Appendix: Quality Assurance Guidelines for Testing Using the OraQuick Rapid HIV-1 Antibody Test

Overview

This appendix includes several items to facilitate conducting testing and performing quality assurance using the OraQuick Rapid HIV-1 Antibody test. The forms provided are examples and templates that can be adapted for local use, adding or deleting fields, as needed. The appendix includes the following:

A. Government regulations

B. Example training checklist for the OraQuick Rapid HIV-1 Antibody Test

C. Example of a temperature log

D. Example log of quality control results

E. Example log of test results

F. Example specimen transfer log

G. External assessment: proficiency testing and other mailed evaluation programs

Appendix A
Government Regulations

Food and Drug Administration (FDA) sales restrictions

To help ensure the quality of testing with the OraQuick test, the FDA approved the test kit it with specific restrictions for its sale. These restrictions apply to the waived test kit. By purchasing the test, the customer agrees to follow these restrictions. The restrictions are outlined below (for the specific FDA language, refer to the OraQuick package insert). The kit purchaser must:

- Be a clinical laboratory, i.e., holds a certificate from the Federal government (Clinical Laboratory Improvement Act of 1988 (CLIA) certificate – see below for details) and any state or other certification that is required.
- Have an established quality assurance program.
- Provide training for testing personnel (operators) using the instructional materials provided by the manufacturer.
- Provide information to persons being tested by giving each a copy of the manufacturer's "Subject Information" pamphlet prior to specimen collection and appropriate information when providing the test results.
- Not use the kit to screen blood or tissue donors.

Clinical Laboratory Improvement Amendment (CLIA) regulations

The OraQuick test is a waived test under Federal regulations—the regulations for the Clinical Laboratory Improvement Amendments of 1988 (CLIA regulations). As a waived test, Federal requirements for the OraQuick test are minimal. The CLIA requirements for sites wishing to offer testing using the OraQuick test are listed below and can be found at http://www.phppo.cdc.gov/clia/regs/toc.asp. Each site must:

- Have a valid CLIA certificate of waiver, certificate of compliance or certificate of accreditation.
- Follow the manufacturer's instructions for performing the test, and
- Permit announced or unannounced inspections by representatives of the Centers for Medicare & Medicaid Services (CMS) under certain circumstances (see §493.35(d) in the regulations at the Web site listed above).
- Perform only waived tests if holding a certificate of waiver.

Government Regulations (continued)

How to obtain a CLIA certificate	All sites planning to offer only the OraQuick test that are not already CLIA certified, must obtain a Certificate of Waiver or be included under a multiple site exception, such as limited public health testing or mobile testing. To obtain a Certificate of Waiver, complete Form CMS-116, found at the following CMS Internet address: http://www.cms.gov/clia/cliaapp.asp. This form asks for information on the facility type (select from a list), hours of operation, estimated annual number of waived tests to be performed, the type of control (nonprofit, for profit or government control) and the total number of individuals involved in performing testing. The facility owner or laboratory director must sign the form. Mail the completed form to the State agency in which your site is located. To find your State agency contact, refer to the information provided at the following Internet address http://www.cms.gov/clia/ssa-map.asp. After the completed form is processed by the State agency, a fee of $150 will be assessed for a Certificate of Waiver. The certificate is valid for two years.
State regulations	In addition to CLIA, some States have specific regulatory requirements for HIV testing. Contact your State agency for information on State requirements. State agency contacts are listed at http://www.cms.gov/clia/ssa-map.asp.
Occupational safety and health regulations	Employers with employees who have an occupational exposure to blood or other potentially infectious materials must meet the U.S. Department of Labor Occupational Health and Safety Administration (OSHA) standards for bloodborne pathogens. Individuals collecting blood specimens or performing the OraQuick test have exposure to blood or other potentially infectious materials resulting from the performance of their duties. Therefore, sites offering the OraQuick test must meet OSHA standards that include, but are not limited to, the following requirements: ▪ Have a written Exposure Control Plan. ▪ Provide personal protective equipment, such as gloves. ▪ Make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure. ▪ Provide post-exposure evaluation and follow-up to all employees who have had an exposure incident. ▪ Provide training for all employees with occupational exposure. ▪ Contain and dispose of biohazard waste following applicable regulations (includes blood and items contaminated with blood or other potentially infectious materials). Refer to state and local regulations regarding disposal of biohazardous materials. **NOTE**: This is an overview of OSHA requirements and is not a complete list. For specific information, visit the OSHA Web site at http://www.osha.gov/SLTC/bloodbornepathogens/index.html.

Appendix B
Example Training Checklist for the OraQuick Rapid HIV-1 Antibody Test

Employee: *Name*_____

Instructions: Fill in dates when the trainee observes and performs each objective or procedural step, as applicable. (If a trainee will not perform a specific task, enter N/A for not applicable.) The trainee should initial when he/she feels the objective/procedure has been mastered and the trainer when he/she thinks the trainee has met the objective or performs the specific procedure competently.

Objective/Procedural Step	**Date Observed**	**Date Performed**	**Trainee's initial and date**	**Trainer's initial and date**
Read OraQuick procedure	N/A			
Read Biohazard Exposure Control Plan	N/A			
Determine if requirements for acceptable testing environment are met (e.g., temperature, lighting, level work space)				
Practice test with negative and positive external controls				
Give person getting tested the "Subject Information" brochure				
Label test device components and appropriate paperwork				
Collect finger-stick specimen, put loop into vial and mix correctly				
Insert test device, time test, read result				
Dispose of lancet and other biohazardous waste appropriately				
Record results on report form and log sheet				
Record internal and external quality control (QC) results in QC log				
Evaluate a new OraQuick test kit lot number and record results in QC log				
Report test result to the person being tested (one negative and one preliminary positive)				
Refer person or collect specimen for confirmatory testing				
Send confirmatory test specimen to referral laboratory and document submission				
Receive referral laboratory results and record results				
Explain what to do if QC results show a problem				

Appendix C
Example Temperature Log

Thermometer location _____

Acceptable temperature range* _____

Month/Year _____

Day	Temperature	Initials	Day	Temperature	Initials
1			17		
2			18		
3			19		
4			20		
5			21		
6			22		
7			23		
8			24		
9			25		
10			26		
11			27		
12			28		
13			29		
14			30		
15			31		
16					

*The acceptable range for test kit storage is 2^{o} to 27^{o} C or 35^{o} to 80^{o} F; the acceptable range for control kit storage is 2^{o} to 8^{o}C or 35^{o} to 46^{o} F; the acceptable range for the testing area is 15^{o} to 27^{o} C or 59^{o} to 80^{o} F.
NOTE: Periodically (e.g., every six months) check thermometer performance and document**.**

Corrective Action

Date	Action Taken	Initials

Reviewed by and date _____

Appendix D
Example Log of Control Results

Date	Time	Test Kit Lot #	Test Kit Exp. Date*	New Lot #, ship-ment ?	Control Kit Lot #	Control Kit Exp. Date	Date controls opened	Negative Control Result	Positive Control Result	Results Accept-able?	Performed by	Reviewed by and Date

*Exp. = Expiration

Corrective Action (use reverse side, if needed)

Date	Action Taken	Initials	Reviewed by and date

Appendix E
Example Log of Test Results

Test Subject ID*	Date and Time Specimen Collected	Kit Lot Number	Kit Expiration Date	Actual Test Incubation Time	Test result N=non-reactive R=reactive I=invalid	Tester	Result and Time Reported to Subject	Confirmatory Testing					Reviewed by and Date
								Track-ing #	Specimen type (blood or oral fluid)	Result	Date result received	Date result given to test subject	

*ID = Identification

Appendix F
Example Specimen Transfer Log

**[Put Referring Facility Name,
Address and Phone Number here]**

Date:_____

Referral Laboratory _____

Specimen Tracking Number	Test Subject ID*	OraQuick Test Result	Date Specimen Collected	Time Specimen Collected	Collected by	Referral Lab Req† Completed (✓)	Date Conf Result Received	Confirm Test Result

*ID = Identification
†Lab Req = Laboratory Requisition
(NOTE: If you use more than one referral laboratory, add a column to record each one.)

Appendix G
External Assessment: Proficiency Testing and Other Mailed Evaluation Programs

Background and overview	Some States may require participation in a State or Centers for Medicare & Medicaid Services (CMS)-approved proficiency testing program, even though this program is not required by CLIA for waived tests. Participating in proficiency testing or an external evaluation program is a relatively easy way to obtain an external assessment of the quality of waived testing. There are several programs in which a site may choose to enroll. Test samples will be received by mail on a periodic basis, usually two to three times per year. These samples include a combination of several (typically five) HIV antibody positive and negative specimens with results known to the program provider, but not to the participants. The participants test the samples as if they were client/patient specimens and send results back to the program provider.
Evaluation reports	In proficiency testing programs, the results from the individual participant sites are compared to the expected values. Each site receives a graded individualized report and summary report showing their performance and the performance of all the participants. In some evaluation programs, such as the Model Performance Evaluation Program (MPEP) offered by the Centers for Disease Control and Prevention (CDC), individual participant results are not graded; instead a summary report is provided with a compilation of results from all participants and a commentary on overall performance.
For more information	For more information, refer to the following Internet sites: ▪ The CDC MPEP for rapid HIV testing can accommodate a limited number of additional sites. For more information and to enroll on-line go to the following Web sites: http://www.phppo.cdc.gov/mpep/default.asp, http://www.phppo.cdc.gov/mpep/enrollment.asp. There is currently no fee to enroll in the MPEP program. ▪ For a list of CLIA approved proficiency testing programs (several of which include HIV testing) go to http://www.cms.gov/clia/ptlist.pdf. This list includes contact information for each program and the tests offered. These programs charge an enrollment fee.