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

Table of Contents

Revision History

Version	Date	Description of Changes
1	9/1/16	Original document
1.1	10/24/16	Web Vision codes, image of collection media
2	11/13/18	New specimen collection kits and lab test numbers
3	7/11/19	Included VDH specific criteria, updated test numbers, updated attachments.
4	10/15/21	Included information on TP-PA
5	3/8/22	Document review and revision conducted by staff from SPS, HHP, and HCS; Viral Hepatitis Section removed and link added to existing Viral Hepatitis QA Manual; HIV testing algorithm updated; male urethral swab instructions included
6	10/31/22	Added instructions for gonorrhea culture and susceptibility testing

Abbreviations

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

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[1,2]. 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[3].

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[4].
    - 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:

[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.
[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 75. https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf

- 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:

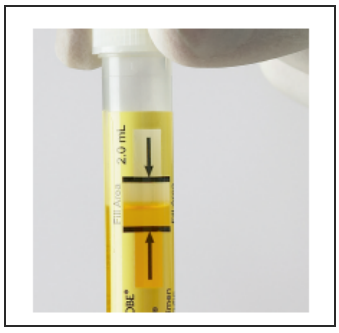
- Label the specimen collection cup before use. It may also be helpful to mark the volume required on the specimen cup.
- Review the collection process with the patient. Instruct them to collect 20-30mL of first catch urine and secure the lid. For best results, female patients should not cleanse the labial area prior to collection.
- While the urine specimen in the collection cup can be stored at 2°C to 30°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.

[5] 2021 Sexually Transmitted Infections Treatment Guidelines. CDC MMWR Vol. 70, No. 4, Page 67. https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf
[6] 2021 Sexually Transmitted Infections Treatment Guidelines. CDC MMWR Vol. 70, No. 4, Pages 67, 75. https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf
[7] Recommendations for the Laboratory-Based Detection of Chlamydia trachomatis and Neisseria gonorrhoeae — 2014 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.

FIRST CATCH URINE SPECIMEN
(20-30 mL)

TRANSFER URINE TO TRANSPORT TUBE
FOLLOW INSTRUCTIONS FOR HANDLING



FILL IN BETWEEN THE TWO BLACK LINES

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[8]. 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 spcimens. 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.

[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[9]. 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[10,11]. 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[12]. Symptoms of rectal and pharyngeal CT/GC are nonspecific and often silent. In fact, 85% of rectal CT/GC infections are asymptomatic in MSM[13].

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

[9] Centers for Disease Control and Prevention. Recommendations for the Laboratory-Based Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. *MMWR* March 14, 2014;63:2.
[10] 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.
[11] 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.
[12] 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.
[13] 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.

rectal specimen is equivalent to, or better than, clinician collection[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:

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

To obtain a rectal specimen, perform the following steps:

- Label the specimen collection tube.
- 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.
- 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, ensure the swab is not contaminated with significant fecal matter, and ensure the lid is tight on the specimen collection tube to prevent spillage.

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[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:

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

To obtain a pharyngeal specimen, perform the following steps:

- Label the specimen collection tube.
- 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[18]. 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 and that the lid is tight on the specimen collection tube to prevent spillage.

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[14] 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.
[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.
[16] 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.
[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.
[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=KJtqxvAstCo.

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 4th 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

LabCorp
Laboratory Corporation of America

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

TEST REQUEST FORMS			
QTY ORD	UOM	DESCRIPTION	PS#
	EA	Form #_____(top corner)	
	EA	Form #_____(top corner)	
	EA	Form #_____(top corner)	
REPORT FORMS			
	Reem	Laser Report Paper (Copy Paper)	4889
	PACK	Laser Request Form W/ Labels	2719
	PAD	Patient Service Cntr Maps	
TUBES			
	EA	SST 3.5ML	39999
	EA	SST 5ML	40004
	EA	SST 8.5ML	39996
	EA	RED 3ML	39955
	EA	RED 10ML	39902
	EA	LAVENDER 3ML	40008
	EA	LAVENDER 4ML	40006
	EA	GRAY 4ML	40021
	EA	GRAY 6ML	39872
	EA	LIGHT BLUE 2.7ML	39961
	EA	ROYAL BLUE 8ML	39975
	EA	GREEN(SODIUM) 4ML	39944
	EA	GREEN(SODIUM) 6ML	39874
	EA	GREEN(SODIUM) 10ML	23636
	EA	GREEN(LITHIUM) 4ML	39924
	EA	GREEN(LITHIUM) 6ML	39931
	EA	URINALYSIS TUBE W/ PRES	23439
	EA	YELLOW ACD SOL A 8.5ML	39935
	EA	YELLOW ACD SOL B 6ML	39887
	EA	LipoProfile Bumble Bee Tube	60360
	EA	PPT Tube	39876
	EA	PST GEL LITH HEP 4.5ML	39878
	EA	K2EDTA TAN TUBE 3ML	39884
	EA	LAV MICROTAINERS	40001
	EA	SST MICROTAINERS	23589
	EA	RED TOP MICROTAINERS	23720
	EA	SERUM TRANSFER TUBES	23597
	EA	AMBER "LIGHT SENSITIVE" TUBES	23598
	EA	FROZEN TRANSFER (Purple)	49482
LABELS			
	EA	SPECIMEN ID	
	EA	PLASMA	
	EA	FROZEN	
	EA	STAT	
	EA	Multi-Requistition	

HISTOLOGY			
QTY ORD	UOM	DESCRIPTION	PS#
	EA	Pre-Filled Formalin 40ml	19500
	EA	Pre-Filled Formalin 90ml	19164
CONTAINERS			
	EA	24HR COLLECTION (NO PRES)	20681
	EA	24HR COLLECTION (BORIC)	48782
	EA	24HR COLLECTION (HCL)	21584
	EA	24HR COLLECTION (ACETIC)	23301
	EA	Light Protected Sterile Cups	20656
	EA	URINE HATS	20669
	EA	SINGLE DRUG SCREEN KITS	47399
	EA	SPLIT DRUG SCREEN KITS	99333
	EA	Temp Strip Sterile Cups	115880
	EA	STERILE YELLOW CAP CONTAINER 90ML	20648
	EA	PEDIATRIC URINE COLL BAGS	19871
	Pack	Paper Urine Coll Cup W/ Lid	90492
	Pack	Paper Urine Coll Cup W/O Lid	48780
BAGS			
	PACK	6"x9" Transport w/ Pouch	19805
	EA	Large Bags	19913
CYTOLOGY			
	TRAY	Thin Prep W/Lavender Broom	33288
	TRAY	Thin Prep W/Brush/Spatula	48123
	TRAY	Sure Path Blue Broom	45726
	TRAY	Sure Path Brush/Spatula	45727
	EA	PAP Coll Kit (one slide)w/ brush	38925
	EA	Fixative Cyto Cytex Pump Spray	21310
NEEDLES			
	BOX	Eclipse Needle 21g X 1 1/4"	33401
	BOX	Eclipse Needle 22g X 1 1/4"	33406
	EA	Butterfly Needle 21g	33435
	EA	Butterfly Needle 23g	33437
	EA	Butterfly Needle 25g	33439
	EA	Needle Holder one Time Use	33357
	BOX	ALCOHOL PADS	90007
	BOX	BAND-AIDS	47909
	EA	PAPER TAPE	108043
	Pack	2X2 GAUZE	93212
ADDITIONAL REQUEST			

MICROBIOLOGY			
QTY ORD	UOM	DESCRIPTION	PS#
	EA	Swab:Pink Amies Gel Bact Cult	49481
	EA	Swab:Purple UTM-Viral	24674
	EA	NASOPHARYNGEAL SWAB ORANGE	93307
	EA	Swab: White Top MRSA	33346
	EA	Swab:Red,Double,Dry,Dacron (Strep)	48222
	EA	Aptima Urine:CT,NG	33291
	EA	Aptima Unisex:CT,NG,TVag	57677
	EA	Aptima Orange Nu-Swab	119391
	EA	PEDIATRIC BLOOD CULTURES BOTTLES	50054
	EA	ADULT BLOOD CULTURE BOTTLES	50053
	EA	Vacutainer, no add: fluid trans	44370
	EA	iFOBT Occult Stool Bottle ONLY	97839
	EA	iFOBT Occult Stool Kit	66668
	EA	Urine Culture Tubes	23643
	EA	Affirm ATTS	56228
	EA	inPouch TV Transport	89997
	EA	HPV Transport Tube	22495
STOOL			
	EA	Para-Pak Stool C&S (Orange)	49628
	EA	Para-Pak O&P(Pink & Gray)	49627
	EA	Para-Pak C-Diff (White)	59517
	EA	Fecal Fat Can (72hr Collection)	3192
MISCELLANEOUS			
	EA	Frozen Keeper	117967
	EA	ORANGE GLUCOLA 50G	26593
	EA	ORANGE GLUCOLA 75G	26594
	EA	ORANGE GLUCOLA 100G	26595
	EA	FRUIT PUNCH 50G	26596
	EA	FRUIT PUNCH GLUCOLA 75G	26597
	EA	FRUIT PUNCH GLUCOLA 100G	26598
	EA	Tourniquet's Blue Latex Free	120712
	EA	Urine Transfer Straws	25067
	BOX	Clean Catch Wipes	26684
	EA	Plastic Pipettes	22178
	EA	Microarray (POC)	89063
	EA	Informseq Prenatal Kit	107762
	EA	FNA Kits	100708
	EA	QuantiFERON TB Kit	121725
	EA	BREATHTEK H. PYLORI	116773
	EA	Bio Fire Kit	93307/24674

Revised 9/14/18

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

Proper Specimen Identification & Labeling

Positive Specimen Identification

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

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

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

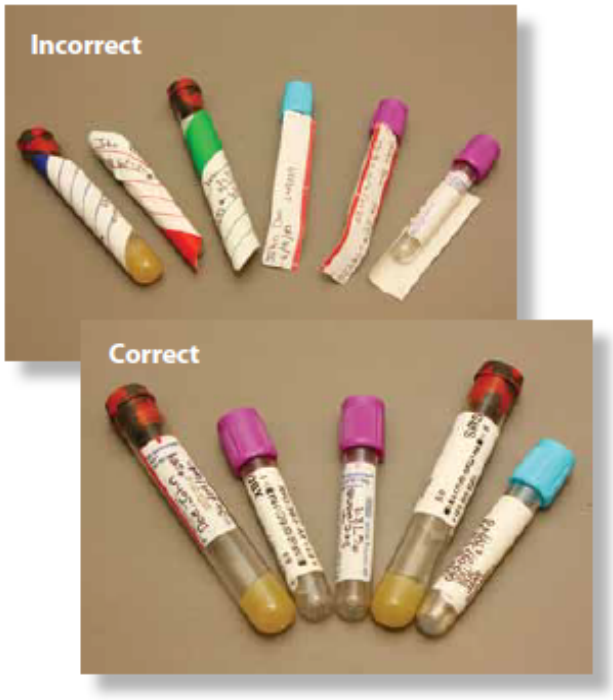
- Patient's name
- Patient's date of birth
- Patient's Social Security number
- Hospital number
- Requisition number
- Accession number
- Unique random number

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

Specimen Labeling

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

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



LabCorp
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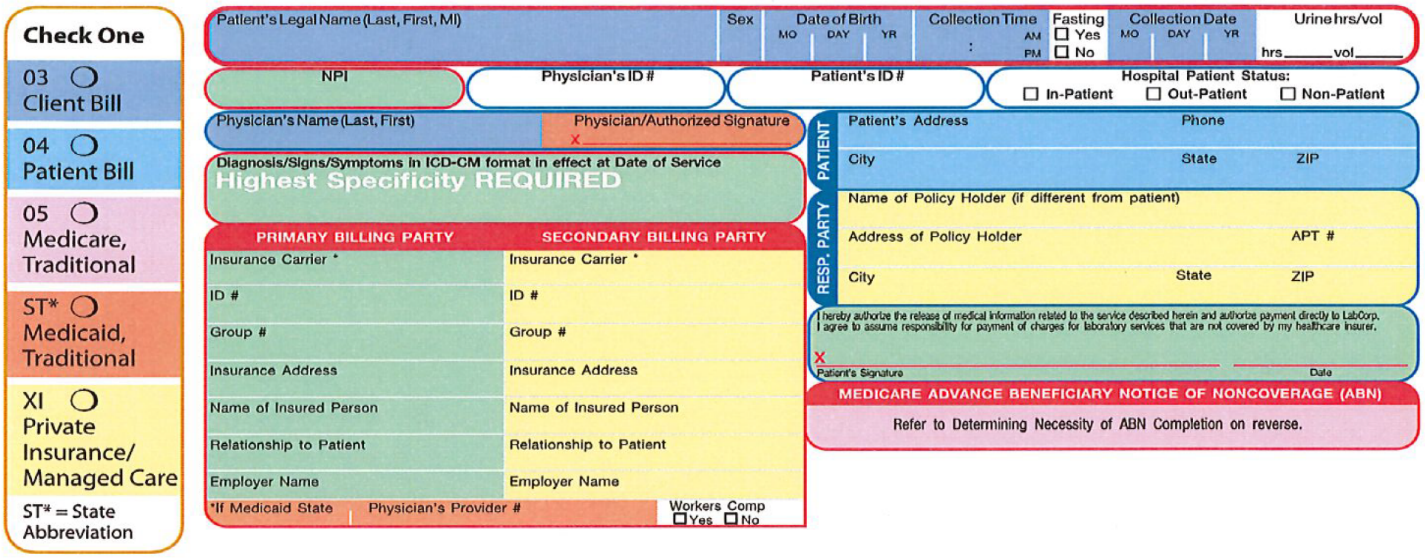
Attachment B2- LabCorp Requisition Form Requirements

LABCORP TEST REQUEST FORM REQUIREMENTS



Client Bill

- Billing Option
- Date Collected
- Time Collected
- Patient Legal Name (Last, First, MI)
- Patient Gender
- Patient Date of Birth
- Physician Last & First Name

Optional

- Patient ID N°
- Physician ID N°

Patient Bill

- Billing Option
- Date Collected
- Time Collected
- Patient Legal Name (Last, First, MI)
- Patient Gender
- Patient Date of Birth
- Patient Address (city, state, & ZIP code)
- Patient Telephone N°, with area code
- Physician Last & First Name

Medicare, Traditional

- Billing Option
- Date Collected
- Time Collected
- Patient Legal Name (Last, First, MI)
- Patient Gender
- Patient Date of Birth
- Patient Address (city, state, & ZIP code)
- Patient Telephone N°, with area code
- Physician Last & First Name
- NPI
- Authorized Signature for Medical Release
- ICD-CM Diagnosis Codes (in format in effect at date of service and at highest specificity)
- ABN Signed & Dated when applicable (Refer to instructions on back of test request form)
- Primary Billing Party - complete Traditional Medicare information
- Secondary Billing Party - complete insurance information as applicable to patient

Medicaid, Traditional

- Billing Option
- Date Collected
- Time Collected
- Patient Legal Name (Last, First, MI)
- Patient Gender
- Patient Date of Birth
- Patient Address (city, state, & ZIP code)
- Patient Telephone N°, with area code
- Physician Last & First Name
- Physician Signature
- NPI
- Authorized Signature for Medical Release
- ICD-CM Diagnosis Codes (in format in effect at date of service and at highest specificity)
- Primary Billing Party - complete Traditional Medicaid information
- List State Abbreviation
- Physician's State Assigned Provider N°

Private Insurance/ Managed Care

- Billing Option
- Date Collected
- Time Collected
- Patient Legal Name (Last, First, MI)
- Patient Gender
- Patient Date of Birth
- Patient Address (city, state, & ZIP code)
- Patient Telephone N°, with area code
- Physician Last & First Name
- NPI
- Authorized Signature for Medical Release
- ICD-CM Diagnosis Codes (in format in effect at date of service and at highest specificity)
- Responsible Party, if different from patient
- Primary Billing Party - complete insurance information, specify if MC or MD HMO/PPO
- Secondary Billing Party - complete insurance information as applicable to patient

Optional

- Hospital Status

Client

Patient

Medicare, Traditional

Medicaid, Traditional

Private Insurance/ Managed Care

Fields not highlighted may be necessary for certain types of testing or to meet individual payor-specific requirements.

LabCorp
Laboratory Corporation of America

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Attachment C- Self Collection of Vaginal Swab for CT/GC (English)

Self-Collection of Vaginal Swab

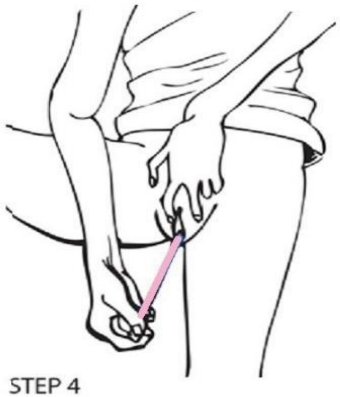
ATTENTION: Read ALL instructions before you begin!

VDH VIRGINIA DEPARTMENT OF HEALTH

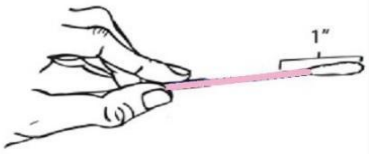
STEP 1
Wash your hands thoroughly.

Step 2
Undress from the waist down. Get into a position where you can comfortable 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.

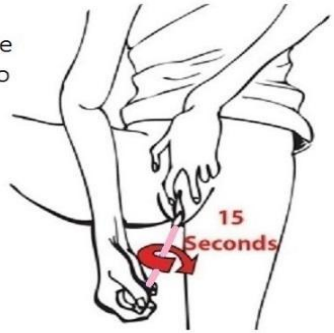


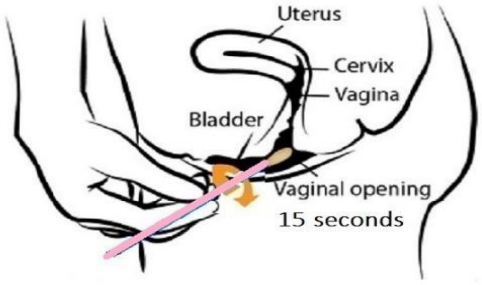
STEP 4
Insert the white tip of the swab about one inch inside the opening of your vagina.



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.

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 D- Self Collection of Vaginal Swab for CT/GC (Spanish)

Auto recogida de hisopo vaginal

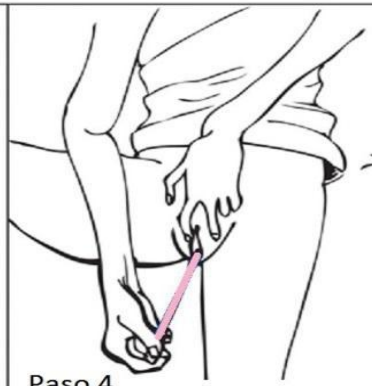
Importante: ¡Lea estas instrucciones antes de comenzar!

VDH VIRGINIA DEPARTMENT OF HEALTH

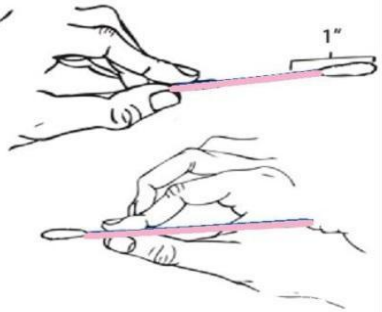
Paso 1
Lávese bien las manos.

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.

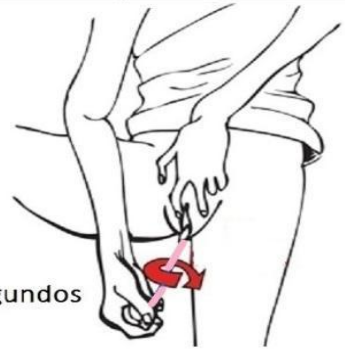


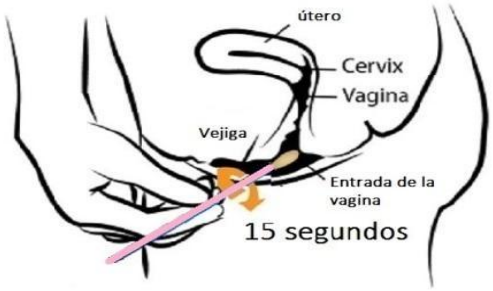
Paso 4
Introduzca la parte del aplicador con algodón como hasta una pulgada dentro de la vagina.



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.





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 E- Self Collection of Rectal Swab for CT/GC (English)

Self-Collection of Rectal Swab

ATTENTION: Read ALL instructions before you begin!

VDH VIRGINIA DEPARTMENT OF HEALTH

STEP 1

Wash your hands thoroughly.

STEP 2

Open the wrapper and remove the swab with the blue handle.

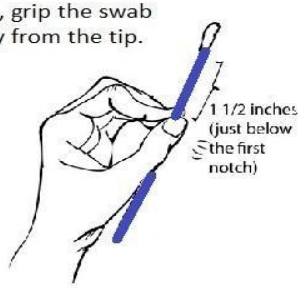
Do not touch the tip of the swab.

STEP 3

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

STEP 4

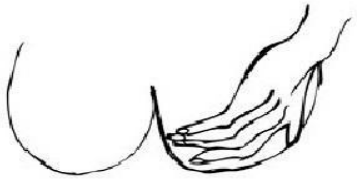
With one hand, grip the swab 1.5 inches away from the tip.

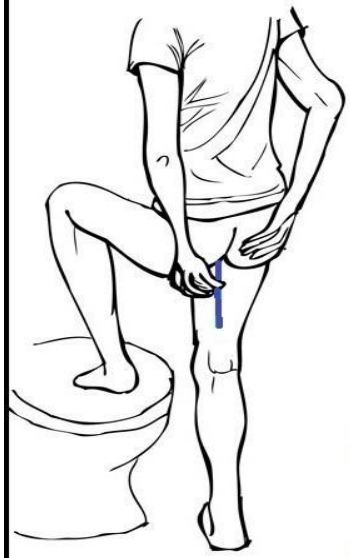


Do NOT use any kind of lubricant (soap, saliva, etc) on either the swab or your body.

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

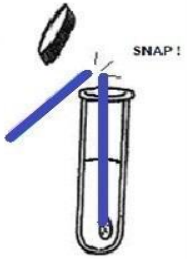
When removing the swab from your rectum, slowly turn it in a circle while pulling it out.

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.

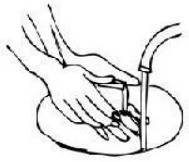
Attachment F- Self Collection of Rectal Swab for CT/GC (Spanish)

Auto Coleccion de Muestra Rectal

Importante: ¡Lea estas instrucciones antes de comenzar!

VDH VIRGINIA DEPARTMENT OF HEALTH

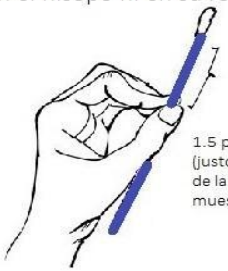
Paso 1
Lávese bien las manos.



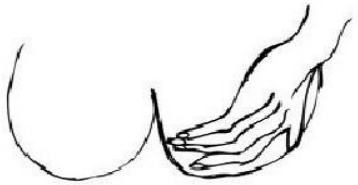
Paso 2
Abra el envoltorio y extraiga el hisopo con mango azul. NO toque la punta del hisopo que tiene el algodon.

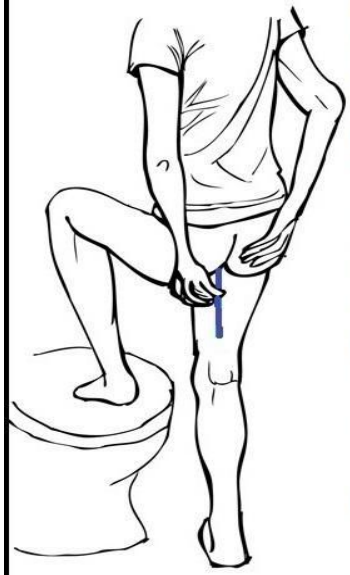
Paso 3
Baje su ropa interior, agachese o levante una pierna y pongala en una repisa, inodoro o una silla.

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 algodon. 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.

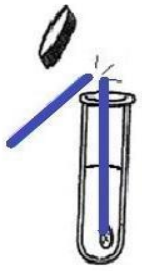
Paso 7
Una vez haya introducido el hisopo en su recto, mueva sus dedos hacia el lado opuesto de su ano, hasta la mitad del hisopo y sostengalo para que se mantenga estable mientras esta introducido en su recto.

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 algodon debe ser introducido hasta el fondo del tubo. Vuelva a tapar firmemente el tubo dejando adentro el hisopo y el liquido.

Paso 13
Lávese muy bien las manos

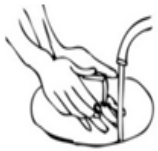
Paso 14
Regrese el tubo con su muestra rectal a su proveedor de salud.

Attachment G- Self Collection of Pharyngeal Swab for CT/GC (English)

Self-Collection of Pharyngeal Swab

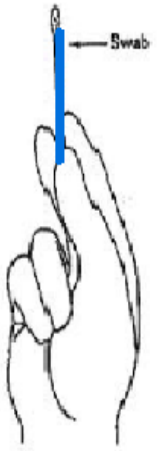
Attention: Read ALL instructions before you begin!

Step 1.

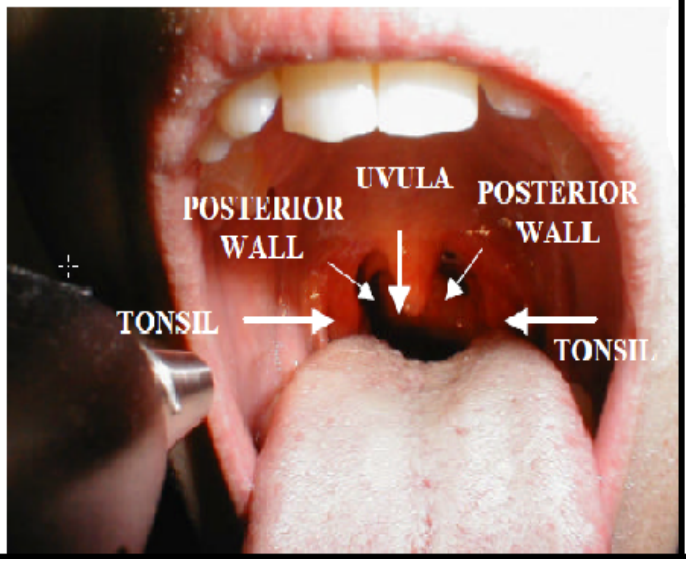


Wash your hands thoroughly.

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

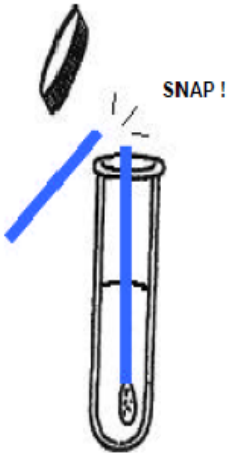


Step 3. Open mouth widely and touch the end of the swab to the 5 areas of the throat.

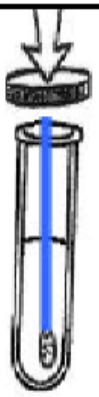


Step 4. Uncap tube and keep upright - do not pour out the clear liquid. Place the swab into the tube.

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 pucture 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

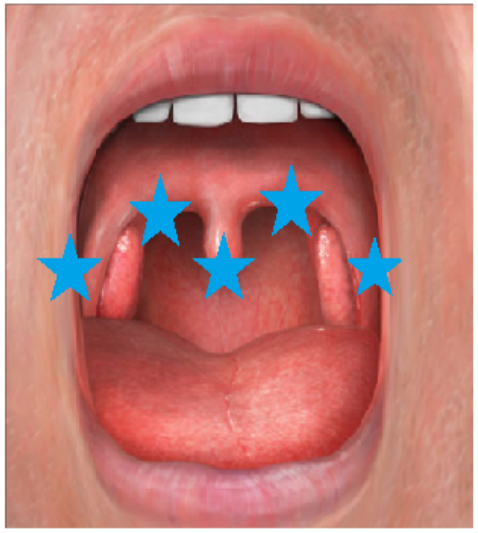
Atención: ¡Lea todas las instrucciones antes de comenzar!

VDH VIRGINIA DEPARTMENT OF HEALTH

Paso 1
Lávese bien las manos.

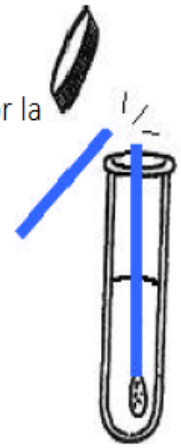
Paso 2
Abra la envoltura y remueva el aplicador agarrándolo por el mango rosado. No toque el área del algodón.

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

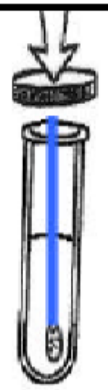


Paso 4
Remueva la tapa y mantenga el tubo de ensayo derecho. No vierta el líquido claro. Coloque el aplicador dentro del tubo.

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



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



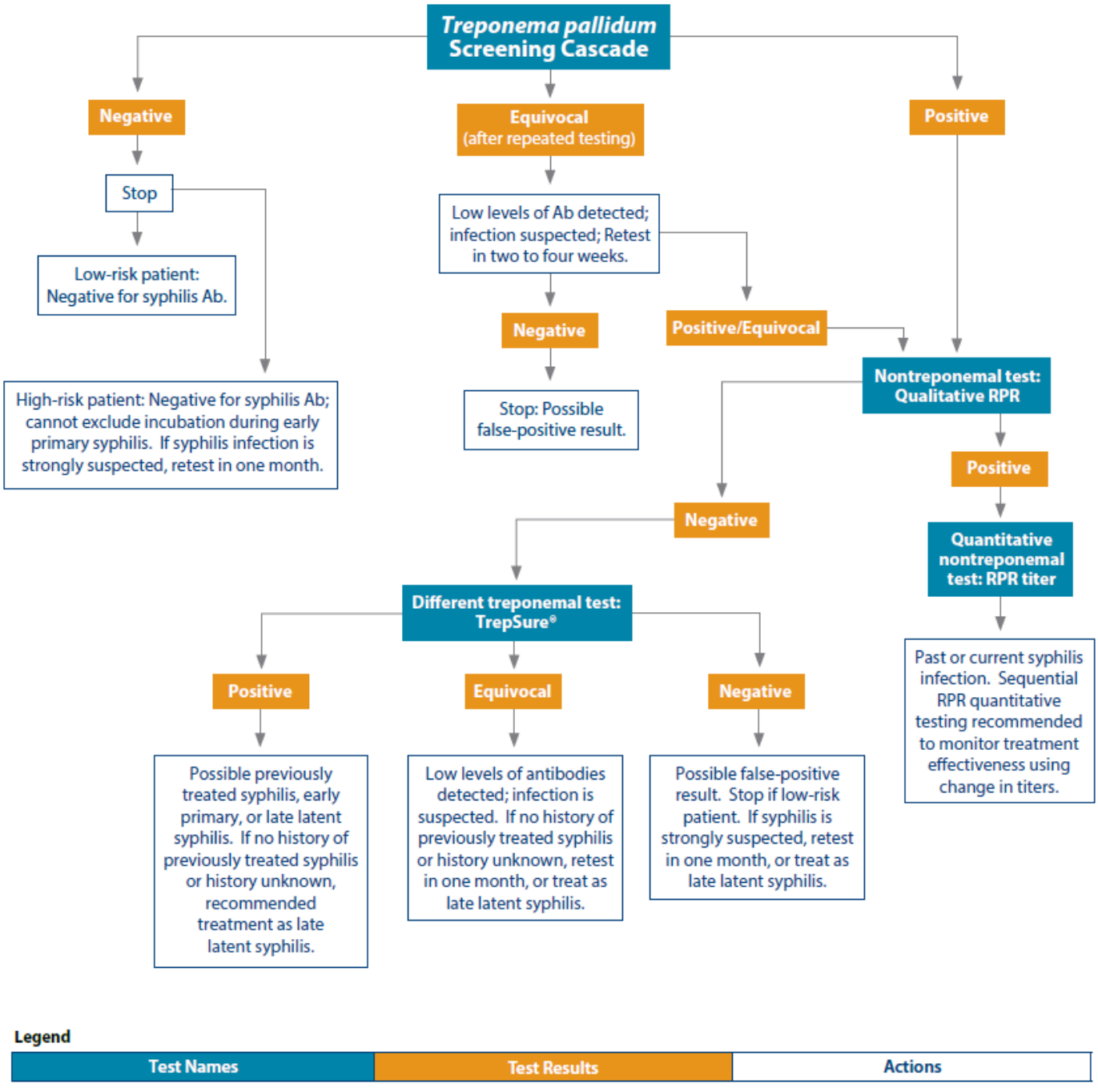
Paso 7
Descarte la envoltura y la parte del aplicador que no necesita.

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

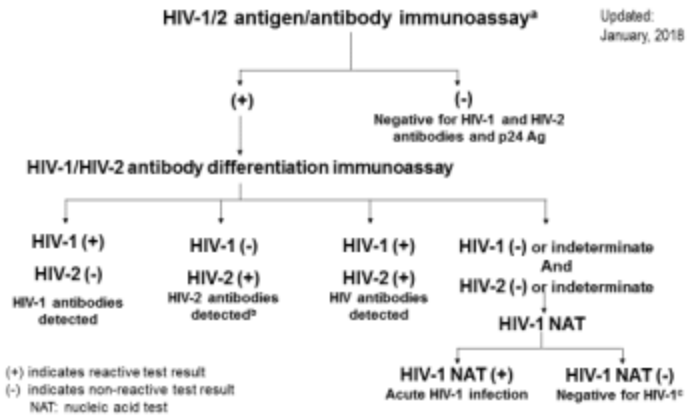


Legend

Test Names	Test Results	Actions

Attachment J - HIV Testing Algorithm

Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens



1. Laboratories should conduct initial testing for HIV with an FDA-approved antigen/antibody immunoassay[a] 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[b], or HIV antibodies, untypable (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).

[a]The FDA-approved single-use rapid HIV-1/HIV-2 antigen/antibody immunoassay can be used as the initial assay in the laboratory HIV testing algorithm for serum or plasma. If any instrumented antigen/antibody test is available, it is preferred due to its superior sensitivity for detecting HIV during acute infection (1,2).
[b]This includes specimens reported as HIV-2 positive with HIV-1 cross-reactivity (3).
[c]Refer to last bullet, item 3 above.

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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://wwwn.cdc.gov/clia/

Attachment J- HIV Testing Algorithm (continued)

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

Guidance for Reporting Results from the HIV Laboratory Diagnostic Testing Algorithm for Serum and Plasma Specimens[a]

	Test Sequence					
	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	Final Algorithm Interpretation[d]	Interpretation for Provider[e] (Sample should be reported as:)	Further Actions[f]
Test Outcomes	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[i], 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 deparment 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