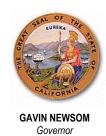


State of California—Health and Human Services Agency California Department of Public Health



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

I. <u>Background</u>

<u>Senate Bill (SB) 306</u> (Pan, Chapter 486, Statutes of 2021) became law effective January 1, 2022. SB 306, <u>among other provisions</u>, expands the abilities of HIV test counselors to meet the needs of clients who are at risk for HIV, HCV, and/or STIs (referenced in SB 306 as sexually transmitted diseases or STDs). As part of efforts to make STD testing widely available across the state, California law now allows HIV test counselors, under specified conditions, to perform HIV, HCV, and/or STD tests if the tests are classified as waived under the federal Clinical Laboratory Improvement Act of 1988 (CLIA) ¹. HIV test counselors who perform CLIA-waived HIV, HCV, and/or STD tests in California must meet specific performance and training requirements.

SB 306 applies only to <u>HIV test counselors</u> and does not apply to licensed medical personnel allowed to perform CLIA-waived tests as part of their regular scope of practice.² These personnel already are permitted under California law to perform CLIA-waived HIV, HCV and/or STD tests. It also does not apply to non-licensed staff operating under the authority of the local public health laboratory director with 20 hours phlebotomy training and under specified requirements, who are already permitted to perform CLIA-waived rapid tests specifically for syphilis³.

³ California Department of Public Health, STD Control Branch. Syphilis Health Check Rapid Point-of-Care Syphilis Testing Fact Sheet and Frequently Asked Questions. Accessed March 27, 2022, at https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/SyphilisHealthCheckFAQ.pdf.



¹ U.S. Centers for Disease Control and Prevention. Waived Tests. Accessed June 5, 2022, at https://www.cdc.gov/labquality/waived-tests.html.

² 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. (<u>Business</u> and <u>Professions Code</u> (<u>BPC</u>) 1206.5).

II. Key Provisions of SB 306

1. Training Requirements for HIV Test Counselors

HIV test counselors may perform CLIA-waived HIV, HCV, and/or STD tests if they meet the following training requirements (along with other requirements as specified):

- Have been trained by the California Department of Public Health (CDPH), Office
 of AIDS (OA) and are working in a HIV testing site funded by CDPH through a
 local health jurisdiction, or its agents OR
- Are working in an HIV testing site that meets both of the following criteria:
 - o Utilizes HIV counseling staff who are trained by OA or its agents and
 - Has a quality assurance plan approved by the local health department in the jurisdiction where the site is located and has HIV testing staff who comply with the quality assurance requirements specified in Section 1230 of Title 17 of the California Code of Regulations OR
- New: Have completed a training course approved by CDPH OA.

2. Use of CLIA-Waived STD tests by HIV Test Counselors

HIV test counselors may perform CLIA-waived tests for HIV, HCV, and/or STDs if, in addition to other requirements, <u>all</u> the following conditions are met:

- a) The performance of the test meets the requirements of CLIA.
- b) The HIV test counselor has been trained and demonstrates proficiency in administering the HIV, HCV, or STD test.
- c) New: The HIV counselor demonstrates sufficient knowledge of HIV, HCV, or STDs to provide appropriate counseling and referrals to patients for the test they are performing. (HSC 120917(a)(1) (A)–(a)(1)(C)).
- d) New: Unless they are also certified as a limited phlebotomy technician, an HIV test counselor certified by CDPH OA or its training agents before January 1, 2022, and who will administer rapid STD tests, must be trained to perform STD tests pursuant to this section before performing a CLIA-waived STD test.

HIV test counselors may not:

- Perform other HIV, HCV, or STD tests that are not waived under CLIA, or
- Perform any other test waived under CLIA unless the counselor meets the statutory and regulatory requirements for performing that other test.

3. Performing Fingerstick to Withdraw Blood for an HIV, HCV, or STD Test

HIV test counselors may perform skin puncture (fingerstick) to withdraw blood for an HIV, HCV, or STD test if they meet <u>all</u> the following requirements:

- a) Are working under the direction of a licensed physician and surgeon.⁴
- b) Have been trained in administering rapid HIV, HCV, or STD tests and in universal infection control precautions as specified.
- c) New: The HIV counselor shall not administer a rapid HIV, HCV, or STD test until they demonstrate proficiency in administering the test. (HSC 120917(a)(1)(D)).

4. Explaining Test Results and Offering Referrals for Follow Up Testing

Clients receiving CLIA-waived HIV, HCV, or STD testing and receiving preliminary positive or reactive results must be informed that the preliminary test result is indicative of the likelihood of HIV infection, HCV exposure, or other STD exposure and that the result may need to be confirmed by an additional more specific test.⁵

Clients receiving "indeterminate" or "positive" test results must be referred to a licensed health care provider whose scope of practice includes the authority to refer patients for laboratory testing for further evaluation.

III. <u>Implementation of SB 306</u>

IV. Resources

CDPH Guidelines

Office of AIDS HIV and HCV Testing Information

⁴ HIV test counselors typically work or volunteer under the direction of the clinician who serves as the laboratory director for the HIV test site's CLIA certificate of waiver. For more information on CLIA certificates of waiver for HIV/HCV testing in non-healthcare settings, see the HCV Rapid Testing FAQs. ⁵ For hepatitis C, more specific tests may include HCV ribonucleic acid (RNA) tests, which are used to detect HCV in the blood and to diagnose current HCV infection. For syphilis, diagnosis is made using both non-treponemal and treponemal serologic tests and should not be made on the basis of a single test result. Clinical history and symptoms are also needed when diagnosing and staging syphilis infections.

- HCV Testing in Non-Health Care Settings Guidelines for Site Supervisors and Testing Coordinators, 2012 (PDF)
- Hepatitis C Testing Frequently Asked Questions, 2022 (PDF)
- OraQuick Rapid HIV Testing Guidelines (PDF)
- Quality Assurance Guidelines for OraQuick HCV Antibody Testing in Non-Healthcare Settings, 2013 (PDF)
- Quality Assurance Plan Template for OraQuick HCV Antibody Testing in Non-Healthcare Settings, 2021 (Word)

STD Control Branch

- Rapid Syphilis Testing Fact Sheet & FAQs (PDF)
- Rapid Syphilis Testing Letter from the Public Health Laboratory Director, 2018 (PDF)