

Hepatitis C Virus (HCV) Rapid Testing in California: Frequently Asked Questions, November 2021

This document provides answers to frequently asked questions for programs in California offering HIV and HCV rapid tests waived under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Use the hyperlinked questions below to jump to the answer to each question.

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I. Staff Training Requirements

Who can provide HIV and HCV rapid testing in California?

Federal law requires facilities performing CLIA-waived tests, such as the rapid HIV or HCV antibody test, to obtain a certificate of waiver and follow manufacturers' test instructions.¹ In addition, California law requires these facilities to have a California clinical laboratory registration.² Local health facilities may be exempt from state licensure requirements under California Business and Profession Code (BPC) section [1241](#). California law specifies which kinds of personnel can perform CLIA-waived tests (see **Figure 1**, page 2). BPC section [1206.5](#) allows medical doctors (MDs), doctors of osteopathic medicine (DOs), nurse practitioners (NPs), physician assistants (PAs), pharmacists,³ registered nurses (RNs), licensed vocational nurses (LVNs),⁴ and medical assistants (MAs),⁵ among others, to perform CLIA-waived testing within their respective scopes of practice.

In order for other non-clinical staff or volunteers not listed above (such as community health workers, patient navigators, alcohol and drug counselors, and case managers) to conduct CLIA-waived HIV and HCV testing, training from the California Department of Public Health (CDPH) Office of AIDS (OA) or its agents is required.⁶ In 2021, OA training agents included Alliance Health Project (AHP), Los Angeles County Department of Public Health (LAC DPH), and San Francisco Department of Public Health (SFDPH).

- **Most Local Health Jurisdictions:** Successful completion of the Basic Counseling Skills Training (BCST) is required for non-clinical staff and volunteers to perform CLIA-waived HIV and HCV rapid testing, except in Los Angeles as noted below. AHP and SFDPH currently offer the BCST.
- **Los Angeles:** Successful completion of the LAC DPH Basic 1 HIV Test Counselor Certification is required for non-clinical staff and volunteers of organizations funded by the LAC DPH Division of HIV and Sexually Transmitted Diseases (STD) Programs who want to perform CLIA-waived HIV rapid testing. To also conduct HCV rapid testing, staff and volunteers must also complete the HCV rapid testing proficiency training.⁷ These trainings are available to organizations in LA County. Organizations in LA County that are not funded by LAC DPH Division of HIV and STD Programs can access training from any OA training agent.⁸

If clinical staff can perform HIV and HCV rapid testing within their scope of practice without taking the BCST, what resources can help prepare them to provide testing?

All staff providing HCV testing should be able to answer questions about hepatitis C, including being able to explain the difference between HCV antibody, which shows past infection, and ribonucleic acid (RNA) testing,

¹ U.S. Centers for Disease Control and Prevention. [CLIA Test Complexities](#).

² California Business and Professions Code section [1265](#).

³ Title 16 California Code of Regulations section [1793.1](#) allows a licensed intern pharmacist to perform the duties of a licensed pharmacist while acting under the supervision of a pharmacist.

⁴ Specific requirements for LVNs are outlined in BPC section [1242.6](#).

⁵ Specific requirements for MAs are outlined in BPC section [2069](#).

⁶ California Health and Safety Code section [120917](#). Senate Bill 306 (Pan, Chapter 486, Statutes of 2021) amended Health and Safety Code Section 120917 to allow training to be delivered using a training course approved by CDPH OA.

⁷ Email trainingquestions@ph.lacounty.gov to register for the LAC DPH HCV rapid proficiency training. All organizations are responsible for providing all HCV test and proficiency samples. Other fees may apply for organizations not funded by LAC Division of HIV and STD Programs.

⁸ Funded organizations will be registered first, with second priority given to non-funded organizations.

which shows if a client has hepatitis C infection now. An HCV RNA test is needed to diagnose current hepatitis C infection and indicates need for linkage to care and curative treatment.

CDPH OraQuick HCV Antibody Testing [Quality Assurance Guidelines](#) are a key resource for staff providing HCV rapid testing. University of Washington has an excellent, free, comprehensive, up to date website, [Hepatitis C Online](#), which features a self-guided course on hepatitis C screening, diagnosis, and treatment. Clinical staff can also receive free training from OraSure, the sole manufacturer of the HCV antibody rapid test in the United States, upon request.⁹ Contact Kay Dendy at kdendy@orasure.com for more information. CDC also has a [good practices checklist](#) for clinical providers and facilities looking to start conducting CLIA-waived testing.

What is the Basic Counseling Skills Training (BCST)?

The BCST is typically a multi-day, in-person course that prepares successful participants to become HIV test counselors authorized to perform CLIA-waived HIV and HCV testing in California.⁶ Training comprises multiple components, including counseling, test kit proficiency, and fingerstick proficiency. For certified phlebotomists, completion of the fingerstick component of the training is optional. Due to the coronavirus disease-19 (COVID-19) pandemic, Alliance Health Project is delivering the BCST completely online until further notice.

Figure 1: Training Requirements for Providing CLIA-Waived Rapid Hepatitis C Testing, 2021

Clinical Staff	<ul style="list-style-type: none">• No additional training requirements• Free training resources are available online and from OraSure Technologies for refreshers
Certified Phlebotomists	<ul style="list-style-type: none">• BCST or, in Los Angeles County, Basic 1 HIV Test Counselor Certification and HCV rapid test training• Fingerstick Proficiency Training is optional
Non-Clinical Staff	<ul style="list-style-type: none">• BCST, including rapid test kit proficiency and fingerstick proficiency or, in LA County, Basic 1 Test Counselor Certification and HCV rapid test training

I was trained as an HIV test counselor before HCV was integrated into the BCST curriculum, do I need additional training to conduct the rapid HCV test?

Yes, additional training is required for HIV test counselors to conduct the CLIA-waived rapid HCV test. Contact CDPH.HEP@cdph.ca.gov and OA.Prevention.Training@cdph.ca.gov, for details on the necessary training. HIV test counselors are not required to take the entire integrated BCST to perform CLIA-waived HCV rapid tests; however, individuals who have not provided HIV testing services recently are encouraged to take the entire integrated BCST to ensure their knowledge is up to date.

How can I register for the Alliance Health Project BCST?

- CDPH OA funds 20 local health jurisdictions through its federal U.S. Centers for Disease Control and Prevention (CDC) HIV prevention grant (**18-1802**). Staff or volunteers affiliated with 18-1802 funded

⁹ For informational purposes only. CDPH does not endorse any company or its products.

health jurisdictions (see **Table 1**) or 18-1802 subcontractors should register for the BCST on the [AHP website](#).¹⁰ State funds cover the training costs for these programs.

- CDPH STD Control Branch funds 22 local health jurisdictions for hepatitis C-related activities with state general fund **HCV Prevention and Collaboration** grants. Staff or volunteers affiliated with HCV Prevention and Collaboration Grant nonprofit partners working in 18-1802 funded jurisdictions should register on the [AHP website](#).¹⁰ State funds cover the training costs for these programs.
- Other staff or volunteers from non-profit organizations not in jurisdictions receiving 18-1802 funds should email ahp.training@ucsf.edu and copy Jen.Shockey@ucsf.edu to register for the BCST. CDPH OA training agents may charge a fee for training counseling staff.¹¹ Organizations interested in requesting a fee-for-service BCST should complete an [online form](#) to request more information.
- Staff employed by for-profit/private narcotic treatment programs (NTPs) or opioid treatment programs (OTPs) should request a training for their group directly from [AHP](#).

Table 1: California Department of Public Health, Office of AIDS, CDC HIV Prevention Grant (18-1802)-Funded Local Health Jurisdictions, January 2019-April 2023

Local Health Jurisdiction
Alameda ¹²
Contra Costa
Fresno
Kern
Marin
Monterey
Orange
Riverside
Sacramento
San Bernardino
San Diego
San Joaquin
San Mateo
Santa Barbara
Santa Clara
Santa Cruz
Solano
Sonoma
Stanislaus
Ventura

¹⁰ Organizations with pending 18-1802 or Prevention and Collaboration Grant subcontracts or partnerships can complete the BCST and register on the [AHP website](#) before an agreement is finalized with the local health jurisdiction. State funds currently cover these training costs.

¹¹ California Health and Safety Code section [120917](#).

¹² The Alameda County funding includes the City of Berkeley.

How much does registering for the AHP BCST cost?

Costs for AHP virtual courses (offered due to COVID-19) are shown in **Table 2**. Costs for in-person trainings vary based on the jurisdiction and payment structure (see **Table 3**). Successful completion of the training includes both the Counselor Skills Training component and Fingerstick Rapid Test Training component (except for certified phlebotomists, for whom the fingerstick component is optional).

Table 2: Virtual Basic Counseling Skills Training Courses, Costs, and Number of Participants, July 2021

AHP Virtual Course	Cost	Number of Participants
Virtual HIV/HCV Counselor Skills Training	\$ 9,900	8 to 12
Virtual Fingerstick Rapid Test Training	\$2,700	12 or less
Virtual HIV/HCV Counselor Skills Training	\$1,000	1
Virtual Fingerstick Rapid Test Training	\$300	1

Table 3: In-Person Basic Counseling Skills Training Courses, Costs, and Number of Participants

Region	Cost	Number of participants
Bay Area ¹³	\$ 9,900	12 or less
Greater Bay Area ¹⁴	\$ 13,500	12 or less
Central Valley ¹⁵	\$ 13,500	12 or less
Southern California ¹⁶	\$ 14,800	12 or less
Bay Area	\$ 11,900	More than 12
Greater Bay Area	\$ 16,200	More than 12
Central Valley	\$ 16,500	More than 12
Southern California	\$ 18,300	More than 12

Can I administer a CLIA-waived rapid test for syphilis if I have taken BCST?

Under a new California law (Senate Bill 306 (Pan, Chapter 486, Statutes of 2021)), HIV test counselors may administer the rapid syphilis test if trained using a course approved by the CDPH OA and able to meet other requirements. CDPH has begun planning to develop training infrastructure for CLIA-waived rapid syphilis tests. Local health jurisdiction Disease Intervention Specialists (DIS) may be able to administer rapid syphilis tests if the Local Public Health Laboratory Director authorizes them to do so. See this [2018 letter from the State Public Health Laboratory Director](#) for more information about DIS testing, and [Syphilis Rapid Point of Care Testing Fact Sheet and Frequently Asked Questions](#) for more information about the rapid syphilis test.

¹³ Includes Berkeley, Alameda, Oakland, and San Francisco

¹⁴ Includes San Jose, Santa Cruz, North Bay, and Sacramento

¹⁵ From Kern County to Stanislaus County

¹⁶ From San Luis Obispo and San Bernardino Counties to San Diego

Where can I find information on phlebotomy training?

Detailed information on phlebotomy training can be accessed from the CDPH Laboratory Field Services web pages listed below. The length and modality of phlebotomy training programs vary. Some programs are offered as short-term intensives conducted during one week of full-time study or as full-day courses over several weekends, while other programs are offered over a semester, often through community colleges. Prices range but often may cost approximately \$1,800-\$2,000. During the COVID-19 pandemic, some phlebotomy programs are offering courses online. For non-clinical staff with less than 40 hours of on-the-job phlebotomy experience, phlebotomy training includes 40 hours of didactic (classroom) instruction from a CDPH-accredited program plus 40 hours of phlebotomy practice including at least 50 blood draws.

- [Training Overview and Academic Prerequisites](#)
- [List of CDPH Approved Phlebotomy Training Programs](#)
- [Phlebotomy Certificate Frequently Asked Questions](#)
- Contact LFSphlebotomy@cdph.ca.gov or CDPH.HEP@cdph.ca.gov for more information.

II. Organizational Requirements

My organization is new to providing HCV rapid testing. What is required beyond staff training?

The U.S. Food and Drug Administration (FDA) requires sites to develop a quality assurance (QA) plan and obtain a CLIA certificate of waiver prior to beginning testing; state law requires that sites obtain an additional state registration prior to beginning testing.¹⁷

How do I develop a QA plan?

A sample HCV rapid testing QA plan template is available on the [CDPH website](#). Testing sites may submit their QA plan to the local health department for approval; the local health department may charge a fee for the QA plan approval.¹¹ See the CDPH OraQuick HCV Antibody Testing [Quality Assurance Guidelines](#) for reference.

How do I apply for a CLIA certificate of waiver and complete the state registration?

1. Identify a laboratory director (i.e., a duly licensed physician or, only for the purposes of CLIA-waived testing, a duly licensed clinical laboratory scientist, limited clinical laboratory scientist, or naturopathic doctor). The laboratory director will assume ultimate responsibility for all aspects of testing, help develop the QA plan, and monitor compliance with regulatory requirements.¹⁸
2. Complete and submit an [online](#) or [paper application](#) to CDPH Laboratory Field Services for a federal CLIA certificate and state registration to perform waived testing in California. A checklist of the required documents and information for CLIA certificates of waiver and state registration is available [online](#). The initial and annual state renewal registration fee is currently \$113 per year for a single site. Upon approval of the state application, a digital copy of the state registration will be sent via email.
3. CDPH Laboratory Field Services will process the CLIA application and provide the federal CLIA program with the necessary information. After receiving an invoice (fee coupon) from the federal CLIA program,

¹⁷ CLIA, 42 United States Code 263a PL100-578; 42 Code of Federal Regulations 493; Title 22 California Code of Regulations section 51211.2, California BPC sections 1241 and 1265.

¹⁸ BPC section [1209](#).

pay the applicable federal fee, which is about \$180 for two years. The federal CLIA certificate will be mailed when the federal CLIA fee is paid.

4. For more information on applying for a CLIA certificate of waiver and state registration, visit the [Laboratory Field Services website](#).

My organization already has a CLIA certificate of waiver and HIV QA plan but is new to rapid HCV testing. Is another CLIA certificate of waiver or updated QA plan necessary?

Sites with existing CLIA certificates do not need to apply for a new CLIA certificate of waiver to add HCV testing to their CLIA certificate, but they will need to update their existing HIV rapid testing QA plan to include QA measures for HCV rapid testing. Updating the list of CLIA-waived tests performed is no longer required when renewing the CLIA certificate for a site that only performs waived tests.¹⁹

My organization does not have a CLIA certificate of waiver or does not have a clinician to serve as a laboratory director. Can we operate under another organization's CLIA certificate of waiver?

An organization with an existing CLIA certificate of waiver may add a secondary site if the testing location will be temporary and changing, such as on a mobile health van or other temporary testing location, and will not occur at a fixed location. According to BPC section [1265](#), addition of a secondary site is also allowable for not-for-profit or local government laboratories conducting no more than a combination of 15 total types of CLIA-waived or moderately complex tests. The primary site laboratory director remains responsible for all secondary sites. The [Secondary Site User Guide](#) lists steps for the primary site to complete online. Contact Lab Field Services at LFScc@cdph.ca.gov or (510) 620-3800 for more details on secondary sites.

Should rapid HCV results be reported to the local health department?

Title 17 California Code of Regulations (CCR) section [2500](#) requires every health care provider, knowing of or in attendance on a case or suspected case of hepatitis C, to report that case to the local health officer for the jurisdiction where the patient resides. While a reactive HCV antibody result alone does not meet the 2020 U.S. [CDC surveillance case definition for hepatitis C](#), clinical providers and community-based organizations conducting HCV testing should be prepared to report new hepatitis C cases confirmed with a positive HCV RNA test to their local health department. Title 17 CCR section [2505](#) requires laboratories to report all test results (both initial and subsequent findings) suggestive of diseases of public health importance (including hepatitis C) to the local health department. For more information on communicable disease reporting, contact your local health department or visit the [CDPH Reportable Diseases and Conditions](#) website.

Where can I find more information on rapid HCV testing?

- [Hepatitis C Testing in Non-Health Care Settings: Guidelines for Site Supervisors and Testing Counselors \(2012\)](#)
- CDPH OraQuick HCV Antibody Testing [Quality Assurance Guidelines for Non-Healthcare Settings \(2013\)](#)
- For other technical assistance questions on HCV rapid testing, contact CDPH.HEP@cdph.ca.gov.

¹⁹ CDPH Laboratory Field Services. [Renewal Application: Online Application System User Manual](#), 10.2020, pages 16-17.