

Quality Assurance (QA) Manual for Laboratory Testing in the Non-clinical Setting



Division of Disease Prevention
Office of Epidemiology

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Revision History

Version	Date	Description of Changes
1	6/9/16	Original document
1.1	9/7/16	Added Conflict of Interest statement
2	8/14/17	Laboratory change from DCLS to LabCorp
3	5/23/18	Added and clarified clinician role section; added Attachment H
3.1	11/15/18	Added all STD testing paid for by OEPI
4	7/17/20	Updated to reflect Recommendations for Quality STD Clinical Services
5	3/8/22	Document review and revision conducted by staff from SPS, HHP, and HCS; Viral Hepatitis Section removed and link added to existing Viral Hepatitis QA Manual; HIV testing algorithm updated; rapid syphilis testing guidance added

Abbreviations

CDC	Centers for Disease Control and Prevention
CT	Chlamydia
DDP	Division of Disease Prevention
EIA	Enzyme Immunoassay
FDA	Food and Drug Administration
GC	Gonorrhea
HAV	Viral Hepatitis A
HBV	Viral Hepatitis B
HCV	Viral Hepatitis C
HIV	Human Immunodeficiency Virus
LHD	Local Health Department
MSM	Men who have sex with men
NAAT	Nucleic Acid Amplification Test
OEpi	Office of Epidemiology
STD QCS	Recommendations for Providing Quality Sexually Transmitted Diseases Clinical Services, 2020
TB	Tuberculosis
VDH	Virginia Department of Health

Purpose

This manual provides information for personnel within non-clinical organizations responsible for the collection and transport of specimens for reportable conditions. Specimen analysis, outcome, diagnosis, and therapeutic decisions are highly sensitive to deviations in collection method, container, transportation, and storage; therefore, all personnel in contact with specimens must ensure the proper collection, preparation, and transportation of specimens to the laboratory.

Non-clinical organizations holding an active agreement with VDH to fund laboratory testing for sexually transmitted diseases (STD), HIV, and/or viral hepatitis must adhere to all program requirements outlined in their memorandum of understanding (MOU) and this quality assurance manual.

Implementing Laboratory Testing Checklist

Non-clinical organizations who are interested in establishing a new testing agreement with the Division of Disease Prevention (DDP) at Virginia Department of Health (VDH) are generally expected to start with rapid HIV testing. Following six months of rapid HIV testing, the VDH contract monitor will evaluate the agency's implementation of rapid testing to determine whether they may scale up to a conventional laboratory testing agreement. Prior to implementing conventional testing, non-clinical organizations must develop and share with their VDH contract monitor internal procedures for notifying clients of results, referral for clinical evaluation and treatment, encouraging partner notification, and providing STD and HIV prevention counseling. Additionally, each location must train employees and have procedures for following blood borne pathogens standards, disposal of biomedical waste, infection control plans, and blood and body fluid exposure.

Please see [Attachment K](#) for a list of requirements for non-clinical organizations to implement testing.

Conflict of Interest

Non-clinical organizations may not provide testing to its own staff. Non-clinical organizations must assist their staff in locating another test site for services. Additionally, if the client to be tested is a friend or associate of the test counselor, and either the client or the test counselor is uncomfortable with the situation, the test counselor shall immediately locate another trained staff person to provide services to the client. The counselor should verify that the client is comfortable with the test counselor performing the counseling and viewing their test result.

Providing Quality STD Services

In January 2020, CDC released [Recommendations for Providing Quality Sexually Transmitted Diseases Clinical Services, 2020 \(STD QCS\)](#). The recommendations include the following sections: 1) sexual history and physical examination, 2) prevention, 3) screening, 4) partner services, 5) evaluation of STD-related conditions, 6) laboratory, 7) treatment, and 8) referral to a specialist for complex STD or STD-related conditions. The sections that follow outline the recommendations as applicable to non-clinical organizations performing laboratory testing through agreements with VDH. Non-clinical organizations should also review CDC's recommendations for sections of this guidance that apply to testing in a non-clinical setting, and to understand the components of quality STD services in a clinical setting.

Non-clinical organizations providing services to transgender persons should have knowledge of their clients' current anatomy and sexual practices before counseling them about STD and HIV prevention. Additional information about caring for transgender persons is available [here](#).

Sexual History and Physical Examination

Non-clinical organization staff should obtain a thorough sexual history. A complete sexual history includes the five P's: **P**artners, **P**ractices, **P**rotection, **P**ast history of STDs, and **P**revention of pregnancy. Ascertaining specific sexual activities and recent partners during the sexual health history will guide counseling messages. A resource for taking a complete sexual health history is available [here](#).

While physical examination is part of the recommended quality STD services, it is only performed by a licensed clinician (i.e. physician, nurse practitioner, physician's assistant), and should not be completed in non-clinical settings. Clients who report symptoms suggestive of a STD (e.g. genital discharge; painful/burning urination;

painless sores on the genitals, anus, mouth; rashes; etc) must immediately receive a referral to the local health department or healthcare provider for a thorough medical evaluation and appropriate treatment.

Prevention Counseling

The primary service in the non-clinical setting for the prevention of HIV and STDs is prevention counseling. Prevention counseling varies in methods, scope, and time and is used to educate clients on changes that would reduce the risk for acquiring and transmitting HIV and STDs.

Screening

Because STDs, HIV, and viral hepatitis can be asymptomatic, laboratory testing is the only method to diagnose these infections. The availability of screening tests is key for identifying gonorrhea, chlamydia, syphilis, hepatitis B, hepatitis C, and HIV. Client-reported exposure, regardless of condom use, should inform screening. A table summarizing screening recommendations for women, pregnant women, men, men who have sex with men (MSM), and persons with HIV is available [here](#).

Evaluation of STD-Related Conditions

STD-related conditions warrant prompt evaluation of signs and symptoms to make an accurate diagnosis and provide timely empiric treatment to prevent complications and onward transmission. Clients who report symptoms that are suggestive of an STD (e.g. genital discharge; painful/burning urination; painless sores on the genitals, anus, mouth; rashes; etc) must immediately receive a referral to the local health department or healthcare provider for a thorough medical evaluation and appropriate treatment.

Partner Services

Partner services consist of various strategies with differing levels of time and effort to enable persons who are exposed to an STD to be identified, tested, and treated. These strategies include 1) guidance regarding notification and care of sex partners, 2) interactive counseling for partner notification, 3) expedited partner therapy (EPT), and 4) health department disease intervention specialist (DIS) elicitation of sex partner information to identify those who might be infected. Non-clinical organizations interested in providing partner services to their clients should contact their contract administrator for more information.

Ordering Clinician

VDH contracts with a commercial laboratory (currently LabCorp) to conduct laboratory testing for chlamydia, gonorrhea, syphilis, HIV, viral hepatitis B, viral hepatitis C, as well as other conditions. Only ordering clinicians (physician, nurse practitioner, physician's assistant) are authorized to submit specimens to commercial laboratories for testing.

The ordering clinician takes responsibility (and may designate additional responsible parties) for receiving and interpreting all test results and ensuring clients with positive/abnormal results receive appropriate follow up care. LabCorp requires the clinician's full name and National Provider Identifier (NPI) to create an account. If an ordering clinician provides a standing order for staff of the non-clinical organization to submit specimens, the ordering clinician should specify expectations for staff regarding who to test, how clients will be notified of results, and how clients with abnormal (positive) results will be treated or referred for treatment. This must be

outlined in a memorandum of understanding or agreement (MOU/MOA) between the ordering clinician and the non-clinical organization.

Non-clinical organizations interested in a testing agreement with VDH are responsible for identifying an eligible medical provider who will serve as their ordering clinician and providing VDH with the clinician's information to create a LabCorp account.

Results

Negative results will be returned via LabCorp's secure online portal, LabCorp Link (previously Beacon), within 2-3 days to the ordering clinician. Reactive or abnormal results may require an additional 1-2 days before they are returned. The ordering clinician or their designee will access Link via a secure login. Unless the non-clinical organization has an established, written agreement with a local health department, the non-clinical organization who performed the test is responsible for contacting clients who have a positive test result and arranging a treatment plan for the client. The resulting report contains Protected Health Information (PHI) and cannot be shared via unencrypted email. More information about using LabCorp Link to access test results can be found [here](#). See [Attachment J](#) for sample test results.

Information Security

Non-clinical organizations are responsible for ensuring all client information and results are secure, [HIPAA compliant](#), and maintained and disposed of according to the Library of Virginia [Records Retention guidelines](#).

Physical Requirements for Specimen Collection

Non-clinical organizations must have all necessary personnel, supplies, and facilities to provide for specimen collection and storage until the specimen is ready for transportation. Requirements for specimen collection in non-clinical settings include the following:

1. Provisions for client privacy while they provide a urine or swab specimen. The following facilities provide adequate privacy for collections:
 - An enclosed stall in a multi-stall restroom
 - A single person restroom
 - A partitioned area that allows for individual privacy
2. A means for washing hands
3. A suitable clean surface for the collector to use as a work area
4. A secure temporary storage area for maintaining specimens until transferred for collection by the applicable laboratory. Procedures must detail the secure handling and storage of specimens. Specimens must NOT be exposed to temperatures outside of the range listed by the laboratory, as this may affect the test results.
5. Procedures or restrictions to prevent:
 - Unauthorized access to the collection materials/supplies
 - Unauthorized access to collection site records

Supply Orders

Contact your LabCorp representative to order additional specimen transport tubes, swab kits, and lab requisition forms. Specimen collection kits may be requested via the LabCorp order form provided to your site ([Attachment A](#)) or through the [LabCorp Link](#) portal.

Ordering Tests

Tests may be ordered using a physical copy of the LabCorp requisition form or using the online ordering system through LabCorp Link. Either method is acceptable. Please note that charges for any test not listed in the active MOU will be transferred back to the non-clinical organization for payment to LabCorp.

[Attachment I](#) includes a guide to completing the hard copy requisition form. The top copy is sent to the lab, and the agency maintains the duplicate copy in the client record.

Labeling Specimens

- Affix a sticker label to the specimen collection tube with the following information:
 - Name (must be an exact match to the lab requisition);
 - Date of birth;
 - Date of specimen collection;
 - Specimen type;
 - LabCorp test number; and
 - Additional client identifier, if available.
- Do not cover the expiration date on the specimen collection tube with the sticker label.
- See [Attachment H](#) for additional information.

Collection of the Blood Specimen

All blood draws must be performed by a trained phlebotomist affiliated with or contracted by the organization conducting the test. Unless specified in the agreement with VDH, VDH funding does not support the additional cost for blood draws or administrative expenses; therefore, if clients are referred to a LabCorp drawing location, the cost of the blood draw will not be covered by VDH and will be transferred to the ordering agency's LabCorp account for payment.

Self-collected Specimens

Self-collection, particularly for rectal specimens, increases the uptake of testing and offers high acceptance among MSM. Self-collection can eliminate access barriers such as stigma, shame, negative interactions with service providers, and concerns about privacy and confidentiality. Published clinical research indicates self-collected specimens have equivalent or better detection rates for rectal, vaginal, and pharyngeal CT/GC compared to clinician collection^{1,2}. It is important when collecting specimens to avoid cross contamination, as cross contamination can yield a false positive result. **Only trained and licensed clinicians may collect specimens from a client. If a trained and licensed clinician is not on duty at the time of collection, the client being tested should collect his or her own specimen.**

Specimen Transport and Storage

As soon as the specimen is collected and the container is appropriately labeled, the specimen container must be placed in an individual biohazard specimen bag. Ensure the lid is tightened on the transport tube to

¹ van der Helm JJ, Hoebe CJ, van Rooijen MS, et al. High performance and acceptability of self-collected rectal swabs for diagnosis of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in men who have sex with men and women. *Sex Transm Dis*. 2009; 36:493-497.

² Lunny C, Taylor D, Hoang L, et al. Self-collected versus clinician-collected sampling for chlamydia and gonorrhea screening: A systematic review and meta-analysis. *PLoS ONE*. 2015; 10:1-23.

prevent spillage. All fields on the paper LabCorp requisition form must be completed (including race/ethnicity) and placed in the side pouch separate from the specimen container. **Do not place the requisition form in the same part of the individual biohazard specimen bag as the specimen.**

Courier

Daily LabCorp courier services are included in the price of the test. However, if your location does not have any specimens, you can call your LabCorp representative to cancel the courier pickup. Have your account number available, as LabCorp may ask for it during the scheduling process.

If your site has a LabCorp pick-up box, you must ensure the specimens do not fall outside of the acceptable temperature range due to extreme weather.

Laboratory Testing

Laboratory testing is a critical component of STD QCS for non-clinical organizations. While the recommendations include several laboratory tests that could and should be a part of STD services, agreements with VDH include laboratory tests to detect the following reportable infections:

- Chlamydia and Gonorrhea
- Syphilis
- HIV
- Hepatitis B
- Hepatitis C

The following pages will discuss in detail the requirements for performing these tests.

Chlamydia/Gonorrhea Testing

Nucleic acid amplification testing (NAAT) represents a significant advancement in chlamydia/gonorrhea (CT/GC) testing. Previously, a culture, a test with comparatively poor sensitivity, was required to diagnose. On May 23, 2019, the FDA cleared Hologic's Aptima Combo 2 Assay and the Cepheid Xpert CT/NG for extragenital NAA testing³.

Specimens for screening may be obtained for any, or all, of the following anatomical sites: genital (urine, vaginal, endocervical, male urethral), pharyngeal, and/or rectal.

Testing to determine re-exposure:

- Due to the high sensitivity of the tests, a period of four weeks must elapse between a positive screening test or treatment for CT/GC and a subsequent test for re-exposure, regardless of the anatomical site⁴.



³ FDA Clears First Diagnostic Tests for Extragenital Testing for Chlamydia and Gonorrhea.

<https://www.fda.gov/news-events/press-announcements/fda-clears-first-diagnostic-tests-extragenital-testing-chlamydia-and-gonorrhea>

⁴ 2021 Sexually Transmitted Infections Treatment Guidelines. CDC MMWR Vol. 70, No. 4, Page 67.

<https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf>

- Individuals who have been treated for CT and/or GC should be retested three months after treatment regardless of whether they believe their sex partners were treated. Scheduling the follow-up visit at the time of treatment is encouraged⁵.

Urine Specimen Collection

Research evidence indicates the performance of male first catch urine samples is equivalent to, and in some situations superior to, urethral swabs. In men, the use of urine samples is highly acceptable and may improve the likelihood of uptake of routine screening.

LabCorp test numbers (at the time of developing this manual):

- **183194** **CT/GC, Urine**

Eligibility

Clients who provide urine samples for a CT/GC screening must:

- Have not urinated in the past hour; and
- Have not had a positive lab test or been treated for CT or GC in the past 4 weeks.

Appropriate specimen collection for transgender persons should be guided by anatomy and preference of the client. Urine specimens are acceptable, but may miss up to 10% of CT/GC infections compared to vaginal swabs.

Any female who has had a hysterectomy should collect a urine specimen. Without a uterus/cervix, there will not be sloughed endocervical cells in the vaginal vault for adequate testing.

Urine Specimen Collection Procedures and Handling

The laboratory will provide specimen collection kits, which include disposable transfer pipette and sterile specimen transport tubes. Urine collection cups do not come with the kit, and must be purchased independently; collection cups do not have to be sterile. The following procedures must be carefully followed to ensure the proper collection and handling of a urine specimen:

- Direct the client to provide first-catch urine (20 to 30 mL of the initial urine stream) into a urine collection cup free of any preservatives.
 - First-catch urine is concentrated, which results in a higher likelihood of pathogen identification in an infected individual, thus yielding the best test sensitivity. Collection of a large volume of urine can reduce the test sensitivity.
 - Female clients should not cleanse the labial area prior to providing a urine specimen.
- While the urine specimen in the collection cup can be stored at 2°C to 30°C for up to 24 hours, it should be transferred to the urine specimen kit **as soon as possible**.
- Remove the cap and transfer 2 mL of urine using the disposable pipette provided in the test kit from the collection cup into the urine specimen transport tube. The fluid level must be between the black fill lines on the urine specimen transport tube label (Figure 1).
- Do not pour the clear liquid out prior to transferring the urine sample from the cup to the tube. The clear liquid is a preservative that provides the specimen with more stability for longer storage.

⁵ 2021 Sexually Transmitted Infections Treatment Guidelines. CDC MMWR Vol. 70, No. 4, Pages 67, 75.

<https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf>

- Urine samples must be transferred from the collection cup to the urine specimen transport tube within 24 hours of collection.
- Re-cap the urine specimen transport tube tightly. This processed urine specimen can be kept at room temperature or in the refrigerator.

Figure 1: Urine Specimen Transfer



FIRST CATCH URINE SPECIMEN
(20-30 mL)

TRANSFER URINE TO TRANSPORT TUBE
FOLLOW INSTRUCTIONS FOR HANDLING

FILL IN BETWEEN THE TWO BLACK LINES

Maintain the integrity of the processed urine specimen with proper and secure storage for transportation and handling. Processed urine specimens must be kept at room temperature or refrigerated until courier collection. **Do not freeze processed urine specimens as it compromises the viability of the CT/GC bacteria that may be present.**

Vaginal Specimen Collection

The vaginal swab sample is preferred for females unless they have had a hysterectomy. First catch urine from females can detect up to **10% fewer** infections when compared with vaginal and endocervical swab samples⁶. Please refer to the urine specimen collection section for guidelines on urine samples.

Appropriate specimen collection for transgender males should be guided by anatomy and preference of the patient. Urine specimens are acceptable, but may miss up to 10% of CT/GC infections compared to vaginal swabs.

LabCorp test numbers (at the time of developing this manual):

- **183194** CT/GC, Vaginal



⁶ Centers for Disease Control and Prevention. Recommendations for the Laboratory-Based Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. *MMWR* March 14, 2014;63:2.

Vaginal Specimen Collection Procedures and Handling

The orange Hologic® Aptima Multitest Swab Specimen Collection Kit (formally Aptima Vaginal Swab Collection Kit) should be used to collect vaginal specimens. Diagrams included in [Attachments F and G](#) of this manual may be posted for client reference. Vaginal specimens may be collected during menstruation.

- Label the specimen collection tube.
- Review the collection process with the client and instruct them to collect the vaginal specimen, put the swab inside the specimen collection tube, align score line with the top edge of the tube, carefully break the swab shaft, seal the tube, and put the sealed tube inside the biohazard specimen bag.
- Visually inspect the swab to assure there is evidence of use and ensure the lid is tight on the specimen collection tube to prevent spillage.
- Place requisition form in the side pouch of the individual biohazard specimen bag separate from the specimen tube to keep it dry.

Extragenital Specimens

Extragenital screening is critically important, particularly among some high-risk populations: **77% of CT and 95% of GC infections are missed** among MSM if screening is only performed at urethral sites⁷. Symptoms of rectal and pharyngeal CT/GC are nonspecific and often silent. In fact, 85% of rectal CT/GC infections are asymptomatic in MSM⁸.

Rectal Specimen Collection

Self-collected specimens increase the uptake of testing among high-risk clients and offer high acceptance among MSM; self-collection can eliminate access barriers such as stigma, shame, negative interactions with service providers, and concerns about privacy and confidentiality. Given adequate instruction, self-collection of a rectal specimen is equivalent to, or better than, clinician collection^{9,10}.

Diagrams included in [Attachments B and C](#) of this manual may be posted for client reference.

LabCorp test numbers (at the time of developing this manual):

- **188672** **CT/GC, Rectal**

Clients who provide a swab sample for rectal CT/GC screening must:

- Have had receptive anal intercourse within the past year, regardless of condom use; and
- Have not had a positive lab test or been treated for CT or GC in the past 4 weeks, regardless of anatomical site.



⁷ Marcus JL, Bernstein KT, Kohn RP, et al. Infections missed by urethral-only screening for chlamydia or gonorrhea detection among men who have sex with men. *Sex Transm Dis.* 2011; 38-922-924.

⁸ Kent CK, Chaw JK, Wong W, et al. Prevalence of rectal, urethral, and pharyngeal chlamydia and gonorrhea detected in 2 clinical settings among men who have sex with men: San Francisco, California, 2003. *Clin Infect Dis.* 2005;41:67-74.

⁹ Sexton ME, Baker JJ, Nakagawa K, et al. How reliable is self-testing for gonorrhea and chlamydia among men who have sex with men? *J Fam Pract.* 2013;62:70-78.

¹⁰ Freeman AH, Bernstein KT, Kohn RP, et al. Swabs for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* pharyngeal infection among men who have sex with men. *Sex Transm Dis.* 2011;38:1036-1039.

Rectal Specimen Collection Procedures and Handling

- The white Hologic® Aptima Unisex Swab collection kit with blue shaft swab should be used to collect rectal specimens.
- Label the specimen collection tube.
- Review the collection process with the client and instruct them to collect the rectal specimen, put the swab inside the specimen collection tube, align score line with the top edge of the tube, carefully break the swab shaft, seal the tube, and put the sealed tube inside the biohazard specimen bag.
- Visually inspect the swab to assure there is evidence of use, ensure the swab is not contaminated with significant fecal matter, and ensure the lid is tight on the specimen collection tube to prevent spillage.
- Complete all fields of the lab requisition form (including race/ethnicity) and place in the side pouch of the individual biohazard specimen bag separate from the specimen tube to keep it dry.

Pharyngeal Specimen Collection

Given adequate instruction, self-collection of a pharyngeal specimen is equivalent to, or better than, clinician collection.^{11,12} The swab should make contact with the key areas of the throat: uvula and left/right posterior walls and tonsils.¹³ Diagrams included in [Attachments D and E](#) of this manual may be posted for client reference.

LabCorp test numbers (at the time of developing this manual):

- **188698** **CT/GC, Pharyngeal**

Clients who provide a swab sample for pharyngeal CT/GC screening must:

- Have had receptive oral intercourse within the past year, regardless of condom use; and
- Have not had a positive lab test or been treated for CT or GC in the past 4 weeks, regardless of anatomical site.

Pharyngeal Collection Procedures and Handling

- The white Hologic® Aptima Unisex Swab collection kit with blue shaft swab should be used to collect pharyngeal specimens.
- Label the specimen collection tube.
- Review the collection process with the client and instruct them to collect the specimen, put the swab inside the specimen collection tube, align score line with the top edge of the tube, carefully break the swab shaft, seal the tube, and put the sealed tube inside the biohazard specimen bag.
- The swab should make contact with the key areas of the throat: uvula and left/right posterior walls and tonsils.¹⁴
- Visually inspect the swab to assure there is evidence of use and that the lid is tight on the specimen collection tube to prevent spillage.



¹¹ Sexton ME, Baker JJ, Nakagawa K, et al. How reliable is self-testing for gonorrhea and chlamydia among men who have sex with men? *J Fam Pract.* 2013;62:70-78.

¹² Freeman AH, Bernstein KT, Kohn RP, et al. Swabs for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* pharyngeal infection among men who have sex with men. *Sex Transm Dis.* 2011;38:1036-1039.

¹³ San Francisco City Clinic. Client instructions for self-collected specimens: pharyngeal and rectal. Available at: <http://www.sfcityclinic.org/providers>. Accessed December 15, 2011.

¹⁴ San Francisco City Clinic. Client instructions for self-collected specimens: pharyngeal and rectal. Available at: <http://www.sfcityclinic.org/providers>.

- Complete all fields of the lab requisition form (including race/ethnicity) and place in the side pouch of the individual biohazard specimen bag separate from the specimen tube to keep it dry.

Syphilis Testing

The screening test for syphilis available through LabCorp is the [T. Pallidum Screening Cascade](#), which uses the reverse algorithm sequence screening. The first test that is conducted is a treponemal chemiluminescence immunoassay (CIA). If the CIA is positive, a quantitative rapid plasma reagin (RPR) is conducted. If the RPR is negative, a TrepSure treponemal test is conducted. See [Attachment L](#) for the Syphilis Testing Algorithm. Additional information about the reverse algorithm is available [here](#). Potential reasons for false positive syphilis results are available [here](#).

Individuals who report symptoms consistent with syphilis (e.g. painless sores on genitals, anus, and/or mouth; unusual rashes on the hands and/or feet; etc) must immediately receive a referral to the local health department or healthcare provider for a thorough medical evaluation and treatment.

LabCorp test numbers (at the time of developing this manual):

- **082345** **T. Pallidum Screening Cascade**

This test requires 1mL serum in a red-top tube or gel-barrier tube.



Rapid Syphilis Testing - Special Considerations

VDH does not purchase or distribute rapid syphilis tests for use by non-clinical organizations. Rapid syphilis tests are point-of-care tests that are used to detect antibodies to *Treponema pallidum*. These tests **cannot** be used to determine whether or not a person has an active syphilis infection. Additional confirmatory testing is required using a venous blood specimen collected by a trained phlebotomist. Non-clinical organizations

Laboratory Test(s) and Finding(s):	
Name/Address of Lab:	
CLIA Number:	
Other Information	
Comments: (e.g., Risk situation [food handling, patient care, day care], Treatment [including dates], Immunization status [including dates], Signs/Symptoms, Exposure, Outbreak-associated, etc.)	
Name, Address, and Phone Number of Person Completing this Form:	Date Reported:
	Check here if you need more of these forms, or call your local health department. <input type="checkbox"/> (Be sure your address is complete.)
For Health Department Use	
	Date Received:
	VEDSS Patient ID:
Please complete as much of this form as possible	
Form Epi-1, 10/2011	

without the capability to perform phlebotomy are encouraged to refer clients to a location capable of

performing the conventional syphilis screening cascade offered by LabCorp (082345). CBOs conducting rapid syphilis testing must have a plan in place to refer a client with a positive rapid syphilis test for confirmatory syphilis testing. An EPI-1 must be completed and submitted to VDH for all positive rapid syphilis tests. The person completing the EPI-1 must **indicate the location and contact information where the client is referred for confirmatory syphilis testing in the Comments box.**

HIV Testing

The screening test for HIV available through LabCorp is the HIV 1/0/2 4th Generation, which automatically reflexes if necessary. See [Attachment M](#) for the HIV Testing Algorithm. Additional information regarding HIV testing is available [here](#).

LabCorp test number (at the time of developing this manual):

- **083935** **Panel 083935 (HIV p24 Antigen/Antibody with Reflex to Confirmation)**

This test requires 2 mL of serum in a gel-barrier tube with red/gray-mottled top or red-top tube.



Check out the latest CDC guidance for HIV testing at non-clinical sites [here](#).

Rapid Testing

Some sites have been approved to conduct rapid HIV testing during outreach events for eligible clients. To review VDH information on rapid testing, click [here](#).

Viral Hepatitis Testing

For information on HBV and HCV testing, access the Viral Hepatitis QA manual [here](#).

The LabCorp test numbers (at the time of developing this manual) are:

- **144473** **HBcAb+HBsAb+Ag (Hepatitis Panel Reflex to IgM)**
- **144050** **HCV Antibody reflex to NAA**

Rapid Testing

Some sites have been approved to conduct rapid HCV testing during outreach events for eligible clients. To review VDH information on rapid testing, click [here](#).

Additional Testing

Additional testing for infections not included on the requisition form is not covered by the VDH OEpi account. No additional test numbers should be written on the OEpi requisition form. Please note that unauthorized laboratory test charges will be transferred back to the non-clinical organization for payment to LabCorp.

Submission Issues that Delay Testing or Prompt Rejections

The following issues have been identified as common reasons for rejections by the laboratory. Additional issues that prompt rejection are available [here](#).

1. Incorrect swab or tube used to collect specimen.
2. Scored collection swabs broken too far above or below the scored line.

3. Missing or inconsistent client name; client name on the specimen collection tube label and the lab requisition form must be consistent. Use printed specimen tube labels whenever possible and put identical labels on all locations.
4. Incorrect or missing specimen source on the specimen collection tube label and/or the lab requisition form.
5. Missing or inconsistent collection date listed on the specimen collection tube label and/or the lab requisition form.
6. Missing indication of “requested test” on the lab requisition form.
7. Use of whiteout on specimen tube label or lab requisition form. Mistakes must be corrected by marking a line and rewriting the correct information above or beside it. Any evidence of whiteout will prompt rejection.
8. Missing or broken foil top of specimen tube; the foil must be intact to preserve the sample integrity. The caps on the specimen tube must be tight to prevent spillage of the preservative.

Treatment and Referrals

Clients can be treated in several ways: by the ordering clinician, by their medical primary care provider, or they can be referred to the local health department. Clients referred to the local health department will receive treatment for [reportable conditions](#) at no cost to the client. However, the client will need to complete the financial eligibility process conducted by the front desk staff and may experience a wait to be seen for treatment. If the client receives other tests or treatment while they are there, they may be subject to charges based on their income and insurance status. The agency should fax a copy of the positive lab result to the health department where the client intends to go for treatment. Many local health departments are only able to see clients who have arranged appointments. Non-clinical organizations must have a MOA/MOU in place with the health departments they plan to refer clients with positive test results to. It is recommended that non-clinical organizations assist clients in scheduling an appointment at a local health department for treatment or further testing. Use the [VDH health department locator](#) to locate the nearest site.

If the ordering clinician treats the client, the most recent [CDC STD Treatment Guidelines](#) should be followed. A confidential morbidity report (Epi-1), which includes information on treatment, must be submitted for reportable diseases diagnosed by the ordering clinician. The reportable disease list and information on submitting the Epi-1 report electronically can be found [here](#).

Referrals should be made to clinicians who have extensive specialized training or experience in diagnosing, treating, and providing follow up for complex STD cases. These providers can include adult and pediatric infectious disease clinicians, maternal-fetal medicine specialists, allergists, ophthalmologists, gastroenterologists, colorectal surgeons, urologists, oncologists, and other specialists. Services can be provided in different sites within a multispecialty practice or hospital system. If uncertain, always refer clients to the local health department.

Attachment A - LabCorp Supply Order Form

FAX ORDER TO 804-261-9340 OR EMAIL ORDER TO RVSUPPLY@LABCORP.COM



PLEASE ALLOW 72 HOURS FOR DELIVERY OF ALL SUPPLY ORDERS

Account Name: _____
 Address: _____
 Ordered by: _____

Phone# _____
 Acct # _____
 Date Ordered: _____

Delivery Route: _____

SUPPLY ORDERS MAY ONLY BE PLACED EVERY 5 BUSINESS DAYS OR SUPPLY SYSTEM MAY REJECT AS DUPLICATE

TEST REQUEST FORMS				HISTOLOGY				MICROBIOLOGY			
QTY ORD	UOM	DESCRIPTION	PS#	QTY ORD	UOM	DESCRIPTION	PS#	QTY ORD	UOM	DESCRIPTION	PS#
	EA	Form # _____ (top corner)			EA	Pre-Filled Formalin 40ml	19500		EA	Swab:Pink Amies Gel Bact Cult	49481
	EA	Form # _____ (top corner)			EA	Pre-Filled Formalin 90ml	19164		EA	Swab:Purple UTM-Viral	24674
	EA	Form # _____ (top corner)		CONTAINERS					EA	NASOPHARYNGEAL SWAB ORANGE	93307
REPORT FORMS					EA	24HR COLLECTION (NO PRES)	20681		EA	Swab: White Top MRSA	33346
	Reem	Laser Report Paper (Copy Paper)	4889		EA	24HR COLLECTION (BORIC)	48782		EA	Swab: Red,Double,Dry,Dacron (Strep)	48222
	PACK	Laser Request Form W/ Labels	2719		EA	24HR COLLECTION (HCL)	21584		EA	Aptima Urine:CT,NG	33291
	PAD	Patient Service Cntr Maps			EA	24HR COLLECTION (ACETIC)	23301		EA	Aptima Unisex:CT,NG,TVag	57677
TUBES					EA	Light Protected Sterile Cups	20656		EA	Aptima Orange Nu-Swab	119391
	EA	SST 3.5ML	39999		EA	URINE HATS	20669		EA	PEDIATRIC BLOOD CULTURES BOTTLES	50054
	EA	SST 5ML	40004		EA	SINGLE DRUG SCREEN KITS	47399		EA	ADULT BLOOD CULTURE BOTTLES	50053
	EA	SST 8.5ML	39996		EA	SPLIT DRUG SCREEN KITS	99333		EA	Vacutainer, no add: fluid trans	44370
	EA	RED 3ML	39955		EA	Temp Strip Sterile Cups	115880		EA	iFOBT Occult Stool Bottle ONLY	97839
	EA	RED 10ML	39902		EA	STERILE YELLOW CAP CONTAINER 90ML	20648		EA	iFOBT Occult Stool Kit	66668
	EA	LAVENDER 3ML	40008		EA	PEDIATRIC URINE COLL BAGS	19871		EA	Urine Culture Tubes	23643
	EA	LAVENDER 4ML	40006		Pack	Paper Urine Coll Cup W/ Lid	90492		EA	Affirm ATTS	56228
	EA	GRAY 4ML	40021		Pack	Paper Urine Coll Cup W/O Lid	48780		EA	inPouch TV Transport	89997
	EA	GRAY 6ML	39872	BAGS					EA	HPV Transport Tube	22495
	EA	LIGHT BLUE 2.7ML	39961		PACK	6"x9" Transport w/ Pouch	19805	STOOL			
	EA	ROYAL BLUE 8ML	39975		EA	Large Bags	19913		EA	Para-Pak Stool C&S (Orange)	49628
	EA	GREEN(SODIUM) 4ML	39944	CYTOLOGY					EA	Para-Pak O&P(Pink & Gray)	49627
	EA	GREEN(SODIUM) 6ML	39874		TRAY	Thin Prep W/Lavender Broom	33288		EA	Para-Pak C-Diff (White)	59517
	EA	GREEN(SODIUM) 10ML	23636		TRAY	Thin Prep W/Brush/Spatula	48123		EA	Fecal Fat Can (72hr Collection)	3192
	EA	GREEN(LITHIUM) 4ML	39924		TRAY	Sure Path Blue Broom	45726	MISCELLANEOUS			
	EA	GREEN(LITHIUM) 6ML	39931		TRAY	Sure Path Brush/Spatula	45727		EA	Frozen Keeper	117967
	EA	URINALYSIS TUBE W/ PRES	23439		EA	PAP Coll Kit (one slide)w/ brush	38925		EA	ORANGE GLUCOLA 50G	26593
	EA	YELLOW ACD SOL A 8.5ML	39935		EA	Fixative Cyto Cytex Pump Spray	21310		EA	ORANGE GLUCOLA 75G	26594
	EA	YELLOW ACD SOL B 6ML	39887	NEEDLES					EA	ORANGE GLUCOLA 100G	26595
	EA	LipoProfile Bumble Bee Tube	60360		BOX	Eclipse Needle 21g X 1 1/4"	33401		EA	FRUIT PUNCH 50G	26596
	EA	PPT Tube	39876		BOX	Eclipse Needle 22g X 1 1/4"	33406		EA	FRUIT PUNCH GLUCOLA 75G	26597
	EA	PST GEL LITH HEP 4.5ML	39878		EA	Butterfly Needle 21g	33435		EA	FRUIT PUNCH GLUCOLA 100G	26598
	EA	K2EDTA TAN TUBE 3ML	39884		EA	Butterfly Needle 23g	33437		EA	Tourniquet's Blue Latex Free	120712
	EA	LAV MICROTAINERS	40001		EA	Butterfly Needle 25g	33439		EA	Urine Transfer Straws	25067
	EA	SST MICROTAINERS	23589		EA	Needle Holder one Time Use	33357		BOX	Clean Catch Wipes	26684
	EA	RED TOP MICROTAINERS	23720		BOX	ALCOHOL PADS	90007		EA	Plastic Pipettes	22178
	EA	SERUM TRANSFER TUBES	23597		BOX	BAND-AIDS	47909		EA	Microarray (POC)	89063
	EA	AMBER "LIGHT SENSITIVE" TUBES	23598		EA	PAPER TAPE	108043		EA	Informseq Prenatal Kit	107762
	EA	FROZEN TRANSFER (Purple)	49482		Pack	2X2 GAUZE	93212		EA	FNA Kits	100708
LABELS				ADDITIONAL REQUEST					EA	QuantIFEROn TB Kit	121725
	EA	SPECIMEN ID							EA	BREATHTEK H. PYLORI	116773
	EA	PLASMA							EA	Bio Fire Kit	93307/24674
	EA	FROZEN									
	EA	STAT									
	EA	Multi-Requestion									




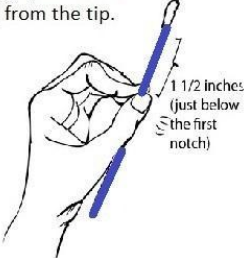
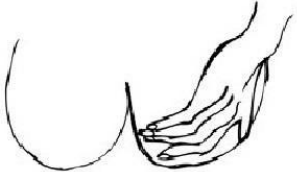


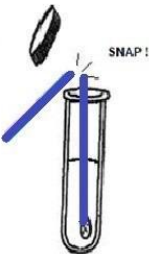


Revised 9/14/18

PLEASE PAY CLOSE ATTENTION TO THE UNIT OF MEASURE. EXAMPLE - 1 EACH = 1 TUBE/1 SWAB/1 CUP

Attachment B – Self Collection of Rectal Swab (English)

Self-Collection of Rectal Swab ATTENTION: Read ALL instructions before you begin!







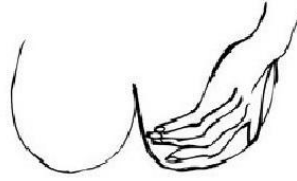




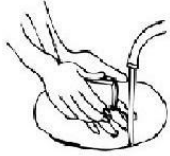
<p>STEP 1 Wash your hands thoroughly.</p>  <p>STEP 2 Open the wrapper and remove the swab with the blue handle.</p>  <p>Do not touch the tip of the swab.</p>	<p>STEP 3</p>  <p>Pull underwear down or off. Squat down, or lift one leg up on a ledge, toilet, or chair.</p>	<p>STEP 4</p> <p>With one hand, grip the swab 1.5 inches away from the tip.</p>  <p>1 1/2 Inches (just below the first notch)</p> <p>Do NOT use any kind of lubricant (soap, saliva, etc) on either the swab or your body.</p>	<p>STEP 5</p> <p>Use your other hand to lift one cheek for easy access to the rectum.</p> 
 <p>STEP 6 Insert the swab 1.5 inches into your rectum until you feel your fingers touch your anus.</p> <p>STEP 7 Once the swab is in, walk your fingers halfway down the swab (away from your body) and grip it there for stability.</p> <p>STEP 8 Gently turn the swab in circles for approximately 30 seconds.</p> <p>STEP 9 When removing the swab from your rectum, slowly turn it in a circle while pulling it out.</p>	<p>STEP 10 Uncap tube and keep upright - do not pour out the clear liquid. Place the swab into the tube.</p>  <p>STEP 11 Align the score line with the top edge of the tube and carefully break the shaft of the swab.</p>  <p>SNAP!</p>	<p>STEP 12 Swab will drop to the bottom of the tube. Screw cap on tightly so it doesn't leak.</p>  <p>STEP 13 Wash your hands thoroughly.</p>  <p>STEP 14 Return the tube to your health care provider.</p>	

Attachment C – Self Collection of Rectal Swab (Spanish)

Auto Coleccion de Muestra Rectal

Importante: ¡Lea estas instrucciones antes de comenzar!



<p>Paso 1 Lávese bien las manos.</p>  <p>Paso 2 Abra el envoltorio y extraiga el hisopo con mango azul. NO toque la punta del hisopo que tiene el algodón.</p> 	<p>Paso 3 Baje su ropa interior, agachese o levante una pierna y pongala en una repisa, inodoro o una silla.</p> 	<p>Paso 4 Con su mano, agarre el hisopo, dejando una pulgada y media (1.5") libre entre sus dedos y la punta del hisopo con algodón. NO utilice ningún tipo de lubricante (jabón, saliva, etcetera) en el hisopo ni en su recto.</p>  <p>1.5 pulgadas (justo debajo de la primera muesca)</p>	<p>Paso 5 Utilice su otra mano para abrir un poco mas su trasero y facilitar el acceso del hisopo en su recto.</p> 
 <p>Paso 6 Inserte el hisopo una pulgada y media (1.5") dentro de su recto hasta sentir sus dedos tocar su ano.</p> <p>Paso 7 Una vez haya introducido el hisopo en su recto, mueva sus dedos hacia el lado opuesto de su ano, hasta la mitad del hisopo y sostengalo para que se mantenga estable mientras esta introducido en su recto.</p> <p>Paso 8 Suavemente y con cuidado gire el hisopo en círculos por aproximadamente 30 segundos, mientras aun este dentro de su recto.</p> <p>Paso 9 Al retirar el hisopo de su recto, girelo lentamente en un círculo mientras lo hala hacia fuera.</p>	<p>Paso 10 Destape el tubo y mantengalo en posición vertical en una superficie plana. NO tire el líquido claro que se encuentra adentro, y luego coloque el hisopo dentro del tubo.</p> 	<p>Paso 12 El hisopo con la punta de algodón debe ser introducido hasta el fondo del tubo. Vuelva a tapar firmemente el tubo dejando adentro el hisopo y el líquido.</p> 	
<p>Paso 11 Alinee la línea con el borde de la entrada del tubo y rompa con cuidado el eje del hisopo marcado con la hendidura.</p> 	<p>Paso 13 Lávese muy bien las manos</p>  <p>Paso 14 Regrese el tubo con su muestra rectal a su proveedor de salud.</p>		

Attachment D – Self Collection of Pharyngeal Swab (English)

Self-Collection of Pharyngeal Swab

Attention: Read ALL instructions before you begin!

Step 1.



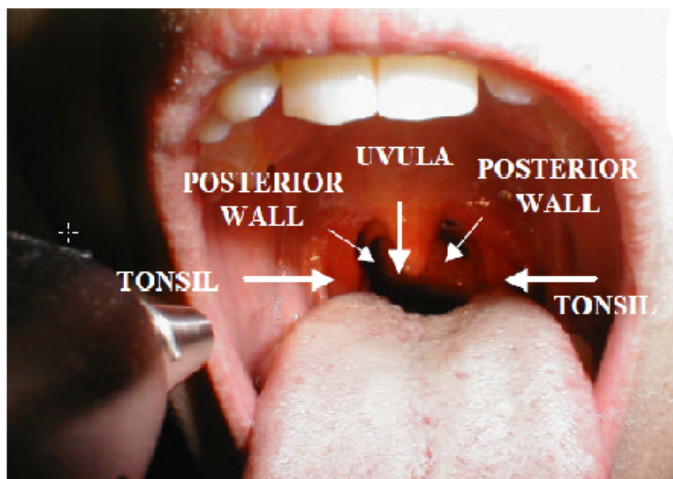
Wash your hands thoroughly.

Step 2. Open the wrapper and remove the swab with the blue handle. Do NOT touch the tip of the swab.

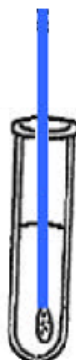
Do NOT touch the tip of the swab.



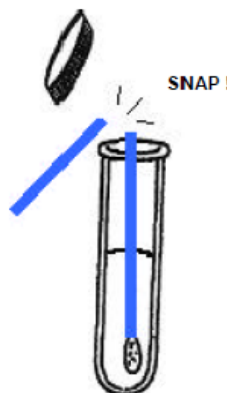
Step 3. Open mouth widely and touch the end of the swab to the 5 areas of the throat.



Step 4. Uncap tube and keep upright - do not pour out the clear liquid. Place the swab into the tube.



Step 5. Align the score line with the top edge of the tube and carefully break the shaft of the swab.



Step 6. Place cap back on the test tube and tighten (do not puncture the foil).



Step 7. Throw away wrapper and unused swab.

Step 8. Wash your hands thoroughly.





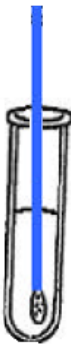
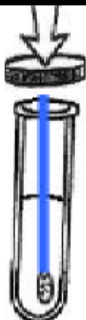

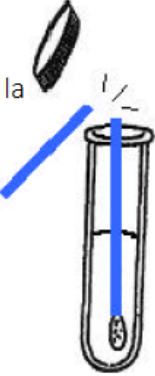

Step 9. Return the tube to your health care provider.

Attachment E – Self Collection of Pharyngeal Swab (Spanish)

Auto-colección de muestra de la faringe

Atención: ¡Lea todas las instrucciones antes de comenzar!







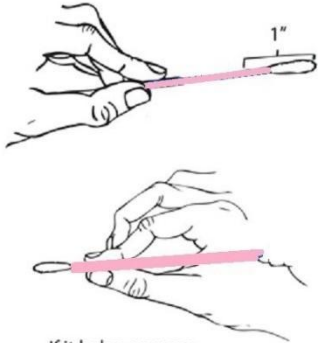

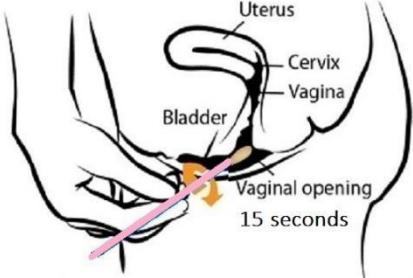




<p>Paso 1 Lávese bien las manos.</p>  <p>Paso 2 Abra la envoltura y remueva el aplicador agarrándolo por el mango rosado. No toque el área del algodón.</p> 	<p>Paso 4 Remueva la tapa y mantenga el tubo de ensayo derecho. No vierta el líquido claro. Coloque el aplicador dentro del tubo.</p> 	<p>Paso 6 Coloque la tapa en el tubo de ensayo. Cuidado que no perfore (rompa) el papel de aluminio al cerrar el tubo.</p> 
<p>Paso 3 Abra bien la boca y que el algodón toque las cinco áreas indicadas de la garganta.</p> 	<p>Paso 5 Centralice el aplicador y pártalo cuidadosamente por la marca.</p> 	<p>Paso 7 Descarte la envoltura y la parte del aplicador que no necesita.</p> <p>Paso 8 Lávese bien las manos.</p>  <p>Paso 9 Devuelva el tubo a su proveedor médico.</p>

Attachment F – Self Collection of Vaginal Swab (English)

Self-Collection of Vaginal Swab

ATTENTION: Read ALL instructions before you begin!







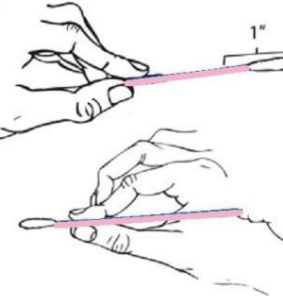






<p>STEP 1 Wash your hands thoroughly.</p>  <p>Step 2 Undress from the waist down. Get into a position where you can comfortably insert a swab into your vagina - such as sitting on the toilet, standing with one foot on a chair, or any position that you would use to insert a tampon.</p> 	<p>Step 3 Open the wrapper and remove the swab with the pink handle. Do NOT touch the tip of the swab.</p> 	 <p>STEP 4 Insert the white tip of the swab about one inch inside the opening of your vagina.</p>	 <p>If it helps, you can grip the swab 1" away from the end of the soft tip, so your fingers will touch your body when the swab is in far enough.</p>
<p>Step 5 Rotate the swab for 15 seconds, making sure the swab touches the walls of your vagina so that moisture is absorbed into the swab.</p>  <p>STEP 6 Remove the swab from your vagina. Don't let the tip of the swab touch anything else.</p> 	<p>Step 7 Uncap tube and keep upright (do NOT pour out the clear liquid). Place the swab into the tube.</p> 	<p>STEP 8 Align the score line with the top edge of the tube and carefully break the shaft of the swab.</p> 	
<p>STEP 9 Swab will drop to the bottom of the tube. Screw cap on tightly so it does not leak.</p> 	<p>STEP 10 Wash your hands.</p>  <p>STEP 11 Return the tube to your health care provider.</p>		

Attachment G – Self Collection of Vaginal Swab (Spanish)

Auto recogida de hisopo vaginal

Importante: ¡Lea estas instrucciones antes de comenzar!



<p>Paso 1 Lávese bien las manos.</p>  <p>Paso 2 Desvístase de la cintura para abajo. Póngase en una posición cómoda para insertar el aplicador en la vagina. Puede sentarse en el inodoro, pararse y colocar la pierna en una silla, o acomodarse en la posición que usaría para colocarse un tampón.</p> 	<p>Paso 3 Abra la envoltura y remueva el aplicador agarrándolo por el mango rosado. No toque el área del algodón.</p> 	<p>Paso 4 Introduzca la parte del aplicador con algodón como hasta una pulgada dentro de la vagina.</p>  <p>Si le ayuda, puede agarrar el aplicador a una pulgada del algodón de manera que sus dedos tocarán su cuerpo cuando el aplicador esté a la distancia deseada.</p> 
<p>Paso 5 Rote (gire) el aplicador por 15 segundos. Asegúrese que el algodón toque las paredes de la vagina de manera que pueda absorber la humedad en ella.</p>  <p>15 segundos</p> <p>Paso 6 Remueva el aplicador de la vagina. No permita que el algodón toque cualquier otra superficie.</p>  <p>15 segundos</p>	<p>Paso 7 Remueva la tapa y mantenga el tubo de ensayo derecho. No vierta el líquido claro. Coloque el aplicador dentro del tubo.</p>  <p>Paso 8 Centralice el aplicador y pártalo cuidadosamente por la marca.</p> 	
<p>Paso 9 Coloque la tapa en el tubo de ensayo. Cuidado que no perfora (rompa) el papel de aluminio al cerrar el tubo.</p>  <p>Paso 10 Lávese bien las manos.</p>  <p>Paso 11 Devuelva el tubo a su proveedor médico.</p>		

Proper Specimen Identification & Labeling

Positive Specimen Identification

According to LabCorp's laboratory accreditation agency, all primary specimen containers must be labeled with 2 identifiers at the time of collection.

In order for a specimen to be considered to have positive identification, the test request form (TRF) and each related specimen container must contain exactly the same name and unique patient identifier.

Examples of acceptable identifiers include, but are not limited to, the following:

- Patient's name
- Patient's date of birth
- Patient's Social Security number
- Hospital number
- Requisition number
- Accession number
- Unique random number

A location (eg, hospital room number) is not an acceptable identifier.



Specimen Labeling

Use of LabCorp-provided specimen collection containers is always advised. Contact your local LabCorp Service Representative for collection devices. In many cases, the collection devices and labels provided by LabCorp are selected to be used in conjunction with LabCorp's automated laboratory systems.

Labels placed on containers that were not provided by LabCorp may have to be trimmed to accommodate our analyzers.



Attachment I – Completing the LabCorp Requisition Form

LabCorp
 To find the nearest patient service center, visit www.abcorp.com or call 888-ABCORP (888-622-2677)

Office of Epidemiology
 1001 Monticello Ave Ste 100
 Norfolk VA 23510
 757-640-0929 VAN
 45019270-0

LI FAX
 Call
 Mail

Specimen/Physician Name _____ Phone Number _____ 0702.2
 Physician Address _____ DL/BLK TO _____

AAA45019270 AAA45019270 AAA45019270
 AAA45019270 AAA45019270 AAA45019270

AAA45019270

1 Select "Account Bill" on every form
 CHECK ONE
 ACCOUNT BILL

2 Write in time and date specimen was collected
 Patient's Legal Name (Last, First, MI) _____ Sex _____ Date of Birth _____ Collection Time _____ Fasting _____ Collection Date _____ Urine Test/Vol _____
 MO DAY YR AM PM MO DAY YR PM

3 Complete with ordering clinician's information
 NP _____ Physician's ID# _____
 Physician's Name (Last, First) _____ Physician Authorized Signature _____

4 Write in patient's information info must match specimen label
 Patient's ID# _____ Hospital Patient Status: In-Patient Out-Patient Non-Patient
 Patient's Address _____ Phone _____
 City _____ State _____ ZIP _____
 Name of Policy Holder (if different from patient) _____
 Address of Policy Holder _____ APT # _____
 City _____ State _____ ZIP _____

5 As long as client signs a consent form, their signature on here is not necessary
 I hereby authorize the receipt of medical information related to the services described herein and authorize payment directly to LabCorp and to assume responsibility for payment of charges for laboratory services that are not covered by my healthcare plan.


 MEDICARE ADVANCE BENEFICIARY NOTICE OF NO COVERAGE (ANM)
 Refer to Determining Necessity of ADN Completion on reverse.


6 Select which tests you want to order
 PRIMARY BILLING PARTY _____ SECONDARY BILLING PARTY _____
 Insurance Carrier _____ Insurance Code _____
 ID # _____
 Group # _____
 Insurance Address _____ Address _____
 Name of Insured Person _____ Insured Person _____
 Relationship to Patient _____
 Employer Name _____ Employer _____
 If Medicaid State _____ Physician Provider # _____ Worker's Comp Yes No

144845 [] HCV Antibody reflex to NAA
 219949 [] HBcAb+IbsAb+IgG
 083935 [] Panel 083935
 082345 [] T pallidum Screening Cascade
 HIV 1/0/2 4TH GENERATION
 180194 [] Chlamydia/GC Amplification SOURCE: _____
 188672 [] Ct/GC NAA, Rectal
 188698 [] Ct/GC NAA, Pharyngeal

Include which specimen source was used for the urogenital test: vaginal, urine

Attachment J – Understanding Test Results



Patient Report
 Acct #: 45012910 Phone: (757) 518-2647 Rte: 00
 Virginia Beach City Hlth Dept
 Office Of Epidemiology
 4452 Corporation Lane
 VA Beach VA 23462


Patient Name & DOB

Specimen Details
 Date collected: 11/14/2017 1215 Local
 Date received: 11/14/2017
 Date entered: 11/14/2017
 Date reported: 11/17/2017 0639 ET

Physician Details
 Ordering: J DAVIDSON
 Referring:
 ID: DAVIDSON J
 NPI: 1306000831

General Comments & Additional Information
 Clinical Info: SRC: URINE

Ordered Items

Chlamydia/GC Amplification; Ct/GC NAA, Rectal; Ct/GC NAA, Pharyngeal

TESTS	RESULT	FLAG	UNITS	REFERENCE	INTERVAL	LAB
Chlamydia/GC Amplification						
Chlamydia trachomatis, NAA	Negative			Negative		01
Neisseria gonorrhoeae, NAA	Negative			Negative		01
Ct/GC NAA, Rectal						
Chlamydia trachomatis, NAA	Positive	Abnormal		Negative		01
Disclaimer: This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.						
Neisseria gonorrhoeae, NAA	Positive	Abnormal		Negative		01
Disclaimer: This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.						
Ct/GC NAA, Pharyngeal						
C. trachomatis, NAA, Pharyn	Negative			Negative		01
Disclaimer: This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.						
N. gonorrhoeae, NAA, Pharyn	Positive	Abnormal		Negative		01
Disclaimer: This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.						

Reference: what a normal test result should be

Result: the patient's result (abnormal results are often in **bold** text)

Specimen Source: indicates which result is for which specimen

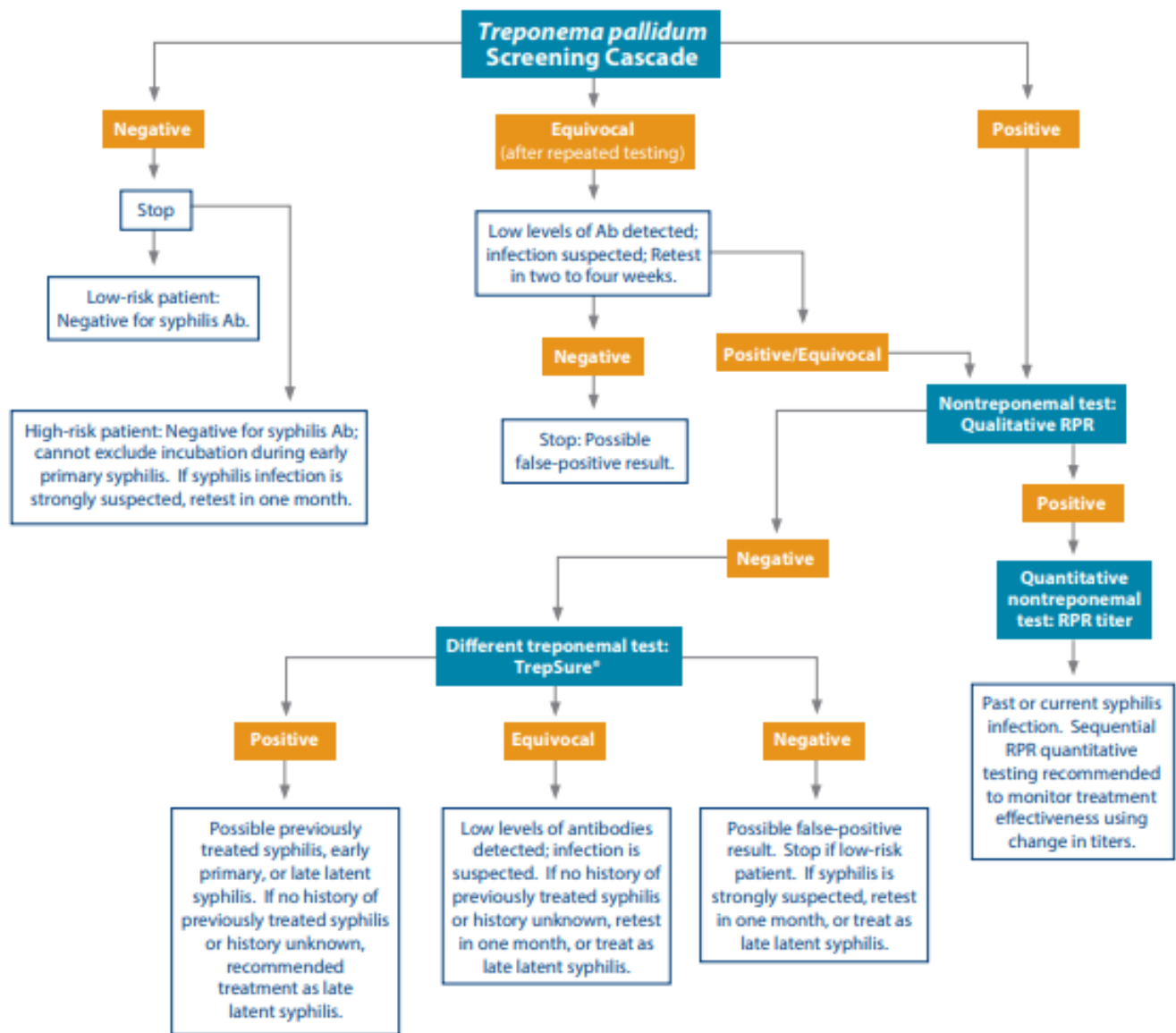
Attachment K – Implementing STD Testing Checklist

- ✓ Successfully implement rapid HIV testing for a minimum of 6 months with a satisfactory evaluation from the VDH contract monitor.
 - ✓ Written policies and procedures (These should already be in place if rapid HIV testing currently performed in the agency).
 - Bloodborne Pathogen Standard Compliance/Infection Control Policy
 - Employee Blood and Body Fluid Exposure Plan
 - Biomedical Waste Storage and Removal
 - HIPAA Compliance
 - Medical Records Security, Storage, Retention, Disposal
 - ✓ Ordering clinician identified
 - Written agreement regarding scope of services, accountability, and liability coverage
 - If ordering clinician is nurse practitioner or physician assistant, written collaborative practice agreement with physician to include required chart reviews
 - See the [Ordering Clinician](#) section of this document for more information.
 - ✓ LabCorp Account set-up – in collaboration with the STD Program Analyst
 - Standing orders
 - Lab requisitions – computerized vs. written
 - Diagnostic codes
 - Courier services
 - ✓ Written policies and procedures for specimen tracking
 - Date
 - Tests ordered
 - Specimens sent
 - Results received
 - ✓ Written policies and procedures for follow-up of results
 - Results reviewed/signed off by provider or designated staff
 - Follow-up of results
 - Review and disposition orders
 - Client notification
 - How
 - When
 - By whom
 - Negative results
 - Education and counseling
 - Retesting recommendations
 - Positive results
 - Warm referrals for follow-up - Collaboration agreements with sites accepting referrals for treatment and follow-up testing
 - Who
 - What
 - When
 - Where
 - How
 - Appropriate use of Medical Records Release or Coordination of Care Release for interagency information exchange
-

- Partner referrals
 - Education and counseling
 - Retesting recommendations
 - [Epi-1 completion](#)
 - [DDP RedCap](#) entry
 - “Unable to contact” protocol
 - How many attempts will be made to notify client of their results?
- ✓ Staff competencies
- Taking a sexual history of clients to inform recommended testing
 - Appropriate use of Personal Protective Equipment (PPE)
 - Specimen collection, handling, and storage
 - Avoiding contamination of work surfaces
 - Avoiding cross-contamination of specimens
 - Client education and counseling
 - Recommendation for full STD and HIV panel depending on sexual history
 - Strategies to prevent STDs and HIV
 - Condoms, PrEP, U=U, routine STD/HIV testing, open and honest communication with sexual partners
 - Instructing clients to self-swab for pharyngeal, vaginal, and rectal specimens for CT/GC NAAT
 - Instructing clients to collect urine specimen for CT/GC NAAT
 - Information about the type of laboratory tests that the client is completing
 - Harm reduction strategies
 - Meticulous data collection, management, and reporting
 - Thorough understanding of the content covered in this QA manual
- ✓ Physical site requirements – see above

Attachment L – Syphilis Screening Cascade

082345 *Treponema pallidum* (Syphilis) Screening Cascade

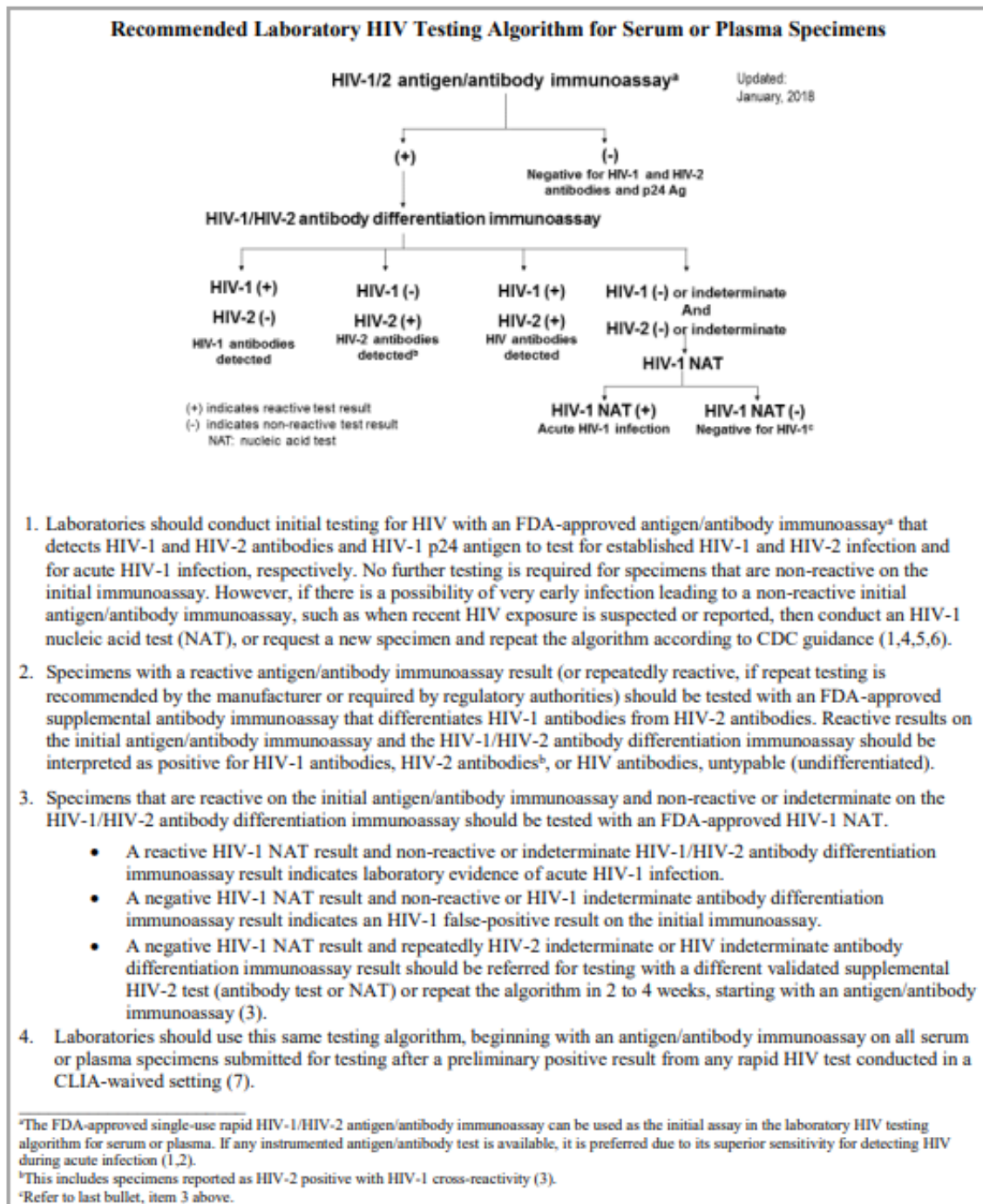


Legend

Test Names	Test Results	Actions
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Figure 1 - Improved Syphilis Reverse Screening Cascade

Attachment M - HIV Testing Algorithm



- 1) Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations <https://stacks.cdc.gov/view/cdc/23447>
 2) Use of the Determine HIV 1/2 Ag/Ab Combo Test with Serum or Plasma in the Laboratory Algorithm for HIV Diagnosis <https://stacks.cdc.gov/view/cdc/48472> 3) Technical Update on HIV-1/2 Differentiation Assays <https://stacks.cdc.gov/view/cdc/40790> 4) Suggested Reporting Language for the HIV Laboratory Diagnostic Testing Algorithm <https://stacks.cdc.gov/view/cdc/45930> 5) Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV-United States, 2016 <https://stacks.cdc.gov/view/cdc/38856> 6) Web content: How Soon Can Clinicians Rule Out Infection? <https://www.cdc.gov/hiv/testing/clinical/index.html>
 7) Web content: Clinical Laboratory Improvement Amendments <https://www.cdc.gov/clia/>

Attachment M - HIV Testing Algorithm (continued)

Guidance for reporting results from the HIV laboratory diagnostic algorithm for use with serum and plasma specimens (4)

Guidance for Reporting Results from the HIV Laboratory Diagnostic Testing Algorithm for Serum and Plasma Specimens ^a						
Test Outcomes	Test Sequence			Final Algorithm Interpretation ^d	Interpretation for Provider ^e (Sample should be reported as:)	Further Actions ^f
	Step 1	Step 2	Step 3			
	HIV-1/HIV-2 Ag/Ab IA ^b	HIV-1/HIV-2 Antibody Differentiation IA ^c	HIV-1 NAT			
	Nonreactive	n/a	n/a	HIV-1 antigen and HIV-1/HIV-2 antibodies were not detected. No laboratory evidence of HIV infection.	HIV negative	If recent HIV exposure is suspected or reported, conduct HIV-1 NAT or request a new specimen and repeat the algorithm according to CDC guidance. ^g
	Reactive	HIV-1 Positive	n/a	Positive for HIV-1 antibodies. Laboratory evidence of HIV-1 infection is present.	HIV-1 Positive	Link patient to HIV medical care and provide appropriate prevention counseling. ^h
	Reactive	HIV-2 Positive	n/a	Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present.	HIV-2 Positive	Link patient to HIV medical care and provide appropriate prevention counseling. ^h
	Reactive	HIV-2 Positive with HIV-1 Cross reactivity	n/a	Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present.	HIV-2 Positive. This result is distinct from HIV positive untypable (undifferentiated).	Link patient to HIV medical care and provide appropriate prevention counseling. ^h
	Reactive	HIV Positive untypable (undifferentiated)	n/a	Positive for HIV-1 and HIV-2 antibodies. Laboratory evidence of HIV-1 and/or HIV-2 infection is present.	HIV Positive	Link patient to HIV medical care and provide appropriate prevention counseling. ^h Provider may consider additional testing for HIV-1 RNA or DNA and HIV-2 RNA or DNA to verify or rule out HIV-1/HIV-2 dual infection. Request additional specimen if original specimen volume is insufficient.
	Reactive	HIV-1 indeterminate, HIV-2 indeterminate, HIV indeterminate	Detected	Positive for HIV-1. Laboratory evidence of HIV-1 infection consistent with an acute HIV-1 infection.	Acute HIV-1 Positive	Link patient to HIV medical care and provide appropriate prevention counseling immediately ^h to expedite prevention practices.
	Reactive	HIV-1 indeterminate	Not detected	HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected.	HIV Negative	If recent HIV exposure is suspected or reported, request a new specimen and repeat the algorithm according to CDC guidance. ^g
Reactive	HIV-2 indeterminate ⁱ	Not detected	HIV antibodies were not confirmed and HIV-1 RNA was not detected. HIV-2 inconclusive.	HIV-1 Negative, HIV-2 inconclusive	Refer sample for testing with a different validated supplemental HIV-2 test (antibody test or NAT) if available. Alternatively, redraw and repeat algorithm in 2-4 weeks to assess HIV-2 infection.	
Reactive	HIV Indeterminate	Not detected	HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected. HIV-2 inconclusive.	HIV-1 Negative, HIV-2 inconclusive	Refer sample for testing with a different validated supplemental HIV-2 test (antibody test or NAT) if available. Alternatively, redraw and repeat algorithm in 2-4 weeks to assess HIV-2 infection.	
Reactive	Negative	Detected	Positive for HIV-1. Laboratory evidence of HIV-1 infection consistent with an acute HIV-1 infection.	Acute HIV-1 Positive	Link patient to HIV medical care and provide appropriate prevention counseling immediately ^h to expedite prevention practices.	
Reactive	Negative	Not detected	HIV antibodies were not confirmed and HIV-1 RNA was not detected.	HIV Negative	If recent HIV exposure is suspected or reported, request a new specimen and repeat the algorithm according to CDC guidance. ^g	
Reactive	Negative or Indeterminate	Invalid or not performed	Inconclusive	Inconclusive	Request an additional specimen and repeat the algorithm. Ensure HIV-1 NAT is performed, if indicated by results of HIV-1/HIV-2 Ag/Ab IA and HIV-1/HIV-2 Ab differentiation IA.	

^a The tests outlined in this table are not FDA approved for oral fluid or dried blood spots. ^b The need for repeating screening IA on an initial reactive test is assay dependent, refer to product package insert. ^c This column contains the Final Assay interpretation per the Genius package insert, the only FDA approved test for this step. We recommend excluding the individual HIV-1 and HIV-2 results on the laboratory report. If they are used, the final assay interpretation or final assay result should also be included. ^d This column contains suggested language to be used for the laboratory report and it can be directly used for reporting from LIMS systems. ^e This column contains simplified language of the previous column, "Final Algorithm Interpretation," and is included here for healthcare providers or other non-laboratorians that may also use this table as a reference document. This does not need to be included on the laboratory report. ^f Comments under "Further Action" can be included as language in the laboratory report or can be used as guidance for laboratorians to discuss test results with healthcare providers or health department staff. ^g Please refer to Centers for Disease Control and Prevention guidance. Available at: <https://www.cdc.gov/hiv/testing/laboratorytests.html>, <https://stacks.cdc.gov/view/cdc/38856> and <https://www.cdc.gov/hiv/testing/clinical/index.html> ^h Please refer to the Centers for Disease Control and Prevention HIV Guidelines and Recommendations to find the most appropriate information by age and risk group for the patient in question. Available at: <http://www.cdc.gov/hiv/guidelines/>. Follow Genius package insert and refer to the CDC Technical Update. Available at: <https://stacks.cdc.gov/view/cdc/40790>