

**Hepatitis C Testing**  
**in Non-Health Care Settings**  
*Guidelines for Site Supervisors and Testing Coordinators*  
California Department of Public Health  
Office of AIDS

**December 2012**



## Table of Contents

*Click to follow links*

<b>INTRODUCTION</b>	<b>1</b>
<b>Overview: OraQuick rapid HCV antibody test</b>	<b>1</b>
<b>CLIA certification</b>	<b>2</b>
<b>Prior to beginning HCV testing in non-health care settings</b>	<b>3</b>
<b>Staff qualifications and training requirements</b>	<b>3</b>
<b>Client health education and referral requirements</b>	<b>4</b>
<b>Contact Information</b>	<b>5</b>
<b>HEPATITIS C OVERVIEW</b>	<b>6</b>
Clinical features	6
Diagnosis	6
Transmission	6
At-risk groups	7
Treatment	7
Prevention	7
<b>PROTOCOL FOR USING HCV ORAQUICK TEST</b>	<b>8</b>
<b>Client risk screening</b>	<b>8</b>
<b>Informed consent</b>	<b>8</b>
<b>Specimen collection and test kit operation</b>	<b>9</b>
<b>Disclosure and referral</b>	<b>9</b>
Non-reactive test result	10
Window period	10
Reactive test result	10
Delivery of test result	10
Combination HIV/HCV testing	11
Referrals for follow-up testing and evaluation	11
Addressing partner notification	12
Invalid Test Result	12
Reporting HCV results to the local health department	12
<b>APPENDICES</b>	<b>13</b>
<b>Appendix A: The Clinical Laboratory Improvement Amendments</b>	<b>14</b>

<b>Appendix B: Assembly Bill 1382 Stakeholder Letter and Fact Sheet</b>	<b>15</b>
<b>Appendix C: Occupational Safety and Health Administration Standards</b>	<b>20</b>
<b>Appendix D: Sample Risk Assessment Form</b>	<b>21</b>
<b>Appendix E: Test Kits Steps for OraQuick HCV Test Procedure</b>	<b>23</b>
<b>Appendix F: Detailed Test Kit Steps for OraQuick HCV Test Procedure</b>	<b>24</b>
<b>Appendix G: Client HCV Test Result Form</b>	<b>27</b>
<b>Appendix H: HCV Referral Resources</b>	<b>28</b>
<b>Appendix I: Additional HCV Training Resources</b>	<b>29</b>
<b>Appendix J: HCV Rapid Testing Training Documentation Checklist</b>	<b>31</b>
<b>Appendix K: Acronyms</b>	<b>32</b>

## INTRODUCTION

---

This manual is intended to provide guidelines to human immunodeficiency virus (HIV) testing sites in non-health care settings such as community-based organizations (CBOs), and to HIV test counselors performing the OraQuick<sup>1</sup> hepatitis C virus (HCV) rapid test. The manual outlines recommendations for conducting OraQuick HCV rapid testing, including provision of HCV testing services and referrals.

Guidelines in this manual are designed to summarize California legal requirements and quality assurance (QA) best practices for non-health care HIV testing sites to perform HCV testing that has been waived under the federal Clinical Laboratory Improvement Amendments (CLIA). It is important to stay in compliance with all federal and state requirements surrounding CLIA-waived testing, including ensuring staff has the required qualifications. However, these guidelines are not intended to be regulatory and are not intended to be used as the basis for disciplinary action. ***A copy of this manual should be readily available for immediate reference to all personnel who conduct testing.***

These guidelines are intended to update and supplement existing policies and procedures outlined in [HCV Testing Services Guidelines \(2007\)](#) and [HIV Counseling and Testing Guidelines \(1997, 2003\)](#). When read online, this document provides underlined hyperlinks between the table of contents and the text, and includes hyperlinks within the document to make navigation simpler.

### Overview: OraQuick rapid HCV antibody test

The OraQuick rapid HCV antibody test is a simple-to-use device that delivers HCV antibody test results in as little as 20 minutes using a single drop of whole blood. It was approved for use in the United States by the U.S. Food and Drug Administration (FDA) in June 2010, and categorized as ‘waived’ under CLIA in November 2011.<sup>2</sup> The OraQuick is very accurate, with sensitivity and specificity performance that meets the standards for FDA approval.

Because HCV OraQuick test results are available in 20-40 minutes, this technology provides HIV test counselors with an unprecedented opportunity to integrate rapid HCV testing into existing HIV rapid testing processes, which include risk assessment, risk reduction counseling, and results disclosure in a single session. This has the benefit of ensuring that a substantially greater proportion of clients will receive their test results, along with result-specific counseling and referrals, than do currently.<sup>3</sup> Challenges

---

<sup>1</sup> Use of brand names is for identification purposes; CDPH does not endorse any company or its products.

<sup>2</sup> See [Appendix A: The Clinical Laboratory Improvement Amendments](#) for further information on CLIA.

<sup>3</sup> Note: This document uses the gender-neutral pronouns ‘they’ and ‘their’ to include individuals who might not identify with the pronouns ‘he’ or ‘she.’ Wherever possible, the California Department of Public Health (CDPH), Center for Infectious Diseases, Office of AIDS (OA) recommends using gender-neutral language in HIV and HCV testing sessions.

include integrating this process into an existing system in ways that 1) minimize disruption; and 2) maximize the effectiveness of the services provided.

Although the OraQuick rapid HCV antibody test is accurate and simple to use, great care is required to effectively implement this technology in HIV testing settings. As with all screening tests for HCV, reactive<sup>4</sup> rapid HCV antibody test results require follow-up testing. Following specific procedures and QA measures is essential to ensuring that all clients testing for HCV receive accurate results. For these reasons, the FDA requires that the HCV OraQuick test only be used, sold, and distributed according to the restrictions described in the package insert.<sup>5</sup>

The OraQuick rapid HCV test checks the blood specimen for the presence of HCV antibodies. The test shows whether a person has had HCV infection sometime in the past. It does not show whether the person currently has HCV infection. It is important to note that the presence of HCV antibodies indicated by the rapid HCV test result *has a different meaning* than the presence of HIV antibodies. In the case of the rapid HIV antibody test, the presence of HIV antibodies means that the person is infected with HIV. In the case of the HCV test, the presence of HCV antibodies means that the person has had HCV infection in the past but might have resolved the infection (cleared the virus from their system). The presence of HCV antibodies does not show whether the person has HCV infection now. A diagnosis of current HCV infection is determined through follow-up HCV nucleic acid testing (NAT), which looks for HCV in the blood.<sup>6</sup>

For more information about the OraQuick HCV rapid test from the test's manufacturer, see the [manufacturer's website](http://www.orasure.com/products-infectious/products-infectious-oraquick-hcv.asp): <http://www.orasure.com/products-infectious/products-infectious-oraquick-hcv.asp> or call 1-800-ORASURE (1-800-672-7873).

## CLIA certification

CLIA is a federal regulation that imposes certain requirements for performing laboratory tests, including simple point-of-care tests such as rapid HIV and HCV tests. There are currently several rapid HIV tests that are classified as 'waived' under CLIA, and the OraQuick rapid HCV antibody test is also classified as 'waived' under CLIA. Federal and state regulations require that organizations intending to perform these tests must apply for and receive a CLIA Certificate of Waiver prior to beginning testing.<sup>7</sup> See [Appendix A: The Clinical Laboratory Improvement Amendments](#) for more information on CLIA. There

---

<sup>4</sup> OA recommends using the terms 'reactive' and 'non-reactive,' rather than 'positive' and 'negative,' to describe HCV antibody test results. A 'reactive' HCV antibody result does not necessarily indicate current HCV infection; HCV NAT is needed to distinguish between past and present HCV infections.

<sup>5</sup> Title 21 United States Code (U.S.C.) 360e(d)(B)(ii). See [FDA Premarket Approval Letter](#) for the HCV OraQuick at [www.accessdata.fda.gov/cdrh\\_docs/pdf8/p080027s001a.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf8/p080027s001a.pdf) and the HCV OraQuick package insert [www.orasure.com](http://www.orasure.com) for more information.

<sup>6</sup> The term 'NAT' describes tests used to detect the presence and/or amount of HCV. Other terms used to describe NAT include 'PCR' (polymerase chain reaction), 'RNA' (ribonucleic acid), 'viral load', 'quantitative' and 'qualitative' testing. For consistency, the term 'NAT' is used throughout this document. <sup>7</sup>

Clinical Laboratory Improvement Amendments of 1988, 42 United States Code 263a PL100-578; 42 Code of Federal Regulations (CFR) 493; Title 22 California Code of Regulations (CCR) 51211.2.

are no additional requirements for medical personnel working within their scope of practice who are permitted to perform CLIA-waived tests.<sup>8</sup>

### **Prior to beginning HCV testing in non-health care settings**

Before implementing rapid HCV testing in any setting, FDA requires that sites obtain a CLIA certificate (as described above) and develop a QA plan.<sup>9</sup> HIV testing sites funded by OA are already required to maintain an HIV testing QA plan. Other HIV testing sites not funded by OA may perform HIV and HCV rapid testing if they use staff trained by OA and have a QA plan. Sites currently performing HIV rapid testing should inform the relevant local health jurisdiction (LHJ) of their intention to implement rapid HCV testing so that the LHJ may update the HIV QA Plan to include QA measures for HCV rapid testing. Sites that do not yet have a QA plan should work with their LHJ to develop one. In accordance with California Health and Safety (H&S) Code 120917, the local health department may charge a fee for the QA plan approval.

Federal law and state regulations require that sites comply with U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) standards for blood-borne pathogens, including requirements for training and posting of procedures and safety precautions.<sup>10</sup> Universal precautions components for inclusion in the QA plan are outlined in [Appendix C: Occupational Safety and Health Administration Standards](#).

### **Staff qualifications and training requirements**

California [Business and Professions \(B&P\) Code 1206.5](#) already allows certain **medical personnel** to perform CLIA-waived HIV and HCV tests. Some examples of personnel authorized by B&P Code 1206.5 to conduct CLIA-waived testing include licensed physicians, physician assistants, registered nurses and licensed vocational nurses.

H&S Code 120917 allows **non-medical personnel** that have been trained as HIV test counselors to perform CLIA-waived HCV tests if they:

1. Have been trained in HIV test counseling by OA or its agents;
2. Work in a HIV testing site that is funded by OA or that uses staff trained by OA or its agents **and** has a QA plan approved by the local health department **and** has HIV testing staff that complies with state regulatory QA requirements.<sup>11</sup>

---

<sup>8</sup> California B&P Code 1206(b); California B&P Code 1206.5. For more information on California laws, visit the [California Legislative Information website](#) at: <http://leginfo.legislature.ca.gov/>.

<sup>9</sup> 42 U.S.C. 263a; California H&S Code 120917.

<sup>10</sup> 29 CFR, Sect. 1910.1030 (2001); 8 CCR 5193.

<sup>11</sup> Title 17 CCR 1230. For more information on California regulations, visit the website of the California [Office of Administrative Law](#) at <http://www.oal.ca.gov/>.

3. Have been trained by OA or its agents in both HIV and HCV test kit proficiency for finger-stick blood tests and in universal infection control precautions, consistent with best infection control practices.

Training to be an HIV test counselor comprises successful completion of the OA Basic Counseling and Testing Skills Training (BCST), which is currently being modified to include proficiency in HCV rapid testing. Staff **not currently trained** as HIV test counselors who wish to provide rapid HCV testing should contact the OA Training Coordinator in order to enroll in a BCST provided by an OA training agent. (See [Contact Information](#) below for information on how to enroll in the OA BCST.) OA training agents may charge a fee for training HIV counseling staff in agencies not funded by OA. Medical personnel listed in B&P Code 1206.5 do not need to complete this training.

***HIV test counselors who completed the OA BCST prior to the inclusion of HCV rapid testing proficiency in the curriculum must be trained by OA or its agents in HCV rapid testing proficiency in order to be in compliance with H&S Code 120917.***

For existing HIV test counselors who wish to perform CLIA-waived HCV testing in addition to HIV testing, training by OA or its agents comprises:

1. Successful completion of the Integrated HCV/HIV Counseling Training, which is available online from OA training agents at the [Alliance Health Project](#); and
2. Proficiency training provided by OA-trained HIV/HCV testing site supervisors.<sup>12</sup>

OA training agents will provide HCV rapid test proficiency training for site supervisors: see [Contact Information](#) to schedule training.

Additional HCV training resources are available in [Appendix I: Additional HCV Training Resources](#). See [Appendix J: HCV Rapid Testing Training Documentation Checklist](#) for a list of HCV training components for HIV test counselors performing rapid HCV testing.

## **Client health education and referral requirements**

H&S Code 120917 requires that HCV testing clients be given the following information:

- A reactive test result means that the client has had HCV infection in the past and may or may not have HCV infection now.
- Additional testing is needed to know if the client has HCV infection now.

---

<sup>12</sup> Title 17 CCR Section 1036.3(a) requires that HIV testing site supervisors have a Baccalaureate Degree; be an HIV test counselor (H&S 120917) or other healthcare professional allowed to perform CLIA-waived HIV testing (B&P Code 1206.5); and, if not a medical professional listed in B&P Code 1206.5, meet the training qualifications for HIV testing personnel in nonmedical settings. More information on the training qualifications for HIV testing sites supervisors is available in the forthcoming *OraQuick HCV Antibody Testing Quality Assurance Guidelines for Non-Healthcare Settings*.

The law also requires that:

- Clients with a reactive HCV antibody test result be referred to a licensed health care provider whose scope of practice includes the authority to refer patients for laboratory testing for further evaluation.

For more information on H&S Code 120917, see [Appendix B: Assembly Bill 1382 Stakeholder Letter and Fact Sheet](#) or visit <http://leginfo.legislature.ca.gov/>.

## **Contact Information**

For more information about HCV training, contact:

Karin Hill, OA Training Coordinator  
Email: [Karin.Hill@cdph.ca.gov](mailto:Karin.Hill@cdph.ca.gov)  
Phone: (916) 319-9461.

For questions about the HCV rapid testing guidelines outlined here, contact:

Rachel McLean, Adult Viral Hepatitis Prevention Coordinator  
Sexually Transmitted Diseases (STD) Control Branch  
Email: [Rachel.McLean@cdph.ca.gov](mailto:Rachel.McLean@cdph.ca.gov)  
Phone: (510) 620-3403.



## HEPATITIS C OVERVIEW

---

HCV infection is caused by HCV and is the most common blood-borne infection in the United States. Approximately 3.9 million (1.9 percent) people in the United States have been infected with HCV; 3.2 million of them are chronically infected. National estimates indicate that there are approximately 475,000 people living with chronic HCV in California. However, these estimates exclude people who are homeless or incarcerated; the true number of people with HCV in California is probably much higher. HCV is the leading reason for liver transplant in the United States. Approximately 25 percent of those infected with HIV are co-infected with HCV. As many as three out of four people with HCV are unaware of their infection.

### Clinical features

Most (70 to 80 out of 100) people with recent HCV infection do not experience any symptoms and are often unaware of their infection. Of every 100 people infected with HCV, approximately 75-85 will go on to develop chronic infection; 60-70 will go on to develop chronic liver disease; 5-20 will go on to develop cirrhosis over a period of 20-30 years; and, without timely detection and treatment, 1-5 will die from the consequences of chronic infection (liver cancer or cirrhosis). Out of 100 people infected with HCV, 15 - 25 will clear the virus on their own, typically within the first six months of infection. HIV infection can lead to more rapid liver disease progression and higher risk of cirrhosis, end-stage liver disease, liver cancer, and liver-related death in people with HCV. It is not clear whether HCV speeds HIV progression.

### Diagnosis

A combination of tests is required to diagnose HCV. HCV antibody (anti-HCV) indicates either past or present infection. A NAT detects the presence of HCV in the blood, and is used to diagnose current HCV infection.

### Transmission

HCV is a blood-borne pathogen and is transmitted primarily by exposure to blood through the skin, such as through sharing contaminated injection equipment. Prior to 1992, many individuals were infected with HCV by blood transfusions or organ transplants. HCV is not efficiently transmitted between long-term monogamous heterosexual partners. However, having HIV increases a person's risk for sexual transmission of HCV. HCV can be transmitted from mother to child during childbirth and is more likely if the mother is co-infected with HCV and HIV.

Transmission of HCV has also occurred in health care and emergency response settings through accidental needle sticks or through failure to follow standard precautions and other infection control guidelines. There are very limited epidemiologic data to suggest additional risks from non-injection (snorted or smoked) cocaine use, but these risks are difficult to differentiate from risks associated with injection drug use and sex with HCV-infected partners.

There is little evidence that HCV is spread by getting tattoos in licensed, commercial facilities. Whenever tattoos or body piercings are given in informal settings or with non-sterile instruments (such as in prison), transmission of HCV and other blood-borne infectious diseases is possible. An estimated 10 to 15 percent of people with HCV have no known risk factors.

### At-risk groups

The Centers for Disease Control and Prevention (CDC) has identified the following groups to be at risk for HCV:

- Current or former injection drug users (IDUs), including those who injected only once many years ago;
- People born during the years 1945 through 1965, many of whom were infected with HCV many years ago and are unaware of their infection;
- Recipients of clotting factor concentrates made before 1987, when more advanced methods for manufacturing those products were developed;
- Recipients of blood transfusions or solid organ transplants before July 1992, when better testing of blood donors became available;
- Chronic hemodialysis patients;
- People with known exposures to HCV, such as:
  - health care workers after needle sticks involving HCV-positive blood; and
  - recipients of blood or organs from a donor who tested HCV positive;
- HIV-positive individuals; and
- Children born to HCV-positive mothers.

### Treatment

The main goal of HCV treatment is to achieve a sustained virological response (SVR), which is defined as undetectable HCV in the blood 24 weeks after the end of treatment. The standard treatment for chronic HCV infection is pegylated interferon plus ribavirin for 6 to 12 months. For people with genotype 1, the standard of care also includes treatment with one of two FDA-approved antiviral drugs (boceprevir or telaprevir) in addition to pegylated interferon and ribavirin. Treatment success is dependent on a number of factors, including age, gender, HIV status, virus genotype, and genetic factors, and will likely improve with new treatment drugs on the market in coming years. Side effects of HCV treatment may include flu-like symptoms, anemia, depression, and rash. Treatment is contraindicated in pregnancy because ribavirin can cause serious birth defects.

### Prevention

Currently there is no vaccine for HCV; however, researchers are working to develop one. Key HCV prevention messages include practicing safer injection; following infection control guidelines in health care settings; and not sharing personal items that might have blood on them such as razors, toothbrushes, nail clippers, and blood glucose monitors. People with chronic HCV infection should be advised to reduce or eliminate intake of alcohol and other substances toxic to the liver.

## **PROTOCOL FOR USING HCV ORAQUICK TEST**

---

This section details best practices for conducting HCV testing using the OraQuick rapid HCV test.

### **Client risk screening**

Clients arriving at the HIV/HCV testing site should be assessed to determine which tests should be offered (i.e., for HIV and/or HCV). OA recommends that HIV testing sites provide a comprehensive risk counseling session that covers both HIV and HCV if the client is at risk for both. Prior experience indicates that streamlined approaches in which both topics are addressed in one counseling session benefit both the test site and the client. Clients should not be required to take an HIV test in order to receive an HCV antibody test. The decision on which service to offer the client, either an HCV counseling session or a combination HCV/HIV counseling session, is based on the risk level of the client as established during the risk assessment process described below.

Specific risk assessment forms may vary by jurisdiction, but should be used to identify risk factors identified by CDC. A sample integrated risk assessment form used for identifying risk factors for HIV, viral hepatitis, and STDs is included in [Appendix D: Sample Risk Assessment Form](#) and may be adapted for local use.

***HCV testing should be offered to all people who do not know their HCV status and who report having ever injected drugs or who report having HIV infection.***

CDC does not recommend HCV testing for people whose sole reported risk factor is receiving a tattoo or piercing in a commercial, professional tattoo or piercing parlor.

The counselor should also assess whether the client has been previously tested for HCV and the client's knowledge of their past HCV test results. If the client reports having been diagnosed with chronic HCV in the past, the counselor should confirm with the client that they are connected with HCV support and care, and, if not, provide referrals. If the client reports having received a previous HCV antibody reactive test result but has never received HCV NAT testing, the counselor should refer them for follow-up NAT testing and other service referrals as appropriate. If the client has not been previously diagnosed with HCV or is unsure of their previous HCV antibody test results and has HCV risk factors identified by CDC, then they should be offered an HCV antibody test.

### **Informed consent**

Specific written consent is not required under California law when providing an HCV test. Prior to implementing HCV testing, testing sites should determine whether verbal or written consent will be collected. HIV testing consent forms may be modified to include HCV testing. Sites should consider asking clients with HCV reactive test results to sign a release of health care information form so that the testing site may share the client's results with the client's health care provider.

## Specimen collection and test kit operation

Once consent has been obtained, the HIV test counselor (or other qualified personnel trained in finger-stick proficiency and authorized to administer a CLIA-waived HCV rapid test) should begin the process of collecting the sample using a HIV test counselor-administered finger-stick and starting the OraQuick test.

As with HIV rapid testing, HCV test kit operation should occur in an appropriate setting away from the counseling area. See forthcoming HCV Testing Quality Assurance Guidelines for more information.

HIV test counselors (or other authorized personnel) should conduct the OraQuick HCV rapid antibody test in accordance with the manufacturer's instructions and with OA-approved training and QA guidelines. See [Appendix E: Test Kits Steps for OraQuick HCV Test Procedure](#) and [Appendix F: Detailed Test Kit Steps for OraQuick HCV Test Procedure](#), respectively, for general and detailed checklists for operating the test kit. Sites should post the checklists in the testing room near the testing area for easy reference.

## Disclosure and referral

For rapid testing, result disclosure occurs immediately following risk assessment counseling and performance of the rapid test. If possible, results disclosure should be conducted by the same counselor to maintain continuity of client-counselor rapport. Counselors should review the meaning of the test results with the client.

Screening for antibodies to HCV is the first step in identifying people living with HCV infection. If antibodies are found, a second test, called a NAT, which looks for the virus itself, is needed to find out whether the client is currently infected with HCV.

If testing is provided in a clinical setting with on-site access to phlebotomy and HCV NAT testing, then clients who test HCV antibody reactive should be offered HCV NAT testing. If NAT testing is not available on-site, then the counselor should refer the client to a clinical provider for follow-up testing via referral to primary care or using available viral hepatitis referral guides. (See page 11 for more information on available referral guides.)

There are three possible results that may be given by the OraQuick rapid HCV antibody test: non-reactive (negative), reactive, and invalid. Disclosure procedures for each are delineated below.

**Reminder:** OA recommends using the terms 'reactive' and 'non-reactive,' rather than 'positive' and 'negative,' when describing HCV antibody test results. OA recommends making clear that a 'reactive' HCV antibody result does not necessarily indicate current HCV infection; HCV NAT is needed to distinguish between past and present HCV infections.

### Non-reactive test result

A 'non-reactive' result means that HCV antibodies were not detected in the blood sample. Disclosure should focus on enhancing the client's intentions to initiate/continue risk reduction activities, and ensuring that the client understands the window period (see below), and how it applies to this test result. (In some cases, people with advanced HIV infection and other immunocompromised individuals might not develop HCV antibodies.)

### Window period

There is an amount of time after HCV infection occurs before antibodies are detectable by the antibody test. This time is called the 'window period.' HCV antibody can be detected in the blood within four to ten weeks after infection. The average window period for the development of HCV antibodies is eight to nine weeks. Ninety out of 100 people exposed to HCV develop antibodies after three months, and 97 out of 100 people have detectable levels of antibodies by six months after infection.

### Reactive test result

A 'reactive' result means that antibodies to HCV were detected and the client needs supplemental HCV NAT to determine if they are currently infected with HCV or have cleared the virus on their own. While most people (three out of four) with HCV antibody reactive test results will have evidence of chronic infection, an important part of the HCV testing process is to emphasize that an HCV antibody test result is **not** a diagnosis of chronic HCV infection.

Training on disclosure of HIV and HCV test results is included in BCST. At a minimum, a disclosure session for a reactive HCV antibody test result should include:

1. Delivery of the test result in direct, neutral tone;
2. Time for the client to process the meaning of the result and the counselor to explore the client's understanding of the result;
3. Referral for follow-up HCV NAT; and
4. Additional information and referrals as needed.

### Delivery of test result

The counselor should follow OA counselor training guidelines for delivery of test results. If possible, the counselor should notify the supervisor/clinic manager that a reactive HCV antibody reactive test result is being delivered, so that the manager can accommodate additional time required for this type of disclosure session. Reactive HCV antibody result delivery might take longer than HCV non-reactive test disclosures. Most clients need some time to explore the significance of their reactive HCV antibody test result before moving on to more pragmatic tasks, such as being referred for follow-up HCV NAT.

Face-to-face disclosure of test results is recommended. H&S Code 123148 does not currently permit electronic disclosure of test results for "antigens indicating hepatitis

infection.”<sup>13</sup> Clients should be given a written copy of their test results. (See [Appendix G: Client HCV Test Result Form](#) for a form that may be used for this purpose.)

### Combination HIV/HCV testing

When both HIV and HCV rapid testing are offered, the counselor should allocate sufficient time to deliver both test results and to ensure client understanding of the meanings, and differences between, these test results during the session. When delivering HIV and HCV test results together, clients might want to hear their HIV results first but the counselor should ask the client which result they want to hear first.

### Referrals for follow-up testing and evaluation

Ensuring that all clients with a reactive HCV antibody test result receive referrals for follow-up HCV NAT testing and evaluation is a principal goal of integrated HIV/HCV testing. All clients with HCV antibody reactive test results should be informed that they had HCV infection in the past and may or may not be infected with HCV. Among 100 persons with a reactive HCV antibody test result, 75 will have chronic (long-term) HCV infection while 25 will have cleared HCV from their system and no longer be infected. The only way to find out if the client is currently infected with HCV is to get a follow-up NAT. Clients must be referred to a licensed health care provider whose scope of practice includes the authority to order laboratory testing for further evaluation in accordance with H&S Code 120917. HCV diagnostic testing is most appropriately delivered in a clinical setting so that people diagnosed with chronic HCV infection can be appropriately linked to care.

CDPH's STD Control Branch has worked with the California Hepatitis Alliance (CalHEP) to develop a viral hepatitis services referral guide, which includes information about where clients can access HCV NAT as well as hepatitis A and hepatitis B vaccination, syringe access, HCV support groups, and programs offering linkages to care. The [guide](http://calhep.org/referralguide.asp) can be accessed at <http://calhep.org/referralguide.asp>. Additionally, some LHJs and CBOs have developed local viral hepatitis services referral guides, which may be a useful resource. (See [Appendix H: HCV Referral Resources](#) for more information.)

When referring clients to follow-up HCV NAT testing or other services, HIV test counselors should familiarize the client with the organization to which the client is being referred. Where possible and with the client present, counselors should do this by calling the agency to which the client is being referred, making the client an appointment or identifying the agency's drop-in hours, and providing the client with the name and phone number of a contact person at the agency to which the client is being referred. Some clients may also benefit from assistance with traveling to follow-up appointments, communicating with health care providers, and navigating the health care system. Organizations conducting HCV testing should establish mechanisms, wherever possible with available resources, for tracking whether clients referred for follow-up testing

---

<sup>13</sup> An antigen is a substance, usually a foreign substance, such as a bacteria or virus, which causes the body to produce antibodies. HCV RNA is an example of an antigen.

attended their follow-up appointments at the referral agency and for identifying clients lost to follow-up to ensure they are linked to appropriate follow-up testing and care.

In addition to providing referrals to follow-up HCV NAT, HIV test counselors should also provide clients with written and verbal information on the meaning of an HCV antibody test result, as well as general information on HCV and ways to promote liver health through preventive services (such as hepatitis A and hepatitis B vaccination) and lifestyle changes (such as reducing alcohol intake). See the forthcoming Resource Guide for HCV Test Counselor Supervisors for informational materials to distribute to HCV testing clients.

If the client has also tested positive for HIV or is already known to be HIV positive, then they should be encouraged to share the HCV test results with their primary health care provider who will be handling their HIV health care.

#### Addressing partner notification

Clients receiving reactive HCV antibody results may have concerns regarding what and how to tell partners about their HCV infection status. CDC guidelines recommend that these clients be encouraged to avoid behaviors that could transmit the virus in case the client does find out that they have chronic HCV infection. Counselors may also help clients determine whether, how and what to tell partners about their HCV antibody test result while awaiting a HCV NAT.

#### Invalid Test Result

An 'invalid' rapid HCV antibody test result means the test was unable to determine if the test result was reactive or non-reactive. This occurs when the internal control line on the HCV rapid test kit does not appear, or line(s) are not appropriately aligned in the result window. A client who receives an invalid test result should be offered the option of retesting or submitting a sample for lab-based standard testing (if available). If a second rapid test yields an invalid result, the client should be encouraged to submit a lab-based sample, and rapid testing external control units should be used to verify that the test kits are functioning properly. (See the test kit package insert and the forthcoming OraQuick HCV Testing Quality Assurance Guidelines for Non-Healthcare Settings for more details on running external controls and other QA activities.)

#### Reporting HCV results to the local health department

Currently, OraQuick HCV screening test results are not reportable to the local health department because test results for the OraQuick HCV antibody test alone do not meet CDC HCV surveillance case definitions.<sup>14</sup> For more [information on reportable disease requirements](#), visit: <http://www.cdph.ca.gov/HealthInfo/Pages/ReportableDiseases.aspx>.

---

<sup>14</sup> A "signal-to-cutoff ratio value predictive of a true positive for the particular assay as defined by CDC" is needed for reactive HCV antibody test results alone to meet the 2012 CDC HCV surveillance case definitions. CDC has not defined a "signal-to-cutoff ratio value predictive of a true positive" for the OraQuick HCV antibody test. The [CDC surveillance case definitions](http://www.cdc.gov/nndss/document/2012_Case%20Definitions.pdf) for acute and 'past or present' hepatitis C can be accessed at [http://www.cdc.gov/nndss/document/2012\\_Case%20Definitions.pdf](http://www.cdc.gov/nndss/document/2012_Case%20Definitions.pdf).

## APPENDICES

---

The following documents are provided as sample templates to assist HIV testing sites in implementing the HCV testing best practices described in these guidelines. Some documents, such as the checklists, should be completed as is. Other documents, such as the risk assessment forms, may be used as is or adapted to meet the needs of the testing site or LHJ in which the site operates. Quality assurance plans should be developed with, and be approved by, local health department representatives.

[Appendix A: The Clinical Laboratory Improvement Amendments](#)

[Appendix B: Assembly Bill 1382 Stakeholder Letter and Fact Sheet](#)

[Appendix C: Occupational Safety and Health Administration Standards](#)

[Appendix D: Sample Risk Assessment Form](#)

[Appendix E: Test Kits Steps for OraQuick HCV Test Procedure](#)

[Appendix F: Detailed Test Kit Steps for OraQuick HCV Test Procedure](#)

[Appendix G: Client HCV Test Result Form](#)

[Appendix H: HCV Referral Resources](#)

[Appendix I: Additional HCV Training Resources](#)

[Appendix J: HCV Rapid Testing Training Documentation Checklist](#)

[Appendix K: Acronyms](#)



## **Appendix A: The Clinical Laboratory Improvement Amendments**

CLIA is a federal regulation that applies to all clinical laboratory tests, such as tests for HIV and HCV. All tests that are approved by FDA are assigned a classification under CLIA: high complexity, moderate complexity, or 'waived.' This classification determines the level of qualifications required for personnel responsible for conducting and overseeing testing, as well as requirements for training, quality assurance, and proficiency testing. Agencies conducting *any* clinical laboratory test, including CLIA-waived tests, must have the appropriate CLIA certificate to authorize such testing.

The OraQuick Rapid HCV Antibody test has been classified as 'waived' under CLIA. Federal and state regulations require all settings intending to use the OraQuick device to obtain a CLIA certificate of waiver authorizing this test to be performed at their physical location. (Sites with a CLIA certificate of waiver may include a non-fixed site, such as a mobile van, under their CLIA certificate if certain conditions are met.) Sites with existing CLIA certificates will need to add the OraQuick Rapid HCV test to their CLIA certificate at the time of their certificate's annual renewal.

The federal agency that regulates CLIA certification is the Centers for Medicare and Medicaid Service (CMS). The CMS website features information on CLIA and an application for [obtaining a certificate of waiver](http://cms.hhs.gov/clia/) at <http://cms.hhs.gov/clia/>.

California has additional requirements for sites performing CLIA-waived testing that are above and beyond those set forth by federal statute. For specific instructions on [applying for a certificate to perform waived testing in California](http://www.cdph.ca.gov/programs/lfs/Pages/ClinicalLaboratoryfacilities.aspx), go to [www.cdph.ca.gov/programs/lfs/Pages/ClinicalLaboratoryfacilities.aspx](http://www.cdph.ca.gov/programs/lfs/Pages/ClinicalLaboratoryfacilities.aspx); download "Laboratory Registration Application Instructions" and complete the forms described there.

The CLIA certification process involved many steps and application forms. For LHJs and CBOs having difficulty navigating this process or that do not know where to start, OA can provide assistance. For assistance contact:

Kama Brockmann  
Specialist for HIV Testing in Health Care Settings  
HIV Prevention Branch  
Office of AIDS  
Phone: (916) 449-5964  
E-mail: [kama.brockmann@cdph.ca.gov](mailto:kama.brockmann@cdph.ca.gov)

For more information about CLIA certification in California, contact:

CDPH's Lab Field Services (Richmond Office)  
E-mail: [LFSRecep@cdph.ca.gov](mailto:LFSRecep@cdph.ca.gov)  
[Website](http://www.cdph.ca.gov/programs/lfs/Pages/default.aspx): [www.cdph.ca.gov/programs/lfs/Pages/default.aspx](http://www.cdph.ca.gov/programs/lfs/Pages/default.aspx)

## Appendix B: Assembly Bill 1382 Stakeholder Letter and Fact Sheet



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



EDMUND G. BROWN JR.  
Governor

February 21, 2012

TO: ALL INTERESTED PARTIES

SUBJECT: HEPATITIS C COUNSELING AND TESTING, ASSEMBLY BILL 1382

On October 9, 2011, Governor Edmund G. Brown, Jr., signed into law Assembly Bill 1382 (Hernandez, Chapter 643, Statutes of 2011) as part of statewide efforts to increase the number of persons, at risk for hepatitis C virus (HCV) infection, who learn their HCV antibody test results and receive results-specific counseling and referrals. The new law amends California Health and Safety Code Section 120917 to allow trained HIV test counselors who are authorized in California to perform HIV tests waived under the federal Clinical Laboratory Improvement Act (CLIA) to also perform CLIA-waived HCV and combination HIV/HCV tests.<sup>1</sup> HIV test counselors performing CLIA-waived HCV tests will need to meet the same performance and training requirements as they do for CLIA-waived HIV testing. (The enclosed fact sheet has more information for HIV testing sites and HIV test counselors.)

This change in law comes after many years of successful integration of HCV antibody testing into HIV testing sites throughout California. Historically, HCV antibody tests were administered by phlebotomy (blood draw) or through a client self-administered finger-stick test. With these test methods, clients often had to wait two weeks to receive their HCV antibody test results and some people failed to return for their results. Rapid HCV testing will allow clients to receive their test results, as well as results-specific counseling and service referrals, in the same day. Many sites are already performing rapid HIV testing, and should be able to integrate rapid HCV testing into their services.

Similar to HIV, HCV is transmissible through the sharing of contaminated injection equipment, and the majority of injection drug users (IDUs) infected with HIV are dually infected with HCV. Currently in the United States, HCV is ranked the number one

---

<sup>1</sup> To date, no combination HIV/HCV rapid test has been approved by U.S. Food and Drug Administration (FDA); however, combination HIV/HCV rapid tests are currently in development. State law allows for use of these tests in the event they are approved by FDA and CLIA-waived for use by non-medical personnel.

All Interested Parties  
Page 2  
February 21, 2012

cause of death among persons with HIV and is the leading cause of liver transplants nationwide. Yet, an estimated 75 percent of people with HCV are unaware of their infection.

Because of the high prevalence and significant consequences of HIV/HCV co-infection among IDUs and other at-risk groups, the Centers for Disease Control and Prevention recommends testing all individuals living with HIV for HCV and also recommends integrating HCV testing into HIV counseling and testing sites, which target at-risk groups. Early detection of HCV is essential to reducing the likelihood of HCV-related liver disease and other complications, and to preventing further disease transmission.

This law is timely given the FDA approval of the first-ever rapid HCV antibody finger-stick test in February 2011 and the CLIA waiver of that test in November 2011. The California Department of Public Health (CDPH), Center for Infectious Diseases, Office of AIDS (OA) and CDPH's Sexually Transmitted Disease (STD) Control Branch, Office of Adult Viral Hepatitis Prevention are working with community partners to develop training materials on HCV counseling and testing for HIV testing sites. Background information on HIV testing is available at the following link: [www.cdph.ca.gov/programs/aids/Pages/TOAPrevention.aspx](http://www.cdph.ca.gov/programs/aids/Pages/TOAPrevention.aspx). Additional materials will be accessible at the same location when they are developed.

For more information on HCV, contact Rachel McLean, Adult Viral Hepatitis Prevention Coordinator, STD Control Branch, by phone at (510) 620-3403 or by e-mail at: [Rachel.McLean@cdph.ca.gov](mailto: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 & Training Program Consultant, OA, at (916) 449-5805 or [Amy.Kile-Puente@cdph.ca.gov](mailto:Amy.Kile-Puente@cdph.ca.gov).

Sincerely,



Karen Mark, M.D., M.P.H.  
Interim Chief, Office of AIDS



James Watt, M.D., M.P.H., Chief  
Division of Communicable Disease Control

Enclosure

Cc: See next page

All Interested Parties

Page 3

February 21, 2012

cc: Rachel McLean, M.P.H.  
Adult Viral Hepatitis Prevention Coordinator  
STD Control Branch  
California Department of Public Health  
850 Marina Bay Parkway, Building P, Second Floor  
Richmond, CA 94804

Ms. Amy Kile-Puente  
HIV Testing and Training Program Consultant  
HIV Prevention Program Section  
Office of AIDS  
California Department of Public Health  
MS 7700  
P.O. Box 997426  
Sacramento, CA 95899-7426

Brian Lew, M.A., Chief  
HIV Prevention Branch  
Office of AIDS  
California Department of Public Health  
MS 7700  
P.O. Box 997426  
Sacramento, CA 95899-7426

Ms. Jacqueline Mincks  
Assistant Chief  
STD Control Branch  
California Department of Public Health  
MS 7320  
P.O. Box 997377  
Sacramento, CA 95814



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



EDMUND G. BROWN JR.  
GOVERNOR

### 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/HCV<sup>1</sup> 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.<sup>2</sup>
- **May perform finger-sticks for CLIA-waived HCV tests if they:**
  - Meet the requirements of CLIA; **and**

---

<sup>1</sup> 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.

<sup>2</sup> 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.<sup>3</sup>
- "Indeterminate" or "positive" (i.e., reactive HCV antibody)<sup>4</sup> 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](mailto: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](mailto:Amy.Kile-Puente@cdph.ca.gov).

---

<sup>3</sup> 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.

<sup>4</sup> 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.

## Appendix C: Occupational Safety and Health Administration Standards

Sites offering rapid HCV testing must meet the U.S. Department of Labor Occupational Safety and Health Administration (OSHA) standards for blood-borne pathogens.<sup>15</sup> Each site must:

- Provide training for all employees with occupational exposure;
- Have a written Exposure Control Plan;
- Provide personnel with protective equipment, such as gloves and laboratory coats;
- Make the hepatitis B vaccination series available to all employees who have the potential for occupational exposure;
- Provide post-exposure evaluation and follow-up to all employees who have had an exposure incident;
- Maintain a sharps injury log for recording percutaneous injuries from contaminated sharps; and
- Contain and dispose of bio-hazardous waste in accordance with applicable regulations.

FDA requires that all individuals operating the OraQuick HCV test device read and be familiar with the following CDC universal precautions guide: [CDC. Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other blood borne pathogens in health-care settings. \*MMWR\* 1988; 37\(24\):377-388.](#)

More detailed information on universal precautions is available at U.S. Department of Labor [OSHA website](http://www.osha.gov/): <http://www.osha.gov/> and the California Department of Industrial Relations, Division of [Occupational Health and Safety \(Cal/OSHA\) website](http://www.dir.ca.gov/occupational_safety.html): [http://www.dir.ca.gov/occupational\\_safety.html](http://www.dir.ca.gov/occupational_safety.html). Key Cal/OSHA documents include:

- Cal/OSHA Exposure Control [Plan for Bloodborne Pathogens](http://www.dir.ca.gov/dosh/dosh_publications/expplan2.pdf): [http://www.dir.ca.gov/dosh/dosh\\_publications/expplan2.pdf](http://www.dir.ca.gov/dosh/dosh_publications/expplan2.pdf)
- Cal/OSHA Best Practices Approach for Reducing Bloodborne Pathogens [Exposure](http://www.dir.ca.gov/dosh/dosh_publications/BBPBest1.pdf): [http://www.dir.ca.gov/dosh/dosh\\_publications/BBPBest1.pdf](http://www.dir.ca.gov/dosh/dosh_publications/BBPBest1.pdf)

---

<sup>15</sup> 29 CFR 1910.1030 (2001)

## Appendix D: Sample Risk Assessment Form

### INTEGRATED HIV/STD/VIRAL HEPATITIS RISK QUESTIONNAIRE

**INSTRUCTIONS:** Please answer the following questions. Mark one response for each question unless instructed otherwise. All of your answers are confidential and will not be shared with anyone. If you need assistance please ask the person who gave you this form.

1. What is your gender identity?  
 Male  
 Female  
 Transgender (male to female)  
 Transgender (female to male)  
 Other identity, specify: \_\_\_\_\_
2. What was your biological gender at birth?  
 Male  
 Female  
 Intersex
3. What is your race/ethnicity (*check all that apply*)?  
 Black / African American  
 American Indian / Alaska Native  
 Asian  
 Native Hawaiian / Pacific Islander  
 Hispanic / Latino(a)  
 White  
 Other race, specify: \_\_\_\_\_  
 I prefer not to answer.
4. What is your date of birth?  
□□/□□/□□□□
5. What county do you live in? \_\_\_\_\_
6. Are you currently homeless?  
 Yes       No
7. Which of the following comes closest to your sexual orientation?  
 Heterosexual / straight  
 Bisexual  
 Gay, lesbian, queer, same gender loving  
 Other orientation, specify: \_\_\_\_\_  
 I do not know my sexual orientation.
8. What is your current health insurance coverage (*check all that apply*)?  
 No health insurance coverage  
 Private (*Kaiser, Blue Cross, etc.*)  
 Medi-Cal (Medicaid)  
 Medicare  
 Military (*active duty, VA, or family*)  
 Indian Health Service  
 Other coverage, specify: \_\_\_\_\_
9. How many people have you had sex with during your lifetime? (*If you answer 0 (zero), go to question #18.*)  
 0  
 1-5  
 6-10  
 11-20  
 20+
10. How many people have you had sex with in the last 3 months? \_\_\_\_\_
11. My sex partners are (*check all that apply*):  
 Men  
 Women  
 Transgender: Male-to-Female  
 Transgender: Female-to-male
12. In the past 12 months have you had anal or vaginal sex without using a condom?  
Anal sex       Yes       No  
Vaginal sex     Yes       No
13. Have you ever been paid for sex or traded sex for drugs, food, clothing, etc?  
 Yes       No
14. Have you ever had sex while high on drugs or alcohol?  
 Yes       No

PLEASE CONTINUE ON OTHER SIDE



15. Have you ever had sex with someone infected with (*check all that apply*)?
- Hepatitis B
  - Hepatitis C
  - HIV/AIDS
  - STD (gonorrhea, chlamydia, syphilis)
  - Not sure

16. Have you ever had sex with someone who injected drugs?
- Yes     No     Not sure

- 16a. If yes, was it (*check all that apply*)?
- Current sex partner
  - Past sex partner

17. Have you ever been told by a doctor or medical provider that you had any of the following (*check all that apply*)?
- Gonorrhea ("clap")
  - Chlamydia
  - Syphilis ("bad blood")
  - Genital Warts (HPV)
  - Herpes
  - Trichomonas ("trich")
  - HIV/AIDS
  - Hepatitis A
  - Hepatitis B
  - Hepatitis C

18. Have you used any of these drugs in the past 12 months (*check all that apply*)?
- Speed (crystal, tina, meth)
  - Crack or powder cocaine
  - Poppers
  - I have not used any of these drugs.

19. Have you ever used a needle to inject drugs?
- Yes     No

- 19a. If yes, did you ever use someone else's needles, cookers, cottons, etc.?
- Yes     No

20. Have you injected any of these drugs in the past 12 months (*check all that apply*)?
- Speed (crystal, tina, meth)
  - Heroin
  - Crack or powder cocaine
  - Other (specify): \_\_\_\_\_

21. Was your mother infected with hepatitis B or hepatitis C when you were born?
- Yes     No     Not sure

- 21a. If yes, which one(s)?
- Hepatitis B
  - Hepatitis C

22. Have you ever been incarcerated in jail, prison, or a detention center?
- Yes     No

23. Did you ever have a blood transfusion before 1992?
- Yes     No     Not sure

24. Have you ever had a tattoo or body piercing (other than your ears) that was not done in a professional shop?
- Yes     No

25. Have you ever received the following vaccines (*check all that apply*)?
- Hepatitis A vaccine
  - Hepatitis B vaccine
  - Hepatitis A & B vaccine (TWINRIX)
  - Not sure

26. Is there anything else that might have put you at risk for HIV, STDs, or hepatitis?
- Yes     No     Not sure

- 26a. If yes, please specify:

\_\_\_\_\_

\_\_\_\_\_

## Appendix E: Test Kits Steps for OraQuick HCV Test Procedure

1. Gather materials.
2. Verify conditions for testing and examine test kit pouch (sufficient lighting, unopened test kit, room temperature, and absorbent pack).
3. Record lot number.
4. Record expiration date.
5. Record initials.
6. Open pouch, remove vial.
7. Affix client number to vial (if applicable).
8. Affix client number to risk assessment form, testing log, etc. (if applicable).
9. Open vial and put in stand.
10. **Put on gloves.**
11. Collect finger-stick blood sample.
12. Visually examine loop.
13. Stir in sample, discard loop in biohazard container.
14. Examine vial – fluid pink?
15. Insert test kit.
16. Record start time and temperature.
17. Record stop time temperature.
18. Read and record results.

Notes:

---

---

---

---

---

---

---

## Appendix F: Detailed Test Kit Steps for OraQuick HCV Test Procedure

### 1. Gather materials.

- *Test kit materials:* an unopened test kit pouch, test kit stand, specimen collection loop, lab slip/risk assessment form (if applicable), client number stickers, gloves, disposable absorbent workspace cover, and instructions.
- *Finger-stick materials:* puncture device, alcohol wipe, sterile gauze or cotton balls, and bandage.
- *Testing space items:* biohazard container, thermometer, clock/timer, good lighting.

### 2. Verify testing conditions and examine test kit pouch.

- Verify lighting is sufficient to perform test kit and read results.
- Test pouch must be unopened, to protect absorbency of test kit pad.
- Test pouch should be at 'room temperature,' between 59° and 99° F. If test kits are stored refrigerated, allow to come to room temperature before operating.
- Side of pouch with test kit in it must contain an absorbent packet. If not, dispose of entire pouch and use a new one.

### 3. Record lot number.

- Lot number is stamped on bottom right of package; record this number on testing log or lab slip (if applicable).

### 4. Record expiration date.

- Expiration month and year is stamped below lot number. Kit expires at the end of the month and year stamped; record expiration date in testing log. Discard kit if expired.

### 5. Record initials.

- Record initials of counselor operating the test kit and reading the results on the testing log or lab slip (if applicable).

### 6. Open pouch, remove vial.

- Feel the pouch to determine which side contains the vial of reagent. Open only that side of the pouch. Remove vial and set pouch aside, leaving the test device in the other side of the pouch until it is needed.

**7. Affix client number to vial (if applicable).**

- Affix client number to back of vial vertically, so the number will be visible when the vial is inserted into test kit stand.

**8. Affix client number to risk assessment form, testing log, etc. (if applicable).**

- From the same sheet of numbers, affix a sticker to the risk assessment form, testing log or lab slip, and other forms that will be linked (as needed).

**9. Open vial and put in stand.**

- Open the vial by gently rocking the lid back and forth. Insert into the stand by sliding the vial in from the top. Ensure the stand is on a flat surface, the vial is seated fully in the stand, and that the client number is visible.

**10. Put on gloves.**

- Universal precautions require that all health care providers use gloves when dealing with potentially infectious fluids. Use gloves to collect finger-stick blood samples, and when handling used test kits and vials, or any other materials that have come into contact with potentially infectious fluids.

**11. Collect finger-stick blood sample.**

- Follow all directions according to your finger-stick device and finger-stick training (i.e., clean client's finger with antiseptic wipe, let finger dry, puncture finger, wipe away first drop of blood), touch the 'loop' to the second drop of finger-stick blood until blood fills loop.

**12. Visually examine loop.**

- Examine loop carefully to ensure that the entire loop is filled with blood.

**13. Stir in sample, discard loop in biohazard container.**

- Use the loop to stir the sample into the vial of reagent. Discard the loop into a biohazard container when finished. Discard any other materials that have contacted potentially infectious agents in biohazard containers according to site infection control guidelines.

**14. Examine vial – fluid pink?**

- Carefully examine vial to ensure that the fluid in the vial appears pink. If not, discard and start over.

**15. Insert test kit.**

- Open other side of pouch, and remove the test kit without touching the absorbent pad. Do not cover the two holes on the back of the test kit with your fingers or any labels. Carefully insert the test kit into the vial. Ensure pad is touching the bottom of the vial and test kit window is facing forward.

**16. Record start time and temperature.**

- Record the time on the testing log in the space labeled 'Start Time.' Record the temperature on the testing log in the space labeled 'Start Temperature.'

**17. Record stop time and temperature.**

- Record the time on the testing log in the space labeled 'Stop Time.' Record the temperature on the testing log in the space labeled 'Stop Temperature.'

**18. Read and record results.**

- Read results between 20 and 40 minutes after test device inserted into vial. Results should be read while the test device is in the vial. Record results in testing log in the space labeled 'Results.'

---

---

---

---

---

---

---

## Appendix G: Client HCV Test Result Form

### Rapid HCV Test Result and Referral Form

Site ID #: \_\_\_\_\_ Client ID #: \_\_\_\_\_

Client Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

#### HCV Antibody Screening Test Result

Reactive (Preliminary Positive) [ ]    Non-Reactive [ ]    Invalid [ ]

Disclosed by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Referral Information

Organization \_\_\_\_\_  
Street Address/Location: \_\_\_\_\_  
City, Zip Code \_\_\_\_\_  
Phone \_\_\_\_\_  
Contact Person (if any) \_\_\_\_\_  
Appointment Date/Time \_\_\_\_\_

Comments: \_\_\_\_\_

---

### Rapid HCV Test Result and Referral Form

Site ID #: \_\_\_\_\_ Client ID #: \_\_\_\_\_

Client Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

#### HCV Antibody Screening Test Result

Reactive (Preliminary Positive) [ ]    Non-Reactive [ ]    Invalid [ ]

Disclosed by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Referral Information

Organization \_\_\_\_\_  
Street Address/Location: \_\_\_\_\_  
City, Zip Code \_\_\_\_\_  
Phone \_\_\_\_\_  
Contact Person (if any) \_\_\_\_\_  
Appointment Date/Time \_\_\_\_\_

Comments: \_\_\_\_\_

## Appendix H: HCV Referral Resources<sup>16</sup>

### [California Hepatitis Alliance](http://calhep.org/referralguide.asp)

(<http://calhep.org/referralguide.asp>)

- Provides information, by county, city, and zip code, about where to obtain HCV NAT; hepatitis A and hepatitis B vaccination; HCV education and support groups; syringe exchange services; and linkages to care for people with chronic HCV infection.

### [California HIV/AIDS Referral Service](http://cdcnpin.org/ca/)

<http://cdcnpin.org/ca/> or 1 (800) 367-2437 (Monday-Friday, 9 a.m. – 4 p.m. Pacific Standard Time)

- Provides information to help individuals find HIV testing, prevention, care and treatment, and support services in their local area.

### [Hepatitis C Support Project](http://www.hcvadvocate.org)

([www.hcvadvocate.org](http://www.hcvadvocate.org))

- Provides information on HCV support groups in the United States and California, as well as other patient education materials and resources.

### [Los Angeles HIV Information](http://www.hivla.org/search.cfm)

<http://www.hivla.org/search.cfm> or 1 (866) 772-2365

- Provides information to help individuals find HIV and viral hepatitis testing, prevention, care and treatment, and support services in Los Angeles.

### [National Prevention Information Network](http://www.hivtest.org)

[www.hivtest.org](http://www.hivtest.org)

- Includes information on hepatitis A and B vaccination and HIV/STD testing; does not currently include information on hepatitis B or hepatitis C testing.

### [San Francisco Viral Hepatitis Referral Guide](http://www.hepcsf.org/uploads/SF_guide_english.pdf)

[http://www.hepcsf.org/uploads/SF\\_guide\\_english.pdf](http://www.hepcsf.org/uploads/SF_guide_english.pdf)

- Provides information to help individuals find viral hepatitis testing, prevention, care and treatment, and support services in San Francisco.

---

<sup>16</sup> Note: This list of websites is provided as a public service. CDPH does not endorse, support, sponsor, or approve the products or services of parties listed here. CDPH does not control or maintain the material presented by other people or organizations on their websites.

## Appendix I: Additional HCV Training Resources

### [AIDS Healthcare Foundation](#)

- AIDS Healthcare Foundation (in Los Angeles) offers a variety of OA-approved trainings for HIV test counselors. Trainings include the Basic I and Basic II, among others. Some restrictions on which programs may access their trainings apply. For more information, contact:  
Myrnelle Dizon  
Lead Trainer  
AHF Public Health Division  
Phone: (213) 405-5812  
Fax: (213) 405-5880  
E-mail: [Myrnelle.Dizon@aidhealth.org](mailto:Myrnelle.Dizon@aidhealth.org)  
Website: [www.aidhealth.org](http://www.aidhealth.org)

### Alliance Health Project

- Alliance Health Project (in San Francisco) offers a variety of OA-approved trainings statewide for HIV test counselors. Trainings include BCST, Continuing Education, and Rapid Testing, which are delivered in-person. AHP also offers an online [Integrated Hepatitis C/HIV Counseling training](#) for HIV test counselors. For more information, please visit their website:  
[http://www.ucsf-ahp.org/HTML2/services\\_providers\\_training.html](http://www.ucsf-ahp.org/HTML2/services_providers_training.html)

### Los Angeles County Department of Public Health, Division of STD and HIV Programs

- Los Angeles County Department of Public Health offers a variety of trainings for HIV test counselors working in programs funded by Los Angeles County, CDPH's OA, or CDC. Trainings include the Basic I and Basic II, HIV/AIDS 101, Hepatitis ABCs, Partner Services, and HIV case management. [For more information](#), please visit their website: <http://publichealth.lacounty.gov/aids/trainings.htm>.

### San Francisco Department of Public Health

- San Francisco Department of Public Health, HIV Prevention Section (HPS) is responsible for providing the necessary training to certify HIV test counselors who provide testing in the community-based sites that are funded by HPS, CDC, or receive other governmental funds for HIV prevention. Currently the following trainings are offered: California Basic HIV Test Counselor Skills Training, OraQuick Proficiency Training, Stat-Pak Training, and Finger-Stick Proficiency Training. For [more information regarding training](#), go to [http://sfhiv.org/testing\\_training.php](http://sfhiv.org/testing_training.php).

### [Harm Reduction Training Institute](#)

([www.harmreduction.org](http://www.harmreduction.org))

- Provides periodic trainings in Hepatitis ABCs and Harm Reduction, among other topics.



### [Hepatitis C Support Project](#)

([www.hcvadvocate.org](http://www.hcvadvocate.org))

- Provides trainings for service providers on HCV, along with health education materials, a list of HCV support groups, and many other resources.

### [Hepatitis Web Study](#)

(<http://depts.washington.edu/hepstudy/index.html>)

- Provides free, interactive, online, case-based learning on HCV clinical screening, diagnosis, clinical management, and treatment for clinicians, as well as free continuing education credits and a glossary of hepatitis-related medical terms.

### [National Training Center for Integrating Hepatitis into HIV/STD Prevention Services](#)

([www.knowhepatitis.org](http://www.knowhepatitis.org))

- Offers free, CDC-approved, online trainings for non-healthcare professionals. Training participants receive a certificate of completion. Training titles include The ABCs of Hepatitis; Recent Advances in the Diagnosis and Treatment of Hepatitis C for Frontline Workers; and Hepatitis C in Persons Living with HIV, among others.

## Appendix J: HCV Rapid Testing Training Documentation Checklist

To be completed by site supervisor and signed by coordinator/supervisor and HIV test counselor performing HCV rapid testing and placed in the counselor's personnel file.

	Training Qualification	Completion Date
<input type="checkbox"/>	Counselor has completed BCST delivered by OA or its agents. <sup>17</sup>	__/__/__
<input type="checkbox"/>	Counselor has completed finger-stick proficiency training delivered by OA or its agents.	__/__/__
<input type="checkbox"/>	Counselor has completed training in HCV rapid test proficiency delivered by OA-trained site supervisor or OA training agents.	__/__/__
<input type="checkbox"/>	Counselor has been trained by OA or its agents in universal infection control precautions and bloodborne pathogen control.	__/__/__
<input type="checkbox"/>	Counselor has completed Integrated HIV/HCV Counseling Training.	__/__/__
<input type="checkbox"/>	Counselor has read and agrees to adhere to the manufacturer's instructions for performing, reading, and interpreting the OraQuick HCV rapid antibody test.	__/__/__
<input type="checkbox"/>	Counselor has read and agrees to adhere to the QA plan.	__/__/__
<input type="checkbox"/>	Counselor has performed at least one observed practice test kit run after training and prior to conducting testing on client specimens (using a control unit or proficiency panel specimen) and has demonstrated proficiency in preparing, running, reading, and interpreting the test.	__/__/__
<input type="checkbox"/>	Counselor agrees to periodic HCV rapid testing proficiency assessments (i.e., during the first three tests run on client specimens; at six months of testing experience; and annually thereafter) as part of QA.	__/__/__
<input type="checkbox"/>	Supervisor has observed the counselor demonstrate the ability to deliver quality HCV testing services, including but not limited to, providing accurate information on the meaning of HCV test results, including the need for follow-up NAT, and appropriate referrals as part of QA.	__/__/__

\_\_\_\_\_  
Signature of HIV Test Counselor  
Date: \_\_/\_\_/\_\_

\_\_\_\_\_  
Signature of HIV Testing Site Supervisor  
Date: \_\_/\_\_/\_\_

<sup>17</sup> OA or its agents offer training components (e.g., BCST and proficiency) alone or in combination.

## **Appendix K: Acronyms**

BCST	Basic Counselor Skills Training
B&P	Business and Professions
CBOs	Community-Based Organizations
CDC	Centers for Disease Control and Prevention
CDPH	California Department of Public Health
CLIA	Clinical Laboratory Improvement Amendment
CMS	Centers for Medicare and Medicaid Services
FDA	U. S. Food and Drug Administration
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
H&S	Health and Safety
IDUs	Injection Drug Users
LHJs	Local Health Jurisdictions
NAT	Nucleic Acid Test
OA	Office of AIDS
OSHA	Occupational Safety and Health Administration
QA	Quality Assurance
STD	Sexually Transmitted Disease(s)