

# Office of Epidemiology Laboratory Screening in the Community Setting



Division of Disease Prevention



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## Purpose

This manual provides information for non-laboratory personnel within community based organizations (CBOs) 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.

## Testing Preparation

### Implementing STI Testing Checklist

Agencies providing safety net services for priority populations who are interested in establishing a new testing agreement with the Division of Disease Prevention (DDP) at Virginia Department of Health (VDH) are generally expected to start with rapid HIV testing. Following six months of rapid HIV testing, the VDH contract monitor will evaluate the agency's implementation of rapid testing to determine whether they may scale up to a clinical testing agreement. Prior to implementing clinical testing, agencies must develop internal procedures for referral, tracking results, partner notification, and follow-up. Additionally, each location must train employees and have procedures for following blood borne pathogens standards, disposal of biomedical waste, infection control plans, and blood and body fluid exposure.

Please see [Attachment J](#) for a list of requirements for non-local health department locations to implement testing.

### Conflict of Interest

Agencies should not provide testing to persons who are employed by the agency providing testing. Additionally, if the client to be tested is a friend or associate of the test counselor, and either the client or the test counselor is uncomfortable with the situation, the test counselor shall immediately locate another staff person to provide services to the client. The counselor should verify that that the client is comfortable with the test counselor performing the counseling and knowing their test result. Test counselors should not provide chlamydia or gonorrhea testing to their co-workers. Agencies should assist their staff in locating another test site for services.

### Ordering Clinician

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

An ordering clinician takes responsibility for receiving and interpreting all test results and ensuring clients with positive/abnormal results receive appropriate follow up care. LabCorp requires the clinician's full name and National Provider Identifier (NPI) to create an account. If an ordering clinician provides a standing order for the CBO staff to submit specimens, the ordering clinician should specify expectations for CBO staff on who to

test and how clients will be notified and treated. This is generally outlined in a memorandum of understanding or agreement (MOU/MOA) between the ordering clinician and CBO.

Agencies interested in testing are responsible for identifying a provider who will serve as their ordering clinician and providing VDH with the clinician's information to create a LabCorp account.

## Results

Negative results will be returned via LabCorp's secure online portal, LabCorp Link (previously Beacon), within 2-3 days to the ordering clinician. Reactive or abnormal results may require an additional 1-2 days before they are returned. The ordering clinician will access Link via a secure login. Unless your organization has an established agreement with a local health department, the CBO site who ordered the test is responsible for contacting clients who have a positive test result and arranging a treatment plan for the client. The resulting report contains Protected Health Information (PHI) and cannot be shared via email.

## Information Security

Sites are responsible for ensuring all client information and results is secure, is [HIPAA compliant](#), and is maintained and disposed of following the Library of Virginia [Records Retention guidelines](#).

## Collection Sites

Collection sites must have all necessary personnel, supplies, and facilities to provide for specimen collection and storage until the specimen is ready for transportation. A collection site must have:

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

## Supply Orders

Contact your LabCorp representative to order additional specimen transport tubes, swab kits, and lab requisition forms. All other supplies such as urine cups, gauze, etc. are the responsibility of the testing agency.

## 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.

## Collection of the Blood Specimen

All blood draws must be performed by your organization's staff. VDH funding does not support additional cost for blood draws or administrative expenses; therefore, if clients are referred to a LabCorp drawing location, the cost of the blood draw will not be covered by VDH.

## Ordering Tests

Tests may be ordered using a physical copy of the LabCorp requisition form or using the online ordering system through LabCorp Link. Either method is acceptable. Please note that if tests are ordered that are not covered by VDH, the test charges will be transferred back to the CBO for payment to LabCorp.

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

## Providing Quality STD Services

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

Providers caring for transgender persons should have knowledge of their clients' current anatomy and patterns of sexual behavior before counseling them about STD and HIV prevention. Additional information about caring for transgender persons is available at <https://www.cdc.gov/lgbthealth/transgender.htm>.

## Sexual History and Physical Examination

The clinician or staff should obtain a thorough sexual history. A complete sexual history includes the five P's—partners, practices, protection, past history of STDS, and prevention of pregnancy. Ascertaining specific sexual activities and recent partners during the sexual health history will guide clinical decisions. A resource for taking a complete sexual health history is available at: <https://www.cdc.gov/std/treatment/sexualhistory.pdf>.

While physical examination is part of the recommended quality STD services, it is only performed by a clinician (i.e. physician, nurse practitioner, physician's assistant). If a clinician is not on site, a physical examination is not performed.

## Prevention

The primary service in the CBO setting for the prevention of HIV and STDs is prevention counseling. Prevention counseling varies in methods, scope, and time and is used to effect client changes to reduce the client's risk for HIV and STD acquisition and transmission.

## Screening

Because many STDs are asymptomatic, testing is the only method to diagnose these infections. The availability of screening tests is key for identifying gonorrhea, chlamydia, syphilis, hepatitis B, hepatitis C, and HIV. Client-reported exposure, regardless of condom use, should inform screening. A table summarizing screening recommendations for women, pregnant women, men, men who have sex with men (MSM), and persons with HIV is available (<https://www.cdc.gov/std/treatment-guidelines/>). Due to the large percentage of at risk populations served by CBOs, it is recommended that all persons presenting for services be screened for reportable STDs.

## Partner Services

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

## Evaluation of STD-Related Conditions

STD-related conditions warrant prompt evaluation of signs and symptoms to make an accurate diagnosis and provide timely empiric treatment to prevent complications and onward transmission. Patients who report symptoms that are suggestive of STD etiology should be referred to the local health department or healthcare provider for a thorough medical evaluation and treatment, even if they are tested in a non-clinical setting. Refer to the STD QCS for recommendations for STD-related conditions that should be clinically evaluated.

## Laboratory Testing

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

- Chlamydia/Gonorrhea

- Syphilis
- HIV
- Hepatitis B
- Hepatitis C

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

### Chlamydia/Gonorrhea Testing

Nucleic Acid Amplification Testing (NAAT) represents a significant advancement in chlamydia/gonorrhea (CT/GC) screening, as previously culture, a test with comparatively poor sensitivity, was required to diagnose. FDA approval for this test is limited to genital specimens; however, research demonstrates the CT/GC NAAT is acceptable for testing extragenital specimens. Because this use of the CT/GC NAAT test is not FDA approved, each laboratory must conduct analytical validation of their methodology. LabCorp completed validation for extragenital NAAT and, per state contract, provides diagnostic testing for local health departments. Specimens for screening may be obtained for any, or all, of the following anatomical sites: genital (urine, vaginal, endocervical), pharyngeal, and/or rectal. 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. This is due to the high sensitivity of the tests.

### Specimen Collection

Self-collection, particularly for rectal specimens, increases the uptake of testing and offers high acceptance among MSM. Self-collection can eliminate access barriers such as stigma, shame, negative interactions with service providers, and concerns about privacy and confidentiality. Published clinical research indicates self-collected specimens have equivalent or better detection rates for rectal, vaginal, and pharyngeal CT/GC compared to clinician collection.<sup>1,2</sup> It is important when collecting specimens to avoid cross contamination, as cross contamination can make the test falsely positive.

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<sup>1</sup> 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.

<sup>2</sup> 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.

### *Urine Specimen Collection*

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

### *Eligibility*

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

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

Transgender males who have had sex reassignment surgery should collect a urine specimen.

Transgender males who have not had sex reassignment surgery may self-collect a vaginal swab or collect a urine specimen. Urine specimens are acceptable, but may miss up to 10% of infections compared to vaginal swabs.

Transgender females with or without a history of sex reassignment surgery should collect a urine specimen.

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

### *Collection Procedures and Handling*

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

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



**Figure 1: Urine Specimen Transfer**



Maintain the integrity of the processed urine specimen with proper and secure storage for transportation and handling. Processed urine specimens must be kept at room temperature or refrigerated until courier collection. Do not freeze processed urine specimens as it compromises the viability of the infecting agent.

### *Vaginal Specimen Collection*

First catch urine from women, while acceptable for screening, might detect up to 10% fewer infections when compared with vaginal and endocervical swab samples.<sup>3</sup>

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

- Have not had a positive lab test or been treated for CT or GC in past 4 weeks.
- Transgender males who have not had sex reassignment surgery may self-collect a vaginal swab or collect a urine specimen. Urine specimens are acceptable, but may miss up to 10% of infections compared to vaginal swabs.

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<sup>3</sup> Centers for Disease Control and Prevention. Recommendations for the Laboratory-Based Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. *MMWR* March 14, 2014; 63:2.

### Collection Procedures and Handling

The Gen-Probe® Aptima Vaginal Swab Specimen Collection Kit should be used to collect vaginal specimens.

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



### Extragenital Specimens

Extragenital screening is critically important, particularly among some high-risk populations: **77% of CT and 95% of GC infections are missed** among MSM if screening is only performed at urethral sites.<sup>4</sup> Symptoms of rectal and pharyngeal CT/GC are nonspecific and often silent.

### Rectal Specimen Collection

Symptoms of rectal CT/GC are nonspecific and often silent; in fact, 85% of rectal CT/GC infections are asymptomatic in MSM<sup>5</sup>. Self-collected specimens increase the uptake of testing among high-risk clients and offer high acceptance among MSM; self-collection can eliminate access barriers such as stigma, shame, negative interactions with service providers, and concerns about privacy and confidentiality. Given adequate instruction, self-collection of a rectal specimen is equivalent to, or better than, clinician collection.<sup>6,7</sup>

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

- Be over 15 years old;
- 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 past 4 weeks, regardless of anatomical site.

### Collection Procedures and Handling

- The Gen-Probe® Unisex Swab Specimen Collection Kit should be used to collect rectal specimens.
- Label the specimen collection tube.

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<sup>4</sup> 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.

<sup>5</sup> 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.

<sup>6</sup> 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.

<sup>7</sup> 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.

- Review the collection process with the client and instruct them to collect the rectal specimen, put the swab inside the specimen collection tube, align score line with the top edge of the tube, carefully break the swab shaft, seal the tube, and put the sealed tube inside the biohazard specimen bag.
- Diagrams included in attachments A and B of this manual may be posted for client reference.
- Visually inspect the swab to assure there is evidence of use, ensure the swab is not contaminated with significant fecal matter, and ensure the lid is tight on the specimen collection tube to prevent spillage.
- Complete all fields of the lab requisition form (including race/ethnicity) and place in the side pouch of the individual biohazard specimen bag separate from the specimen tube to keep it dry.



### Pharyngeal Specimen Collection

Given adequate instruction, self-collection of a pharyngeal specimen is equivalent to, or better than, clinician collection.<sup>8,9</sup> The swab should make contact with the key areas of the throat: uvula and left/right posterior walls and tonsils.<sup>10</sup>

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

- Be over 15 years old;
- 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 past 4 weeks, regardless of anatomical site.

### Collection Procedures and Handling

- The Gen-Probe® Unisex Swab Specimen Collection Kit should be used to collect pharyngeal specimens.
- Label the specimen collection tube.
- Review the collection process with the client and instruct them to collect the specimen, put the swab inside the specimen collection tube, align score line with the top edge of the tube, carefully break the swab shaft, seal the tube, and put the sealed tube inside the biohazard specimen bag.
- The swab should make contact with the key areas of the throat: uvula and left/right posterior walls and tonsils.<sup>11</sup>
- Diagrams included in attachments C and D of this manual may be posted for client reference.



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<sup>8</sup> 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.

<sup>9</sup> 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.

<sup>10</sup> San Francisco City Clinic. Client instructions for self-collected specimens: pharyngeal and rectal. Available at: <http://www.sfcityclinic.org/providers>. Accessed December 15, 2011.

<sup>11</sup> San Francisco City Clinic. Client instructions for self-collected specimens: pharyngeal and rectal. Available at: <http://www.sfcityclinic.org/providers>.

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

### Syphilis Testing

The screening test for syphilis available through LabCorp is the T Pallidum Screening Cascade, which uses the reverse algorithm sequence screening. The first test that is conducted is a treponemal chemiluminescence immunoassay (CIA), if it is positive, a quantitative rapid plasma reagin (RPR) is conducted; if the RPR is negative, a TrepSure treponemal test is conducted. See [Attachment M](#) for the Syphilis Testing Algorithm. Additional information about the algorithm is available at: <https://www.labcorp.com/assets/5131>. Some potential reasons for false positives are available at: <https://www.cdc.gov/std/tg2015/syphilis.htm>.

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

- 082345            T Pallidum Screening Cascade

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



### HIV Testing

The screening test for HIV available through LabCorp is the HIV 1/0/2 4<sup>th</sup> Generation, which automatically reflexes if necessary. Additional information regarding HIV testing is available at: <https://www.vdh.virginia.gov/disease-prevention/testing-hepatitis-hiv-and-stds/>.

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

- 083935            Panel 083935

2 mL of serum is needed in a gel-barrier tube with red/gray-mottled top or red-top tube.



## Viral Hepatitis Testing

### Hepatitis A

The VDH Office of Epidemiology (OEpi) account does not cover any tests for hepatitis A. CBOs should recommend the hepatitis A and hepatitis B vaccines. Local health departments may offer the hepatitis A and/or hepatitis B vaccine; contact the VDH Immunization Program for more information:

<http://www.vdh.virginia.gov/immunization/>.

### Hepatitis B

Use the OEpi LabCorp requisition form to request a HBV combo test (HBsAb+HBcAb+HBsAg) with reflex to IgM test for clients who meet at least one defined criteria. Additional information about eligibility and test interpretation is available at <https://www.vdh.virginia.gov/disease-prevention/disease-prevention/viral-hepatitis/providers/>.

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

- 219949 Hepatitis Panel Reflex to IGM, HBcAb+HBsAb+Ag

Blood specimen collection supplies and requirements for serum (HBV combo test):

- Collection media: 10 mL red-top tube or gel-barrier tube
- Volume: 7 mL of serum is the minimum amount required to run the HBV combo test
- Specimen storage instructions: room temperature
- Sample stability: 14 days at room temperature, refrigerated or frozen and three freeze/thaw cycles



### Hepatitis C

#### Rapid

Some sites have been approved to conduct rapid viral hepatitis C (HCV) testing during outreach events for eligible clients. Complete information on rapid testing is available at <http://www.vdh.virginia.gov/disease-prevention/disease-prevention/viral-hepatitis/providers/>.

#### Conventional

Use the LabCorp requisition form to request a HCV Antibody reflex to NAA (LabCorp test number 144045) for clients who meet the defined criteria (e.g., reactive rapid HCV antibody test). The “reflex to NAA” indicates that if the HCV Ab is positive, LabCorp will automatically test for HCV RNA via nucleic acid amplification (NAA). HCV RNA is the confirmatory test. Other HCV tests are not authorized on the account. If an alternative test is clinically indicated, contact the viral hepatitis testing coordinator for assistance. Additional information about eligibility and test interpretation is available at <https://www.vdh.virginia.gov/disease-prevention/disease-prevention/viral-hepatitis/providers/>.

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

- 144045 HCV Antibody reflex to NAA

Blood specimen collection supplies and requirements for HCV conventional blood draw testing:

- Container: Red-top tube or gel-barrier tube
- Collection: If tube other than a gel-barrier tube is used, transfer separated serum to a plastic transport tube. Do not freeze gel-barrier tube (pour off serum first)
- Volume: 3mL of serum is the required minimum to run the test; 5mL is preferred
- Specimen storage instructions: Refrigerate
- Stability Requirements: 3 days room temperature; 14 days refrigerated and frozen; 3 freeze/thaw cycles



### Additional Testing

Additional testing for infections not included on the requisition form is not covered by the VDH OEpi account. No additional test numbers should be written on the requisition form. Please note that if tests are ordered that are not covered by VDH OEpi, the test charges will be transferred back to the CBO for payment to LabCorp.

### Labeling Specimens

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

### Submission Issues that Delay Testing or Prompt Rejections

The following are some common reasons for rejections by the laboratory. Additional reasons that would prompt rejection are available at <https://www.labcorp.com/resource/introduction-to-specimen-collection>.

1. Incorrect swab or tube used to collect specimen.
2. Missing or inconsistent client name; client name on the specimen collection tube label and the lab requisition form must be consistent. Use printed specimen tube labels whenever possible and put identical labels on all locations.
3. Incorrect or missing specimen source on the specimen collection tube label and/or the lab requisition form.
4. Missing or inconsistent collection date listed on the specimen collection tube label and/or the lab requisition form.

5. Missing indication of “requested test” on the lab requisition form.
6. 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.
7. 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.

### Lab Results

Lab results are sent through the online LabCorp Link system. One staff person at your organization will be set up as the account administrator. This person has the capacity to add/delete additional users to the account. LabCorp can provide training for LabCorp Link use to find lab results.

See [Attachment I](#) for sample test results.

### Courier

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

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

### Treatment

Clients can be treated in several ways: by the ordering clinician, by their medical primary care provider, or they can be referred to the local health department. Clients referred to the local health department will receive treatment for reportable conditions at no cost to the client. However, the client will still participate in the financial eligibility conducted by the front desk staff and need to wait to be seen for treatment. If the client receives other tests or treatment while they are there, they may be subject to charges based on their income and insurance status. The agency should fax a copy of the positive lab result to the health department where the client intends to go. Many local health departments are only able to see clients who have arranged appointments. It is recommended that CBOs assist clients in scheduling an appointment at a local health department. Use the VDH health department locator to locate the nearest site

<http://www.vdh.virginia.gov/health-department-locator/>.

If the ordering clinician treats the client, the most recent CDC STD Treatment Guidelines should be followed. The guidelines were most recently updated in 2015 and available at <https://www.cdc.gov/std/tg2015/default.htm>. A confidential morbidity report (Epi-1), which includes information on treatment, must be submitted for reportable diseases diagnosed by the ordering clinician. The Epi-1 report can be submitted electronically. Visit <http://www.vdh.virginia.gov/surveillance-and-investigation/commonwealth-of-virginiastate-board-of-health/> for the electronic Epi-1 form and a list of reportable diseases.

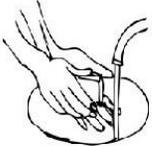
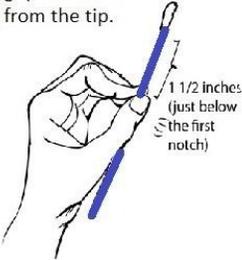
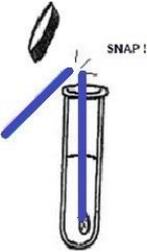
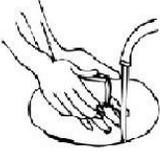
## Referral

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

## Attachment A – Self Collection of Rectal Swab (English)

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



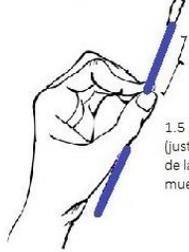
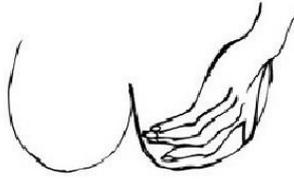
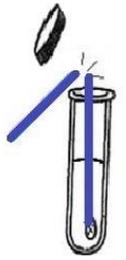
<p><b>STEP 1</b> Wash your hands thoroughly.</p>  <p><b>STEP 2</b> Open the wrapper and remove the swab with the blue handle.</p>  <p>Do not touch the tip of the swab.</p>	<p><b>STEP 3</b></p> <p>Pull underwear down or off. Squat down, or lift one leg up on a ledge, toilet, or chair.</p> 	<p><b>STEP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

## Attachment B – Self Collection of Rectal Swab (Spanish)

### Auto Coleccion de Muestra Rectal

Importante: ¡Lea estas instrucciones antes de comenzar!



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

## Attachment C – Self Collection of Pharyngeal Swab (English)

### Self-Collection of Pharyngeal Swab

Attention: Read ALL instructions before you begin!

#### Step 1.



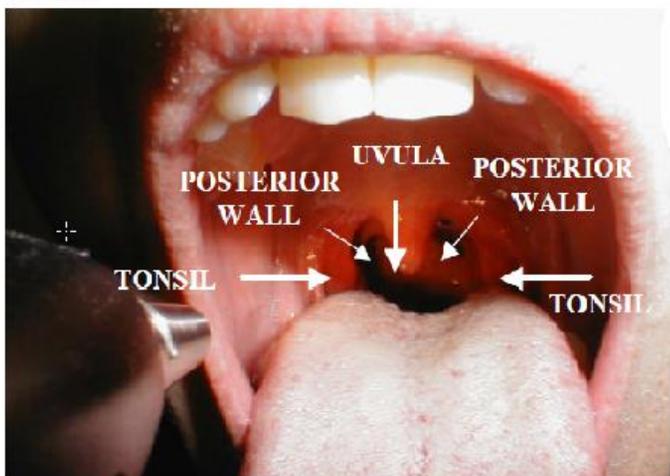
Wash your hands thoroughly.

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

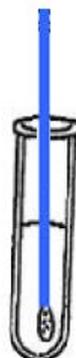
Do NOT touch the tip of the swab.



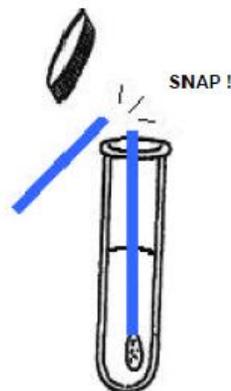
**Step 3.** Open mouth widely and touch the end of the swab to the 5 areas of the throat.



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



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



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



**Step 7.** Throw away wrapper and unused swab.

**Step 8.** Wash your hands thoroughly.



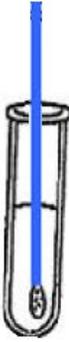
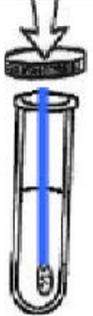
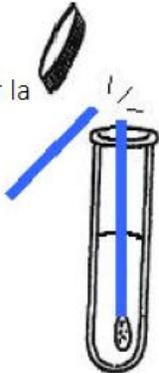
**Step 9.** Return the tube to your health care provider.

## Attachment D – Self Collection of Pharyngeal Swab (Spanish)

### Auto-colección de muestra de la faringe

Atención: ¡Lea todas las instrucciones antes de comenzar!



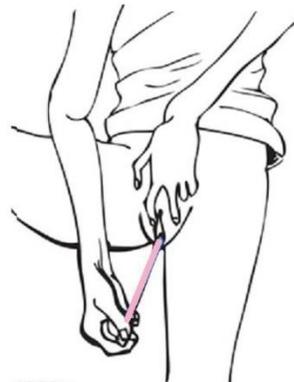
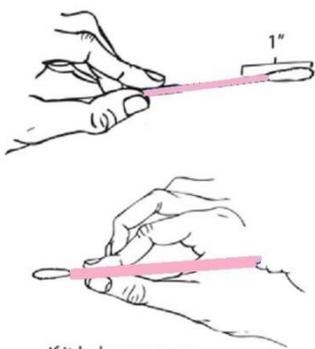
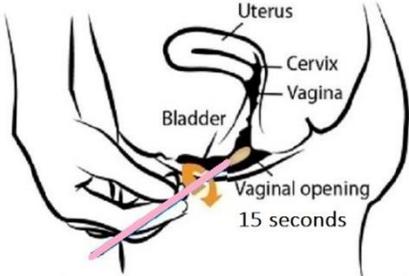
<p><b>Paso 1</b> Lávese bien las manos.</p>  <p><b>Paso 2</b> Abra la envoltura y remueva el aplicador agarrándolo por el mango rosado. No toque el área del algodón.</p> 	<p><b>Paso 4</b> Remueva la tapa y mantenga el tubo de ensayo derecho. No vierta el líquido claro. Coloque el aplicador dentro del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

# Attachment E – Self Collection of Vaginal Swab (English)

## Self-Collection of Vaginal Swab

ATTENTION: Read ALL instructions before you begin!



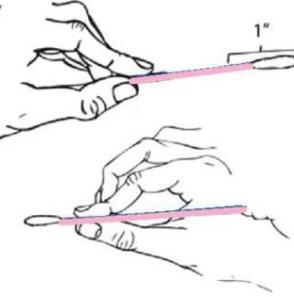
<p><b>STEP 1</b> Wash your hands thoroughly.</p>  <p><b>Step 2</b> Undress from the waist down. Get into a position where you can comfortably insert a swab into your vagina - such as sitting on the toilet, standing with one foot on a chair, or any position that you would use to insert a tampon.</p> 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

## Attachment F – Self Collection of Vaginal Swab (Spanish)

### Auto recogida de hisopo vaginal

Importante: ¡Lea estas instrucciones antes de comenzar!



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

# Proper Specimen Identification & Labeling

## Positive Specimen Identification

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

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

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

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

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



## Specimen Labeling

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

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





## Attachment I – Understanding Test Results



**Patient Report**

Acct #: 45012910    Phone: (757) 518-2647    Rte: 00

Virginia Beach City Hlth Dept  
Office Of Epidemiology  
4452 Corporation Lane  
VA Beach VA 23462



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**Patient Name & DOB**

**Specimen Details**

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

**Physician Details**

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

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**General Comments & Additional Information**  
Clinical Info: SRC: URINE

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

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

**Reference:** what a normal test result should be

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

**Specimen Source:** indicates which result is for which specimen

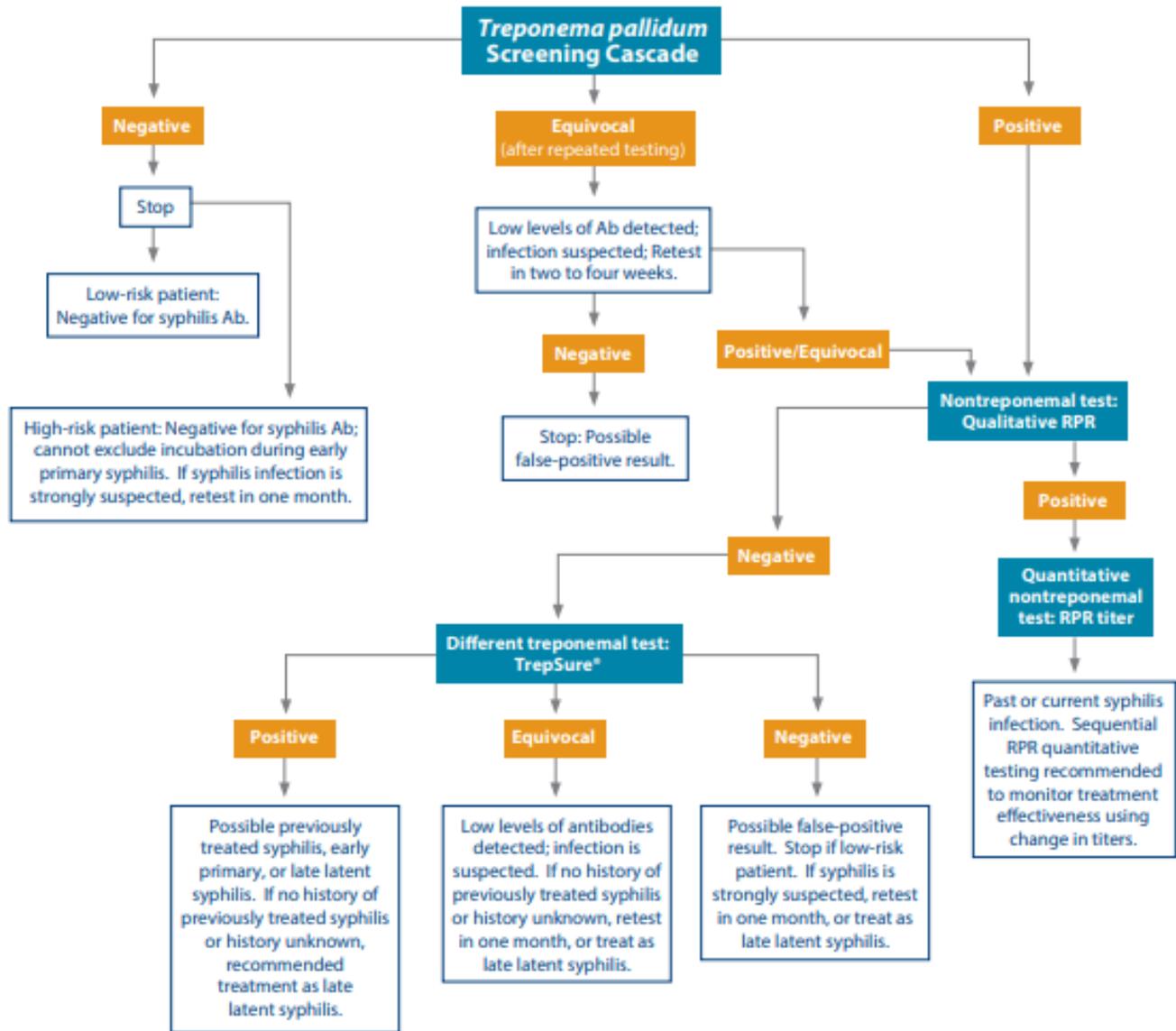
## Attachment J – Implementing STI Testing Checklist

- ✓ Successfully implement rapid HIV testing for a minimum of 6 months with a satisfactory evaluation from the VDH contract monitor.
- ✓ Written policies and procedures (These should already be in place if rapid HIV testing currently performed in the agency.)
  - Bloodborne Pathogen Standard Compliance/Infection Control Policy
  - Employee Blood and Body Fluid Exposure Plan
  - Biomedical Waste Storage and Removal
  - HIPAA Compliance
  - Medical Records Security, Storage, Retention, Disposal
- ✓ Ordering clinician identified
  - Written agreement regarding scope of services, accountability, and liability coverage
  - If ordering clinician is nurse practitioner or physician assistant, written collaborative practice agreement with physician to include required chart reviews
  - Standing lab order requirements as outlined in “Chlamydia/Gonorrhea Screening at Community Based Organizations,” VDH Office of Epidemiology Division of Disease Prevention: STD Surveillance, Operations, & Data Administration (SODA)
- ✓ LabCorp Account set-up – in collaboration with Health Promotion Coordinator, VDH
  - Standing orders
  - Lab requisitions – computerized vs. written
  - Diagnostic codes
  - Courier services
- ✓ Written policies and procedures for specimen tracking
  - Date
  - Tests ordered
  - Specimens sent
  - Results received
- ✓ Written policies and procedures for follow-up of results
  - Results reviewed/signed off by provider or designated staff
  - Follow-up of results
    - Review and disposition orders
    - Client notification
      - How
      - When
      - By whom
    - Negative results
      - Education and counseling
      - Retesting recommendations
    - Positive results
      - Warm referrals for follow-up - Collaboration agreements with sites accepting referrals for treatment and follow-up testing
        - Who
        - What
        - When
        - Where

- How
    - Appropriate use of Medical Records Release or Coordination of Care Release for interagency information exchange
    - Documentation of treatment
    - Partner referrals
    - Education and counseling
    - Retesting recommendations
    - Epi-1 completion
    - E2Virginia entry
  - “Unable to contact” protocol
- ✓ Staff competencies
  - Sexual history-taking
  - Appropriate use of Personal Protective Equipment (PPE)
  - Specimen collection, handling, and storage
  - Avoiding contamination of work surfaces
  - Avoiding cross-contamination of specimens
  - Client education and counseling
    - Must include recommendation for syphilis and conventional HIV testing at referral site(s)
    - Teaching clients how to self-swab for pharyngeal, vaginal, and rectal swabs
    - Teaching clients how to correctly collect urine specimen for CT/GC NAAT
    - Testing information
    - Harm reduction strategies
  - Meticulous data collection, management, and reporting
  - Knowledge of and compliance with guidelines “Chlamydia/Gonorrhea Screening at Community Based Organizations,” VDH Office of Epidemiology Division of Disease Prevention: STD Surveillance, Operations, & Data Administration (SODA)
- ✓ Physical site requirements – see above

Attachment K – Syphilis Screening Cascade

082345 *Treponema pallidum* (Syphilis) Screening Cascade



Legend

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