OraQuick Rapid HIV and Hepatitis C Testing Procedures and Quality Assurance Plan

[Site Name Here]
[Site Address Here]

[Insert Date created/updated]

[This document is intended to be used as a template to designate specific personnel to various tasks at each site, and to more specifically define local, site-specific quality assurance procedures within the structure of the Office of AIDS guidelines. Each site must have on file at the HIV/HCV testing site a complete quality assurance plan that has been approved by the local health department prior to implementing rapid testing for HIV and/or HCV. Sites with existing HIV rapid testing QA plans may work with their local health jurisdictions to modify site QA plans to include HCV rapid testing QA activities.]

INTRODUCTION	<u>3</u>
EMERGENCY CONTACTS	<u>4</u>
PROCEDURES	
CLINIC FLOW PROCEDURESPAPERWORK, DOCUMENTATION PROCEDURESREFERRAL PROCEDURESREFERRAL PROCEDURESREFERRAL PROCEDURESREFERRAL PROCEDURESREFERRAL PROCEDURESREFERRAL PROCEDURESREFERRAL PROCEDURES	4
COUNSELOR SUPPORT OTHER	5
QUALITY ASSURANCE ACTIVITIES	5
PERSONNEL TEST KIT STORAGE MONITORING TEST KIT INVENTORY MONITORING TEST KIT STORAGE AREA TEMPERATURE MONITORING CONTROL UNIT STORAGE AREA TEMPERATURE RUNNING EXTERNAL QUALITY CONTROLS	6 6 7
DOCUMENTS AND RECORDS	.10
STORAGEREVIEW OF QA DOCUMENTATION	11
SAFETY	<u>.13</u>

Introduction

This document outlines site-specific guidelines and quality assurance (QA) measures for HIV test counselors and supervisors conducting rapid HIV and hepatitis C virus (HCV) testing in non-healthcare settings in California, as allowed under Health and Safety Code Section 120917. This document serves as a supplement to the California Department of Public Health/Office of AIDS (CDPH/OA) Guidelines for Hepatitis C Testing in Non-Healthcare Settings, 2012 the CDPH/OA OraQuick HCV Antibody Testing Quality Assurance Guidelines for Non-Healthcare Settings, 2012, and the CDPH/OA HIV Counseling and Testing Guidelines. In addition to the procedures and quality assurance activities described in this document, [site name here] will adhere to the QA plan components detailed in the CDPH/OA Guidelines for Hepatitis C Testing for Non-Healthcare Settings, 2012; the CDPH/OA OraQuick HCV Antibody Testing Quality Assurance Guidelines for Non-Healthcare Settings, 2012, the CDPH/OA Guidelines for Rapid HIV Testing in Counseling and Testing Settings, 2003; and preceding guidance where applicable.

Quality assurance 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. Quality assurance activities should be in place during the entire testing process, from the time a client requests testing to the providing of the test result and referrals. An effective QA program is one that is integrated into routine practices in a given setting.

Quality assurance guidelines contained in this document are specific to the site named, and focus primarily on quality assurance procedures for OraQuick rapid HIV and HCV testing. Guidance regarding quality assurance for other aspects of HIV counseling and testing activities is available in previous CDPH/OA guidance documents (2003, 1997). Sites with existing QA plans may work with their local health jurisdictions to modify site QA plans to include HCV testing QA activities.

Emergency Contacts

Position	Name	Phone Number
Lab Director		
Testing coordinator		
Site supervisor		
QA lead		
Fire emergency		
Medical emergency		
Biohazard exposure		
[add others as necessary]		

Procedures

[Describe site-specific procedures here, such as clinic flow, site-specific paperwork, where things are stored, and anything that varies from or requires more explanation/description than provided by the CDPH/OA guidelines.]

Clinic Flow Procedures

[Describe clinic flow procedures here – from greeting/calling up the client to where consent, fingerstick, testing, counseling procedures are to be performed, etc. Include counselor rotation, etc. if appropriate.]

Paperwork, documentation procedures

[Describe documentation/paperwork procedures here – where to store completed risk assessment forms, testing logs, consent forms, additional forms; how and when to make entries into a trouble-shooting log, etc.]

Referral procedures

[Describe referral procedures here, including where people with a HIV positive or preliminary HIV positive test result are linked to care and people with a reactive HCV antibody test result can be referred for follow-up HCV nucleic acid testing.

Counselor Support

[Describe sources of client support, including regularly scheduled debriefing sessions, procedures for rotating a counselor out for a break after a difficult session, "best practices" or trouble-shooting sessions; etc.]

Other

[Describe other procedures here.]

Quality Assurance Activities

Although there are specific quality assurance 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.

Personnel

The personnel designated below [by name and/or title] are responsible for the specified QA duties listed at [site name here].

[Add any duties not listed here or in the QA section; revise duty description if necessary to clearly describe duties as assigned at this site.]

Responsibilities	Conducted by
Develop/update site QA plan	
Final approval of site QA plan	
Conduct or assign QA tasks, including external control processes, test kit storage, control unit storage	
Provide for test kit distribution and inventory processes	
Initial review of QA documentation	
Final review of QA documentation	
Oversee testing process	
Ensure personnel are qualified for assigned duties	
Conduct periodic competency evaluation	

Test kit storage

[Describe test kit storage location (e.g., cabinet 3 in room 102) and storage conditions (e.g., cabinet is to be locked or room is to be locked; which personnel have key, or where is key located; where in cabinet thermometer with maximum and minimum temperatures is to be located, etc.)]

[If a "primary" site will store test kits for distribution to a satellite, mobile site, describe that process here, including how frequently test kits will be distributed, who is responsible for distribution, and processes for returning test kits to primary site, if any; describe and account for this arrangement in inventory procedures, as well.]

Monitoring test kit inventory

[Describe process for monitoring inventory here. Include who will receive deliveries, how they will be documented, how you will track/reconcile tests used with tests remaining, etc. Depending upon inventory control procedures, you may want to break this down into several distinct responsibilities, below.]

Receive test kit delivery		
Responsibilities	[Describe action here – e.g., receives boxes, records on inventory log with initials, writes delivery date on box, stores in cabinet, etc.]	
When	[e.g. when shipment arrives?]	
By whom	[Insert name and/or position here of the person responsible for this activity – e.g. lead counselor, shift lead,]	
Corrective action(s)		
Corrective action(s) [Describe problem solving action here – e.g., if delivery doesn't match order, if units are expired, etc. – refuse delivery? Contact supervisor? Contact manufacturer?]		

Next inventory process item		
Responsibilities	[Describe action here.]	
When		
By whom	[Insert name and/or position here of the person responsible for this activity – e.g., lead counselor, shift lead,]	
Corrective action(s)		
[Describe problem solving action here.]		

Monitoring test kit storage area temperature

Storage area for test kits must be equipped with an accurate thermometer. Temperature control log must be posted on storage unit. Test kit storage area must be continuously maintained within temperature range specified by manufacturer in the package insert.

Test kit Temperature Monitoring	
Responsibilities	Record temperature from thermometer in test kit storage space onto temperature control log.
When	[How frequently and at what time will this be done – daily, at beginning of shift? Twice daily?]
By whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective action(s)	
[Describe corrective action here – report to supervisor, adjust temperature, run controls, etc. Specify who will do this.]	

Monitoring control unit storage area temperature

Refrigerated storage area for control units must be equipped with an accurate thermometer. Temperature control log must be posted on storage unit. Control unit storage area must be continuously maintained within temperature range specified by manufacturer in the package insert.

Control Unit Ter	Record temperature from thermometer in control unit refrigerator onto temperature control log.	
When	[How frequently and at what time will this be done – daily, at beginning of shift? Twice daily?]	
By whom	[Insert name and/or position here of the person responsible for this activity.]	
Corrective action(s)		
[Describe corrective action here and specify who will do this.]		

Running External Quality Controls

External quality controls will be run according to the manufacturer's instructions. Results will be recorded on the External Quality Control Log. External Quality Controls will be run under the following conditions:

External Controls: New Setting/Change of conditions		
Responsibilities	[e.g., run controls, record on external quality control log.]	
When	[e.g., if testing room changes, lighting changes, or beginning testing in a new setting.]	
By whom	[Insert name and/or position here of the person responsible for this activity.]	
Corrective action(s)		
[Describe corrective action here – e.g., report to supervisor, do not begin testing, etc.]		

External Controls: New Shipment/Lot	
Responsibilities	[e.g., run controls, record on external quality control log.]
When	[Specify when this will occur – when the shipment arrives, or later, before using the new stock? If later, make sure inventory process includes a step in which arriving boxes are marked to indicate whether controls have been run.]
By whom	[Insert name and/or position here of the person responsible for this activity]

Corrective action(s)

[Describe corrective action here.]

External Controls: Test Storage Out of Temperature Range		
Responsibilities	[e.g., document problem, run controls, record on external quality control log, etc.]	
When	[Specify when this will occur – immediately or prior to next shift? Is the person who checks temperature storage the same one who will run controls? If not, include in that process instructions to notify person responsible for running controls – e.g., QA lead. Also, a mobile unit may elect to suspend rapid testing until returning to home base, and then run controls, while a stationary clinic may elect to run controls mid-clinic, if necessary, in order to continue to offer rapid testing.]	
By whom	[Insert name and/or position here of the person responsible for this activity.]	

Corrective action(s)

[Describe corrective action here - e.g., if controls fail, discontinue client testing, report to supervisor, enter actions taken in troubleshooting log for each step to resolution, etc.]

External Controls: Periodic Intervals	
Responsibilities	[e.g., run controls, record on external quality control log.]
When	[Specify when this will occur, based on testing volume. See guidelines for recommendations.]
By whom	[Insert name and/or position here of the person responsible for this activity.]

Corrective action(s)

[Describe corrective action here - e.g., if controls fail, discontinue client testing, report to supervisor, enter actions taken in troubleshooting log for each step to resolution, etc.]

External Controls: Suspected Test Kit Failure	
Responsibilities	[e.g., document the problem, run controls, record on external quality control log, etc.]
When	[Specify when this will occur – whenever two invalids, more than a certain number of positive results in specified period of time, other event that leads you to believe test kits are not working? Also, see comments in "out of temperature range" above.]
By whom	[Insert name and/or position here of the person responsible for this activity.]

Corrective action(s)

[Describe corrective action here - e.g., if controls fail, discontinue client testing, report to supervisor, enter actions taken in troubleshooting log for each step to resolution, etc.]

Documents and Records

[List any documents or records that are not included or have been modified from the CDPH/OA Rapid HIV Testing Guidance, CDPH/OA Guidelines for Hepatitis C Testing in Non-Healthcare Settings, 2012; the CDPH/OA OraQuick HCV Antibody Testing Quality Assurance Guidelines for Non-Healthcare Settings, 2012; and other guidance documents. Include copies of new/modified

documents in the index of this document. Recommend including written instructions for use of new documents, as well.]

Storage

Current training documentation will remain in personnel files until separation. Other documentation, including QA documents and logs, will be stored [where?] for three years beyond the contract year.

Review of QA documentation

Initial Review of QA Documentation		
Responsibilities	[e.g., review QA logs, including Copy and store in file, and submit originals to [lab director] for final review – describe the process, whatever it is.]	
When	[Specify when this will occur – e.g., monthly, within two weeks of the end of the previous month]	
By whom	[Insert name and/or position here of the person responsible for this activity – e.g. C&T coordinator/site manager or designee.]	

Corrective action(s)

[e.g., follow-up with personnel responsible for documenting QA, document explanation in troubleshooting log, if necessary revise procedures, etc.]

Responsibilities	QA Documentation [e.g., review QA logs, including Sign, return to— describe the process, whatever it is.]	
When	[Specify when this will occur – e.g., monthly, within two weeks of the end of the previous month]	
By whom	[Insert name and/or position here of the person responsible for this activity – e.g. Lab Director or qualified designee.]	
Corrective action(s)		
[Describe corrective action here]		

Updating QA Plan

QA plan will be updated on an annual basis to ensure compliance with new requirements, and to revise/improve existing procedures.

Update QA Plan		
Responsibilities	[e.g., review product package insert for changes in requirements; incorporate changes to policies and procedures; include changes to correct problems or difficulties, and submit to supervisor for review.]	
When	[Specify when this will occur – should be done annually, but better to specify a specific time of year – e.g., November of each year, or sometime when other duties are lighter.]	
By whom	[Insert name and/or position here of the person responsible for this activity – e.g. testing coordinator/site manager or designee.]	
Corrective action(s)		
[Describe corrective action here]		

Review Updated QA Plan		
Responsibilities	[e.g., review updated QA plan for compliance with any changes in requirements; etc. If acceptable, sign and deliver to]	
When	[Specify when this will occur – e.g., to have new plan in place by beginning of calendar year?]	
By whom	[Insert name and/or position here of the person responsible for this activity – e.g. testing coordinator and/or lab director.]	
Corrective action(s)		
[Describe corrective action here]		

Safety

All appropriate safety measures will be observed, in compliance with the U.S. Department of Labor Occupational Safety and Health Administration (OSHA) standards for blood-borne pathogens, and Universal Precautions, as outlined by the federal Centers for Disease Control and Prevention (CDC).