

Virginia Department of Health

Division of Disease Prevention

Office of Epidemiology

v. 6.0

Last Updated: 02/05/2024

Quality Assurance Manual for Laboratory Testing

Clinical Settings

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Revision History

Version	Date	Description of Changes
1.0	06/09/2016	<ul style="list-style-type: none">• Original document.
1.1	09/07/2016	<ul style="list-style-type: none">• Added <i>Conflict of Interest</i> section.
2.0	08/14/2017	<ul style="list-style-type: none">• Mentions of Laboratory changed from DCLS to LabCorp.
3.0	05/23/2018	<ul style="list-style-type: none">• Modified the <i>Ordering Clinician</i> section.• Added <i>Proper Specimen Identification and Labeling</i> document as Attachment H.
3.1	11/15/2018	<ul style="list-style-type: none">• Added all STD testing paid for by OEPI.
4.0	07/17/2020	<ul style="list-style-type: none">• Updated to include content from Recommendations for Providing Quality Sexually Transmitted Diseases Clinical Services from the CDC.
5.0	03/08/2022	<ul style="list-style-type: none">• Document review and revision conducted by SPS, HHP, and HCS staff.• <i>Viral Hepatitis</i> section removed.• Link added to existing Viral Hepatitis QA Manual.• HIV testing algorithm updated.• <i>Rapid Syphilis</i> section and testing guidance added.
6.0	08/13/2024	<ul style="list-style-type: none">• Updated language to include non-LabCorp testing facilities.• Updated syphilis cascade testing algorithm from Trep-Sure EIA to TPPA.

Purpose

This manual provides information for personnel within 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 and collection method, container, transportation, and storage. All personnel in contact specimens must ensure the proper collection preparation, and transportation of specimens to the laboratory.

Eligibility

The clinician should obtain a thorough sexual history. Patient-reported exposure, regardless of condom use, should inform screening. Ascertaining specific sexual activities and recent partners during the sexual health history will guide clinical decisions. Please see this [CDC resource for taking a complete sexual health history](#).

Providers caring for transgender persons should have knowledge of their patients' current anatomy and sexual practices before counseling them about STD and HIV prevention. Please see this [CDC resource for caring for transgender persons](#).

For local health departments (LHDs), the [VDH sexual health history](#) form completed by the patient should serve as the basis for informing screening. This form should not be used in lieu of a thorough sexual history obtained by the clinician, but as a tool to complement the assessment.

Test Ordering

VDH has an established contract with LabCorp to conduct laboratory testing. Organizations who maintain an MOU or MOA with VDH shall use LabCorp for their laboratory testing, unless otherwise specified in an MOU or MOA or at a time where VDH established a contract with another commercial laboratory to conduct laboratory testing. For sites that use LabCorp services, LabCorp requires the clinician's full name and National Provider Identifier (NPI) to create an account. Sites that do not use LabCorp should follow the processes for account creation outlined in their agreement with their commercial lab.

Supply Orders

For sites that use LabCorp, contact your local 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 or through the [LabCorp link portal](#). Sites that do not use LabCorp should follow the processes for supply ordering outlined in their agreement with their commercial lab.

Ordering Tests

For sites utilizing LabCorp, tests may be ordered using a physical copy of the LabCorp requisition form or using the online ordering system through LabCorp link. [Completing a LabCorp Requisition Form \(see Attachment C\)](#) includes a guide for completing a physical copy of the requisition form; however, organizations may opt to use the LabCorp Link portal to create and print requisitions. The top copy of physical requisitions will be sent to the lab in the outer pocket of a specimen collection bag, and the agency maintains the duplicate carbon copy in the client record.

Tests for reportable conditions covered by the Office of Epidemiology (OEpi) are preprinted on the requisition form. These tests include chlamydia (CT), gonorrhea (GC), syphilis, HIV, viral hepatitis B (HBV), viral hepatitis C (HCV), and Hemoglobin A1c (Hemoglobin A1c is available for LHDs only). OEpi covers specific tests identified by unique LabCorp test numbers. To ensure ordering of the correct test number and avoid charges being transferred to the ordering agency, please only order eligible tests outlined in this document.

Additional testing for infections such as Trichomoniasis, HPV, HSV, Pap tests, and bacterial vaginosis are not covered by the OEpi account. These tests should be charged to a patient's insurance or covered by the ordering agency's account (general account for LHDs). If a patient needs testing for an additional non-reportable condition, an additional specimen must be collected and submitted using a non-OEpi account requisition form. If an unauthorized test is ordered through the OEpi requisition form, the test charge will be sent back to the ordering agency. LHDs can refer to [billing guidance](#) for patients attending STD clinics.

Sites that do not use LabCorp should follow the processes for test ordering outlined in their agreement with their commercial lab.

Specimen Collection

This section details how to properly prepare, collect, and label specimens. Instructions include physical requirements for specimen collection, blood and self-collected specimens, labeling specimens, and transporting/storing specimens.

Physical Requirements for Specimen Collection

Clinical organizations must provide the necessary personnel, supplies, and facilities to provide for specimen collection and storage until the specimen is ready for transportation. Requirements for specimen collection in clinical settings include:

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, as well as written procedures that 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. Temperature ranges for specimens can be found by using [LabCorp's Test Code Lookup](#) page.
5. Written procedures or restrictions to prevent unauthorized access to the collection materials/supplies and unauthorized access to collection site records.

Blood Specimens

All phlebotomy must be performed by VDH or contract agency personnel. OEpi funding does not generally support additional costs for phlebotomy or administrative expenses; therefore, if patients are referred to a

LabCorp drawing location, the cost must be paid by the agency. An agency with extenuating circumstances may contact wyatt.johnson@vdh.virginia.gov to request an exception to this policy.

Self-Collected Specimens

Self-collection of extragenital swab specimens increases the uptake of chlamydia and gonorrhea testing and has high acceptance among men who have sex with men (MSM), particularly for rectal specimens. Published clinical research indicates that self-collected specimens have equivalent or better detection rates for rectal, vaginal, and pharyngeal CT/GC compared to clinician collection^{1,2}. Patients should be encouraged to self-collect extragenital specimens. A trained and licensed clinician may also collect a patient's extragenital specimen(s) if on duty.

Labelling Specimens

When completing a LabCorp requisition form, the stickers on the requisition form need to include two pieces of identifying information as well as the type of specimen. For example, when labeling chlamydia and gonorrhea swabs, you should include name, date of birth, and a circled "V" for vaginal, "P" or "T" for pharyngeal or throat, and "R" for rectal. These stickers will be affixed to the specimen collection tube as soon as specimens are drawn. Ensure that the expiration date on the specimen collection tube is not obstructed with the sticker label. For urine samples, ensure that the spectroscopy window is not obstructed with the sticker label. Up-to-date instructions for specimen collection and labelling can be found on LabCorp's [Introduction to Specimen Collection](#) page.

Sites who do not utilize LabCorp should follow their lab's instructions for specimen labelling.

Specimen Transport and Storage

A specimen tube must be placed in an individual biohazard specimen bag as soon as the specimen is collected and the container is appropriately labeled, ensuring the lid is tightened on the transport tube to prevent spillage. For sites utilizing LabCorp, all fields on the paper LabCorp requisition form must be completed (including race/ethnicity) and placed in the outer pocket of the biohazard specimen bag separate from the collected specimens. Do not place the requisition form in the same part of the individual biohazard specimen bag as the specimen.

Courier

For sites utilizing LabCorp, 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.

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.

Laboratory Testing

Chlamydia and 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. Extragenital screening is critically important, particularly among some high-risk populations: 77% of Chlamydia and 95% of Gonorrhea infections are missed among MSM if screening is only performed at urethral sites .

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-exposure⁴.
 - For pharyngeal gonorrhea only, CDC recommends a test of cure two weeks after treatment.
 - If the test of cure is positive, effort should be made to perform a confirmatory culture before retreatment. Individuals should be referred/linked to a clinician for an evaluation. All positive tests of cure should undergo antimicrobial susceptibility testing.
- 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 Specimens

The LabCorp test number for this test as of 02/09/2024 is [183194, CT/GC, Urine]. Use the [LabCorp test lookup portal](#) for the most up-to-date information regarding specimen volume requirements, storage, and stability.

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.

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.

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.

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

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

Collection Procedure and Handling

For sites utilizing LabCorp, 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 (see the *Supply Orders* section above). Collection cups do not have to be sterile. The following procedures enumerate the steps for proper specimen collection and handling of a urine specimen according to LabCorp standards and must be carefully followed. For sites not utilizing LabCorp, sites should refer to the proper collection and handling procedures outlined by the commercial lab they have an agreement with.

1. 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.
2. While the urine specimen in the collection cup can be stored from 2°C–30°C for up to 24 hours, specimens should be transferred to the urine specimen kit as soon as possible.
3. Remove the cap and transfer 2mL 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 (see 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.
 - Urine samples must be transferred from the collection cup to the urine specimen transport tube within 24 hours of collection.
4. Immediately place a label on the specimen transport tube, ensuring not to block the fill-line window between the two black lines. If this window is blocked, the specimen will be unable to run.
5. Re-cap the urine specimen transport tube tightly. This processed urine specimen can be kept at room temperature or in the refrigerator. Maintain the integrity of the processed urine specimen with proper and secure storage for transportation and handling.
 - Do not freeze processed urine specimens as it compromises the viability of the CT/GC bacteria that may be present.



Figure 1 - After 20-30mL of a first-catch urine specimen is collected in a collection cup, use the provided pipette to transfer the specimen to the transport tube. Ensure that the transport tube is filled with liquid between the two black lines. If the liquid level of the specimen in the transport tube does sit between the two black lines, the specimen will be unable to run.

Male Urethral Specimen Collection

Research indicates the performance of male first catch urine samples is equivalent to, and in some situations superior to, urethral swabs⁶. During shortages of urine collection kit supplies, the clinician may opt to perform male urethral specimen collection in lieu of urine specimen collection. The white Hologic Aptima Unisex Swab collection kit with blue shaft swab should be used to collect male urethral specimens. Clinicians should collect this specimen for the patient. To obtain a male urethral specimen, perform the following steps:

- Ensure the patient has not urinated for at least one hour prior to specimen collection.
- Label the specimen collection tube.
- Insert the specimen collection swab 2-4cm into the urethra. Gently rotate the swab clockwise for two to three seconds in the urethra to ensure adequate sampling. Withdraw the swab carefully.
- Remove the cap from the white Hologic Aptima Unisex Swab collection kit and immediately place the swab into the specimen transport tube. Carefully break the swab shaft at the scoreline; use care to avoid splashing of contents. Recap the specimen transport tube tightly.

Vaginal Specimens

The LabCorp test number for this test as of 06/25/2024 is [183194, CT/GC, Vaginal]. Use the [LabCorp test lookup portal](#) for the most up-to-date information regarding specimen volume requirements, storage, and stability.

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.

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 in both English and Spanish are included in [Self-Collection for Vaginal Swabs \(see Attachments D and E\)](#) and may be posted for client reference. Vaginal specimens may be collected during menstruation. The following procedures enumerate the steps for proper specimen collection and handling of a vaginal specimen according to LabCorp standards and must be carefully followed. For sites not utilizing LabCorp, sites should refer to the proper collection and handling procedures outlined by the commercial lab they have an agreement with.

1. Label the specimen collection tube.
2. 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.
3. 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.

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.

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

Rectal Specimens

The LabCorp test number for this test as of 06/25/2024 is [188672, CT/GC, Rectal]. Use the [LabCorp test lookup portal](#) for the most up-to-date information regarding specimen volume requirements, storage, and stability.

Extragenital screening is critically important, particularly among some high-risk populations: 77% of Chlamydia and 95% of Gonorrhea 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.

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.

Collection Procedures and Handling

The white *Hologic® Aptima Unisex Swab* collection kit with blue shaft swab should be used to collect rectal specimens. 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 in both English and Spanish are included in [Self-Collection for Rectal Swabs](#) (see Attachments F and G) and may be posted for client reference. The following procedures enumerate the steps for proper specimen collection and handling of a rectal specimen according to LabCorp standards and must be carefully followed. For sites not utilizing LabCorp, sites should refer to the proper collection and handling procedures outlined by the commercial lab they have an agreement with.

1. Label the specimen collection tube.
2. 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.
3. 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.
4. Complete all required fields of the lab requisition form (including race/ethnicity) and place the top copy in the side pouch of the individual biohazard specimen bag separate from the specimen tube to keep it dry.

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.

Pharyngeal Specimens

The LabCorp test number for this test as of 06/25/2024 is [188698, CT/GC, Pharyngeal].

Use the [LabCorp test lookup portal](#) for the most up-to-date information regarding specimen volume requirements, storage, and stability.

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 tonsils¹³.

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 in the past 4 weeks.
 - For pharyngeal gonorrhea only, CDC recommends a test of cure two weeks after treatment.
 - If the test of cure is positive, effort should be made to perform a confirmatory culture before retreatment. Individuals should be referred/linked to a clinician for an evaluation. All positive tests of cure should undergo antimicrobial susceptibility testing.

Collection Procedures and Handling

The white Hologic® Aptima Unisex Swab collection kit with blue shaft swab should be used to collect pharyngeal specimens. Diagrams in both English and Spanish are included in [Self-Collection of Pharyngeal Swabs \(see Attachments H and I\)](#) and may be posted for client reference. The following procedures enumerate the steps for proper specimen collection and handling of a pharyngeal specimen according to LabCorp standards and must be carefully followed. For sites not utilizing LabCorp, sites should refer to the proper collection and handling procedures outlined by the commercial lab they have an agreement with.

1. Label the specimen collection tube.
2. 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. Emphasize that the swab should make contact with the key areas of the throat: uvula and left/right posterior walls and tonsils¹⁴.
3. 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.
4. Complete all required fields of the lab requisition form (including race/ethnicity) and place the top copy in the side pouch of the individual biohazard specimen bag separate from the specimen tube to keep it dry.

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>. Accessed December 15, 2011.

Syphilis Testing

The LabCorp test number for this test as of 06/25/2024 is [082345, T. Pallidum Screening Cascade]. Use the [LabCorp test lookup portal](#) for the most up-to-date information regarding specimen volume requirements, storage, and stability.

For sites utilizing LabCorp, 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 Treponema Pallidum Particle Agglutination (TPPA) treponemal test is conducted. A diagram of this can be found in [Syphilis Testing Algorithm](#) (see Attachment J). Additional information about the reverse algorithm is available in [LabCorp's test lookup page for the syphilis cascade](#). See [CDC guidance for potential reasons for false positives](#).

IMPORTANT • Please refer to [CDC screening guidelines](#) for who should be referred for syphilis testing. Additionally, VDH has released guidance for localities with high incidence of syphilis where all people of reproductive age should be screened. Please see the Syphilis Screening Recommendations in Virginia PDF on [the VDH syphilis Healthcare Providers page](#).

RPR

The LabCorp test number for this test as of 06/25/2024 is [006072, RPR]. Use the [LabCorp test lookup portal](#) for the most up-to-date information regarding specimen volume requirements, storage, and stability.

A standalone RPR can be requested on the OEpi account. The standalone RPR should only be used for post-treatment titers. The RPR is not for use as a screening test.

HIV Testing

The LabCorp test number for this test as of 06/25/2024 is [083935, HIV p24 Antigen/Antibody with Reflex to Confirmation]. Use the [LabCorp test lookup portal](#) for the most up-to-date information regarding specimen volume requirements, storage, and stability.

The screening test for HIV available through LabCorp is the HIV p24 Antigen/Antibody, which automatically reflexes if necessary in the [HIV Testing Algorithm](#) (see Attachment K). Additional information regarding HIV testing is available on [VDH's HIV, STD, and Viral Hepatitis Testing page](#). The latest CDC guidance for HIV testing at clinical sites can be found on [CDC's HIV Testing in Nonclinical Settings page](#).

Viral Hepatitis Testing

The LabCorp test number for these tests as of 06/25/2024 are

- [144473, Hepatitis Panel Reflex to IgM (HBcAb+HBsAb+Ag)]
 - [144050, HCV Antibody Reflex to NAA]
-

Use the [LabCorp test lookup portal](#) for the most up-to-date information regarding specimen volume requirements, storage, and stability.

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

Hemoglobin A1C

The LabCorp test number for this test as of 06/25/2024 is [001453, Hemoglobin A1C].

Use the [LabCorp test lookup portal](#) for the most up-to-date information regarding specimen volume requirements, storage, and stability.

The Hemoglobin A1c test is available for LHDs on the Office of Epidemiology requisition form for suspected Tuberculosis (TB) cases. Additional information on the TB program is available on the [VDH Tuberculosis webpage](#).

Adding Tests after a Specimen has been Collected

Add-on tests can be requested electronically via [LabCorp Link](#). Healthcare professionals may also call LabCorp Customer Service at 1-800-462-4344 (press option 2 for healthcare provider; then option 2 again for add-on testing). Callers will be asked for the account number and specimen number they wish to request an add-on test for. The customer service representative will take the verbal order and then fax an authorization form to the ordering facility for signature by the ordering provider or authorized personnel.

Submission Issues that Delay Testing/Prompt Rejections

The following issues have been identified as common reasons for rejections by the laboratory. Additional issues that prompt rejection are available on [LabCorp's Introduction to Specimen Collection page](#).

- Incorrect swab or tube used to collect specimen.
- Scored collection swabs broken too far above or below the scored line.
- 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.
- Incorrect or missing specimen source on the specimen collection tube label and/or the lab requisition form.

- Missing or inconsistent collection date listed on the specimen collection tube label and/or the lab requisition form.
- Missing indication of "requested test" on the lab requisition form.
- 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.
- 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.

Attachment A

LabCorp Supply Ordering 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: _____ Phone# _____

Address: _____ Acct# _____

Delivery Route: _____ Ordered by: _____ Date Ordered: _____

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

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)						EA	NASOPHARYNGEAL SWAB ORANG	93307	
REPORT FORMS											
	Reem	Laser Report Paper (Copy Paper)	4889	EA	24HR COLLECTION (NO PRES)	20681		EA	Swab: White To MRSA	33346	
	PACK	Laser Request Form W/ Labels		EA	24HR COLLECTION (BORIC)	48782		EA	Swab:Red,Double,Dry,Dacron (Strep)	48222	
	PAD	Patient Service Cntr Maps		EA	24HR COLLECTION (HCL)	21584		EA	Aptima Urine:CT,NG	33291	
				EA	24HR COLLECTION (ACETIC)	23301		EA	Aptima Unisex:CT,NG,TVag	57677	
				EA	Light Protected Sterile Cups	20656		EA	Aptima Orange Nu-Swab	119391	
	EA	SST 3.SML	39999	EA	URINE HATS	20669		EA	PEDIATRIC BLOOD CULTURES BOTTLES	50054	
	EA	SST SML	40004	EA	SINGLE DRUG SCREEN KITS	47399		EA	ADULT BLOOD CULTURE BOTTLES	50053	
	EA	SST 8.SML	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 IOML	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		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				EA	Para-Pak O&P(Pink & Gray)	49627		
	EA	GREEN(SODIUM) 6ML	39874				EA	Para-Pak C-Diff (White)	59517		
	EA	GREEN(SODIUM) IOML	23636	TRAY	Thin Prep W/Brush/Spatula		EA	Fecal Fat Can (72hr Collection)	3192		
	EA	GREEN(LITHIUM) 4ML	39924	TRAY	Sure Path Blue Broom	45726	EA	Frozen Keeper	117967		
	EA	GREEN(LITHIUM) 6ML	39931	TRAY	Sure Path Brush/Spatula		EA	ORANGE GLUCOLA SOG	26593		
	EA	URINALYSIS TUBE W/ PRES	23439	EA	PAP Coll K"t(one slide)w/ brush		EA	ORANGE GLUCOLA 75G	26594		
	EA	YELLOW ACD SOLA 8.SML	39935				EA	ORANGE GLUCOLA 100G	26595		
	EA	YELLOW ACD SOL B 6ML	39887					G			
	EA	LipoProfil mble ee Tube	3				EA	FRUIT PUNCH GLUCOLA 75G	26597		
	EA	PPTTube	39876	BOX		33406	EA	FRUIT PUNCH GLUCOLA IOOG	26598		
	EA	PST GEL LITH HEP 4.SML	39878	EA	Butterfly Needle 21g	33435	EA	Tourniquet's Blue Latex Free	120712		
	EA	K2EDTA TAN TUBE 3ML	39884	EA	Butterfly Needle 23g	33437	EA	Urine Transfer Straws	25067		
	EA	LAV MICROTAINERS	40001	EA	Butterfly Needle 25g	33439					
	EA	SST MICROTAINERS	23589	EA	Needle Holder one Time Use	33357	BOX	Clean Catch Wi es	26684		
	EA	RED TOP MICROTAINERS	23720	BOX	ALCOHOL PADS	90007	EA	Plastic Pipettes	22178		
REMARKS											
LABELS						ADDITIONAL REQUEST					
	EA	AMBER "LIGHT SENSITIVE" TUBES	23598	EA	PAPER TAPE	108043	EA	Informseq Prenatal Kit	107762		

Attachment C

Completing the LabCorp Requisition Form

1 CHECK ONE
 ACCOUNT BILL

2 Patient Name (Last, First, MI) _____ Sex _____ Date of Birth _____ Collection Time _____ Fasting _____ Collection Date _____ Urine hrs/vol _____
MO DAY YR AM Yes No PM No MO DAY YR

3 _____

4 NPI _____ Physician's ID# _____ Physician's Name (Last, First) _____ Physician/Authorized Signature _____
X

5 Patient's Address _____ Phone _____
City _____ State _____ ZIP _____
Name of Policy Holder (if different from patient) _____
Address of Policy Holder _____ APT # _____
State _____ ZIP _____

6

PRIMARY BILLING PARTY	SECONDARY BILLING PARTY
Insurance Carrier *	Insurance Carrier *
ID #	ID #
Group #	Group #
Insurance Address	Insurance Address
Name of Insured Person	Name of Insured Person
Relationship to Patient	Relationship to Patient
Employer Name	Employer Name
*If Medicaid State Physician's Provider #	Workers Comp <input type="checkbox"/> Yes <input type="checkbox"/> No

TRAVEL LOG ID		
PST HR#	DATE	LOG#
083935	HIV 1/0/2 4TH GENERATION Panel 083935	183194 [] Chlamydia/GC Amplification SOURCE: _____
082345	[] T pallidum Screening Cascade	188672 [] Ct/GC NAA, Rectal
		188698 [] Ct/GC NAA, Pharyngeal

1

Select "Account Bill" on every form.

2

Write in the patient's information. This information must match the information on the specimen label.

3

Write in the time and date of specimen collection.

4

Complete the ordering clinician's information.

5

No signature is necessary if a consent form is completed.

6

Select which tests were completed, ensuring that urogenital tests are marked either vaginal or urine.

Attachment D

Self-Collection for Vaginal Swabs (English)

A full-sized photo is available on the next page.

Self-Collection of Vaginal Swab

ATTENTION: Read ALL instructions before you begin!

STEP 1
Wash your hands thoroughly.




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.



Step 3
Open the wrapper and remove the swab with the pink handle. Do NOT touch the tip of the swab.




STEP 4
Insert the white tip of the swab about one inch inside the opening of your vagina.

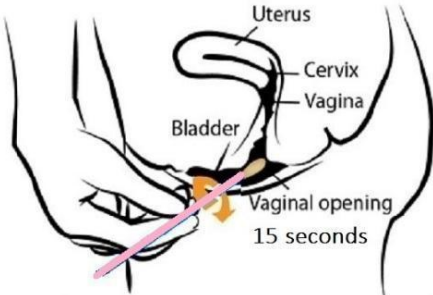



If it helps, you can grip the swab 1" away from the end of the soft tip, so your fingers will touch your body when the swab is in far enough.


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.




STEP 6
Remove the swab from your vagina. Don't let the tip of the swab touch anything else.



Step 7
Uncap tube and keep upright (do NOT pour out the clear liquid). Place the swab into the tube.




STEP 8
Align the score line with the top edge of the tube and carefully break the shaft of the swab.




SNAP!

STEP 9
Swab will drop to the bottom of the tube. Screw cap on tightly so it does not leak.



STEP 10
Wash your hands.



STEP 11
Return the tube to your health care provider.

Attachment E

Self-Collection for Vaginal Swabs (Spanish)

A full-sized photo is available on the next page.

Auto recogida de hisopo vaginal

Importante: ¡Lea estas instrucciones antes de comenzar!

Paso 1
Lávese bien las
manos.



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.



Paso 3
Abra la envoltura y remueva
el aplicador agarrándolo por
el mango rosado. No toque
el área del algodón.



Paso 4
Introduzca la parte del
aplicador con algodón
como hasta una pulgada
dentro de la vagina.

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.

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.



15 segundos



Paso 6
Remueva el aplicador de la
vagina. No permita que el
algodón toque cualquier otra
superficie.

Paso 7
Remueva la tapa y
mantenga el tubo de
ensayo derecho. No
vierta el líquido claro.
Coloque el aplicador
dentro del tubo.



Paso 8
Centralice el aplicador y
pártalo cuidadosamente por
la marca.



Paso 9
Coloque la tapa
en el tubo de
ensayo.
Cuidado que no
perfore (rompa)
el papel de
aluminio al
cerrar el tubo.



Paso 10
Lávese bien las manos.






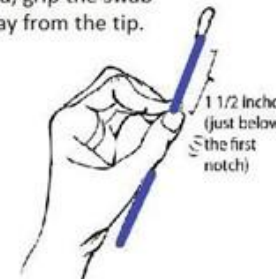






Paso 11
Devuelva el tubo a su proveedor
médico.

Attachment F

Self-Collection for Rectal Swabs (English)

A full-sized photo is available on the next page.

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 G

Self-Collection for Rectal Swabs (Spanish)

A full-sized photo is available on the next page.

Auto Coleccion de Muestra Rectal

Importante: ¡Lea estas instrucciones antes de comenzar!

Paso 1
Lávese bien
las manos.



Paso 2
Abra el envoltorio
y extraiga el
hisopo con mango
azul. NO toque la
punta del hisopo
que tiene el
algodon.



Paso 3
Baje su ropa interior,
agachese o levante una
pierna y pongala en una
repisa, inodoro o una
silla.



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.



Paso 5

Utilice su otra mano para abrir un poco mas su trasero y facilitar el acceso del hisopo en su recto.



Paso 6

Inserte el hisopo una pulgada y media (1.5") dentro de su recto hasta sentir sus dedos tocar su ano.

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.

Paso 8

Suavemente y con cuidado gire el hisopo en círculos por aproximadamente 30 segundos, mientras aun este dentro de su recto.

Paso 9

Al retirar el hisopo de su recto, girelo lentamente en un círculo mientras lo hala hacia fuera.

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.



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.



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.



Paso 13

Lávese muy bien las manos



Paso 14


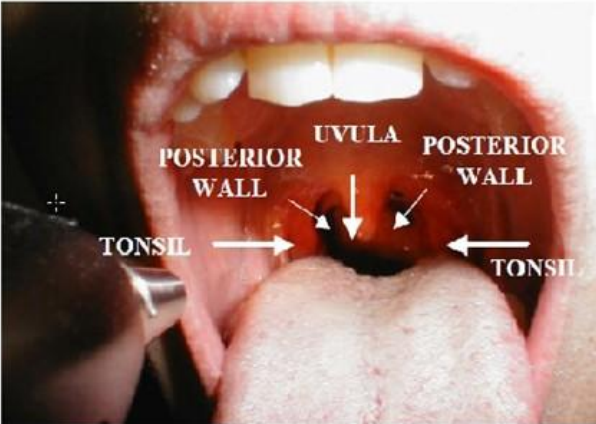

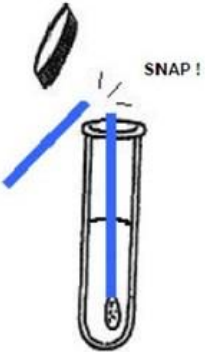


Regrese el tubo con su muestra rectal a su proveedor de salud.

Attachment H

Self-Collection for Pharyngeal Swabs (English)

Self-Collection of Pharyngeal 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. Do NOT touch the tip of the swab.</p> <p>Step 3. Open mouth widely and touch the end of the swab to the 5 areas of the throat.</p> 	<p>Step 4. Uncap tube and keep upright - do not pour out the clear liquid. Place the swab into the tube.</p>  <p>Step 5. Align the score line with the top edge of the tube and carefully break the shaft of the swab.</p> 	<p>Step 6. Place cap back on the test tube and tighten (do not puncture the foil).</p>  <p>Step 7. Throw away wrapper and unused swab.</p> <p>Step 8. Wash your hands thoroughly.</p>  <p>Step 9. Return the tube to your health care provider.</p> <p>VDH VIRGINIA DEPARTMENT OF HEALTH</p>
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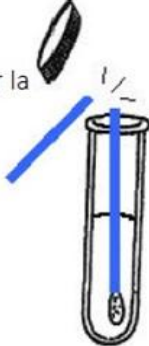

Attachment I

Self-Collection for Pharyngeal Swabs (Spanish)

Auto-colección de muestra de la faringe

Atención: ¡Lea todas las instrucciones antes de comenzar!

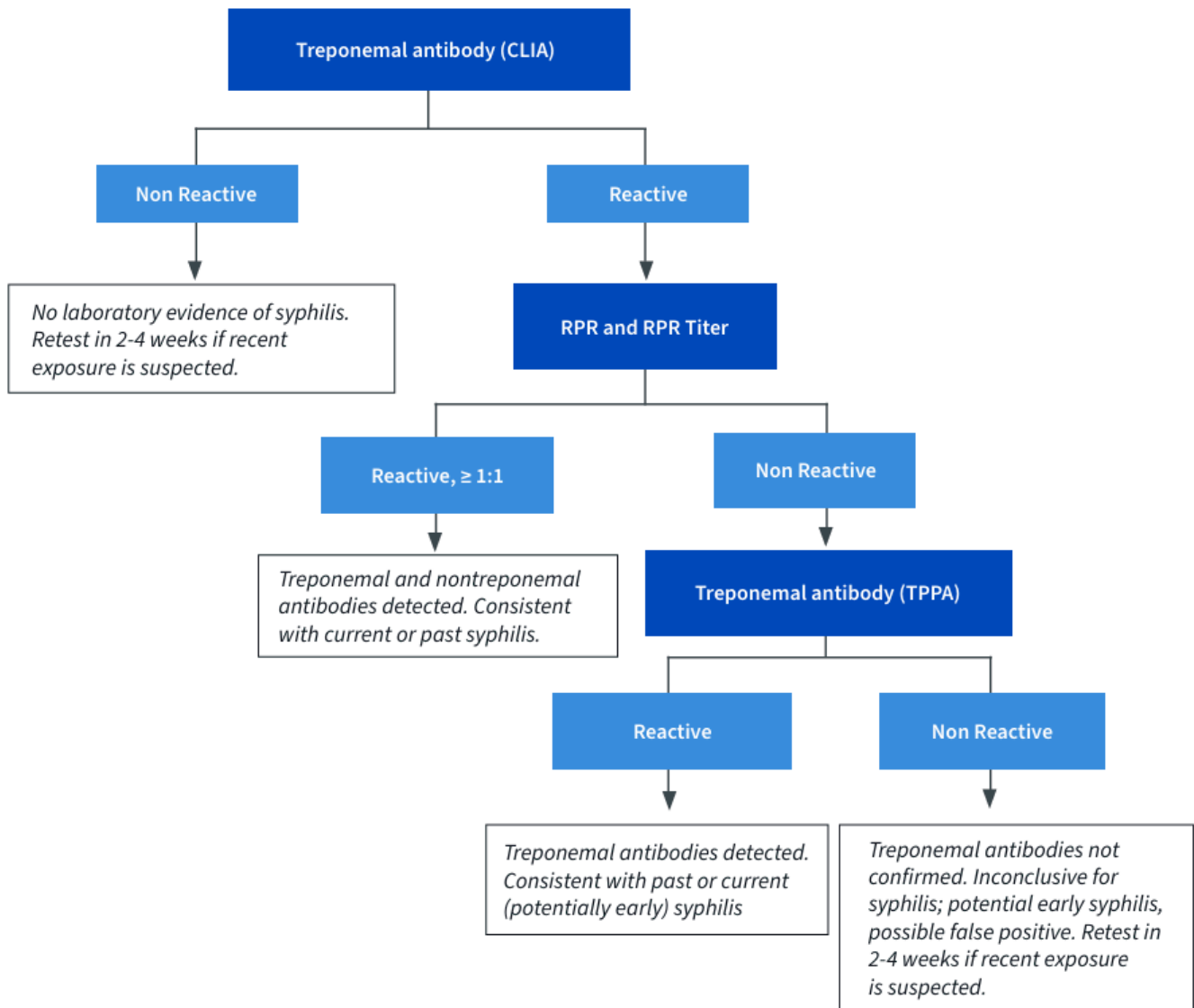


<p>Paso 1 Lávese bien las manos.</p>  <p>Paso 2 Abra la envoltura y remueva el aplicador agarrándolo por el mango rosado. No toque el área del algodón.</p> 	<p>Paso 4 Remueva la tapa y mantenga el tubo de ensayo derecho. No vierta el líquido claro. Coloque el aplicador dentro del tubo.</p> 	<p>Paso 6 Coloque la tapa en el tubo de ensayo. Cuidado que no perfora (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 J

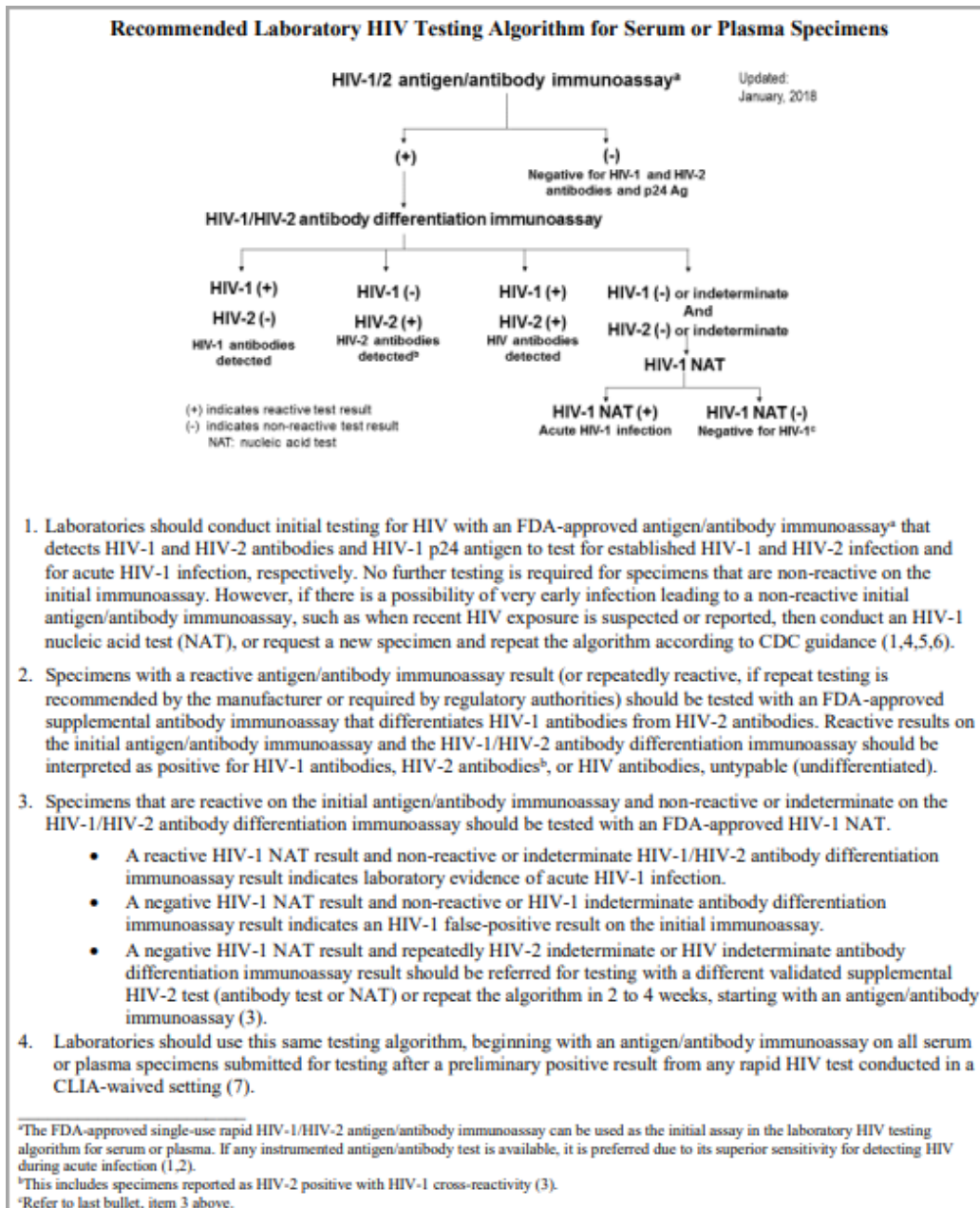
Syphilis Testing Algorithm

This algorithm demonstrates the screening cascade for LabCorp test 082345, *T. Pallidum* Screening Cascade.



Attachment K

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/>

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 Geenius 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/> i. Follow Geenius package insert and refer to the CDC Technical Update. Available at: <https://stacks.cdc.gov/view/cdc/40790>