Hepatitis C Virus (HCV) Rapid Ribonucleic Acid (RNA) Testing Systems, Cartridges, Supplies, and Training Needs Assessment Announcement, February 2026

Background

The U.S. Centers for Disease Control and Prevention (CDC) recommends all adults 18-79 years of age be tested for hepatitis C at least once in their lifetime; people who are pregnant be tested for hepatitis C during each pregnancy; and people at ongoing risk for hepatitis C receive routine periodic screening. Yet many people with hepatitis C remain unaware of their infection and racial health disparities in California among people with hepatitis C persist.

In July 2025, Assembly Bill 116 (Health omnibus trailer bill, Chapter 21, Statutes of 2025) included a one-time $1 million authorization for the California Department of Public Health (CDPH) to expend AIDS Drug Assistance Program (ADAP) Rebate Funds available for encumbrance or expenditure until June 30, 2026, for rapid HCV RNA testing technology and supplies for local health jurisdictions (LHJs) and community-based organizations (CBOs) in California.[1] As of November 2025, only one HCV RNA rapid testing platform has been U.S. Food and Drug Administration (FDA)-approved and Clinical Laboratory Improvement Amendments (CLIA)-waived: the Cepheid GeneXpert Xpress, Xpert HCV test, which is performed via fingerstick and returns results in 40-60 minutes.[2] Funds will be used to purchase the following testing equipment and/or supplies for in-kind distribution to eligible LHJs and CBO applicants:

- Cepheid GeneXpert Xpress Systems (Xpert Xpress testing machines come in two sizes: one with two slots for test kit cartridges, one with four slots for test kit cartridges; machine selection will be based on anticipated site specific testing volume; successful applicants will be eligible to receive one machine per organization)
- Cepheid Xpert HCV RNA rapid test cartridges, which must be used by the expiration dates specific to each lot number
- HCV RNA test controls
- Testing supplies (high flow lancets for finger-stick blood collection, underpads, alcohol prep pads, gauze pads, gloves, bandages, etc.)

Note: Testing systems and supplies provided in response to this needs assessment will be delivered as “in-kind support” ONLY. For example, if an LHJ or CBO is awarded a GeneXpert

[1] Assembly Bill 116 (Chapter 21, Statutes of 2025), Section 118(a)(3)
[2] Brand names used for informational purposes only. CDPH does not endorse any company or its products.

Xpress system, CDPH will purchase the system directly from the supplier; the supplier will then ship the testing machine and/or Cepheid Xpert HCV RNA test cartridges and controls directly to the LHJ or CBO, which will then assume ownership of, and responsibility for maintaining, the testing equipment. LHJs/CBOs will maintain the machines, which do not need to be returned to CDPH. Supplies are limited. Responding to this needs assessment does NOT guarantee receipt of supplies or of receiving the full amount of in-kind support requested.

Eligibility Criteria and Priority Settings and Populations for In-Kind Support

LHJs and CBOs in California are eligible to apply for in-kind support. Cepheid Xpert HCV RNA tests are only FDA-approved for use in individuals at risk for HCV or with hepatitis C signs and symptoms, and should not be used with the general, asymptomatic population. To promote racial and health equity and make effective use of public resources, CDPH in-kind support for the following populations and settings, with a prioritization for programs with **ten or more HCV antibody reactive results among program clients per month in the past year**.

Priority Settings

- Community Health Centers, including Federally Qualified Health Centers, Urban Indian Health centers, Tribal Health Clinics, Health Care for the Homeless clinics, Health Centers for Residents of Public Housing, and Rural Health Clinics, including clinics offering medication for opioid use disorders (MOUD) or contingency management
- Public health safety net hospital emergency departments, such as rural county hospitals with limited access to HCV testing due to geographic or socioeconomic barriers
- Fixed site, mobile outreach, and street medicine programs primarily serving people experiencing homelessness
- HIV prevention and harm reduction programs serving priority populations
- Mental health and/or substance use disorder treatment (behavioral health) programs
- Public health clinics
- HIV clinics
- Sexually transmitted infection clinics
- Syringe services programs

If funding permits:

- Jails (excluding state prisons, where HCV testing is separately funded)

Priority Populations

- Racial/ethnic communities disproportionately affected by hepatitis C in California

- People experiencing homelessness
- People who have been incarcerated
- People who smoke or snort crack/cocaine, fentanyl, heroin, or methamphetamine
- People who have inject drugs
- People with HIV

Organizational Infrastructure Requirements

General Operating Expenses

Organizations requesting HCV equipment, test kits and controls, supplies, and/or training need to have the basic infrastructure necessary to conduct HCV antibody and/or HCV RNA testing. Basic infrastructure may include, but not be limited to, staffing/volunteers, physical space (fixed site or mobile health van), tables, computers for data entry, lighting, etc. LHJs and CBOs that receive in-kind testing equipment support are responsible for paying for salary, benefits, indirect, rent, travel, or any other supplies or training not listed below needed to operate their hepatitis C testing programs.

HCV Rapid Test Kits and Controls

Organizations requesting CLIA-waived Cepheid Xpert HCV RNA test equipment and/or test cartridges and controls **must have the following infrastructure in place prior to requesting HCV equipment and/or test kits.** (CDPH may reopen the application periodically to allow organizations that do not yet have this infrastructure in place at the time of this application to request in-kind support in the future.)

1. **Current CLIA certificate of waiver as well as a quality assurance (QA) plan that includes QA procedures for HCV rapid RNA testing**. For more information about CLIA, including how to apply for a CLIA Certificate of Waiver, visit the CDPH Laboratory Field Services website. HIV and HCV rapid testing and QA guidelines, HCV rapid testing QA plan templates, and frequently asked questions on CLIA-waived HIV and HCV testing in non-healthcare settings are available on the CDPH HIV and HCV Testing website. (Testing and QA guidelines specific to CLIA-waived rapid HCV RNA testing are under development.)
2. **Licensed or trained personnel**: Medical professionals (medical doctor (M.D.s), nurse practitioners (N.P.s), physician assistants (P.A.s), pharmacists, pharmacist student interns, licensed vocational nurses (L.V.N.s), medical assistants (M.A.s), etc.) listed in Business and Professions Code Section 1206.5 may administer CLIA-waived tests, including the Cepheid Xpert HCV rapid RNA test, as part of their regular scope of medical practice.
3. **Important note on use of the Cepheid Xpert HCV test by HIV test Counselors:**

- California Health and Safety Code 120917 requires that HIV test counselors be trained on and demonstrate proficiency using the rapid HCV RNA testing technology either by CDPH Office of AIDS or its agents, or using a CDPH approved curriculum, before using the Cepheid Xpert HCV RNA test with program clients.
- As of November 2025, the HIV test counselor training on how to use the OraQuick HCV rapid test offered by University of California San Francisco, Alliance Health Project or Los Angeles Department of Public Health does not qualify HIV test counselors to perform the Cepheid Xpert HCV rapid RNA test.
    - Potential future opportunities for HIV test counselor training on the Cepheid Xpert Xpress HCV RNA test:
        - As of January 2026, San Franciso Department of Public Health is developing and piloting a training curriculum specific to the Cepheid Xpert HCV rapid HCV RNA test for local use and state approval.
        - University of California Los Angeles is piloting an online HIV test counselor training, but it does not yet include instruction on the Cepheid Xpert HCV rapid RNA test.

4. **Refrigerator to store HCV rapid test kits controls** within the temperature range listed in the HCV rapid testing package insert.
5. Ability to perform HCV testing and collect and **report patient-level, identifying data for clients receiving HCV RNA testing services** using in-kind support in a secure, timely manner as requested by CDPH and consistent with Title 17 California Code of Regulations, Section 2505.
6. **Ability to treat or link clients who have a positive HCV RNA test result to care** needed to treat current hepatitis C infection, either on-site (recommended), via active linkage (preferred), or by referral (acceptable).
7. **Ability to provide or link clients who have a negative HCV RNA test result to preventive services**, directly or via referral, if they remain at risk for HCV infection.

HCV Testing Supplies

Organizations requesting HCV testing supplies for phlebotomy (i.e., for clients who decline the rapid HCV RNA fingerstick test or who are undergoing laboratory testing for treatment initiation or monitoring) will be expected to work with the laboratory that will be processing their specimens to obtain and use the appropriate supplies needed to perform testing according to the specifications of that laboratory. **CDPH will not be providing butterfly blood collection sets, tubes, centrifuges, specimen pickup, etc.**

Data Requirements

By requesting in-kind support, applicants agree to maintain and submit to CDPH the requested documentation for the type of in-kind support received, at the frequency and using the method options requested, in Table 1 (page 5 of this announcement).

CDPH expects all sites in California conducting rapid HCV RNA testing to submit HCV RNA test results (including positive and negative results) in compliance with Title 17 California Code of Regulations (CCR) 2505.

CDPH will provide more information to in-kind Cepheid Xpert HCV RNA test recipient sites about their options for securely submitting patient-level HCV RNA test results to public health. **Reporting methods may include, but not be limited to, one or more of the following options:**

- Uploading line-listed Excel HCV RNA rapid testing logs to an online secure file transfer protocol site;
- Entering client information into the California Reportable Diseases Information Exchange (CalREDIE) Provider Portal;
- Submitting electronic laboratory reports into CalREDIE (or local surveillance systems in LHJs that do not participate in CalREDIE for HCV electronic laboratory reporting); and/or
- Entering individual results or line lists into the CDC SimpleReport system, if available.

Table 1: In-Kind Support Data Requirements, Frequency, and Reporting Methods

In-Kind Support	Data Requirement	Frequency	Reporting Method
Cepheid GeneXpert Xpress Systems (testing machine)	Packing slip confirming receipt	Upon receipt of supplies shipment	Via email to cdph.hep@cdph.ca.gov
Cepheid Xpert HCV rapid RNA test cartridges, controls, HCV testing supplies	Packing slip confirming receipt	Upon receipt of supplies shipment	Via email to cdph.hep@cdph.ca.gov
Cepheid Xpert HCV rapid RNA test cartridges	Client-level information (name, date of birth, etc.) and HCV RNA test results (including positives and non-positives) consistent with Title 17 CCR 2505	Monthly HCV testing logs are due by the 15th of the month after testing was conducted	To be determined; CDPH will provide a list of available options

Timeline for Supplies Requests

Date/Time	Milestone
February 17, 2026	**Supplies Announcement and Survey Released**
March 11, 1-2:30 p.m.	**Optional Informational / Question and Answer Zoom Session** This optional session will provide an overview of the announcement and application and provide time for potential applicants to ask questions. **Registration Link** After registering, you will receive a confirmation email containing information about joining the meeting.
March 31, 2026, 11:59 p.m.	**Due Date for Supplies Requests (submitted via Qualtrics survey)**
To Be Determined	**Notification of Supplies Awarded** Note: The timing, number, and size of testing machines, test cartridges, controls, and supplies allocations will depend on administrative approval of purchase orders, availability of supplies (such as during supply chain shortages), and other factors. Allocations may be made on a rolling basis.

How to Apply

Interested organizations should complete the online request form by March 31, 2026, 11:59 p.m**.** The online request form is available at: https://forms.office.com/Pages/ResponsePage.aspx?id=URsxH9n2U0GbrFXg75ZBuPqUWyep6n5Ji4DRfSIDIxBUM0RHTVZaSUFNODk5TldLMURIT1U0QVhMUC4u

Review Process

Each application will be reviewed by CDPH staff for eligibility and prioritization consistent with Assembly Bill 116 (Chapter 21, Statutes of 2025), Section 118 (a)(3), factors such as need in the specific geographic area will be considered when making allocation decisions.

Further Information

Please direct any questions about this supplies request opportunity to cdph.hep@cdph.ca.gov.