OraQuick HCV Antibody Testing Quality Assurance Guidelines for Non-Healthcare Settings

California Department of Public Health
Office of AIDS

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INTRODUCTION

This manual is intended to provide quality assurance (QA) guidelines to HIV testing sites in non-healthcare settings such as community-based organizations (CBOs), and to HIV test counselors performing the OraQuick hepatitis C virus (HCV) rapid test.

This manual has been adapted with permission from the forthcoming 2012 "Guide to Integrating HCV Rapid Testing into HIV Testing Settings" by OraSure Technologies. It is designed to summarize QA best practices for non-health care HIV testing sites to perform HCV tests that have been waived under the federal Clinical Laboratory Improvement Amendments (CLIA).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 available for immediate reference to all testing personnel.***

Guidelines contained in this document focus on QA procedures for OraQuick rapid HCV testing. Although the OraQuick HCV rapid test device is simple to use and can provide reliable results when the manufacturer's instructions are followed, mistakes can occur at any point in the testing process. Quality assurance is an essential component of ensuring that clients receive accurate test results. More information about the OraQuick rapid HCV test is available at the manufacturer's website: www.orasure.com/products-infectious/products-infectious-oraquick-hcv.asp or 1-800-ORASURE (1-800-672-7873).

Key Differences from *OraQuick Rapid HIV Testing Guidelines, 2003*

Many sites hoping to provide HCV rapid testing have extensive experience offering HIV rapid testing and have HIV rapid testing QA plans in place. These guidelines are intended to supplement general QA guidelines outlined in *Hepatitis C Testing in Non-Healthcare Settings, 2012* and to update previous guidelines in *HCV Testing Services Guidelines (2007)*; *OraQuick Rapid HIV Testing Guidelines (2003)*; and *HIV Counseling and Testing Guidelines, Policies and Recommendations (1997)*, where applicable.

The quality assurance guidelines for HCV rapid testing are similar to those for HIV rapid testing outlined in the 2003 OA guidance. Two key differences are highlighted here:

1. Training and personnel qualifications
   California Health and Safety (H&S) Code 120917(e) allows **non-medical personnel** that have been trained as HIV test counselors to perform CLIA-waived HCV tests if they:
   a. Have been trained in HIV test counseling by OA or its agents;
   b. 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.[1]

[1] 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/.

In addition, H&S Code 120917(b) prohibits non-medical personnel that have been trained as HIV test counselors from performing CLIA-waived HCV tests until they 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.

See *Hepatitis C Testing in Non-Healthcare Settings, 2012* for more information on training in HCV rapid testing for HIV test counselors and Appendix A: Personnel Qualifications and Typical Responsibilities for more information on training qualifications for laboratory directors, site supervisors, and HIV test counselors. Medical personnel who may perform CLIA-waived tests within the scope of their practice do not need additional training to perform CLIA-waived HCV tests.

2. Storage temperature for HCV rapid test kits and controls
   The temperature ranges required by the test manufacturer (OraSure) for storage of the OraQuick HCV rapid testing kit are slightly different than those required for storage of the OraQuick HIV rapid testing kit. Sites conducting both rapid HIV testing and rapid HCV testing should be sure to store test kits and control units in the overlapping areas of the temperature ranges for both tests. See Appendix B: HIV and HCV Rapid Test Kit Storage and Operation Temperatures Guide for a summary of the temperature ranges for HIV and HCV test kits and controls.

After reviewing these guidelines, sites should work with their local health jurisdictions (LHJs) to update their QA plans to include HCV rapid testing activities.

QUALITY ASSURANCE FOR HCV RAPID TESTING

QA refers to planned and systematic activities designed to ensure that that testing is being carried out correctly, results are accurate, and that errors or substandard procedures are detected and corrected to avoid adverse outcomes. QA activities should be in place during the entire testing process, from the time a client requests testing to the provision of the test result and referrals. An effective QA program is one that is integrated into routine practices in a given setting.

The basic elements of a QA program must be in place before offering testing. These basic elements, the building blocks of a QA program, are listed below and explained in more detail in the rest of this document.

Preparing for implementation

Sites should take a number of preparatory steps prior to implementing rapid HCV testing. Some of these may have already been addressed in sites performing rapid HIV testing. Before offering rapid HCV testing to clients, site supervisors should:

- Identify the individual(s) who will take lead responsibility for managing the QA program. Likely candidates include the testing coordinator, the county health officer, the CLIA-waived laboratory director, or the clinic manager.

- Identify the physical space in which testing will occur and ensure that it meets the requirements outlined in Appendix C: Best Practices for OraQuick HCV Testing Settings.
- Adapt the guidelines contained in this document to reflect QA protocols specific for the setting. Specifically identify who is responsible for which QA tasks, when, where, and how often they will be performed, and how they will be documented.
- Create mechanisms for communication so that QA issues are brought to the attention of the appropriate individual. For instance, although the site supervisor may be responsible for ensuring that there is adequate lighting in the testing area, it is likely that testing personnel will be the first to notice if a bulb burns out.
- Ensure that testing sites meet all applicable federal, state, and other regulatory requirements, including compliance with CLIA, Occupational Safety and Health Administration (OSHA), and infection control guidelines.
- Verify the testing process. That is, once protocols are established in writing, verify that the procedures work as expected. Walk through the process in each of the settings of intended use. Make sure that all of the necessary components are in place: staff is trained and competent, test kits are functional, counseling, biohazard disposal, and other procedures are functional and efficient.
- See Appendix I: OraQuick HCV Testing Site Preparation Checklist for a more complete list.

Personnel and training qualifications

Having qualified, trained staff that perform and supervise OraQuick HCV testing and the various activities in the QA program is one of the most important factors for ensuring accurate and reliable results.

Personnel qualifications

Adequate selection, training and preparation for lab directors, site supervisors, and HIV test counselors prior to implementing rapid HCV testing is a critical component of QA. In accordance with H&S Code 120917, OraQuick HCV testing must be conducted by personnel qualified both to perform the finger-stick and to operate the test kit. Appendix A: Personnel Qualifications and Typical Responsibilities lists key personnel involved in the testing process, their training qualifications, and their typical QA responsibilities. Each LHJ may adapt the designations listed in the table to suit the structure of their organization, provided the qualifications for laboratory director, site supervisors, and testing personnel are met. Community-based organizations conducting rapid HCV testing should consult with their LHJ regarding the QA standards in their jurisdiction.

Although there are specific QA duties assigned to various personnel, *every* person involved in the testing process has the responsibility to both 1) complete the QA duties assigned to them, and 2) to bring any other QA issues noted to the attention of appropriate supervisory personnel. Testing personnel, as the “front line” workers, are likely to be the first to notice changes in testing conditions that may impact quality of testing, including temperature control issues, lighting, safety issues, etc. These

personnel should be encouraged to be attentive to all aspects of the testing process, and to discuss with their supervisor any issues that may require attention.

Training qualifications for HIV test counselors

Training by OA to be an HIV test counselor comprises successful completion of the OA Basic Counseling Skills Training (BCST) provided by OA training agents. Non-medical personnel who are not currently trained as HIV test counselors and who wish to provide rapid HCV testing should enroll in a BCST. The BCST curriculum is currently being modified to include proficiency in HCV rapid testing. ***HIV test counselors who completed the OA BCST prior to the inclusion of HCV rapid testing proficiency in the BCST curriculum must be trained in HCV rapid testing proficiency and integrated HIV/HCV counseling in order to be in compliance with H&S Code 120917.*** See *Hepatitis C Testing in Non-Healthcare Settings, 2012*, for more information on training requirements for existing HIV test counselors wishing to perform OraQuick HCV testing.

HCV testing staff should also be prepared to accurately discuss HCV with clients. See Counseling section of this document for more information on considerations for supervising HCV testing staff.

Documentation of this training should be kept on file at the testing site. See *Hepatitis C Testing in Non-Healthcare Settings*, Appendix J: HCV Rapid Testing Training Documentation Checklist, which may be used for this purpose.

Desirable personnel qualities

The following qualities are worthwhile to consider when selecting personnel to perform the OraQuick HCV test:

- *Sincerity and commitment* – A dedication to performing testing according defined procedures, including QA measures;
- *Responsibility and initiative* – A sense of personal responsibility for the entire testing process, and the initiative to notify appropriate supervisory personnel of any QA concerns;
- *Literacy* – The ability to read instructions, record results, and document QA procedures;
- *Organizational skills* – The ability organize and manage several tasks simultaneously, to the extent required by job duties; and
- *Decision-making skills* – The ability to interpret results and be able to recognize and handle problems that might arise.

Immediate supervisors should be aware of the skills and abilities of testing personnel, and provide supervision and oversight accordingly.

Competency assessment

At periodic intervals, the site supervisor should document HIV test counselors' competency in performing all tasks for which an individual is responsible, including both counseling skills and testing responsibilities. Ideally, the supervisor performing the

competency assessment would “shadow” the counselor through the entire testing process, from obtaining informed consent through result disclosure counseling.

Recommendations for test kit competency assessment

Site supervisors should observe and document competency for HCV testing personnel by assessing each of the elements of the operation in accordance with the items in Appendix D: OraQuick HCV Test Kit Competency Checklist. This assessment should be performed:

1. Once in the clinical setting after training and prior to conducting testing on client specimens (using a control unit or proficiency panel specimen);
2. During the first three tests conducted on client specimens;
3. After six months of testing experience; and
4. Subsequently, on an annual basis.

For sites where separate personnel perform counseling duties and testing duties, each should be evaluated independently within their work environment. If testing personnel have the responsibility for running several tests simultaneously, these organizational skills should also be evaluated for compliance with local protocols.

Documentation of competency assessment should be maintained in the personnel file.

Process control procedures

Prior to conducting tests on client samples, and on an ongoing basis, certain procedures must be performed to ensure that the test kits are operating correctly to provide accurate results, the storage areas for the test kits and control units are acceptable, and the testing area is suitable. These activities include monitoring the temperature in the storage area(s) for the test kits and control units, monitoring inventory, and running external controls. These procedures are an integral part of QA and are collectively referred to a process control procedures.

Monitoring storage area temperature

OraQuick HCV rapid test kits must be stored within the temperature range specified by the manufacturer’s test kit package insert (currently 36 - 86° F, 2° - 30° C), and control units must be stored within the temperature range specified by the manufacturer’s control unit package insert (currently 36° – 46° F, 2° - 8° C – i.e., under refrigeration). Control units may NOT share a refrigerator with food items. Test kits do not require refrigeration, but may be refrigerated if desired. Test kits must come to room temperature (currently 59° F - 99° F, 15° - 37° C) before use. (See test kit package insert and control kit package insert at http://orasure.com/products-infectious/products-infectious-oraquick-hcv.asp, under “Resources”, for more information. See also Appendix B: HIV and HCV Rapid Test Kit Storage and Operation Temperatures Guide, which may be posted in the storage area for test kits and controls as a reference.)

To monitor temperature, the site supervisor should place a digital thermometer in each storage area (e.g., on the shelf in the refrigerator or cabinet where the items are stored) that is able to record both the minimum and maximum temperature. This will enable the

site supervisor to identify whether the temperature of the test kit storage area goes out of the allowable range, such as during a power outage. A temperature control log should be posted on the outside of the cabinet or refrigerator; temperature should be checked and recorded daily on days when the site is open. (See Appendix E: OraQuick HCV Test Kit Storage Temperature Log and Appendix F: OraQuick HCV Control Unit Storage Temperature Log for a sample temperature control logs.)

For mobile testing units or settings where temperatures may fluctuate over the course of a few hours, sites should monitor temperature in the portable/temporary storage area more frequently, such as hourly. If testing and/or control units used in the field are to be returned to main stock, sites should use a separate temperature control log to verify that the units were maintained in continuous temperature compliance while off-site. If there are doubts about the testing area temperature or whether test kits have stayed within the appropriate range, sites should run reactive and negative external controls as described below. If the controls perform as expected, the tests may be used. Once the control vials are opened, they are stable for eight weeks. Sites should record on the vial the date the control is opened and discard unused open controls after eight weeks.

Monitoring inventory

It is important to monitor test kit and control unit inventory in order to avoid 1) running out, and 2) units expiring on the shelves. Test kits and control units have a defined shelf life and must not be used past their expiration dates, so it is important to put procedures in place that ensure an adequate, but not excessive supply, and to ensure that older test kits/control units are used first.

To avoid theft, it is also important to control inventory by using secure storage areas and sufficiently stringent monitoring procedures. Inventory log sheets should account for each test, and indicate whether it was used to test a client sample, to run external controls, for training/practice purposes, or was not used for some reason, such as past expiration date, faulty packaging, storage temperature non-compliance, etc.

External quality controls

Each OraQuick HCV rapid testing device is equipped with an “internal” control device that consists of a line that appears next to the “C” in the device window when a valid result is obtained. This control verifies that sufficient sample was collected, and that the sample and reagent migrated through the device properly.

In addition to this internal control, the test manufacturer also makes available external OraQuick HCV Antibody Test Kit controls, which must be run periodically to verify that the device is accurately detecting HCV antibodies and to check if the person conducting the test performs it correctly. External controls are purchased separately from test kits.

An external quality control unit consists of two vials of clear fluid made from human plasma. Each vial contains enough fluid to run approximately 25 OraQuick HCV tests. One vial contains fluid that will test HCV antibody non-reactive (negative); the other vial contains fluid that will test HCV antibody reactive. The external quality control process consists of running two OraQuick HCV tests—one using a drop of fluid from the reactive control vial, and one using fluid from the negative control vial—to ensure that the OraQuick HCV tests are obtaining the proper result.

When to run external controls

External controls are run to verify that the test kits are working as expected, that operators are performing the test properly, and that results are accurate and legible in a given setting. Controls should be run:

- By each new operator prior to performing testing on client specimens;
- In each new setting or when conditions in a setting have changed significantly;
- When opening a new test kit lot/whenever a new shipment of test kits is received;
  If the temperature of the test *storage area* falls outside of acceptable range (36 - 86° F for the OraQuick HCV rapid test);
- If the temperature of the *testing area* falls outside of acceptable range (59 - 99° F for the OraQuick HCV rapid test);
- At recommended intervals depending on the volume of tests performed and not less frequently than once per month; and
- Whenever two invalid results in a row are obtained.

By each new operator prior to performing testing on client specimens

This is to verify that new operators are able to run the test properly. As part of the competency assessment HIV test counselors who are trained by OA or its agents in HCV rapid testing and finger-stick proficiency should perform at least one test in the testing environment under the supervision of the site supervisor prior to testing client samples. Control unit or proficiency panel samples may be used for this purpose.

In each new setting or when conditions in a setting have changed significantly

Controls should be run in each new setting to verify that all of the elements of the setting (e.g., lighting, temperature, level surface, etc.) are sufficient to yield the correct result. If conditions in an existing setting conditions change significantly, controls should be run again.

When opening a new test kit lot/whenever a new shipment of test kits is received

A “lot” consists of about 1000 tests kits that were manufactured together and which will all bear the same lot number on the outside of the test kit package. A “shipment” is the quantity of test kits that arrive in a single delivery. External control testing will verify that the lot/shipment is functioning properly after the shipping process.

If a shipment contains units from a single lot, one set of controls on that shipment will verify the functionality of both the lot and the shipment. If the shipment contains units from more than one lot (i.e., contains more than one lot number), external controls must be run on each lot.

If the temperature of the test storage area falls outside of acceptable range

If the test kit storage area in either a primary or satellite/temporary location is suspected to have fallen outside the acceptable temperature range as specified in the manufacturer’s package insert, external controls must be run to verify that the test kits are still functioning properly prior to resuming use of the kits to test client specimens.

If test kits from a satellite/temporary storage area are to be re-integrated into primary stock, it must be verified that they have been maintained in continuous temperature

compliance, or external controls must be run to verify that the test kits are still functioning properly before they are re-integrated into the primary storage area.

If the temperature of the testing area falls outside of acceptable range

If the temperature of the area where test kits are operating falls outside the recommended range as specified in the manufacturer's package insert, external controls should be run to verify that the test kits are functioning properly in this environment. In this instance, OA recommends that testing be suspended until the temperature in the testing area can be adjusted to within the acceptable range.

At recommended intervals depending on the volume of tests performed and not less frequently than once per month

External controls must be run periodically, to verify that existing stock continues to function properly. Testing sites should run controls at the recommended intervals described in the table on the following page and should run controls at least once per month. If controls fail (i.e., the reactive or non-reactive control vial yields an incorrect result and it is determined that it was not a result of faulty controls), all of the tests run since the last successful control test are called into question. In that event, sites would need to contact the clients who tested and ask clients to return for re-testing. To avoid this kind of scenario, it is important to err on the side of running more frequent controls.

Recommended intervals for conducting external quality controls are presented in the table on the following page.

Site volume	Tests performed per month	When to run controls
Low	Less than 25	Every 2-4 weeks (no less frequently than once per month)
Intermediate	Between 25 – 500	Every 25- 50 tests
High	Greater than 500	Daily

For ease of implementation, it is better to determine specific times to run controls (e.g., in a setting that averages 50 tests per week, run controls every Monday and Thursday morning before clinic hours) rather than electing to run controls every 25 tests, as this may inconveniently fall in the middle of clinic hours, disrupting clinic flow.

Whenever two invalid results in a row are obtained

If two invalid results in a row are obtained, running controls will help determine if repeated invalid results are due to the test device or the specimen. If the same test kit lot gives repeated invalid results, the test kits may no longer be fit for use. If controls are successful, invalid results may be due to the client specimen. In that case, the client

should then be offered another type of HCV testing, such as through a blood draw (if available on-site) or Home Access kit[2] or by referral to another HCV testing site.

If an excessive number of test devices produce invalid results, or if there is any other reason to suspect that the test kits are not functioning as expected, external controls should be run. If external controls are successful, troubleshooting procedures should attempt to determine if the problem lies with the test operator, the environment, etc. in order to determine the necessary corrective action.

Documents and records

An effective QA program uses comprehensive documentation. Documentation serves the dual purposes of providing structure to ensure that necessary QA activities take place, and providing evidence that all measures were successfully completed. Periodic supervisory review of QA documentation is essential. QA documents should be stored for three years past the end of the testing period so that if problems arise, documentation can be easily accessed for informational purposes.

Use of the OraQuick HCV rapid testing device requires specific documentation, some of which sites may already have in place for rapid HIV testing. The following aspects of the QA and quality control process should be documented: training for testing personnel, appropriate test kit and control unit storage, appropriate test kit operation, external quality control, and trouble-shooting efforts when problems arise.

Documents have been created to meet each of these needs and are included in the appendix of this guide. Below is a brief description of each of these documents.

Training documentation

Documentation for all required training should be on file. Such documentation may consist of letters of successful completion, certificates of attendance, certification documents, etc., as appropriate. (See *Hepatitis C Testing in Non-Healthcare Settings, 2012*, Appendix J: HCV Rapid Testing Training Documentation Checklist, for a log to document training of testing personnel.)

Test kit storage temperature log

A log documenting storage temperature for test kits should be used to document storage temperatures in primary storage sites and temporary storage sites, such as a mobile testing unit. Temperature should be recorded periodically according to site protocols – typically daily when the agency is open, but more frequently for less temperature-stable settings such as mobile units. (See Appendix E: OraQuick HCV Test Kit Storage Temperature Log for a log to document test kit storage temperatures.)

Control unit storage temperature log

A log documenting storage temperature for control units should be used to document storage temperatures of the refrigerated space where control units are stored. Temperature should be recorded periodically according to site protocols – usually daily when the agency is open. (See Appendix F: OraQuick HCV Control Unit Storage Temperature Log for a log to document control unit storage temperatures.)

[2] For more information on the Home Access HCV test, see *HCV Testing Services Guidelines* (2007).

External quality control log

A log documenting external quality control (QC) procedures should be used anytime external quality control tests are conducted. The log should include the date and time of QC testing, lot number and expiration of the test kit, lot number and expiration date of the controls, control results, etc. Data from this log may be compared to testing logs and information contained in the testing database to verify that control testing is done at appropriate intervals, and to identify which tests may be called into question in the event of a QC failure. The log should be used to document problems that arise during the external QC process and any corrective actions taken to address them. (See Appendix G: OraQuick HCV External Quality Control Log for a log to document external QC.)

Test results log

A log documenting the lot number, test start and finish date and time as well as results and referrals provided for each client should be used for all HCV rapid tests performed. This can be helpful when identifying the kit or lot number when two or more tests in a row produce invalid results. This log can also be useful for tracking client outcomes (e.g., results delivered and referrals provided to follow-up testing). (See Appendix H: OraQuick HCV Testing Results Log for a log to use for documenting test results.)

Site preparation checklist

Site supervisors and testing coordinators should complete Appendix I: OraQuick HCV Testing Site Preparation Checklist for each site conducting rapid HCV testing prior to beginning testing. A copy of this document should remain on file for each site.

Troubleshooting log

A troubleshooting log for documenting problems or unusual occurrences can be invaluable for detecting patterns, for after-the-fact investigation when something fails, and a basis for discussion regarding ways to improve the process. No formal log sheet has been developed for this topic, but the ideal would be to designate a notebook as the troubleshooting log. Each entry should include:

1. Date
2. Person making the entry
3. A description of the problem or event
4. The action(s) taken to resolve the problem or deal with the event
5. The outcome of that action (e.g., whether the problem was resolved, etc.)

The log book should include guidance regarding what is appropriate to enter in the log book, such as any invalid test results, any out of range temps, missed temperature checks, unusual client reactions, etc. Space to suggest alternative actions, write down questions and document other developments may also be useful.

If problems arise, organizations should contact their local health department for assistance. For problems with the OraQuick HCV test, contact OraSure directly.

Phone: 1-800-ORASURE (1-800-672-7873)

Email: customercare@orasure.com

Errors

If staff happens to accidentally enter incorrect information or enter information in the wrong blank, draw a single line through the mistake(s) and initial and date the line in the margin with black or blue ink. Do not use white out or otherwise erase errors. If using electronic documents, show edits using strikethroughs (a line through the words or numbers) or a similar word processing feature but do not delete old information.

Review of QA documentation

The Lab Director is responsible for the final review of all QA documentation and should determine an appropriate process for reviewing all QA documentation on at least a monthly basis. (Site supervisors should monitor QA and QA documentation on an ongoing basis.) Documentation for review should at a minimum include:

- Analytic process information recorded on the testing log (e.g., test kit expiration date, time and temperature of test kit operation, etc.);
- External Quality Control log information;
- Test kit and control unit storage temperature logs; and
- Training documentation.

If the QA review results in questions or issues concerning the adequacy of QA procedures, the Lab Director and/or Site Supervisor should initiate immediate corrective action. If there are any issues that call into question the accurate functioning of the rapid test kits, rapid testing should be suspended until accurate functioning is verified by external control processes and clients seeking testing should be offered referrals.

The review process should occur during the first two weeks of each month for the previous month. Additionally, an annual review should be conducted to monitor personnel qualifications, including continuing education needs, competency assessments, and qualifications of new personnel.

Troubleshooting and problem solving

Each site should have a method to detect and document problems that occur at any point in the testing process, especially those that may affect the accuracy of test results. Significant problems should be immediately reported to the appropriate supervisory personnel and documented in the troubleshooting log described above.

At a minimum, testing personnel should be aware of troubleshooting procedures and events which require the notification of supervisory personnel, including all of the events listed in the troubleshooting table below. Additionally, testing personnel should be specifically trained regarding:

- What to do (whom to report to) when QA problems need to be addressed (light bulb is out, temps out of range, thermometer/clock missing, etc.);
- When to discontinue testing (external controls fail, or two invalids in a row, and external controls not available on site, etc.); and
- How to document problems/action taken – such as in a troubleshooting log book.

Problem	Action
Control testing fails to yield accurate results	Retest with a new control unit to determine whether failure was a result of test kits or control units. (Do not test client specimens until proper functioning of the test kits has been verified.)
Second attempt at control testing fails with new control unit	Do not test client specimens until problem is resolved. Notify Supervisor; notify manufacturer. Consult troubleshooting log to identify possible reasons for failure. Begin preparations to notify clients who tested since last successful external control test that previous HCV test result may not be reliable. If other stock/lots of rapid HCV tests are available, client rapid testing may be resumed after proper test functioning of this stock/lot has been verified by external control testing. Otherwise offer only standard or Home Access testing, either on-site, if available, or by referral.

Problem	Action
Two invalid test results occur in a row while testing client specimens	Offer clients standard testing or Home Access. Do not test further client specimens until problem is resolved. Run controls to determine if invalid results are due to client sample or test kits. If controls fail, see above.
Test kit storage area temperature exceeds recommended range.	Run external controls to verify test kits continue to function properly.

Primary vs. satellite sites

Procedures for managing inventory, monitoring storage, and running external controls may vary depending upon the structure of the LHJ or CBO conducting HCV testing. One way to centralize the responsibilities of process control activities is to designate one or more sites as “primary” sites and other sites as “satellite” sites. In this system, the primary site(s) are responsible for performing many of the tasks related to external control testing, which may save time and money and increases efficiency.

One example of a primary/satellite combination would be a mobile testing unit as a satellite of its “home base” site. In this setup, test kits and control units would be stored at the primary site, which would then be responsible for the bulk of the process control tasks such as test kit and control unit storage temperature monitoring, and periodic external control testing. The mobile unit, as a “satellite” site, would only take as many tests as needed for a short time period, and would not be required to run periodic external test controls. Note that although the mobile testing unit would not need to run periodic external controls, external controls would be needed for the unit as a “new

setting," and to troubleshoot problems, such as in the event that test kit storage on the van exceeded the recommended range, in the event of two invalid test results in a row, or in other scenarios outlined in the "When to run controls" section above.

Counseling

In addition to QA procedures designed to ensure effective testing procedures, QA practices surrounding counseling will assist sites in delivering quality services.

Selection of counselors for rapid testing

Counselors selected to perform rapid test counseling should, at a minimum, 1) be capable of engaging the client around HCV risk behaviors, and 2) be willing and able to conduct an effective HCV reactive antibody test disclosure session.

Counselors operating rapid test kits should also be trained and assessed as competent to collect the specimen, adhere to QA and safety plans, and accurately read the result.

All staff providing HCV services should be knowledgeable and adequately trained to deal with the client issues that may arise in testing for HCV. Many of the issues and concerns raised in an HCV testing session are similar to those raised in a HIV counseling session with clients who have similar risk profiles. However, the messages surrounding the meaning of HCV test results are quite different than that for HIV and HIV testing counselors conducting HCV testing should be adequately prepared to explain the meaning of both test results.

Evaluating counseling skills

Current guidelines recommend that counseling skills be evaluated at least annually by a supervisor and/or senior counselor. During the initial implementation phase of rapid HCV testing, counseling skills, especially those related to rapid testing, should be initially evaluated at the first 1-3 HCV rapid testing sessions, at six months, and then annually. Existing counselor evaluation forms may be adapted to include issues of specific concern to rapid HCV testing. (See Appendix J: HCV Test Counseling Skills Checklist.) Training, group discussion, peer "shadowing," or other activities may be used to address areas for improvement identified during the HCV counseling evaluation. (See *Hepatitis C Testing in Non-Healthcare Settings, 2012*, for a list of OA training agents and other HCV training resources for HIV test counselors. See also the forthcoming *Resource Guide for HCV Testing Supervisors, Counselors and Clients in Non-Healthcare Settings* for sample HCV testing messages and additional information.)

Supporting counselors

HCV testing can be emotionally taxing for counselors. Counselors providing HCV rapid testing services may find challenging their new testing responsibilities and situations, such as delivering HCV antibody reactive results with little notice and potentially delivering many more HCV reactive results than HIV preliminary positive test results in the same client population. This can be especially difficult when many communities lack sufficient resources for follow-up HCV NAT testing and evaluation.

Because of the additional difficulties associated with rapid testing, it is even more important to provide support to counselors. Specific areas of necessary support vary somewhat by venue and personnel qualifications and capacities, but may include:

- *"Back-up" result reading*. It may be useful in some settings to have a second counselor or supervisor do a "back-up" reading of each test result, to verify that the result is as recorded. An alternative would be to establish a procedure that would allow counselors to call for a "back-up" reading of a particular result, if they felt that this was necessary. These procedures may relieve some of the stress associated with the new responsibility of reading HCV rapid test results.
- *Result delivery consultation*. Prior to delivering an HCV antibody reactive result, counselors may benefit from briefly consulting with a senior counselor or supervisor to establish a strategy for client-centered result disclosure. Given that many counselors who have not previously delivered HCV antibody reactive results to clients may be called upon to do so, this practice may be helpful.
- *Post-disclosure debriefing*. Especially after delivering an HCV antibody reactive result, but also after some non-reactive disclosures, a debriefing session with a supervisor and/or other counselors may be useful for discussing concerns and suggestions for dealing with difficult counseling elements. If testing duties are performed by non-counselors, it may be useful to include them in the debriefing, as well, since they also interact with clients. If possible, it may be useful to have a backup staffer to relieve a counselor who has just had a particularly taxing session.
- *Emotional/stress release*. Other emotion/stress release tactics may also be called for, such as professional counseling, counselor support groups, etc.

APPENDICES

The following documents are provided as sample templates to assist HIV testing sites in meeting the QA best practices described in this manual. Some documents, such as the checklists, may be used as-is. Other documents, such as the testing logs, may be used as-is or adapted to meet the needs of the testing site or LHJ in which the site operates.

Appendix A: Personnel Qualifications and Typical Responsibilities

Personnel	Qualifications	Typical QA Responsibilities
Laboratory Director	Medical Doctor (MD) or otherwise licensed to direct clinical laboratory (Business & Professions (B&P) Code Section 1209);	• Monitor compliance with regulatory requirements, including CLIA, OSHA, bloodborne pathogens; • Assure competency of supervisory personnel to conduct QA activities; • Review final QA documentation; • With testing coordinator and/or site supervisor, delegate QA tasks to appropriate personnel; and • Assume ultimate responsibility for all aspects of testing.
Testing Coordinator /Site supervisor	• Baccalaureate Degree (17 California Code of Regulations (CCR) Section 1036.3(a)); • HIV test counselor (H&S 120917) or other healthcare professional allowed to perform CLIA-waived testing (B&P Code 1206.5); • If nonmedical personnel, meets training qualifications for HIV testing personnel in nonmedical settings (listed below).	• With lab director, develop/adapt QA plan for local use; • Conduct or assign QA tasks in specific settings, including external control processes, test kit storage, control unit storage; • Provide for test kit distribution and inventory processes; • Review initial QA documentation; • Oversee testing process and resolve technical problems; • Conduct periodic competency evaluation; and • Ensure personnel are qualified for assigned duties.

Testing Personnel (performing CLIA-waived HCV tests)	• HIV test counselor (or other healthcare professional listed in B&P Code 1206.5); • Meets the requirements of CLIA;[3] • **For HIV test counselors only** (H&S Code 120917): ○ Have been trained in HIV test counseling by OA or its agents; **and** ○ Work in a HIV testing site that is funded by OA or that uses staff trained by OA or its agents **and** that has a QA plan approved by the local health department **and** has HIV testing staff that complies with state regulatory QA requirements (specified in Title 17 CCR 1230). ○ Have been trained by OA-trained HIV testing site supervisor or OA 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. ○ Have been trained by OA or its agents in integrated HIV/HCV counseling messages	• Follow manufacturer's directions and site QA and safety procedures; • Document test-specific QA measures such as time and temperature of test during processing; and • Bring to attention of supervisor any QA concerns noted.

[3] Clinical Laboratory Improvement Amendments of 1988, 42 United States Code 263a PL100-578; 42 Code of Federal Regulations 493; Title 22 CCR 51211.2.

Appendix B: HIV and HCV Rapid Test Kit Storage and Operation Temperatures Guide

	Test kit storage temperature	**Control unit storage temperature**	**Test kit operating temperature**
OraQuick Advance HIV Antibody 1/2 Rapid Test	35 - 80° F (refrigeration is optional)	35 - 46° F (under refrigeration)	59 - 99° F (room temperature)
OraQuick HCV Rapid Test	36 - 86° F (refrigeration is optional)	35 - 46° F (under refrigeration)	59 - 99° F (room temperature)
Overlap	36 - 80° F (refrigeration is optional)	35 - 46° F (under refrigeration)	59 - 99° F (room temperature)

Appendix C: Best Practices for OraQuick HCV Testing Settings

As with HIV rapid testing, HCV test kit operation should occur in an appropriate setting away from the counseling area.

Best practices for the testing area are as follows:

1. The area should have sufficient space to store testing materials such as gloves, cotton balls, test kit pouches, etc., as well as sufficient biohazard disposal containers needed for daily clinic operation. (Additional test kit and supplies storage may be located elsewhere.)
2. There should be appropriate disposal for biohazardous materials, including sharps and non-sharps, and non-biohazardous materials.
3. The area should have a secure, clean, flat surface upon which the test kit may develop. This surface should be located and secured to minimize the likelihood of spillage.
4. The area should be clean and well-lit.
5. A digital clock and a digital thermometer for monitoring the time and temperature of developing testing kits should be appropriately located within the testing area. Calibration services for thermometers may be available from local public health laboratory facilities.
6. The areas in which test kits are stored and operated during clinic hours should be temperature controlled and monitored to remain within the appropriate temperature range for test kit storage and operation.
7. The area should be securable against unauthorized access and arranged to ensure that developing test kit result windows are not be visible to unauthorized personnel, including subsequent clients, to maintain confidentiality.
8. The area should be, at a minimum, visually separate from the counseling area, and should require the counselor to exit the counseling area to retrieve the result. This allows the counselor an opportunity to discreetly consult with other staff prior to delivering the test result, and minimizes distraction to the client.
9. The area should be designated off-limits to smoking, eating, drinking, and applying make-up (including lip balm), or any other activities that increase the chance of exposure to hazardous materials.

Appendix D: OraQuick HCV Test Kit Competency Checklist

- ❑ Gathers/arranges all materials
- ❑ Verifies condition for testing (sufficient lighting)
- ❑ Examines test kit pouch (unopened, room temperature, absorbent packet)
- ❑ Records lot number
- ❑ Records expiration date
- ❑ Records initials
- ❑ Affixes client number to back of vial (if applicable)
- ❑ Affixes client number to risk assessment form, testing log, etc. (if applicable)
- ❑ Successfully opens and positions vial in stand (no spillage, vial to bottom of stand, surface on which stand is flat)
- ❑ **Wears gloves for all subsequent steps**
- ❑ Collects finger-stick blood sample (cleans client's finger with antiseptic wipe, performs finger-stick, wipes away initial blood drop, collects second blood drop using testing loop)
- ❑ Visually examines loop to ensure it is full of sample
- ❑ Stirs in sample, discards loop in biohazard container
- ❑ Examines vial for pink fluid
- ❑ Successfully inserts test kit (no spillage, window forward, pad touching bottom of vial)
- ❑ *Did NOT remove test kit until ready to insert*
- ❑ *Did NOT cover two holes on the back of the test kit while handling*
- ❑ *Did NOT touch flat pad when inserting test kit*
- ❑ Records start time and temperature on testing log
- ❑ Records stop time and temperature on testing log
- ❑ Reads and records results
- ❑ Successfully completes all steps (if not, note what was missing/incorrect on the next page)

Notes:

Appendix E: OraQuick HCV Test Kit Storage Temperature Log

(Check daily, as scheduled, or after trigger event such as power outage.)

Thermometer location _____

Month/Year _____

Acceptable temperature range: 2° to 27° C or 36° to 86° F

Date/Time	Temperature	Corrective action taken when temperature is out of range	Storage location	Initials

Appendix F: OraQuick HCV Control Unit Storage Temperature Log

(Check daily or after trigger event such as power outage.)

Thermometer location _____

Month/Year _____

Acceptable temperature range: 35° to 46° F

Date/Time	Temperature	Corrective action taken when temperature is out of range	Storage location	Initials

Appendix G: OraQuick HCV External Quality Control Log

				Test Kit		Control Kit			Negative Control			Reactive Control				
Date	**Site**	**Initials**	**QC code**	**Lot #**	**Exp. Date**	**Lot #**	**Closed vial exp.**	**Open vial exp.**	**Start time/ temp**	**End time/ temp**	**Result (circle one)**	**Start time/ temp**	**End time/ temp**	**Result (circle one)**	**Result acceptable?****	
									: °	: °	R N I	: °	: °	R N I	**Yes**	**No**
									: °	: °	R N I	: °	: °	R N I	**Yes**	**No**
									: °	: °	R N I	: °	: °	R N I	**Yes**	**No**
									: °	: °	R N I	: °	: °	R N I	**Yes**	**No**
									: °	: °	R N I	: °	: °	R N I	**Yes**	**No**
									: °	: °	R N I	: °	: °	R N I	**Yes**	**No**
									: °	: °	R N I	: °	: °	R N I	**Yes**	**No**
									: °	: °	R N I	: °	: °	R N I	**Yes**	**No**

QC Code – reason for running external controls

New setting
New operator
New test kit lot
New test kit shipment
Environmental change—temperature outside range in storage area
Environmental change—temperature outside range in test area
Environmental change—low lighting
Scheduled periodic test
Other – document reason on back

Control Vial Expiration Dates

Closed vial expiration – expiration date printed on control unit package by manufacturer.

Open vial expiration – eight weeks from the date vials are opened. This date should be written on the packaging when first opened and recorded above when used.

Control unit may not be used if either open or closed expiration date has passed.

Result Codes

R Reactive

N Negative

I Invalid

****Acceptable Control Results****

Both negative and reactive control units must yield correct results. If either yields an incorrect result, result of external quality control procedure is unacceptable. In this case, DO NOT conduct client tests until problem is resolved. Document problem and corrective action taken on back of this form.

Problem Documentation

Date	Unique ID	Initials	Lot #	Exp. date	Problem	Corrective Action Taken

Appendix H: OraQuick HCV Testing Results Log

Date:	Site ID #	Lot #	Start Time	Start Temp	Results	Follow-up
(Affix Patient/Client Label Here)			□□□□□ □AM □□□□□ □PM	°F	❑ Non-Reactive ❑ Reactive ❑ Invalid	❑ HCV NAT (on-site) ❑ HCV NAT (referral) ❑ Other: (specify)
	Test Counselor ID #	Exp. Date:	Stop Time	Stop Temp		
			□□□□□ □AM □□□□□ □PM	°F		
Date:	Site ID #	Lot #	Start Time	Start Temp	Results	Follow-Up
(Affix Patient/Client Label Here)			□□□□□ □AM □□□□□ □PM	°F	❑ Non-Reactive ❑ Reactive ❑ Invalid	❑ HCV NAT (on-site) ❑ HCV NAT (referral) ❑ Other: (specify)
	Test Counselor ID #	Exp. Date:	Stop Time	Stop Temp		
			□□□□□ □AM □□□□□ □PM	°F		
Date:	Site ID #	Lot #	Start Time	Start Temp	Results	Follow-Up
(Affix Patient/Client Label Here)			□□□□□ □AM □□□□□ □PM	°F	❑ Non-Reactive ❑ Reactive ❑ Invalid	❑ HCV NAT (on-site) ❑ HCV NAT (referral) ❑ Other: (specify)
	Test Counselor ID #	Exp. Date:	Stop Time	Stop Temp		
			□□□□□ □AM □□□□□ □PM	°F		
Date:	Site ID #	Lot #	Start Time	Start Temp	Results	Follow-Up

(Affix Patient/Client Label Here)			□□□□□ □AM □□□□□ □PM	°F	❑Non-Reactive ❑Reactive ❑Invalid	❑ HCV NAT (on-site) ❑ HCV NAT (referral) ❑ Other: (specify)
	Test Counselor ID #	Exp. Date:	Stop Time	Stop Temp		
			□□□□□ □AM □□□□□ □PM	°F		

Appendix I: OraQuick HCV Testing Site Preparation Checklist

Site name _____

Site address
(physical location) _____
Street

_____
City State Zip

Site manager _____

Phone number _____

Legal/Administrative Notes:

- ❑ CLIA certification (Certificate # _____) _____

Safety

- ❑ OSHA/ Blood-borne Pathogen Compliance _____

Personnel Qualifications & Training

- ❑ Basic HIV counseling skills training (documentation on file) _____
- ❑ Finger-stick training completed (documentation on file) _____
- ❑ Rapid HCV test kit training completed (documentation on file) _____
- ❑ Integrated HIV/HCV counseling training completed (documentation on file) ____

Test Kit Storage

- ❑ Area secured against unauthorized access _____
- ❑ Temperature controlled/acceptable _____
- ❑ Thermometer located in storage area _____
- ❑ Temperature control log sheet posted _____
- ❑ Inventory procedures established _____

Control Unit Storage

- ❑ Non-food refrigerator _____
- ❑ Thermometer located on refrigerator shelf _____
- ❑ Temperature control log posted _____

Testing Area

- ❑ Separate from counseling area _____
- ❑ Secured against unauthorized access _____
- ❑ Confidentiality measures in place _____
- ❑ Thermometer near testing area _____
- ❑ Clock near testing area _____
- ❑ Testing area clean & well-lit _____
- ❑ Flat surface for undisturbed test kit processing _____
- ❑ Biohazard disposal (sharps and non-sharps) _____
- ❑ Step-by-step instructions posted (optional) _____
- ❑ Result pictures posted (optional) _____
- ❑ Universal Precautions posted (optional) _____

Materials

- ❑ Testing materials (Test kits, loops, stands, etc.) _____
- ❑ Finger-stick materials (finger-stick devices, bandages, etc.)
- ❑ Forms & Documents (Risk assessment, testing log, etc.) _____
- ❑ Protective gear (gloves, lab coats, etc.) _____
- ❑ Other _____ _____

Counseling and Testing Process Verified

- ❑ 1 complete testing process "dry run" successful _____
- ❑ Personnel proficient with process, paperwork _____
- ❑ Personnel familiar with referral guidelines _____
- ❑ Personnel aware of site's emergency procedures _____
- ❑ Competency assessment completed (on file) _____
- ❑ External control testing successfully completed _____

Quality Assurance Plan

- ❑ Written and approved QA plan completed (on file) _____

Notes:

_____

_____

_____

_____

_____

Appendix J: HCV Test Counseling Skills 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.

Counselor Name: _____ Counselor ID #: _____ (if applicable)

Reviewer Name: _____ Date of Review: ___/___/___

Session Type: ☐ HCV Rapid Test (One-Session) ☐ Other HCV Test (Two-Session)

Instructions: From the supervisor's direct observation of the counselor and the supervisor's understanding of HIV and HCV counseling and testing best practices, the supervisor should use the following performance rating to review the counselor. Mark one area only on the performance rating and give written feedback as needed.

CE **Consistently Exceeds all standards** **MA** **Meets All standards and in many cases exceeds them** **M** **Meets standards** **PM** **Partially Meets minimum standards: improvement needed** **FM** **Fails to Meet standards; performance unacceptable**	**CE**	**MA**	**M**	**PM**	**FM**
I. Content of Client-Centered Counseling Sessions					
1. Counselor introduced self, explained the purpose/process of the testing session, provided assurances of confidentiality, and appropriately gathered informed consent as per site protocol.					
Comments:					
2. Counselor assessed the client's knowledge about hepatitis C, including transmission, risk factors, etc., as needed and provide the client with the opportunity to ask questions.					
Comments:					
3. Counselor explored factors that may put the client at risk for HCV, showing comfort with discussing explicit topics (such as sexual and/or needle sharing behaviors), using terminology most comfortable for the client.					
Comments:					

CE **Consistently Exceeds all standards** **MA** **Meets All standards and in many cases exceeds them** **M** **Meets standards** **PM** **Partially Meets minimum standards: improvement needed** **FM** **Fails to Meet standards; performance unacceptable**	**CE**	**MA**	**M**	**PM**	**FM**
I. Content of Client-Centered Counseling Sessions, Continued					
4. Counselor assessed the client's preparedness for disclosure of the test result.					
Comments:					
5. Counselor provided accurate information about the meaning of the test result in plain and clear language. For anti-HCV reactive results, counselor explained that the client may or may not have HCV and that a follow-up test is needed to find out if they have HCV now.					
Comments:					
6. Counselor worked with the client to develop a realistic, incremental risk reduction plan, as appropriate, including steps to avoid transmission (if screening result is non-reactive and client has ongoing risk) or avoid possibly transmitting HCV to others while waiting for a follow-up HCV NAT (if screening result is reactive).					
Comments:					
7. Counselor explored the client's support system when appropriate.					
Comments:					
II. Referrals					
1. Counselor provided appropriate referrals for client, including to HCV NAT and evaluation for clients with HCV antibody reactive results.					
Comments:					

CE **Consistently Exceeds all standards** **MA** **Meets All standards and in many cases exceeds them** **M** **Meets standards** **PM** **Partially Meets minimum standards: improvement needed** **FM** **Fails to Meet standards; performance unacceptable**	**CE**	**MA**	**M**	**PM**	**FM**
III. Counseling Skills					
1. Counselor asked open-ended questions and allowed the client time to fully respond without interruption (client talked more than the counselor).					
Comments:					
2. Counselor demonstrated active and empathetic listening skills.					
Comments:					
3. Counselor maintained a neutral stance.					
Comments:					
IV. Data Collection					
1. Counselor gathered all needed information for testing forms in the course of the testing session, where appropriate.					
Comments:					
2. Counselor did not allow data collection or completion of testing forms to interfere with the client-centered counseling session.					
Comments:					
3. Counselor accurately and fully filled out testing forms and checked them for completion after the close of the session.					
Comments:					

Additional Comments:

Suggestions for Improvement

Appendix K: Acronyms

AIDS	Acquired Immunodeficiency Syndrome
B&P	Business and Professions
BCST	Basic Counselor Skills Training
BPC	Business and Professions Code
CBO	Community Based Organization
CCR	California Code of Regulations
CDPH	California Department of Public Health
CLIA	Clinical Laboratory Improvement Amendment
H&S	Health and Safety
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
LHJ	Local Health Jurisdiction
NAT	Nucleic Acid Test
OA	Office of AIDS
OSHA	Occupational Safety and Health Administration
QA	Quality Assurance
QC	Quality Control