

# HCV Rapid Test Results Disclosure and Guidelines for HIV Test Counselors and HIV Testing Site Supervisors

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# Objectives

1. Review background prior to the law allowing HIV test counselors to perform rapid hepatitis C virus (HCV) antibody tests
2. Briefly review HCV natural history and screening and diagnostic tests
3. Describe state requirements for HIV test counselors disclosing HCV rapid test results and providing follow-up referrals
4. Address frequently asked questions regarding the HCV testing and Quality Assurance (QA) guidance

# Background: 2010-2011

- California law already allowed OA-trained HIV test counselors to perform HIV tests that had been waived under CLIA\*
- OraSure developed the first-ever CLIA-waived, fingerstick rapid HCV antibody test
- Assemblymember Hernandez introduced legislation (AB 1382) allowing HIV test counselors to perform the HCV rapid test

\* Clinical Laboratory Amendments of 1998

# Background: 2010-2011

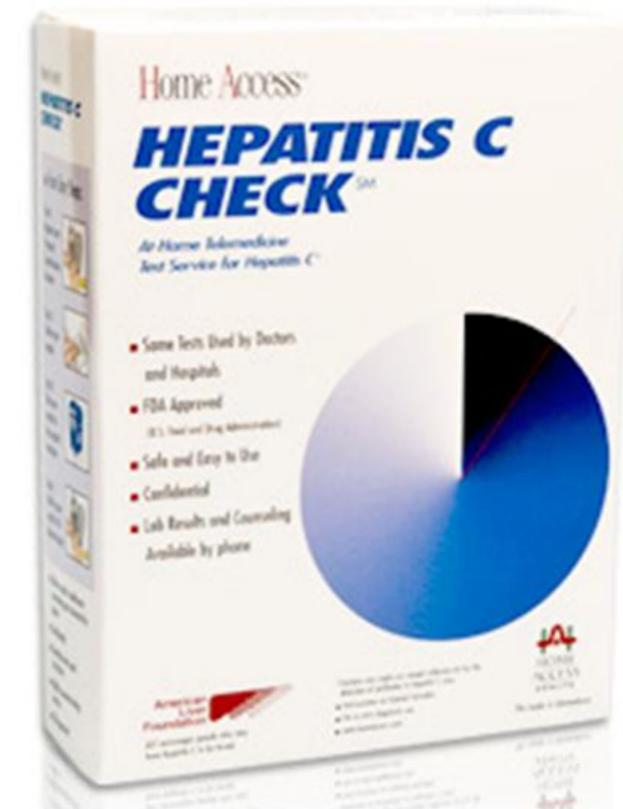
- Hepatitis C community advocates were concerned about the proposed bill
- They wanted to ensure that counselors were giving clients accurate information about the meaning of reactive HCV test results

# The Natural History of HCV

- Among 100 people initially infected with HCV:
  - 75-85 will go on to develop chronic (long-term) HCV infection
  - 15-25 will clear the hepatitis C virus on their own, typically within the first six months of infection
  - All 100 will have a HCV antibody reactive test result

# HCV Screening Tests

- HCV antibody (anti-HCV)
  - Looks for history of HCV:  
“Have you ever had hepatitis C before?”
  - If reactive means you may or may not have HCV now
  - Does not tell you if you have HCV infection now



# HCV Diagnostic Tests

- HCV nucleic acid test (NAT)
  - Looks for the virus itself: “Do you have hepatitis C now?”
  - No CLIA-waived test available
  - Also called HCV RNA test or HCV PCR test



# Health and Safety Code 120917

- Requires that HIV test counselors give clients who receive HCV antibody testing the following information:
  - Test results that are reactive mean that the client has had HCV infection in the past and may or may not have HCV infection now
  - Additional testing is needed to determine whether the client has HCV now

# Health and Safety Code 120917

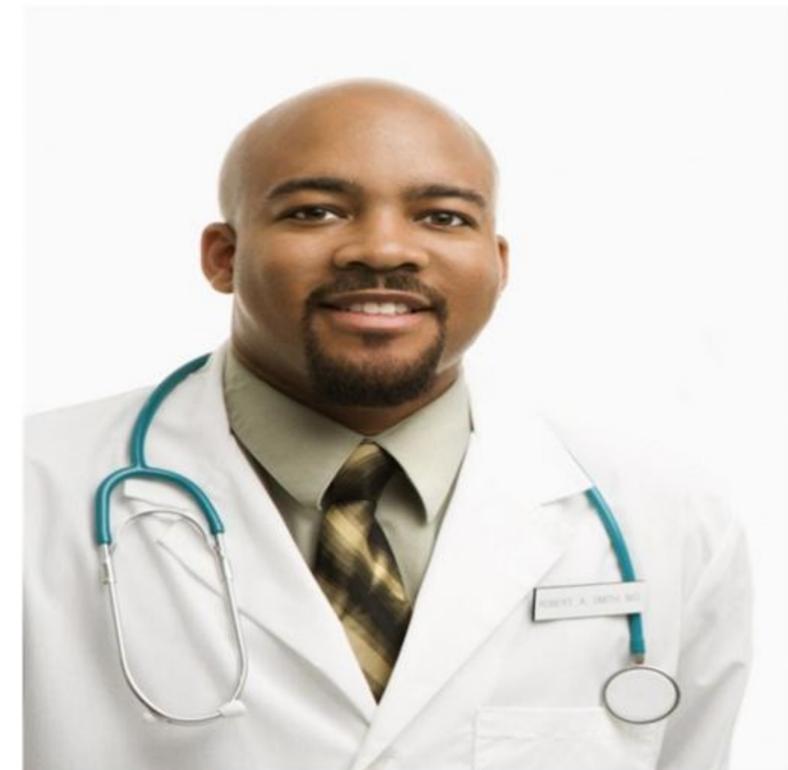
- Requires that
  - “Indeterminate” or “positive” (i.e., reactive HCV antibody) test results must be referred to a licensed health care provider whose scope of practice includes the authority to refer patients for laboratory testing for further evaluation.

# Differences between HIV and HCV Testing Messages

- HIV antibody:
  - client has HIV infection
  - client should be linked to care
- HCV antibody:
  - client had HCV in the past
  - client may or may not have HCV now
  - client should be referred to follow-up testing to find out if they have HCV infection now

# HCV Testing Follow-up

- If HCV antibody non-reactive
  - Discussion of window period
  - Risk reduction, referrals
- If HCV antibody reactive
  - Referral for HCV NAT, evaluation by primary care provider or local provider
  - Discussion of social support, plan until follow-up testing
    - Avoid alcohol; get hep A, hep B vaccine if not immune or infected



# HCV Testing Resources\*

The screenshot shows the CalHEP website interface. At the top left is the CalHEP logo with the tagline "California Hepatitis Alliance" and "Advocacy. Awareness. Access." To the right is a "Get Involved!" button. A navigation bar contains links for "About Us", "Policy issues", "Education Center", "Members", "News", and "Referral Guide". A search bar is located on the right side of the navigation bar. Below the navigation bar is a "Home" link. The main content area features a "Viral Hepatitis Services Referral Guide" section. This section includes a dropdown menu for selecting a county, a "Search" button, and instructions to "Select a COUNTY from the dropdown and click search, or click a county on the map." Below this are two input fields for ZIP CODE and CITY, each with a "Search" button. A map of California counties is displayed, with labels for DEL NORTE, SISKIYOU, HODOG, TRINITY, SHASTA, LASSEN, HUMBOLDT, TEHAMA, PLUMAS, MENDOCINO, GLENN, BUTTE, SIERRA, COLUSA, YUBA, NEVADA, LAKE, SUTTER, YUBA, PLACER, and EL DORADO. On the left side of the page, there is a red box with the text "Email Newsletter icon, E-mail Newsletter icon, Email List icon, E-mail List icon" and a "Sign up for our Email Newsletter" section with a "GO" button. Below this is a "For Email Marketing you can trust" statement and a "Find us on Facebook" button.

\* Source: <http://calhep.org/referralguide.asp>

# Frequently Asked Questions

**Q:** Can medical personnel perform the HCV rapid test without completing the California Department of Public Health (CDPH), Office of AIDS (OA) HCV test training?

**A:** Yes, if their medical license allows them to do CLIA-waived testing.\* For example:

- Medical doctors
- Nurse practitioners
- Registered nurses
- Pharmacists & pharmacy student interns
- Licensed vocational nurses\*\*

\* For a complete list, see Business & Professions Code Section 1206.5

\*\* Training requirements described in Business and Professions Code Section 1242.6

# Frequently Asked Questions

**Q:** Can the logs and protocols in the OA guidelines be used in healthcare settings?

**A:** Yes, you are welcome to use them in **medical settings**. However, remember that medical personnel allowed to perform CLIA-waived testing are not required to complete OA training to use the HCV rapid test.

# Frequently Asked Questions

**Q:** Can phlebotomists perform the HCV rapid test without doing the OA training?

**A:** No, phlebotomy certification alone does not qualify phlebotomists to perform CLIA-waived HCV rapid tests in California.

# Frequently Asked Questions

**Q:** Will there be new funds for HCV testing attached to this new HCV testing guidance?

**A: No. However...**

- Jurisdictions receiving OA HIV prevention dollars may use these funds for HCV testing and referral services
- CDPH/Office of Viral Hepatitis Prevention has a limited supply of HCV test kits and will send information soon on how to apply for an allotment of HCV rapid test kits
- The CA Department of Alcohol and Drug Programs now allows their HIV Set-Aside funds to be used for HCV testing for both HIV positive and HIV negative people

# Frequently Asked Questions

**Q:** We already do HIV rapid testing. What do we need to do to offer HCV rapid testing?

**A:** See OA guidelines.\* **Key highlights:**

- Modify QA plan to include HCV rapid testing and submit to local health department for review and approval
- Add HCV rapid test to CLIA certificate of waiver (can be done at the time of annual renewal)
- Get site supervisor trained by OA to train HIV testing staff in HCV rapid test proficiency
- Train staff in HCV rapid test kit proficiency
- Enroll staff in the AHP online HCV counseling training

\* To access the HCV rapid testing guidelines, visit <http://cdph.ca.gov/HCVtest>.

# Frequently Asked Questions

**Q:** When will the HCV rapid test kit proficiency training for HIV testing site supervisors be available?

**A:** Soon! We're working on it and apologize for the delay...

**Q:** Once the HCV rapid testing proficiency training for HIV testing site supervisors is available, how do I sign up?

**A:** Contact Karin Hill, OA Training Coordinator, at [Karin.Hill@cdph.ca.gov](mailto:Karin.Hill@cdph.ca.gov).

# Frequently Asked Questions

**Q:** How do I access the online Integrated HCV/HIV Counseling training for my staff?

**A:** Go to the Alliance Health Project website:

[http://www.ucsf-ahp.org/HTML2/services\\_providers\\_training.html](http://www.ucsf-ahp.org/HTML2/services_providers_training.html)

- Click on “HIV Counseling and Testing Training”
- Click on Integrated Hepatitis C/HIV Counseling “Online”
- Once completed, you will receive certificates of completion and OA will be notified which staff have completed the training.

**Q:** Can I access the online training if my LHJ does not receive OA HIV prevention funding?

**A:** Yes.

# Next Steps

- This webinar and these slides will be recorded and posted on the OA website at <http://cdph.ca.gov/HCVtest>.
- OA will complete development of the HCV rapid test kit proficiency training for HIV testing site supervisors and make this training available as soon as possible
- Office of Viral Hepatitis Prevention will disseminate information about how to apply for HCV rapid test kits

# Contact Information

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[www.cdph.ca.gov/programs/pages/ovhp.aspx](http://www.cdph.ca.gov/programs/pages/ovhp.aspx)

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<http://www.cdph.ca.gov/programs/aids/Pages/HCVTestingNonHealthcare.aspx>

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<http://www.cdph.ca.gov/programs/aids/Pages/OAHIVTestNonHealthcare.aspx>