Quality Assurance (QA) Manual for Laboratory Testing in the Clinical Setting

Division of Disease Prevention
Office of Epidemiology

Virginia Department of Health
109 Governor St
Richmond, VA 23219
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# Revision History

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<td>9/1/16</td>
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<tr>
<td>1.1</td>
<td>10/24/16</td>
<td>Web Vision codes, image of collection media</td>
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<td>2</td>
<td>11/13/18</td>
<td>New specimen collection kits and lab test numbers</td>
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<td>3</td>
<td>7/11/19</td>
<td>Included VDH specific criteria, updated test numbers, updated attachments.</td>
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<td>4</td>
<td>10/15/21</td>
<td>Included information on TP-PA</td>
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<td>5</td>
<td>3/8/22</td>
<td>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; male urethral swab instructions included</td>
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<td>6</td>
<td>10/31/22</td>
<td>Added instructions for gonorrhea culture and susceptibility testing</td>
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Abbreviations

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Purpose

This document provides information for Virginia Department of Health (VDH), Division of Disease Prevention (DDP) contracted agency personnel 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.

Supply Ordering

Specimen collection kits may be requested via the LabCorp order form provided to your site (Attachment A) or through the LabCorp Link portal.

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. A CDC resource for taking a complete sexual health history is available here.

Providers caring for transgender persons should have knowledge of their patients’ current anatomy and sexual practices before counseling them about STD and HIV prevention. Additional information about caring for transgender persons is available here.

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.

**Completing the Requisition Form**

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. See Attachment B2 for additional information.

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 located here.

**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 patient identifier, if available (e.g., WebVision number for local health departments).
- Do not cover the expiration date on the specimen collection tube with the sticker label.
- See Attachment B1 for additional information.

**Collecting 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 due to the COVID-19 pandemic may contact Brianna.Carey@vdh.virginia.gov to request an exception to this policy.
Self-collected Specimens

Self-collection, particularly for rectal specimens, increases the uptake of testing and offers high acceptance among Men who have sex with men (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. It is important when collecting specimens to avoid cross contamination, as cross contamination can yield a false positive result.

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 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.

Chlamydia/Gonorrhea Testing

Nucleic Acid Amplification Testing (NAAT)

NAAT represents a significant advancement in 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 testing.

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.

Subsequent testing:

- **Test of cure**
  - Any person with pharyngeal GC should return 7-14 days after initial treatment for a test of cure; however, testing at seven days might result in an increased likelihood of a false positive test result. If the NAAT is positive, efforts should be made to perform a confirmatory culture before retreatment. All positive cultures for test of cure should undergo antimicrobial susceptibility testing.
  - A test of cure is not needed for persons who receive a diagnosis of uncomplicated urogenital or rectal CT or GC and who are treated with any of the recommended or alternative regimens.
- **Testing to determine re-exposure**

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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 site\(^5\).

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 encouraged\(^6\).

**The LabCorp test numbers for CT/GC NAA testing** (at the time of developing this manual) are:

- 183194  CT/GC Amplified (urine, endocervical, vaginal, male urethral)
- 188698  CT/GC NAA, Pharyngeal
- 188672  CT/GC NAA, Rectal

**Urine Specimen Collection**

Research indicates the performance of male first catch urine samples is equivalent to, and in some situations superior to, urethral swabs\(^7\). In men, the use of urine samples is highly acceptable and may improve the likelihood of uptake of routine screening.

Patients 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.

Any person 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.

Appropriate specimen collection for transgender persons 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.

To obtain a urine specimen, perform the following steps:

- Label the specimen collection cup before use. It may also be helpful to mark the volume required on the specimen cup.
- Review the collection process with the patient. Instruct them to collect 20-30mL of first catch urine and secure the lid. For best results, female patients should not cleanse the labial area prior to collection.
- While the urine specimen in the collection cup can be stored at 2\(^\circ\)C to 30\(^\circ\)C for up to 24 hours, it should be transferred to the urine specimen kit as soon as possible.
- Transfer 2mL of urine into the transport tube using the provided disposable pipette. The correct volume of urine has been added when the fluid level is between the two black lines on the tube label.
- 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.

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\(^7\) Recommendations for the Laboratory-Based Detection of Chlamydia trachomatis and Neisseria gonorrhoeae — 2014 [https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6302a1.htm](https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6302a1.htm)
• Re-cap the urine specimen transport tube tightly. Ensure the lid is tightened on the transport tube to prevent spillage.
• Processed urine specimens must be kept at room temperature or refrigerated until courier collection. Do not freeze processed urine specimens.

**Male Urethral Specimen Collection**

Research indicates the performance of male first catch urine samples is equivalent to, and in some situations superior to, urethral swabs. 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 2-4 cm 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.

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8 Recommendations for the Laboratory-Based Detection of Chlamydia trachomatis and Neisseria gonorrhoeae — 2014
https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6302a1.htm
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 samples. 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.

The orange Hologic® Aptima Multitest Swab Specimen Collection Kit (formally Aptima Vaginal Swab Collection Kit) should be used to collect vaginal specimens. Given adequate instruction, self-collection of a vaginal specimen is equivalent to, or better than, clinician collection. Vaginal specimens may be collected during menstruation. Diagrams may be posted for patient reference (Attachments C and D).

To obtain a vaginal specimen, perform the following steps:
- Label the specimen collection tube.
- Review the collection process with the patient and instruct them to collect the vaginal specimen. Clinicians may collect a specimen during physical exam in lieu of self-collection, if desired.
- Put the swab inside the specimen collection tube, align the score line with the top edge of the tube and carefully break the swab shaft. Seal the tube.
- Visually inspect the swab to assure there is evidence of use, the preservative liquid is still in the tube, and the lid on the specimen collection tube is tight to prevent spillage.

Extragenital Specimen Collection
Extragenital testing for CT/GC is critically important, particularly among some high-risk populations. Seventy-seven percent (77%) of CT and 95% of GC infections are missed among MSM if screening is only performed at urethral sites. Symptoms of rectal and pharyngeal CT/GC are nonspecific and often silent. In fact, 85% of rectal CT/GC infections are asymptomatic in MSM.

Rectal Specimen Collection
The white Hologic® Aptima Unisex Swab collection kit with blue shaft swab should be used to collect rectal specimens. Given adequate instruction, self-collection of a

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rectal specimen is equivalent to, or better than, clinician collection\textsuperscript{14,15}. Diagrams may be posted for patient reference (Attachments E and F).

Patients who provide a swab sample for rectal CT/GC screening must:
\begin{itemize}
  \item Have had receptive anal intercourse within the past year, regardless of condom use; and
  \item Have not had a positive lab test or been treated for CT or GC in the past 4 weeks, regardless of anatomical site.
\end{itemize}

To obtain a rectal specimen, perform the following steps:
\begin{itemize}
  \item Label the specimen collection tube.
  \item Review the collection process with the patient and instruct them to collect the rectal specimen. Clinicians may collect a specimen during physical exam in lieu of self-collection, if desired.
  \item Put the swab inside the specimen collection tube, align the score line with the top edge of the tube and carefully break the swab shaft. Seal the tube.
  \item 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.
\end{itemize}

**Pharyngeal Specimen Collection**

The white Hologic® Aptima Unisex Swab collection kit with blue shaft swab should be used to collect pharyngeal specimens. Given adequate instruction, self-collection of a pharyngeal specimen is equivalent to, or better than, clinician collection\textsuperscript{16,17}. Diagrams may be posted for patient reference (Attachments G and H).

Patients who provide a swab sample for pharyngeal CT/GC screening must:
\begin{itemize}
  \item Have had receptive oral intercourse within the past year, regardless of condom use; and
  \item Have not had a positive lab test or been treated for CT or GC in the past 4 weeks, regardless of anatomical site.
\end{itemize}

To obtain a pharyngeal specimen, perform the following steps:
\begin{itemize}
  \item Label the specimen collection tube.
  \item Review the collection process with the patient and instruct them to collect the pharyngeal specimen. The swab should make contact with the key areas of the throat: uvula and left/right posterior walls and tonsils\textsuperscript{18}. Clinicians may collect a specimen during physical exam in lieu of self-collection, if desired.
  \item Put the swab inside the specimen collection tube, align the score line with the top edge of the tube and carefully break the swab shaft. Seal the tube.
  \item 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.
\end{itemize}


\textsuperscript{15} 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.


\textsuperscript{17} 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.

\textsuperscript{18} San Francisco City Clinic. Patient instructions for self-collected specimens: pharyngeal and rectal. Available at: http://www.sfcityclinic.org/providers.
Some patients prefer clinician collection. The same collection technique of making contact with the key areas of the throat (uvula and left/right posterior walls and tonsils) should be observed. An instructional video is available at https://www.youtube.com/watch?v=KJtqxyAstCo.

Gonorrhea Culture
GC culture testing is required to evaluate suspected cases of GC treatment failure.
A specimen source must be included with the requisition in order to successfully perform the test and prevent rejection of the specimen.

The LabCorp test number (at the time of developing this manual) is:
- 008128  GC Culture Only  SOURCE: ________
- The pink Aimes swabs need to be ordered specifically for the culture, as the swabs that are used for NAA testing are not appropriate for this purpose.

Gonorrhea Susceptibility Testing
GC susceptibility testing is required for all suspected cases of GC treatment failure, and for all the positive gonorrhea cultures after a positive NAAT test of cure.
- 183130 - Susceptibility, N. gonorrhoeae
  ○ This test is to be requested only when adding a susceptibility test to a positive GC result on test 008128 GC Culture Only. The testing location/ordering health department needs to call LabCorp Customer Service and request a verbal add-on of the test 183130 as soon as the positive GC culture result for test 008128 is received. LabCorp customer service would then fax a written authorization form to the LHD site that would need to be signed and returned via fax.

Syphilis Testing
Screening Cascade
The screening test for syphilis available through LabCorp is the Treponema pallidum Screening Cascade, which uses the reverse sequence algorithm. The first test that is conducted is an EIA, if it is positive, a quantitative RPR is conducted; if the RPR is negative, an additional treponemal test, different from the initial test, is conducted. See Attachment I for the Syphilis Testing Algorithm. Some potential reasons for false positives are available at: www.cdc.gov/std/treatment-guidelines/syphilis.htm.

The LabCorp test number (at the time of developing this manual) is:
- 082345  T. pallidum (Syphilis) Screening Cascade

Volume Required: 1mL in red-top or gel-barrier tube
Storage: Room temperature; centrifuge within two hours of collection
Stability: Room temperature for seven days; refrigerated for 14 days; frozen for 14 months

RPR
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.
The LabCorp test number is (at the time of developing this manual):

- 006099      RPR

**Volume Required:** 1mL in red-top or gel-barrier tube  
**Storage:** Room temperature  
**Stability:** Room temperature for seven days; refrigerated for 7 days; frozen for 7 days; freeze/thaw cycles x3

### TP-PA

A standalone TP-PA may be requested on the OEPI account in special circumstances, when the reverse cascade results are ambiguous.

The TP-PA specimen must be submitted in a BD Gold SST tube. It will need to be spun within 2 hours and submitted as a refrigerated specimen. If a specimen is placed in a lock box for after-hours pick up, that specimen will need to be placed with a “refrigerated” gel-pack. The specimen bag should be marked “refrigerate”. Since the majority of LabCorp specimens are submitted as room temperature, the refrigerated specimen should not be included with those. **It must be clearly marked so the courier places the specimen in the refrigerated car cooler.**

To request a TP-PA test, please email Brianna.Carey@vdh.virginia.gov and include the following information:

1. Name of the clinician requesting the test
2. The health department that the clinician is associated with
3. The clinician’s email address

This step is necessary to ensure that the specimen will be appropriately routed to the Centers for Disease Detection laboratories, which performs this test instead of LabCorp.

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

- 082605      TP-PA

### HIV Testing

The screening test for HIV available through LabCorp is the HIV 1/0/2 4\textsuperscript{th} Generation, which automatically reflexes to antibody differentiation and qualitative NAA if necessary. See Attachment J for the recommended laboratory HIV testing algorithm for serum or plasma specimens. Additional information regarding HIV testing is available [here](#). The latest CDC guidance for HIV screening in the clinical setting is available [here](#).

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

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

**Volume Required:** dedicated unopened, 2mL in red-top or gel-barrier tube  
**Storage:** Room temperature; refrigerated for shipping  
**Stability:** Room temperature for 48 hours; refrigerated/frozen for 14 days; freeze/thaw cycles x 5

### 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

**Hemoglobin A1c**
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 [here](#).

The LabCorp test number (at the time of developing this manual) is:
● 001453                  Hemoglobin A1c

**Volume Required:** 4mL in Lavender-top (EDTA) tube, green-top (lithium heparin) tube, or gray-top (sodium fluoride) tube

**Storage:** Room temperature

**Stability:** Room temperature/refrigerated/frozen for 14 days; freeze/thaw cycles x 3

**Adding Tests after the 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.

**Issues that Delay Testing or Prompt Rejections**
The following are issues identified as common reasons for rejections by the laboratory. Additional issues that cause rejections are available [here](#).

1. Incorrect swab or tube used to collect the specimen.
2. Scored collection swabs broken too far above or below the scored line.
3. Missing or inconsistent patient name; patient 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.
Attachments
## 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**

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

**TEST REQUEST FORMS**

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Please pay close attention to the unit of measure. Example - 1 each = 1 tube/1 swab/1 cup.
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 C- Self Collection of Vaginal Swab for CT/GC (English)

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.

**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.

**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.
Auto recogida de hisopo vaginal

Important: ¡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, parase y colocar la pierna en una silla, o, acomódase 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.

**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.

**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.
Self-Collection of Rectal 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.

STEP 3
Pull underwear down or off. Squat down, or lift one leg up on a ledge, toilet, or chair.

STEP 4
With one hand, grip the swab 1.5 inches away from the tip.

Do NOT use any kind of lubricant (soap, saliva, etc) on either the swab or your body.

STEP 5
Use your other hand to lift one cheek for easy access to the rectum.

STEP 6
Insert the swab 1.5 inches into your rectum until you feel your fingers touch your anus.

STEP 7
Once the swab is in, walk your fingers halfway down the swab (away from your body) and grip it there for stability.

STEP 8
Gently turn the swab in circles for approximately 30 seconds.

STEP 9
When removing the swab from your rectum, slowly turn it in a circle while pulling it out.

STEP 10
Uncap tube and keep upright - do not pour out the clear liquid. Place the swab into the tube.

STEP 11
Align the score line with the top edge of the tube and carefully break the shaft of the swab.

STEP 12
Swab will drop to the bottom of the tube. Screw cap on tightly so it doesn’t leak.

STEP 13
Wash your hands thoroughly.

STEP 14
Return the tube to your health care provider.
Attachment F- Self Collection of Rectal Swab for CT/GC (Spanish)

Auto Colección 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 algodón.

Paso 3
Baje su ropa interior, agáchese o levante una pierna y ponga 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, salva, etcétera) 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
Insértelo 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 sosténgalo para que se mantenga estable mientras esté introducido en su recto.

Paso 8
Suavemente y con cuidado gire el hisopo en círculos por aproximadamente 30 segundos, mientras aún 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 manténgalo 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 G - Self Collection of Pharyngeal Swab for CT/GC (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.

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.

VDH VIRGINIA DEPARTMENT OF HEALTH
Attachment H- Self Collection of Pharyngeal Swab for CT/GC (Spanish)

Auto-colección de muestra de la faringe
Atención: ¡Lea todas las instrucciones antes de comenzar!

Paso 1
Lávese bien las manos.

Paso 2
Abra la envoltura y remueva el aplicador agarrándolo por el mango rosado. No toque el área del algodón.

Paso 3
Abra bien la boca y que el algodón toque las cinco áreas indicadas de la garganta.

Paso 4
Remueva la tapa y mantenga el tubo de ensayo derecho. No vierta el líquido claro. Coloque el aplicador dentro del tubo.

Paso 5
Centralice el aplicador y pártalo cuidadosamente por la marca.

Paso 6
Coloque la tapa en el tubo de ensayo. Cuidado que no perforre (rompa) el papel de aluminio al cerrar el tubo.

Paso 7
Descarte la envoltura y la parte del aplicador que no necesita.

Paso 8
Lávese bien las manos.

Paso 9
Devuelva el tubo a su proveedor médico.
Attachment I – Syphilis Testing Algorithm

082345  Treponema pallidum (Syphilis) Screening Cascade

Treponema pallidum Screening Cascade

Negative

Equivocal (after repeated testing)

Positive

Low levels of Ab detected; infection suspected; Retest in two to four weeks.

Negative

Stop: Possible false-positive result.

Positive/Equivocal

Nonreponenral test: Qualitative RPR

Positive

Quantitative nontreponemal test: RPR titer

Negative

Past or current syphilis infection. Sequential RPR quantitative testing recommended to monitor treatment effectiveness using change in titers.

Stop

Low-risk patient: Negative for syphilis Ab.

High-risk patient: Negative for syphilis Ab; cannot exclude incubation during early primary syphilis. If syphilis infection is strongly suspected, retest in one month.

Low-risk patient: Negative for syphilis Ab.

Different treponemal test: TrepSure®

Positive

Possible previously treated syphilis, early primary, or late latent syphilis. If no history of previously treated syphilis or history unknown, recommended treatment as late latent syphilis.

Equivocal

Low levels of antibodies detected; infection is suspected. If no history of previously treated syphilis or history unknown, retest in one month, or treat as late latent syphilis.

Negative

Possible false-positive result. Stop if low-risk patient. If syphilis is strongly suspected, retest in one month, or treat as late latent syphilis.

Legend

<table>
<thead>
<tr>
<th>Test Names</th>
<th>Test Results</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>
1. Laboratories should conduct initial testing for HIV with an FDA-approved antigen/antibody immunoassay that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen to test for established HIV-1 and HIV-2 infection and for acute HIV-1 infection, respectively. No further testing is required for specimens that are non-reactive on the initial immunoassay. However, if there is a possibility of very early infection leading to a non-reactive initial antigen/antibody immunoassay, such as when recent HIV exposure is suspected or reported, then conduct an HIV-1 nucleic acid test (NAT), or request a new specimen and repeat the algorithm according to CDC guidance (1,4,5,6).

2. Specimens with a reactive antigen/antibody immunoassay result (or repeatedly reactive, if repeat testing is recommended by the manufacturer or required by regulatory authorities) should be tested with an FDA-approved supplemental antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies. Reactive results on the initial antigen/antibody immunoassay and the HIV-1/HIV-2 antibody differentiation immunoassay should be interpreted as positive for HIV-1 antibodies, HIV-2 antibodies, or HIV antibodies, untypeable (undifferentiated).

3. Specimens that are reactive on the initial antigen/antibody immunoassay and non-reactive or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay should be tested with an FDA-approved HIV-1 NAT.
   - A reactive HIV-1 NAT result and non-reactive or indeterminate HIV-1/HIV-2 antibody differentiation immunoassay result indicates laboratory evidence of acute HIV-1 infection.
   - A negative HIV-1 NAT result and non-reactive or HIV-1 indeterminate antibody differentiation immunoassay result indicates an HIV-1 false-positive result on the initial immunoassay.
   - A negative HIV-1 NAT result and repeatedly HIV-2 indeterminate or HIV indeterminate antibody differentiation immunoassay result should be referred for testing with a different validated supplemental HIV-2 test (antibody test or NAT) or repeat the algorithm in 2 to 4 weeks, starting with an antigen/antibody immunoassay (3).

4. Laboratories should use this same testing algorithm, beginning with an antigen/antibody immunoassay on all serum or plasma specimens submitted for testing after a preliminary positive result from any rapid HIV test conducted in a CLIA-waived setting (7).

Footnotes:
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
6. Web content: Clinical Laboratory Improvement Amendments https://www.cdc.gov/clia
### Guidance for Reporting Results from the HIV Laboratory Diagnostic Testing Algorithm for Serum and Plasma Specimens

#### Test Sequence

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
<th>Final Algorithm Interpretation</th>
<th>Interpretation for Provider</th>
<th>Further Actions</th>
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<tr>
<td>HIV-1/HIV-2 Ag/Ab IA</td>
<td>HIV-1/HIV-2 Antibody Differentiation IA</td>
<td>HIV-1 NAT</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Nonreactive</td>
<td>n/a</td>
<td>n/a</td>
<td>HIV-1 antigen and HIV-1/HIV-2 antibodies were not detected. No laboratory evidence of HIV infection.</td>
<td>HIV negative</td>
<td>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.</td>
</tr>
<tr>
<td>Reactive</td>
<td>HIV-1 Positive</td>
<td>n/a</td>
<td>Positive for HIV-1 antibodies. Laboratory evidence of HIV-1 infection is present.</td>
<td>HIV-1 positive</td>
<td>Link patient to HIV medical care and provide appropriate prevention counseling.</td>
</tr>
<tr>
<td>Reactive</td>
<td>HIV-2 Positive</td>
<td>n/a</td>
<td>Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present.</td>
<td>HIV-2 Positive</td>
<td>Link patient to HIV medical care and provide appropriate prevention counseling.</td>
</tr>
<tr>
<td>Reactive</td>
<td>HIV-2 Positive with HIV-1 Cross reactively</td>
<td>n/a</td>
<td>Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present.</td>
<td>HIV-2 Positive; This result is distinct from HIV positive untypeable (undifferentiated).</td>
<td>Link patient to HIV medical care and provide appropriate prevention counseling. 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.</td>
</tr>
<tr>
<td>Reactive</td>
<td>HIV Positive untypeable (undifferentiated)</td>
<td>n/a</td>
<td>Positive for HIV-1 and HIV-2 antibodies. Laboratory evidence of HIV-1 and/or HIV-2 infection is present.</td>
<td>HIV-1 Positive</td>
<td>Link patient to HIV medical care and provide appropriate prevention counseling immediately to expedite prevention practices.</td>
</tr>
<tr>
<td>Reactive</td>
<td>HIV-1 Indeterminate, HIV-2 Indeterminate, HIV Indeterminate</td>
<td>Detected</td>
<td>Positive for HIV-1, laboratory evidence of HIV-1 infection consistent with an acute HIV-1 infection.</td>
<td>Acute HIV-1 Positive</td>
<td>If recent HIV exposure is suspected or reported, request a new specimen and repeat the algorithm according to CDC guidance.</td>
</tr>
<tr>
<td>Reactive</td>
<td>HIV-1 Indeterminate</td>
<td>Not detected</td>
<td>HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected.</td>
<td>HIV Negative</td>
<td>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.</td>
</tr>
<tr>
<td>Reactive</td>
<td>HIV-2 Indeterminate</td>
<td>Not detected</td>
<td>HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected. HIV-2 inconclusive.</td>
<td>HIV-1 Negative, HIV-2 inconclusive</td>
<td>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.</td>
</tr>
<tr>
<td>Reactive</td>
<td>HIV Indeterminate</td>
<td>Not detected</td>
<td>HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected. HIV-2 inconclusive.</td>
<td>HIV-1 Negative, HIV-2 inconclusive</td>
<td>Link patient to HIV medical care and provide appropriate prevention counseling immediately to expedite prevention practices.</td>
</tr>
<tr>
<td>Reactive</td>
<td>Negative</td>
<td>Detected</td>
<td>Positive for HIV-1, laboratory evidence of HIV-1 infection consistent with an acute HIV-1 infection.</td>
<td>Acute HIV-1 Positive</td>
<td>If recent HIV exposure is suspected or reported, request a new specimen and repeat the algorithm according to CDC guidance.</td>
</tr>
<tr>
<td>Reactive</td>
<td>Negative or Indeterminate</td>
<td>Invalid or not performed</td>
<td>HIV antibodies were not confirmed and HIV-1 RNA was not detected.</td>
<td>Inconclusive</td>
<td>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.</td>
</tr>
</tbody>
</table>

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**a.** The tests outlined in this table are 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 for the Genius package insert, 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-laborators 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 laborators to discuss test results with healthcare providers or health department staff. **g.** Please refer to the Centers for Disease Control and Prevention guidance. Available at [https://www.cdc.gov/hiv/testing/laboratorytests.html](https://www.cdc.gov/hiv/testing/laboratorytests.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/L Follow Genius package insert and refer to the CDC Technical Update. Available at: [https://stacks.cdc.gov/view/cdc/40790](https://stacks.cdc.gov/view/cdc/40790)