Testing for HIV, Sexually Transmitted Infections (STIs), and Viral Hepatitis in The Field: Over-The-Counter, CLIA-Waived, and Self-Collected Lab-Based Tests

Many people with HIV, STIs, and/or viral hepatitis are unaware of their infections. Point of care and over-the-counter tests, if implemented correctly, may increase awareness for those with HIV, STIs and HCV infections. This document summarizes the technical and training requirements for increasing access to testing in field-based locations. Table 1 summarizes existing tests; Table 2 (page 2) describes the characteristics and requirements for several types of tests; and Table 3 (page 3) shows who can assist individuals perform a test.

1) **Rapid over-the-counter (OTC) tests** have marketing authorization by the U.S. Food and Drug Administration (FDA) for an individual to test themselves. The individual obtains their own sample (urine, oral fluid or fingerstick blood), processes the sample, and reads their own test results.
2) **Rapid Clinical Laboratory Improvement Amendments (CLIA) waived tests** have been FDA approved and require a CLIA waiver. They are used in clinical settings as well as in non-traditional settings such as mobile vans, health fairs, and other venues where tests are performed under a supporting laboratory director's CLIA certificate of waiver. Eligible clinical staff, trained public health staff, or HIV test counselors collect and process the specimen, read the test results, disclose the results to the individual, and report the results to public health under the laboratory director.
3) **Self-collected lab-based tests** have been FDA approved or developed by a laboratory for an individual to collect their own specimen and send the specimen to a laboratory. The laboratory processes the specimen, gives results to the ordering clinician or directly to the individual (by phone or online portal), and reports results to public health under the lab director.

Notes: Rapid OTC tests and rapid CLIA-waived tests are also considered 'point-of-care,' as testing is conducted at the time and location of the patient encounter. Some programs (e.g., TakeMeHome) may offer test kits for individuals that include a combination of rapid over-the-counter tests and self-collected lab-based tests.

Table 1: Examples of tests: (Informational only. California Department of Public Health (CDPH) does not endorse any company or its products.)

	Rapid Over-the-Counter Tests	Rapid CLIA-Waived Tests	Self Collected Lab-Based Tests
Examples	• First to Know Syphilis Test • OraQuick In-Home HIV Test	• Syphilis Health Check • DPP HIV-Syphilis • OraQuick HCV Rapid Antibody Test • Cepheid Xpert Xpress HCV ribonucleic acid (RNA) Test • Visby Medical Sexual Health Test (gonorrhea, chlamydia, and trichomonas) • Binx io (gonorrhea and chlamydia) • Cobas® liat chlamydia (CT)/ Neisseria gonorrhea (NG) and CT/NG/mycoplasma genitalium (MG) assays • Multiple rapid HIV tests: U.S. Centers for Disease Control and Prevention (CDC) List Link	• Simple 2 STD Test Kit: (Gonorrhea/Chlamydia) • Other lab-developed tests

Table 2: Characteristics and Requirements for Field-Based Testing with 1) Rapid Over-the-Counter Tests; 2) Rapid CLIA-Waived Tests; and 3) Self-Collected Lab-Based Tests

Characteristic	Rapid Over-the-Counter (OTC) tests used for self-testing[1]	Rapid CLIA-waved tests AND OTC tests performed by staff[2]	Self-collected lab-based tests
CLIA Certificate of Waiver	Not needed for self-testing. If performed by staff, test becomes CLIA-waived and all CLIA-waived requirements apply	Required [link to CLIA]	Not needed
Time to results	Less than 1 hour	Less than 1 hour	Several days
Preparation Required	Person self-testing reviews and follows instructions for sample collection, test processing and result interpretation	CLIA certificate of waiver CLIA-covered staff training	Person self-collecting reviews and follows instructions for sample collection
Who can perform a fingerstick for blood?	Person self-testing can perform fingerstick on themselves Certain staff may assist (Table 2)	CLIA-covered staff[3] or phlebotomists (see Table 2)	Person self-collecting can perform on themselves Certain staff may assist (Table 2)
Who runs the test and reads results?	Person self-testing runs the test and must read and interpret their own test result. They may choose to tell staff the result and/or show test result to staff for verification or tracking	CLIA-covered staff[3] run test and interpret results	Person self-collects the sample, laboratory runs and results test
Who discloses test results?	Self-test, no disclosure needed	Staff disclose results	Laboratory – either through contracted provider or through online portal
Who records results?	Not required. If person self-testing shares result with staff, may be charted as a patient-reported test result	Staff records test results	Laboratory documents results
Is reporting to public health required?	Person self-testing is not required to report results to public health	Providers and laboratories are required to report positive tests for reportable diseases (and negative tests, upon request) to public health [4]	Providers and laboratories are required to report positive tests for reportable diseases (and negative tests, upon request) to public health[4]
Is test working correctly? (Controls)	Internal control line in each test must be visible to person self-testing	Internal control line in each test AND periodic control tests (specific to the manufacturer) run by the testing site	Per laboratory testing protocol
Supplies Needed in the Field	Test box has all supplies/instructions, access to hand washing, timer	Gloves, lancets, gauze, antiseptic wipes, bandages, absorbent workspace cover, biohazard sharps container, biohazard bag, timer, testing machine (for some tests)	Test box has all supplies/instructions, access to hand washing
Disposal	Regular trash	Differs by test: usually biohazard sharps container, biohazard bag	Per test kit directions

Table 3: Type of Assistance Allowed for Sample Collection (by Staff Credentials) for 1) Rapid Over-the-Counter Tests; 2) Rapid CLIA-Waived Tests; and 3) Self-Collected Lab-Based Tests

Staff Credentials	Type of Assistance Allowed	Rapid Over-the-Counter Tests used for self-testing	Rapid CLIA-Waived Tests AND OTC tests performed by staff	Self-Collected Lab-Based Tests
Any person who has read test directions (while maintaining confidentiality)	Coaching and non-technical assistance: Verbally explain/coach a person through sample collection or self-test processing and verification of patient-interpreted test result. May include assisting with paperwork, labeling, online registration, etc.	Allowed, when patient self-tests	N/A	Allowed, when patient self-collects
Certified Phlebotomy Technicians	Use of lancet for fingerstick blood sample only	Allowed—if patient applies blood to test	Allowed—if person covered by CLIA-waiver applies blood to test	Allowed—can apply blood to blood-spot card or fill microtainer
Physicians, Nurse Practitioners, Physician Assistants, Pharmacists and Pharmacy Student Interns, Registered Nurses: health care providers able to perform CLIA-waived tests within scope of practice under Business and Professions Code (BPC) 1206.5. Under BPC 1242-1243, LVNs, Psychiatric Technicians and Medical Assistants with specific training*	Sample collection for CLIA-waived testing, use of OTC tests as CLIA-waived tests, and use of lancet for fingerstick blood sample	Allowed to assist with fingerstick—then patient applies blood, performs and reads own test	Allowed	Allowed
HIV test counselors who have either been trained by CDPH Office of AIDS or its agents or completed a CLIA-waived test training course approved by CDPH Office of AIDS, including fingerstick blood training and proficiency*	***Limited to HIV, HCV, and STI tests*** with training specific to the test being performed: Sample collection for CLIA-waived testing, use of OTC tests as CLIA-waived tests, and use of lancet for fingerstick blood sample	Allowed to assist with fingerstick—then patient applies blood, performs and reads own test. Test counselor may verify the result after it has been read by the patient	Allowed —if trained and authorized to perform the specific test	Not allowed
Disease Investigators under Local Public Health Laboratory supervision, when trained according to criteria in the July 2018 letter from the State Public Health Laboratory Director*	***Limited to syphilis tests*** with specific training: CLIA-waived testing, use of OTC tests as CLIA-waived tests, and use of lancet for fingerstick blood sample	Allowed to assist with fingerstick—then patient applies blood, performs and reads own test. Disease Investigators may verify the result after it has been read by the patient	Allowed—if trained and authorized to perform the specific test	Not allowed

[1] **Can a staff member observe and coach an individual to self-test using an over-the-counter test without the test becoming a CLIA waived test?**
Yes, a staff member can observe and coach an individual who is self-testing with an over-the-counter test. Additionally, after the person self-testing reads their own result, a staff member can verify that result without it becoming a CLIA waived test. However, if the staff member performs any part of the test or interprets the result prior to the individual self-testing, the test becomes a CLIA waived test and CLIA rules and requirements apply.

[2] **Can a staff member perform or interpret a rapid over-the-counter test (for another individual)?**
Yes, if the staff member has met the CLIA-waived credentials and training/authorization for the specific test (see Table 2). When an OTC test is performed or interpreted by a staff member (i.e. not used as a self-test), it becomes a CLIA-waived test and CLIA rules and requirements apply. The staff member performing or interpreting the test result is subject to CLIA-requirements and should meet the criteria for being eligible to perform CLIA-waived tests in California AND be operating under a valid CLIA waiver. See CMS: OTC Home Testing and CLIA Applicability FAQs

[3] **Who can perform CLIA-waived tests in California?**
There are three pathways for eligibility to perform CLIA-waived tests in California.

1. ***Scope of Practice***: A health care provider able to perform CLIA-waived tests within their scope of practice under BPC 1206.5 may perform CLIA-waived tests without any additional specific training besides following the test kit manufacturer's package insert. Medical personnel allowed to perform CLIA-waived tests under California law include physicians and surgeons, nurse practitioners, physician assistants, pharmacists and pharmacy student interns, registered nurses, and, if certain conditions are met, licensed vocational nurses and medical assistants. Please refer to BPC 1206.5 and other related laws for a complete listing and description of required conditions.
2. ***HIV Test Counselors***: In accordance with Health and Safety Code 120917, HIV test counselors who have either been trained by CDPH Office of AIDS or its agents or completed a training course approved by CDPH Office of AIDS, and who meet other requirements specified in California law, may perform the CLIA-waived test(s) on which they have been trained and for which they have demonstrated proficiency. Training is specific to each test and is currently available for HIV and HCV antibody tests—future trainings may include rapid syphilis testing, HCV RNA testing or other tests. See Training HIV Test Counselors to Use Rapid Tests for HIV, Hepatitis C Virus (HCV), and Sexually Transmitted Infections (STIs) - Senate Bill 306 (Pan, Chapter 486, Statutes of 2021) Fact Sheet for more information, including specific requirements for fingerstick blood draws.
3. ***Disease Investigation Specialists (DIS)***: A local disease investigation specialist or other non-licensed local health department staff may perform a CLIA- waived syphilis test under the authority of the Public Health Laboratory Director, subject to meeting requirements in the July 2018 letter from the State Public Health Laboratory Director.
    a. CLIA-waived rapid syphilis tests must be FDA-cleared, approved as waived tests, and used according to the manufacturer's instructions.
    b. Blood collection is performed by skin puncture only.
    c. Testing is performed on-site and reported directly to the person requesting the test.
    d. A minimum of 20 hours of in-person basic phlebotomy didactic training approved by CDPH Laboratory Field Services (LFS) is completed. DIS with phlebotomy certifications from LFS-approved programs have already met that training requirement. Note: phlebotomy training is no longer available online.

[4] **What are reporting requirements for results?**
California Code of Regulations, Title 17, Section 2500 requires health care providers to report known or suspected cases of reportable diseases (and negative results upon CDPH or LHJ request) to the jurisdiction where the patient resides. California Code of Regulations, Title 17, Section 2505 requires laboratories to report test results suggestive of reportable diseases to the local health department.