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Assembly Bill 1382 – Hepatitis C Testing Key Provisions

Assembly Bill (AB) 1382 (Hernandez, Chapter 643, Statutes of 2011) expands the abilities of the HIV test counselor to meet the needs of clients who are at risk for both HIV and hepatitis C virus (HCV). As part of efforts to make HCV testing widely available to all, California law now allows HIV counselors, under specified conditions, to perform HCV or combination HIV/HCV¹ tests if the tests are classified as waived under the federal Clinical Laboratory Improvement Act (CLIA). HIV test counselors who perform CLIA-waived HCV tests must meet the same performance and training requirements as they do for CLIA-waived HIV testing.

AB 1382 applies only to **HIV test counselors** who are authorized to perform CLIA-waived HIV and HCV tests, and does not apply to licensed medical personnel.

Under the provisions of AB 1382, HIV test counselors:

- **May perform CLIA-waived HCV tests in addition to HIV tests if they:**
 - Have been trained by the California Department of Public Health (CDPH), Center for Infectious Diseases, Office of AIDS (OA) and are working in an OA-funded HIV counseling and testing (C&T) site; **or**
 - Are working in an HIV C&T site that meets **both** of the following criteria:
 - 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 C&T staff who comply with the quality assurance requirements specified in Section 1230 of Title 17 of the California Code of Regulations.²

- **May perform finger-sticks for CLIA-waived HCV tests if they:**
 - Meet the requirements of CLIA; **and**

¹ AB 1382 also addresses combination HIV/HCV rapid tests, which are currently in development. AB 1382 allows HIV test counselors to perform these tests in the event they are approved by the U.S. Food and Drug Administration and CLIA-waived.

² The quality assurance requirements for HIV testing sites were described in a November 16, 2010 [letter](#).

- Upon specific authorization from a licensed physician and surgeon. Authorization includes the following requirements:
 - Working under the direction of a licensed physician and surgeon.
 - Having been trained in both rapid HIV, HCV, or combination HIV/HCV test proficiency for skin puncture blood tests, oral swab tests, and in universal infection control precautions, consistent with best infection control practices established by the Division of Occupational Safety and Health in the Department of Industrial Relations and the federal Centers for Disease Control and Prevention.

Under the provisions of AB 1382, HIV test counselors may not:

- Perform other HIV or HCV 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.

Under the provisions of AB 1382, clients receiving:

- Preliminary (HCV antibody reactive) test results are to be informed of the likelihood of HCV exposure and that the result must be confirmed by an additional, more specific test.³
- “Indeterminate” or “positive” (i.e., reactive HCV antibody)⁴ test results are to be referred to a licensed health care provider whose scope of practice includes the authority to refer patients for laboratory testing for further evaluation.

Related Information

- [AB 1382 \(Hernandez, Chapter 643, Statutes of 2011\) full text.](#)
- [Viral hepatitis information](#) from CDPH’s Office of Adult Viral Hepatitis Prevention.
- [HIV C&T resources](#) for service providers from OA.
- For more information, contact Rachel McLean, Adult Viral Hepatitis Prevention Coordinator, Sexually Transmitted Disease Control Branch, by phone at (510) 620-3403 or by e-mail: rachel.mclean@cdph.ca.gov.
- HIV testing sites interested in offering the HCV rapid test and community-based programs interested in becoming an HIV testing site should contact Amy Kile-Puente, HIV Testing and Training Program Consultant, HIV Prevention Program Section, OA, at (916) 449-5805 or Amy.Kile-Puente@cdph.ca.gov.

³ More specific tests may include HCV nucleic acid tests, which are used to detect HCV in the blood and to diagnose current HCV infection. Approximately one in four people with a reactive HCV antibody test result have cleared the virus on their own and do not have current HCV infection.

⁴ Using the terms “reactive” and “non-reactive,” rather than “positive” and “negative,” to describe HCV antibody test results, may help reduce confusion among HCV testing clients. Forthcoming OA guidance for HCV testing emphasizes that test counselors should make clear that a “reactive” HCV antibody result does not necessarily indicate current HCV infection; HCV nucleic acid testing is needed to distinguish between past and present HCV infections.