiosis/Anaplasmosis, Spotted Fever Rickettsiosis, and Lyme Disease.
- ☑ For a positive interferon-gamma release assay (IGRA) for (latent) Tuberculosis Infection (TBI), attach a copy of the lab result to this form. For a positive tuberculin skin test (TST) for any child or adolescent < 18 years of age, document the TST result in millimeters (mm) of induration in the "Comments" field at right; fax this form directly to the Tennessee Tuberculosis Elimination Program: (615) 253-1370.

Directions for Laboratories:

- ☑ Laboratories should report to Public Health via electronic laboratory reporting (ELR) or a printed laboratory report, rather than by completing this form, unless provider information or patient demographics are missing in the lab report. Then, complete this form only for the missing information and attach the lab report.
- ☑ Laboratories are not required to report information in the Clinical Information section.
- ☑ The information required (if available) for printed lab reports includes:
  (1) Patient demographics (shown on the right, including address)
  (2) Ordering provider and facility name, phone number, address
  (3) Performing laboratory name, phone number, and address
  (4) Reporting facility name, phone number, address
  (5) Date of the laboratory report
  (6) Test performed (may differ from the test ordered)
  (7) Accession number
  (8) Specimen and collection date
  (9) Result (quantitative and qualitative), interpretation, and reference range
- ☑ See the Reportable Diseases website for the ELR requirements.

Report

Disease/Event: | **Date of Report:** ___/____/_____

Reporter Name: | **Phone:** ( )

Lab Report: ☐ Attached ☐ Not Tested ☐ Report Unavailable

Provider

Provider Name:

Primary Facility/Practice:

Phone: ( ) | **Fax:** ( ) | **County:**

Patient Demographics

Patient Name:

Date of Birth: ____/____/_____ (mm/dd/yyyy)
***Age:** _____ ☐ Months

Race:
☐ American Indian/ Alaska Native
☐ Asian
☐ Black/ African American
☐ Hawaiian/ Other Pacific Islander
☐ White
☐ Unknown

Sex:
☐ Male
☐ Female
☐ Unknown

Ethnicity:
☐ Hispanic
☐ Not Hispanic
☐ Unknown

Street Address:

City: | **State:**

County: | **Zip Code:**

Phone: ( ) | **Phone:** ( )

Clinical Information

Illness Onset Date: ____/____/_____ | **Hospitalized?** ☐ Yes ☐ No ☐ Unknown

Hospital Name:

Admission Date: ____/____/_____ | **Discharge Date:** ____/____/_____

Pregnant? ☐ Yes ☐ No ☐ Unknown | **Died?** ☐ Yes ☐ No ☐ Unknown

Symptoms?[H] hepatitis cases only ☐ Yes ☐ No ☐ Unknown

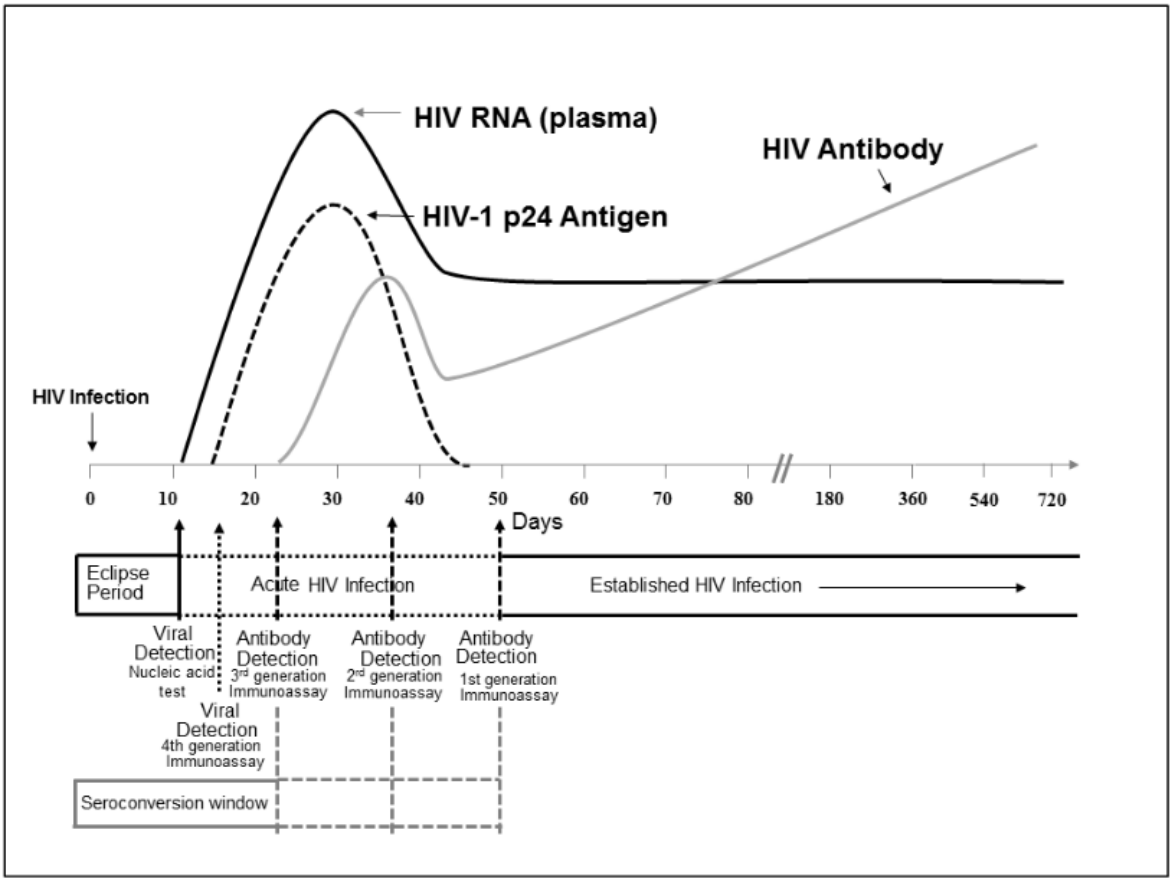
Fever?[T] tickborne diseases only ☐ Yes ☐ No ☐ Unknown

STD Treatment: Date: ____/____/_____
Medications:

Comments:

Reportable Diseases and Events are declared to be communicable and/or dangerous to the public and are to be reported to the local health department by all hospitals, physicians, laboratories, and other persons knowing of or suspecting a case in accordance with the provision of the statutes and regulations governing the control of communicable diseases in Tennessee (T.C.A. §68 Rule 1200-14-01-.02).

Appendix E: Sequence of appearance of laboratory markers for HIV-1 infection



Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. Available at http://dx.doi.org/10.15620/cdc.23447. Published June 27, 2014.
Accessed [May 29, 2019].