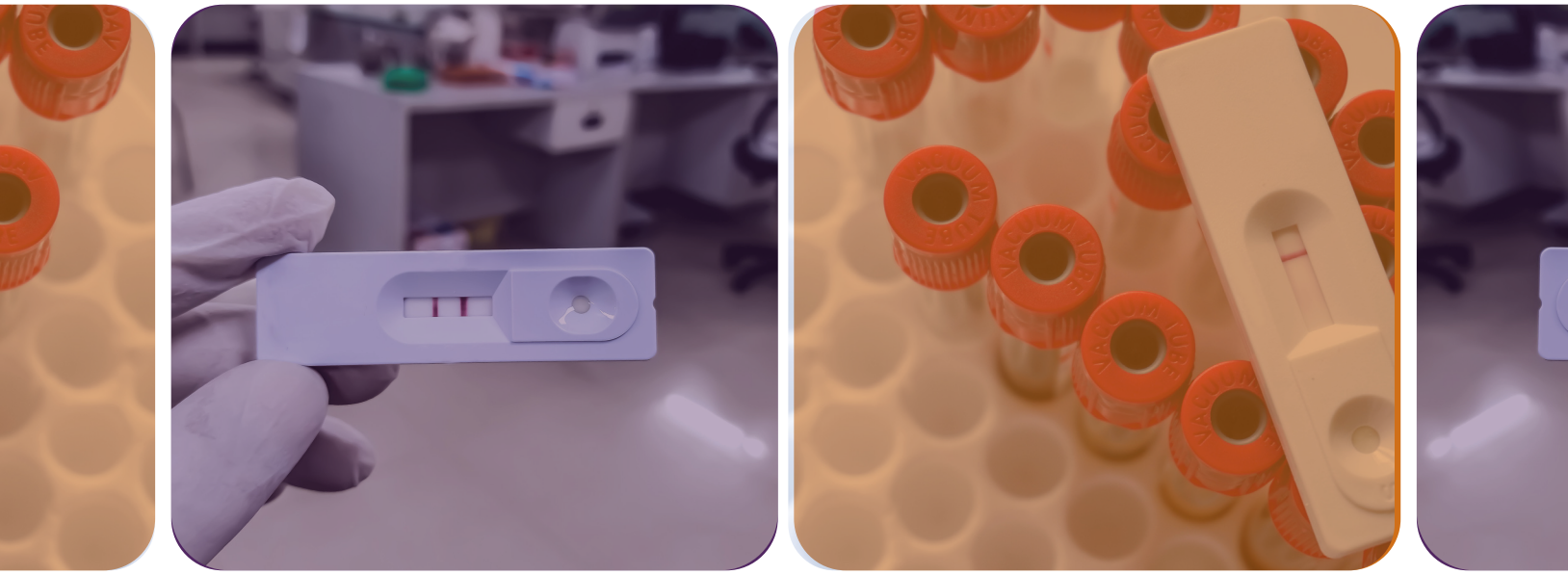

Point-of-Care Testing for Sexually Transmitted Infections Toolkit

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Overview of Point-of-Care Tests

Point-of-care testing is when a test is performed at or near the patient's point of care in a clinical facility or other site of patient care and the results are available before the patient leaves. Point-of-care tests (POCTs) usually produce results in under one hour, with some tests showing results in as little as 10-15 minutes. The faster results may allow treatment, or other next steps in the patient's care, while the patient is still at their initial visit or interaction. They also allow healthcare providers to make more informed decisions by basing the treatment plan on the specific pathogen detected rather than on clinical suspicion alone. While POCTs are beneficial in many circumstances, not every setting, staffing, or patient population is ideal for POCT use. This toolkit can support decision-making on the use of POCTs for sexually transmitted infections (STIs), including human immunodeficiency virus (HIV), by local health departments, clinic managers, and other care providers.

Regulation of Point-of-Care Tests

Term	Definition/Explanation
FDA-Cleared Test	Testing device that has been cleared by the FDA for use in the US; all FDA-cleared tests are manufactured with a package insert that specifies their use, including acceptable specimens and their collection methods.
CLIA Regulation	CLIA are regulations governed by the CMS; their purpose is to establish quality standards for clinical laboratory testing to ensure that patient test results are accurate and reliable; clinical laboratory testing is governed by the CLIA and involves activities such as documentation of staff training and proficiency.
Laboratory-Developed Test (LDT)	Test that has not gone through regular FDA clearance (except for emergency uses) but can nevertheless be performed at local laboratories if the local clinical laboratory director reviews and approves test performance data according to CLIA regulations.
CLIA-Waived Test	Test device maker can apply for the label "CLIA waived" during FDA clearance review; it indicates that the test can be safely performed by non-laboratorians, typically due to its simplicity and low risk of erroneous results; CLIA-waived tests can be good candidates for self-testing but not all are automatically approved for self-testing; some CLIA-waived tests still require equipment that cannot be transported to a home and thus cannot be adapted for home self-testing.

In the case of POCTs, the Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS), and state Medicare/Medicaid agencies ensure the quality and reliability of the testing.

All POCTs must be cleared by the FDA to be used in the U.S. The FDA ensures that POCTs meet certain safety and performance standards. The FDA also determines the criteria for tests to be considered "simple" i.e., with a low risk of error.

Once a test is approved for use by the FDA, it is important to ensure the test is used correctly and those conducting the test follow the manufacturer's specifications and instructions.
To ensure this, Congress created quality testing standards and passed the Clinical Laboratory Improvement Amendments (CLIA).[1] CMS regulates testing through CLIA to ensure the accuracy and reliability of test results for all laboratory testing on human specimens used to inform the diagnosis, prevention, and treatment of disease, or assessment of health.

1. Clinical Laboratory Improvement Amendments of 1988 (CLIA) https://www.gpo.gov/fdsys/pkg/USCODE-2011-title42/pdf/USCODE-2011-title42-chap6A-subchapII-partF-subpart2-sec263a.pdf

CLIA Waivers for Point-of-Care Tests

Some tests are CLIA-waived, and others are non-CLIA waived. The CLIA waiver requirements depend on the complexity of the test and not the lab where it is performed. CLIA-waived tests are "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result" as determined by the FDA.[2] Examples include tests cleared by the FDA for home use (e.g., COVID-19 self-collected home tests) or those where the manufacturer provided scientific data that verifies CLIA waiver criteria are met.[3]

There are no federal requirements for the education-level of personnel performing CLIA-waived tests, but state and local regulations may require staff to have specific licenses or professional qualifications to perform POCTs.

Non-CLIA-waived POCTs are considered moderate or high complexity and therefore must be performed by trained laboratorians.[4] Most non-waived POCTs fall into the moderate complexity category. Laboratories or other sites that perform these tests, such as physician offices or urgent care centers, must have a CLIA certificate and be inspected every two years to confirm they meet the CLIA quality standards.[5] In the case of STI tests, this includes advanced molecular tests such as certain human papillomavirus (HPV) or Trichomonas vaginalis (TV) assays and laboratory-based nucleic acid amplification tests (NAATs) for the detection of Chlamydia trachomatis (CT)/Neisseria gonorrhoeae (GC) which require specialized equipment and staff trained to perform and interpret these tests.[6]

POCTs must be approved and meet certain criteria to receive a waiver under CLIA. CLIA-waived POCTs can be performed without a clinical laboratory on site but still must work with a laboratory to seek CMS approval by filing a CLIA Application for Certification through CMS.

Once the Testing Site Receives the CLIA Certificate of Waiver:

- The site can only perform waived tests.
- The testing personnel must follow the manufacturer's instructions while conducting waived tests.[7]
- The site must pay the certificate renewal fee every two years.
- The site's applicable CMS state agency must be notified about changes in site ownership, name, address, or director within 30 days.
- The site's applicable CMS state agency must be notified if the testing site wants to add tests that are not waived to their testing options.
- The testing site must allow CMS representatives on-site for announced or unannounced inspections.

2. http://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5; "How to Obtain a CLIA Certificate of Waiver" https://www.cdc.gov/cliac/docs/addenda/cliac0210/Addendum-F.pdf
3. US Food and Drug Administration, "CLIA Waiver by Application" https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clia-waiver-application
4. See citation 3; 42 CFR Subpart M: Personnel for Nonwaived Testing
5. 42 CFR Subpart H: Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing; 42 CFR Subpart J: Facility Administration for Nonwaived Testing; 42 CFR Subpart K: Quality System for Nonwaived Testing
6. Gaydos CA, Manabe YC, Melendez JH. A Narrative Review of Where We Are With Point-of-Care Sexually Transmitted Infection Testing in the United States. Sex Transm Dis. 2021 Aug 1;48(8S):S71-S77. doi: 10.1097/OLQ.0000000000001457. PMID: 34110728; PMCID: PMC8284360.
7. This means all the instructions in the product insert from "intended use" to "limitations of the procedure."

Sexually Transmitted Infection Point-of-Care Tests

STIs are detected using various methods and tests depending on the infection, the patient, and the availability of tests. The landscape of available tests is ever changing as new tests are developed and approved.

Point-of-Care Test Benefits

POCTs expand opportunities for diagnosing and treating STIs. They are portable and, if CLIA-waived, can be used by a wide array of staff, not just clinicians or laboratorians, and in a variety of settings, including non-clinical ones, increasing access for those most at risk for STIs.[8]

POCTs also provide rapid results that may allow for same-day initiation of treatment for STIs, which may disrupt spread of infection, help with clinic flow, and save time by not requiring the patient to schedule another appointment to discuss the results or disease investigation specialists or other staff to seek them out to ensure that the patient receives the needed care or treatment.[9,10] Thus, POCT and rapid results may be particularly valuable at increasing both testing and treatment among populations that face barriers accessing health services and consequently can address gaps and inequities in STI services and outcomes.[11]

POCTs can be more comfortable for the patient in several ways. Many POCTs do not use phlebotomy, which may put patients more at ease. Additionally, the use of POCTs in non-clinical settings, including in the field or in a trusted, familiar space, may reduce STI testing stigma and increase uptake of testing.[12] A patient's trust may increase when a test is performed in front of them or in the same location, rather than at a remote laboratory. As patients do not have to wait or return to obtain their results, this approach may also reduce patient anxiety.

Ultimately, POCTs can increase access to and uptake of testing, reduce time to treatment, and reduce the risk of cases going untreated.

When possible, use a multiplex POCT to detect more than one infection at a time (e.g. syphilis and HIV). This is especially true for populations that experience disproportionate risk for multiple infections or those who do not have consistent access to healthcare services.

Positive STI/HIV tests must be reported to the health department according to state and local requirements. For questions about reporting, providers should check with their local public health authority.

Benefits of POCTs

- **Portable and can be used in a variety of settings**
- **Non-clinical staff can administer them (if CLIA-waived)**
- **Rapid results --> faster treatment and reduced loss to follow-up**
- **Can be more comfortable for patient**

8. Elrobaa IH, Khan K, Mohamed E. The Role of Point-of-Care Testing to Improve Acute Care and Health Care Services. Cureus. 2024 Mar 1;16(3):e55315. doi: 10.7759/cureus.55315. PMID: 38434607; PMCID: PMC10905651.; Nichols JH. Utilizing Point-of-Care Testing to Optimize Patient Care. EJIFCC. 2021 Jun 29;32(2):140-144. PMID: 34421482; PMCID: PMC8343046.; St John A. The Evidence to Support Point-of-Care Testing. Clin Biochem Rev. 2010 Aug;31(3):111-9. PMID: 24150515; PMCID: PMC2924123.;

9. Unemo M, Cole M, Lewis D, Ndowa F, Van Der Pol B. (Eds.) (2023) Laboratory and point-of-care diagnostic testing for sexually transmitted infections, including HIV; World Health Organization. ISBN 978-92-4-007708-9 (electronic version)

10. Lingervelder, D., Koffijberg, H., Kusters, R. et al. Health Economic Evidence of Point-of-Care Testing: A Systematic Review. PharmacoEconomics Open 5, 157–173 (2021). https://doi.org/10.1007/s41669-020-00248-1; Unemo M, Cole M, Lewis D, Ndowa F, Van Der Pol B. (Eds.) (2023) Laboratory and point-of-care diagnostic testing for sexually transmitted infections, including HIV; World Health Organization. ISBN 978-92-4-007708-9 (electronic version)

11. Elrobaa IH, Khan K, Mohamed E. The Role of Point-of-Care Testing to Improve Acute Care and Health Care Services. Cureus. 2024 Mar 1;16(3):e55315. doi: 10.7759/cureus.55315. PMID: 38434607; PMCID: PMC10905651.; St John A, Price CP. Existing and Emerging Technologies for Point-of-Care Testing. Clin Biochem Rev. 2014 Aug;35(3):155-67. PMID: 25336761; PMCID: PMC4204237.

12. St John A, Price CP. Existing and Emerging Technologies for Point-of-Care Testing. Clin Biochem Rev. 2014 Aug;35(3):155-67. PMID: 25336761; PMCID: PMC4204237.

Point-of-Care Test Limitations

Although POCTs provide quicker results, there are limitations to consider when deciding to use a POCT versus a laboratory test, especially when conducting a POCT outside of a clinical setting, such as during outreach sessions in the community. Space and treatment limitations are particularly important to consider.

Space

Offering point-of-care testing requires thinking through the logistics of the testing site to ensure the patient has a confidential, safe, and comfortable place to receive counseling, collect the sample, and to receive treatment and further resources after the test. It may be challenging for patients to self-collect urine or vaginal swabs if there are not easily accessible bathrooms. Some POCTs require electricity or battery-powered readers, so access to electrical outlets should also be considered.

Treatment

It may be more difficult to provide treatment when testing outside the clinical setting, depending on the treatment regimen, the need for confirmatory testing, or if those conducting the test are not licensed to deliver treatments.[13]

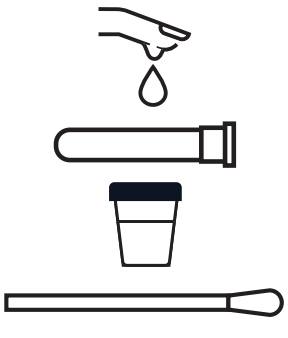
Patients should be advised on what a positive result means, and if needed, for follow-up for confirmatory testing, treatment, or other care. They should also be counseled on how to inform their sexual partner(s).

Some injections can be given outside clinical settings, but this requires more coordination and effort from providers. The recommended treatment for syphilis is an injection of penicillin G, with the dosage and length of treatment dependent on the stage of the infection.[14] Similarly, the recommended treatment for gonorrhea is a single dose injection of ceftriaxone.

Additional confirmatory testing and/or direct patient management may be needed. See below section on specific considerations for syphilis and HIV.

Infection-Specific Testing

Table 1: Specimen types utilized in POCTs for different STIs



	Syphilis	Chlamydia + Gonorrhea	Trichomoniasis	HIV
Blood	X			X
Oral Fluid				X
Urine		X	X	
Oral/Genital Swab		X		

13. https://www.cdc.gov/std/treatment-guidelines/
14. STI Clinical Treatment Guidelines, 2021. MMWR Recomm. Rep. 2021;70(4). https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf

The guidance below comes from the manufacturers of the currently available CLIA-waived POCTs for STIs—consult the test inserts and all manufacturer guidance for more information on the materials and environment needed for use of the selected STI POCT. See Appendix 2 for additional information on the steps to conduct a POCT.

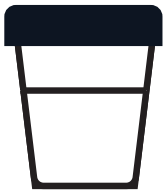
Syphilis Point-of-Care Tests

Providers of syphilis POCTs can be clinicians, laboratorians, or non-clinical individuals who are properly trained in the testing methods. Syphilis POCTs can be administered in testing sites that have a CLIA waiver. The testing environment should be a clean area with comfortable places for the patient to sit while they are having their blood sample collected.

Syphilis POCTs use whole blood specimens that require a small amount of blood to be taken from the patient and put directly onto the test device. These tests are like those used to test blood sugar (e.g., for diabetes). The test kit should include all items needed to collect the blood and transfer it to the test device. It is important to follow all test instructions to ensure the right amount of blood is collected safely. Providers can facilitate patient comfort by ensuring that the patient receives sufficient counseling and explanation of the test beforehand.

Gonorrhea, Chlamydia, and Trichomoniasis Point-of-Care Tests

POCTs for GC, CT, and TV should be performed by individuals who are properly trained in the handling and collection of urine samples, vaginal swabs, and/or extragenital swabs (rectal and pharyngeal swabs). The appropriate environment in which to conduct these tests depends on which samples are being used for testing.



Urine

POCTs that use urine specimens require patient-collection and are used for testing for genital CT and GC infections. It is important to provide the patient with detailed instructions prior to specimen collection. The patient goes into a bathroom to collect urine in a cup. Ideally, there would be single-person bathrooms for use. There should also be enough sinks for both the patient and the provider to wash their hands before and after handling the urine sample. The urine cup may or may not be provided with the testing kit and providers should ensure they have enough stocked. The provider then uses other materials from the test kit, such as a pipette and collection tube, to gather the specific amount of urine that is needed for testing. This testing mechanism requires significantly more private space including a bathroom than other POCTs, which limits its usefulness in non-clinic-based settings.

Vaginal/Rectal/Oral Swab

Vaginal swabs are the most accurate sample type for females being tested for genital CT, GC, and TV infections. Depending on the test, swabs can be collected by either the provider or the patient. To collect vaginal swabs, providers or patients will insert the swabs included in the test kit, following the manufacturers' instructions. The provider or patient then uses the other test materials provided to continue processing the collected specimen. This testing format requires the most space and privacy for private patient-provider interaction—both for consultation and collection of the specimen. Staff should be available to answer any additional questions that arise during specimen collection. Some tests may be used with extragenital specimens.

HIV Point-of-Care Tests

HIV POCTs are conducted with whole blood or plasma. For those that rely on whole blood, the test kit should include the items needed to collect the patient's blood and transfer it to the test device. A sterile lancet should be used to prick the patient's finger to produce drops of blood. There is also a POCT for HIV that uses oral fluid. Oral fluid specimen tests require the patient to be swabbed along the outer surfaces of the upper and lower gums of their mouth. The swab is provided with the test kit, and it should be handled with care according to the test instructions. Providers should ensure that the patient has not had anything to eat or drink or chewed gum in the last 15 minutes and has not used any oral care products (e.g., mouthwash, toothpaste) in the last 30 minutes before collecting a sample.

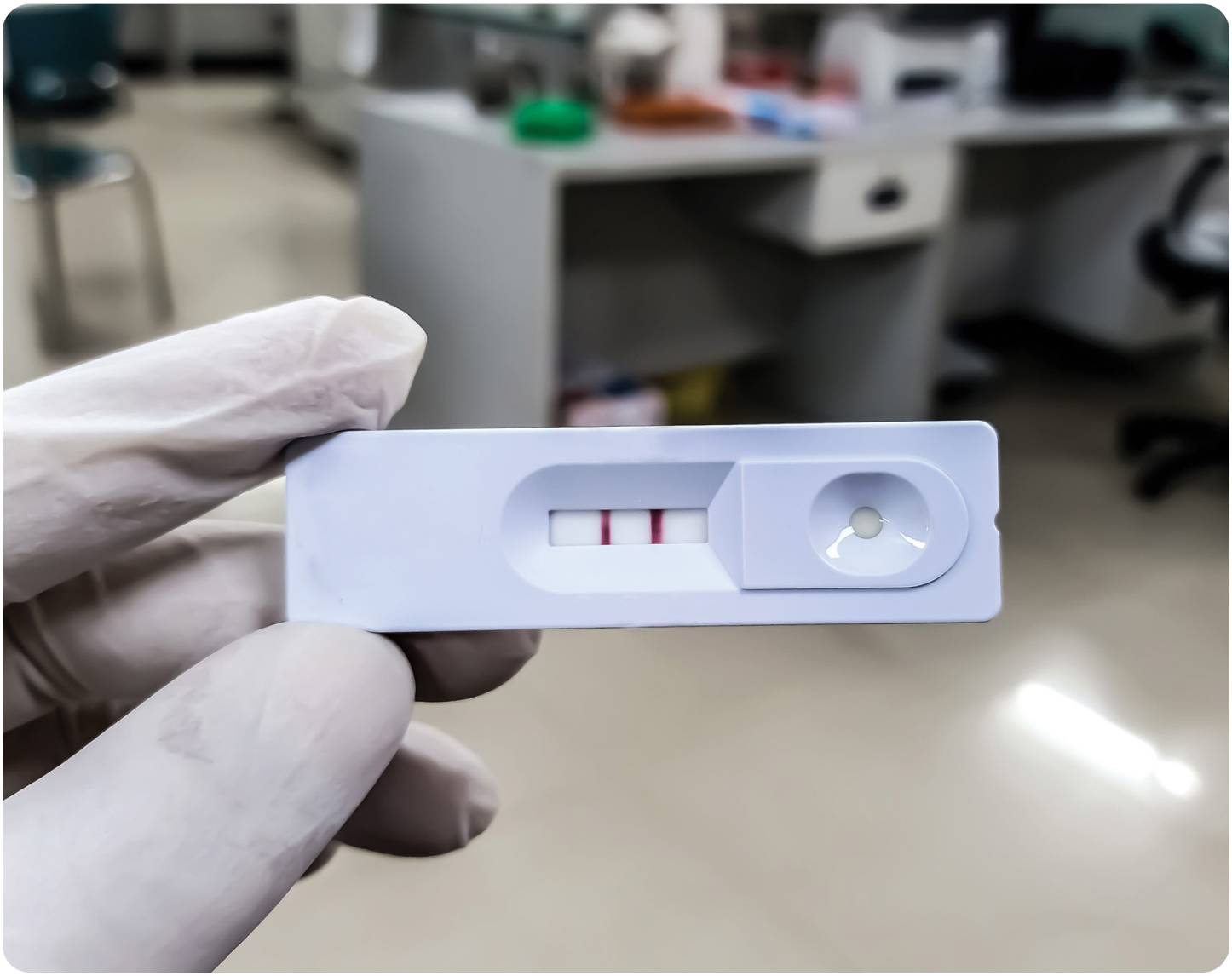
Considerations for STI Point-of-Care Test Use

When considering POCT use, it is essential to balance the benefits and limitations for the designated setting. While there are no federal requirements regarding who can perform CLIA-waived tests, state or local requirements must be considered and testing personnel must have the necessary level of education, license(s), or professional qualifications to perform them.[15]

POCTs may be particularly advantageous for populations that are less likely to return for treatment after lab-based testing, including rural communities, people who are unstably housed, people who use drugs, people in short-term incarceration, or pregnant women not in prenatal care. Depending on the STI, the patient may receive same-day treatment and/or counseling that is tailored to their diagnosis and unique situation. Laboratory testing may be more appropriate for people who have regular access to health care, people who are likely to follow-up for diagnosis results and treatment, people in geographic areas where syphilis is rare, or in a hospital environment where the patient will be staying more than 48 hours and rapid results are not needed for care.[16]

Additionally, some tests may not be approved for all populations—in particular, certain POCTs have not been evaluated in patients under the age of 17. Physical characteristics of the setting should also be considered to ensure the patient's safety, wellbeing, and privacy.

For more information on the steps for conducting POCT, see Appendix 2.



Special Considerations for Syphilis Point-of-Care Testing

The currently available syphilis POCTs are treponemal only, meaning they do not distinguish between an active and previously treated infection.[17] A positive result on a treponemal-only POCT is considered a presumptive diagnosis which requires confirmatory laboratory-based treponemal and non-treponemal testing. If the patient has no previous history of syphilis, a positive POCT result is enough to initiate treatment.[18] Syphilis POCTs have a lower sensitivity and specificity than a laboratory test. Sensitivity refers to how well a test can identify the presence of a disease or illness correctly, while specificity refers to how well a test can identify the absence of a disease or illness correctly. POCTs with lower sensitivities may have more 'false negatives', which means more people who do have an STI will not be identified by the test. POCTs with lower specificities may have more 'false positives' and in these instances, people who do not have syphilis will be incorrectly identified as having one.

If treatment is not provided on-site, patients should be assisted with linkage to recommended confirmatory testing and treatment before leaving the testing site.

Syphilis POCTs are appropriate for populations that are less likely to have recurrent syphilis infections, such as women. These tests can also be considered for populations with a high incidence of STIs but low likelihood of successfully treated previous syphilis infections such as in American Indian or Alaska Native women and Black and Latino heterosexuals.[19]

With the currently available POCT, a lab-based test (non-treponemal) for syphilis is best practice because it indicates whether a positive result is based on a prior or active case of syphilis and allows for staging of the infection which is important to determine the best course of treatment. If a lab-based test can be done with likely successful follow-up for treatment after the results are received, it always makes sense to use a lab-based test and/or do a confirmatory lab-based test after a positive POCT result. If any other factors are present, consider those factors to determine whether a POCT or presumptive treatment is more appropriate. Presumptive treatment is treatment without a confirmatory test either based on symptoms or a positive POCT. Positive results from syphilis POCTs (which are treponemal-only) require confirmatory lab-based testing to differentiate between current and past infections. However, presumptive treatment may be initiated based on POCT results alone when:

The patient has no history of syphilis

Follow-up for confirmatory testing is unlikely

The patient is pregnant or at high risk of transmitting infection

15. Yenice S. (2021). Training and Competency Strategies for Point-of-Care Testing. EJIFCC, 32(2), 167–178.
16. Point-of-care testing for sexually transmitted infections in low-resource settings Vargas, S. et al. Clinical Microbiology and Infection, 2022 July; 28(7): 946-951
17. STI Clinical Treatment Guidelines, 2021. MMWR Recomm. Rep. 2021;70(4). https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf
18. STI Clinical Treatment Guidelines, 2021. MMWR Recomm. Rep. 2021;70(4). https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf
19. National Syphilis and Congenital Syphilis Syndemic Federal Task Force, Considerations for the Implementation of Point of Care Tests for Syphilis. https://www.hhs.gov/sites/default/files/nscss-considerations-for-the-implementation-of-syphilis-poc-tests.pdf

Table 2: Assessing Syphilis POCT Use

This table covers some scenarios where either a POCT or lab-based test may be recommended and others where either option may make sense. This table is not exhaustive.

● = Do Not Use

○ = Instances where either option may make sense, choice of test may be left to the provider's discretion taking into consideration various patient factors.

● = Use

Patient Factors	POC Test	Lab Test	Additional Considerations
Known, Previous Syphilis Infection	●	●	
Symptomatic	○	○	If signs or symptoms consistent with syphilis are present, presumptive treatment should be facilitated immediately. A POCT may support shared decision-making if follow-up is unlikely and there is no known history of syphilis treatment, but treatment should not be delayed. A lab-based test can be used to do staging to determine additional treatment needs.
Asymptomatic	○	○	Use lab-based unless there are other factors present that would not allow for follow-up after a lab-based test. Do not use POCT in cases where there is a high likelihood of syphilis based on communicated behavioral risk(s).
Currently Pregnant	○	○	Because of high rates of congenital syphilis, use POCT for rapid results and immediate next steps. If an additional factor (e.g., inconsistent access to healthcare) is also present, consider presumptive treatment without confirmatory test.
Unlikely to Encounter Tester or Related Provider Again	●	●	If an individual is unlikely to be found for treatment after a lab-based confirmatory test, treatment after a positive POCT may be the best course of action.
In a Location with a High Rates of Syphilis	○	○	A significant risk factor for syphilis is living in a location with a high rate of syphilis. In that case, the chance of a positive POCT because of a prior infection is high so lab-based testing is preferrable but if there are other factors that mitigate this (e.g., inconsistent healthcare access), reconsider POCT use.
In a Location with Low Syphilis Rates	○	○	If an individual is living in a location with low syphilis prevalence, the chance of a POCT positive being based on a prior infection is lowered. This increases the usefulness of the POCT.
In a Population with High Syphilis Rates	○	○	If an individual is in a population with high syphilis prevalence, the chance of a positive POCT because of a prior infection is high so lab-based testing is preferrable. But if there are other factors that mitigate this (e.g., inconsistent healthcare access), reconsider POCT use.
In a Population with Low Syphilis Rates	○	○	If an individual is in a population with low syphilis prevalence, the chance of a POCT positive being based on a prior infection is lowered. This increases the usefulness of the POCT.
Consistent Access to Healthcare	●	●	

Special Considerations for Other STIs

When using POCTs for STIs in the genitals, vaginal swabs are the ideal specimen for CT, GC, and TV in women, while urine samples are the ideal specimen for CT and GC in men.[20,21,22] A negative POCT performed with these specimens does not rule out the potential for extragenital infections. If there is any chance of an individual having a rectal or oral/pharyngeal infection, those areas should also be tested. Locations for conducting testing should allow for sufficient privacy and comfort to collect these samples.

Potential for antimicrobial resistance (AMR) is an important factor to be considered, especially when testing for gonorrhea. Neisseria gonorrhoeae, the causative agent of gonorrhea, is a global public health concern as it has developed resistance to all commonly prescribed antimicrobials.[23] To most effectively prevent antimicrobial resistant gonorrhea, providers should consult the most recent version of the CDC's STI Treatment Guidelines to determine the treatment plan for someone who tests positive.[24]

HIV POCTs are intended for screening persons with a high risk for HIV, not for screening the general population.[25] Some populations who may be at particularly high risk for HIV include people who inject drugs, people with a sexual partner who is HIV positive, sex workers, men who have sex with men, and people who have multiple sex partners. Providers should assess each person to determine which type of HIV POCT is best suited for their needs and comfort; for example, a rapid HIV test that uses an oral fluid sample or fingerstick blood may be better for people who inject drugs because they could have collapsed blood vessels that make other blood-based tests difficult.[26] A person with a positive HIV POCT result should immediately be referred to medical care and case management for further confirmatory testing and provision of treatment.

Conclusion

POCTs provide rapid results. Having rapid results may benefit the patient/client. Having rapid results may also be beneficial to the STI program or provider and consequently may facilitate next steps in care. Likely, this will mean reducing time to treatment and decreasing the chance of an individual with an STI not being treated. Even with those potential benefits, POCTs may not be appropriate or ideal in all situations. The setting and comfort of the staff and patients should be considered when determining whether to use POCTs. At the same time, the infection that is being tested for, and the population being tested have significant implications on the utility of POCTs. All these factors must be considered before implementing the use of POCTs.

20. Centers for Disease Control and Prevention. (2021, July 22). Chlamydial infections - STI treatment guidelines. Centers for Disease Control and Prevention. https://www.cdc.gov/std/treatment-guidelines/chlamydia.htm
21. Centers for Disease Control and Prevention. (2022, September 21). Gonococcal infections among adolescents and adults - STI treatment guidelines. Centers for Disease Control and Prevention. https://www.cdc.gov/std/treatment-guidelines/gonorrhea-adults.htm
22. Centers for Disease Control and Prevention. (2022b, September 21). Trichomoniasis - STI treatment guidelines. Centers for Disease Control and Prevention. https://www.cdc.gov/std/treatment-guidelines/trichomoniasis.htm
23. Gaydos, C. A., & Melendez, J. H. (2020). Point-by-Point Progress: Gonorrhea Point of Care Tests. Expert review of molecular diagnostics, 20(8), 803–813. https://doi.org/10.1080/14737159.2020.1778467
24. Centers for Disease Control and Prevention. (n.d.). Preventing antibiotic-resistant gonorrhea by changing treatment guidelines and educating health care providers. Centers for Disease Control and Prevention. https://www.cdc.gov/high-impact-prevention/php/case-studies/gonorrhea-guidelines-education.html#:~:text=To%20prevent%20antibiotic-resistance%20gonorrhea,clinics%20following%20this%20regimen%20included:
25. Arora, D. R., Maheshwari, M., & Arora, B. (2013). Rapid Point-of-Care Testing for Detection of HIV and Clinical Monitoring. ISRN AIDS, 2013, 287269. https://doi.org/10.1155/2013/287269
26. Arora, D. R., Maheshwari, M., & Arora, B. (2013). Rapid Point-of-Care Testing for Detection of HIV and Clinical Monitoring. ISRN AIDS, 2013, 287269. https://doi.org/10.1155/2013/287269

Appendix 1: Glossary of Terms

Chlamydia Trachomatis

The bacteria that causes the sexually transmitted infection known as chlamydia. Referred to as CT.

Neisseria Gonorrhoeae

The bacteria that causes the sexually transmitted infection known as gonorrhea. Referred to as GC.

Treponema Pallidum

The bacteria that causes the sexually transmitted infection known as syphilis.

Trichomonas Vaginalis

The parasite that causes the sexually transmitted infection known as trichomoniasis.

FDA-Cleared Test

A testing device that has been cleared by the FDA for use in the U.S.; all FDA-cleared tests are manufactured with a package insert that specifies their use, including acceptable specimens and their collection methods.

Laboratory-Developed Tests (LDT)

A test that has not gone through regular FDA clearance (except for emergency uses) but can nevertheless be performed at local laboratories if the local clinical laboratory director reviews and approves test performance data according to CLIA regulations.

CLIA-Waived Test

Test that can be safely performed by non-laboratorians, typically due to its simplicity.

Clinical Laboratory Improvement Amendments (CLIA) Regulation

Regulations governed by the CMS with the purpose to establish quality standards for clinical laboratory testing to ensure that patient test results are accurate and reliable.

Specificity

How well a test can identify the absence of a disease or illness correctly. Lower specificity increases the likelihood of false positives.

Sensitivity

How well a test can identify the presence of a disease or illness correctly. Lower sensitivity increases the likelihood of false negatives.

Appendix 2: Steps for Using a Point-of-Care Test

Personnel

All staff need to be properly trained and undergo competency assessments for each test method before starting to test. Tests must be performed according to the manufacturers' instructions and updated training is required whenever the manufacturer makes changes to the instrumentation, kits, or test methods. A qualified individual such as a certified laboratory technical staff person or a manufacturer representative may train the staff members in patient preparation, sample collection, instrument calibration, instrument maintenance, and quality control. The testing staff need to keep their skills related to delivering and interpreting the test up to date; previously trained staff should have their competency reassessed if they have not been trained for a long time, or if they have not been regularly testing patients. A log showing the completion dates of the training sessions and competency assessments for each staff member and for each testing method should be kept.

Testing personnel should be trained in proper storage of reagents and other supplies for testing. Personnel need to monitor the storage conditions of all reagents, controls, and testing materials to ensure accurate results. This includes regular checks to confirm that storage temperatures remain within the specified range, as improper temperature can compromise the integrity of these materials. Additionally, personnel must track lot numbers and expiration dates, verifying new lot numbers upon arrival to ensure consistent performance. Testing should never be conducted outside of the designated temperature range, as this could lead to inaccurate or invalid results. Proper documentation of these procedures is essential for ensuring accurate results.

Some of the frequently encountered challenges faced by staff are new instrument evaluation, finding appropriate test environments, data management, ensuring quality testing and quality control, lab safety, and proper disposal of samples, reagents, tests, and other potentially hazardous waste. Providers conducting POCTs should reach out to their local laboratory, contact the test manufacturer, or utilize an online POCT management software for help with addressing these issues.[27]

Quality Control Testing

Quality control testing confirms the provider is performing the test correctly and the test is functioning as expected. It identifies any issues with the test (e.g., reagent deterioration, test equipment failure, environmental conditions, or human error) to be resolved before continuing to test the samples of real patients.

POCTs have both internal and external controls. Internal controls help to establish if the test is working properly, if enough test sample was used, if the sample is moving through the test strip as it should, and if the electronic components of the test are functioning. The external controls reveal if the testing process is being performed correctly by the test provider, if the results are being interpreted correctly, and if the control results are within the expected ranges.

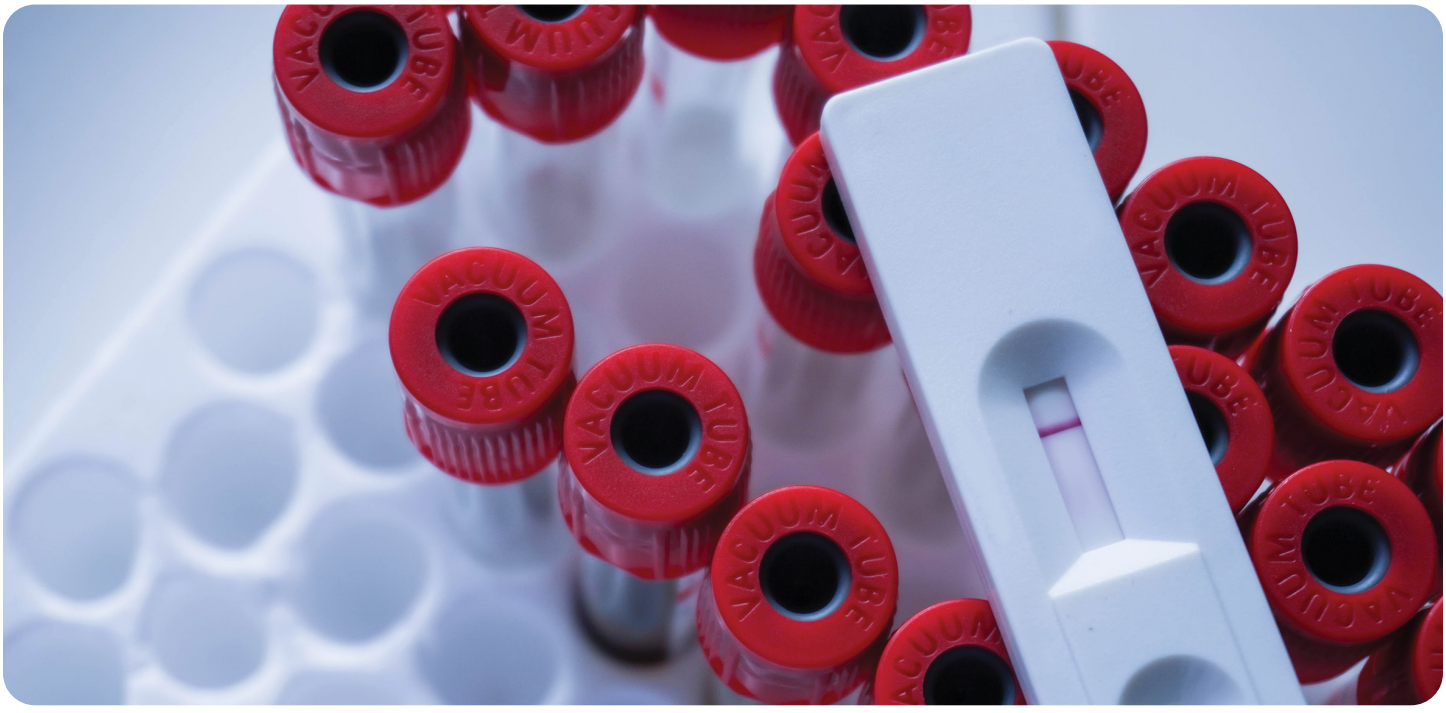
The personnel who conduct the POC testing should also conduct quality control testing. The POCT manufacturer's instructions should indicate how often quality control testing should occur. Controls should be tested with each new shipment of reagents or test kits, any change in lot numbers, and each new testing personnel. Quality control testing should also occur when significant elements of the testing site, materials, or personnel are changing. Other aspects to gauge the necessity of quality control testing include the stability of the test based on expiration dates and storage practices, large environmental changes such as power outages or temperature fluctuations, and competency of the testing personnel based on experience and the recency of their training. Quality control testing results should be recorded in a log and reviewed periodically to analyze trends over time and identify problems that could affect patient testing. See this booklet for examples of quality control logs.

27. Yenice S. (2021). Training and Competency Strategies for Point-of-Care Testing. EJIFCC, 32(2), 167–178.

If the quality control testing reveals unexpected results, the problem must be identified and corrected before any patient results are reported. Activities to identify a problem include:

- Confirm the manufacturer's instructions were followed exactly.
- Check the POCT materials, such as the reagents, test kits, or control materials, to see if they could have been outdated, damaged, or stored incorrectly.
- Determine if the controls and reagents could have been cross contaminated by switching caps.
- Check the manufacturer's instructions or the testing site's procedural guidance for troubleshooting steps.
- If needed, reach out to the manufacturer, technical representative, or testing supervisor for more assistance.
- Once the problem is found and corrected, conduct the quality control testing again. If the results are now acceptable, retest the patient sample and report the results.

Information in the subsequent sections are based on the CDC's document, Ready? Set? Test!, which explains the steps and considerations of CLIA-Waived testing.[28]



28. Ready? Set? Test! (n.d.). https://www.cdc.gov/lab-quality/docs/waived-tests/ReadySetTest_2024_Final.pdf

Before the POCT

Proper preparation before using a POCT is critical to ensuring an accurate test result. Before collecting a sample, providers must ensure the testing environment is ready, the patient is well informed, and the test is set up for safe and accurate use.

Prepping the Test and Testing Environment:

1. Set up the testing environment with strong lighting and make sure the surfaces are clean and dry.
2. Ensure that you have enough reagents, test kits, and other supplies for testing.
3. Perform daily checks of the temperature in the testing and reagent storage areas.
4. Let refrigerated reagents and test kits come to room temperature before starting to test.
5. Inspect the reagents, vials, and test kits and throw away any that appear discolored, damaged, contaminated, or expired.
6. Prepare the reagents according to the manufacturer's instructions.
7. Inspect the testing equipment and perform any equipment calibration checks that may be needed.
8. Place the most recent copy of the test manufacturer's instructions where it can be easily accessed and consulted during the testing process.
9. Confirm that all test kit components are from the same kit lot, as reagents should not be mixed between different lot numbers.
10. Conduct all quality control testing according to the manufacturer's guidance.

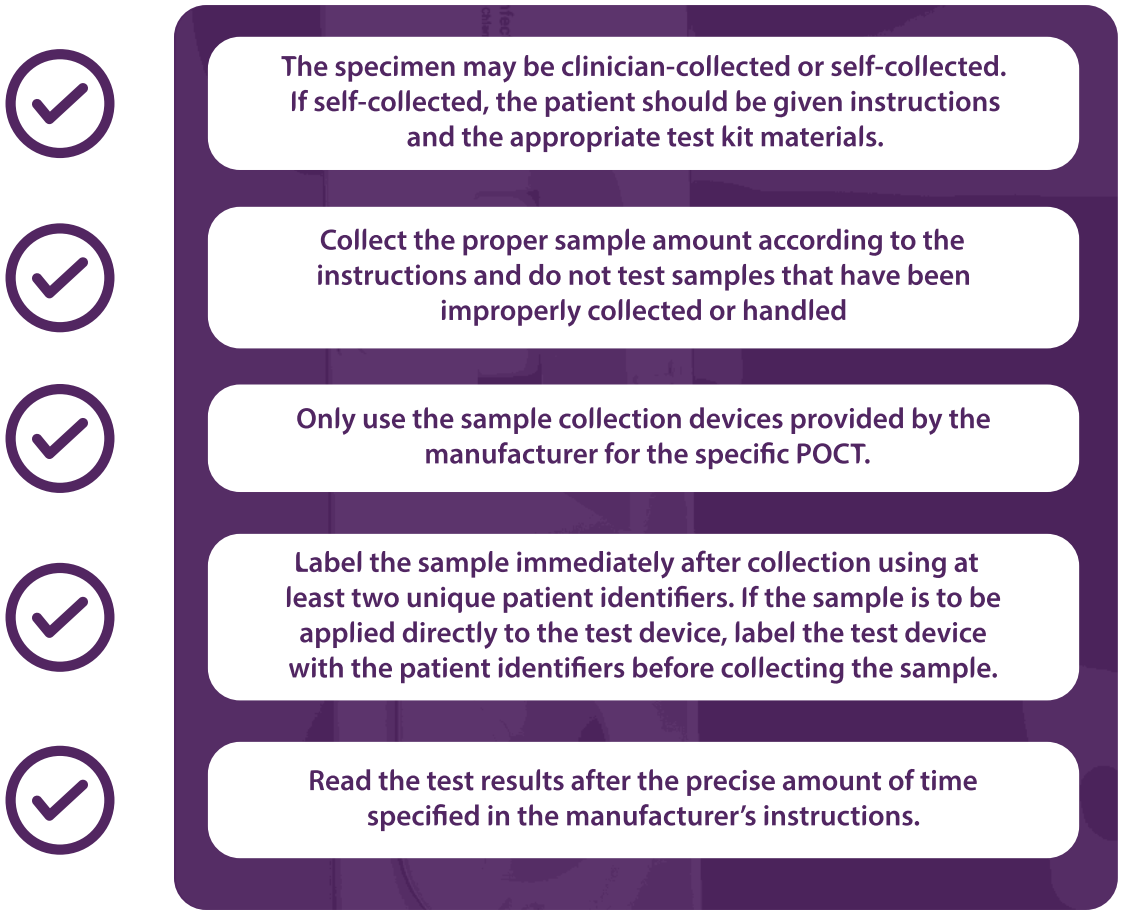
Prepping the Patient

Before conducting a POCT, the tester should:

- Confirm the patient's identity using at least two unique identifiers, such as name and date of birth.
- Counsel the patient on what the test is for, what the possible results are, and what the implications of the results may be. This is especially important in HIV testing
- Ensure the patient has completed any necessary test preparation the instructions describe.
- Ask the patient about medical conditions, medications, vaginal gels, creams, washes, antiperspirant, or other interfering substances that could affect the test results.
- Inform the patient of the benefits and limitations of POC testing. Getting a quicker result could mean a faster connection to treatment or further testing but might be less accurate for some POCTs leading to unnecessary treatment or missed infections.
- Obtain the patient's consent to perform the POCT.

During the Test

Once the testing environment, POCT, and patient are all prepared, providers can begin the testing process. Depending on the type of test, providers should ensure the patient is given the appropriate amount of privacy for specimen collection. The most essential consideration is that the POCT manufacturer's instructions are followed exactly during all the test steps to produce an accurate result.



After the Test

Once the POCT is completed, providers must read the results based on the guidance from the test manufacturer. These results will inform the next steps for the patient and should be properly communicated to the patient and any relevant health authorities that require reporting.

Reading the Results

Consult the Manufacturer's Instructions for How to Interpret the Test Result:

- STI POCTs will usually have qualitative results that can be interpreted as positive, negative, reactive, non-reactive, or invalid.

If the Result is Invalid:

- Perform the test again, making sure to follow the instructions closely to prevent another invalid result. This may require collecting a new sample.

If the Result is Negative/Non-Reactive:

- Consult a clinician or the manufacturer's instructions to determine if additional testing is needed and inform the patient of the decision. If additional testing is needed, help to connect the patient to those services.

If the Result is Positive/Reactive:

- Depending on the STI, the result may need to be confirmed through laboratory testing.
- If no confirmation is needed, treat the patient.

Recording the Results

- Record all results according to a standardized system set in place by the testing site.
- For quantitative results, record them in the appropriate units of measurement. For qualitative results, use words or abbreviations (e.g. "Positive" or "Pos") instead of symbols (e.g. "+").
- Be sure to record any invalid results. After correcting the issue and testing again, record the new result if it is acceptable. See this booklet for examples of testing results logs.

Reporting to the Patient

- Verbally communicate the test results to the patient.
- Counsel the patient on what their positive result means and if needed, how to inform their sexual partner(s) and follow up for additional care. Before the patient leaves the testing site, they should be assisted with linkage to recommended confirmatory testing and treatment as soon as possible.
- Give the patient a written test report that is legible, standardized across the testing site, and issued promptly.
- Only give test results to those authorized by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
- When sending test results through electronic medical record systems, follow site-specific policies and procedures.