

*RAPID HIV TESTING
IN OREGON*

*Using OraQuick® Advance
Rapid HIV- 1 / 2 Antibody Test*

**INFORMATION &
QUALITY ASSURANCE
GUIDANCE**

Specifically For
Oregon DHS HIV Prevention Program-Funded
Public Sector Testing Sites in Oregon

OREGON DEPARTMENT OF HUMAN SERVICES
HIV PREVENTION PROGRAM



Credits

Thanks to the Washington State Health Department HIV Prevention Program who generously shared with us their October 2005 document titled, "Washington State Rapid HIV Testing Information". This information, although specific to Washington State, provided a solid framework to help us create this Oregon-specific guidance.

The quality assurance guidance in this document is based on the CDC document: Quality Assurance Guidelines for Testing Using the OraQuick® Rapid HIV-1 Antibody Test, updated for the OraQuick® HIV-1 / 2 Antibody Test.

For more information, contact the HIV Prevention Program:

Oregon Department of Human Services
HIV/STD/TB Program
800 NE Oregon Suite 1105
Portland, Oregon 97232
(971) 673-0153

NOTICE

Organizations implementing rapid testing should also refer to the product manufacturer's material (product inserts and CDC guidance) to develop their programs.

This document augments the manufacturer's materials by providing information that is specific to Oregon rules and HIV Prevention Program funding requirements. This document also offers specific guidance regarding developing quality assurance protocols that are specific to the OraQuick® Advance Rapid HIV- 1 / 2 Antibody Test.

For more information about Oregon rules governing HIV testing and specific program requirements for organizations funded by the State HIV Prevention Program, contact DHS HIV Prevention Program at (971) 673-0153.

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LICENSING / CERTIFICATION

Overview

The OraQuick® Advance Rapid HIV 1 / 2 Antibody test is categorized as a “waived” test by the Food and Drug Administration (FDA), the agency that is charged with the categorization of tests for the Clinical Laboratory Improvement Amendments (CLIA) program. The CLIA program is overseen by the Centers for Medicare and Medicaid Services (CMS). The objective of the CLIA is to ensure quality laboratory testing for all labs. CLIA comprises quality standards for all laboratories to ensure accuracy, reliability, and timeliness of test results regardless of where the test is performed.

A CLIA Certificate of Waiver must be obtained to perform tests that have been determined to be the least complicated of all medical tests and can be performed outside of a laboratory setting. This means that they are simple to perform & interpret, accurate, and present no reasonable risk of harm to the person being tested or the person performing the test. Waived tests are available only to licensed professionals or testing sites—not directly to consumers.

Synopsis of CLIA Requirements for a Certificate of Waiver (OAR 333-024-0005 Through 333-024-0055)

Performance of even a single laboratory test on specimens derived from the human body for the purpose of diagnosis and treatment or assessment of health requires a Clinical Laboratory Improvement Amendments (CLIA) certificate. Laboratories in Oregon are **not** required to have an Oregon Clinical Laboratory License in addition to a valid CLIA certificate.

A facility that already has a CLIA certificate to perform tests that are categorized as more complex than waived tests need not apply for a Certificate of Waiver. They must add information about the waived tests they intend to perform to their existing CLIA certificate.

A facility performing **only** waived tests (such as OraQuick) must apply for a Certificate of Waiver and meet minimum requirements as indicated below.

- Obtain a valid CLIA certificate and pay the appropriate fee (\$150) which authorizes performance of waived tests only for a period of up to two years;
- Participate in inspections for compliance and to validate that only waived tests are performed and all other applicable requirements are met;
- Perform tests only at the written request (standing order) of one of the following, within their scope of practice. Highlighted are the positions most appropriate for writing a standing order to perform HIV tests:
 - Medical Doctor (MD)
 - Doctor of Osteopathy (DO)
 - Doctor of Podiatric Medicine (DPM)
 - Physician's Assistant (PA)
 - Doctor of Chiropractic Medicine (DC)
 - Naturopathic Doctor (ND)
 - Licensed Direct Entry Midwife
 - Doctor of Dental Science (DDS)
 - Doctor of Medical Dentistry (DMD)
 - Optometric Physicians (OD)
 - Certified Nurse Practitioner (NP)

- Certified Nurse Midwife (CNM)
 - Certified Registered Nurse Anesthetist (CRNA)
 - **Clinical Nurse Specialist (CNS)**
- Maintain a copy of this order for 2 years (5 and 6 years for Medicare and Medicaid reimbursement);
 - Perform only waived tests;
 - Follow manufacturer's instructions for test performance including quality control (QC), calibration & instrument maintenance;
 - Provide written procedures for testing personnel and make readily available;
 - Maintain complete records for each specimen tested, including QC, calibration and instrument maintenance for 2 years;
 - Maintain records on all testing personnel indicating laboratory training & experience;
 - Meet Department standards for safety, disposal of hazardous and infectious waste;
 - Report cases of HIV and AIDS to the State DHS HIV/STD/TB Program and local health department (where applicable) in accordance with reporting laws and procedures. The physician/clinician is responsible for reporting to the state and local health departments and maintaining a log of such reporting;
 - Inform Laboratory Compliance & Quality Assurance of changes in **laboratory name, owner, director, or address** within 30 days after a change occurs;
 - Refer specimens only to laboratories operating in compliance with CLIA. The referring laboratory must not revise results or information directly related to interpretation of results provided by the testing laboratory

Complete the CLIA application form HCFA-116.

Please note that the individual designated as laboratory director assumes full responsibility and legal liability for all laboratory testing conducted under the authority of the CLIA certificate issued. Staff in a laboratory with a CLIA waived certificate may perform only tests designated as waived.

Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

Mail applicable forms to: Laboratory Compliance & Quality Assurance P.O. Box 275 Portland, OR 97207-0275.

DO NOT SEND MONEY WHEN YOU SUBMIT YOUR APPLICATION.

A fee coupon will be issued by CMS following the processing of your application. CLIA fees are based on test complexity, number of specialties performed and the estimated annual test volume. The fee for a CLIA waived certificate is \$150 for two years.

The CLIA application form HCFA-166 is available at this link:

<http://oregon.gov/DHS/ph/lcqa/docs/form116.pdf>

Reporting CLIA Changes to DHS

Laboratories with existing CLIA certificates must notify DHS of changes to information originally submitted on a CLIA application within 30 days of the change. Changes that must be reported are changes in laboratory name, site/ mailing address, director/owner name, federal tax ID number, phone/fax number, addition/deletion of tests performed, and laboratory complexity.

The Oregon Laboratory Change Notification form is available at this link:

<http://oregon.gov/DHS/ph/lcqa/docs/notify.pdf>

CONFIDENTIALTY

Confidentiality of records, personal information gathered from clients, HIV testing, and test results, is of the utmost importance.

All client information and records must be maintained using an approach consistent with Oregon law and, if applicable, the Privacy and Security Requirements developed by the federal government in the Health Insurance Portability and Accountability Act (HIPAA).

Client information must be kept strictly confidential and records should be managed and stored in a secure manner. Agencies providing rapid HIV testing must develop confidentiality policies and procedures that will prevent unauthorized persons from learning information shared in confidence. Confidential information includes any material, whether oral or recorded in any form or medium that identifies, or can readily be associated with the identity of, a person and is directly related to their health and care. Information relating to an HIV testing and an individual's HIV/AIDS status is protected under confidentiality guidelines and Oregon Administrative Rules and Oregon Revised Statutes (OAR 333-012-0270) (ORS 433.008).

In recognition of the very sensitive nature of these conditions, medical record protection for HIV and AIDS, like those for substance abuse and mental health, are protected more rigorously than other medical information. Minimum professional standards for any agency handling confidential information should include providing employees with appropriate information regarding confidentiality guidelines and legal regulations (and where applicable, the federal HIPAA privacy regulations).

All staff involved in HIV testing and counseling activities with access to testing results and counseling information should sign a confidentiality statement acknowledging their awareness and understanding of: 1) the legal requirements under state and federal law not to disclose HIV/AIDS information, and 2) the legal and agency consequences of such a disclosure. In accordance with the Oregon DHS HIV Prevention Program Contract Element for HIV prevention-funding, this confidentiality statement should be reviewed and re-signed annually.

SPECIAL CONSIDERATIONS

Providing Preliminary Reactive Results

In Oregon, a preliminary reactive rapid HIV antibody test cannot be used to diagnose HIV infection. Confirmatory testing must be conducted before a diagnosis of HIV infection can be determined.

When informing a patient of preliminary reactive results, State of Oregon and CDC guidance suggests that you:

- 1) Explain the meaning of reactive screening test result in simple terms, avoiding technical jargon;
- 2) Emphasize the importance of confirmatory testing, administer confirmatory testing and schedule a post-test session for results, or refer to another testing program for confirmatory testing;
- 3) Promote the importance of taking precautions to prevent transmitting infection to others while awaiting results of confirmatory testing.

All reactive rapid HIV test results require confirmatory testing. CDC described protocols for confirming reactive rapid HIV tests based on a consultation convened in January 2003 with expert laboratory scientists, FDA, and the Centers for Medicare and Medicaid Services. These protocols recommend:

- 1) Confirm all reactive rapid HIV test results with Western blot (WB), even if an enzyme immunoassay (EIA) screening test is negative (OSPHL has protocols to do this). Use the following as guidance for specimen collection for confirmatory testing:
 - a. Whole blood venipuncture is best.
 - b. Oral fluid (OraSure) is acceptable if whole blood venipuncture is not immediately available.
- 2) If the confirmatory test result is negative or indeterminate, report discordant test results on Discordant Results Questionnaire available at <http://www.oregon.gov/DHS/ph/hiv/>, AND provide the following additional testing:
 - If the original confirmatory specimen was a blood specimen, advise the client to return for repeat testing one month from the date of the rapid test preliminary positive.
 - If the original confirmatory specimen was an oral fluid specimen:
 - Immediately repeat the confirmatory test using a blood specimen.
 - If the repeat blood specimen confirmatory test is still negative or indeterminate, advise client to return for repeat testing one month from the date of the rapid test preliminary positive.
- 3) If confirmatory test result is positive, no further confirmatory testing is recommended.

No-Shows for Confirmatory Results

For those sites that offer anonymous rapid testing, counselors should both offer and *strongly encourage* **confidential** confirmatory testing. Confidential confirmatory testing will assure that clients receive confirmatory results, are offered partner counseling and referral services, and receive referral into appropriate case management and care services.

For those clients who agree to confidential confirmatory testing, Oregon requires agencies to report the HIV test result and refer locating information on confidential clients (that do not return for their positive HIV results) to local and State health departments in accordance with OAR 333-018-0015.

Confirmatory Testing: HIV-1 or HIV-2?

OraQuick® ADVANCE HIV-1/2 screens for both HIV-1 and HIV-2 but a reactive result does not differentiate between the two. To confirm for HIV-1, an HIV-1 Western Blot is used. To confirm for HIV-2, an HIV-2 Western Blot is used.

In Oregon, the standard procedure is to conduct confirmatory testing for HIV-1. Because HIV-2 is extremely rare in Oregon and in the U.S., most laboratories do not have the testing materials necessary to conduct HIV-2 confirmatory testing. Most laboratories will automatically conduct HIV-1 confirmatory testing only, unless requested otherwise.

Because OraQuick® ADVANCE HIV-1/2 screens for both HIV-1 and HIV-2, there is the potential to serve the unusual client who is at risk for HIV-2. In those rare cases where a client could be at risk for HIV-2 infection, another sample will need to be collected and sent to the Oregon State Public Health Laboratory (OSPHL) for HIV-2 confirmatory testing. If there is risk reported for HIV-2 on the Test Request Form, the lab will perform confirmatory testing for HIV-1 and send a sample to CDC for confirmatory testing for HIV-2 (2-4 week turnaround time).

Persons at risk for HIV-2:

- A sex or needle-sharing partner of a person known to be infected with HIV-2
- A child of a woman who is known to be infected with HIV-2;
- A child of a woman who has any of the above risk factors for HIV-2.
- A person who received a blood transfusion in:
- A person who received a non-sterile injection in:
- A sex or needle-sharing partner of a person from:

} **Africa**

Specifically Cape Verde, Ivory Coast, Gambia, Guinea-Bissau, Mali, Mauritania, Nigeria, Sierra Leone, Benin, Burkina Faso, Ghana, Guinea, Liberia, Niger, São Tomé, Senegal, Togo, Angola and Mozambique.

INFORMED CONSENT

A general medical consent does not adequately cover HIV testing unless the HIV test is performed within the context of prenatal HIV testing (ORS 433.045; ORS 433.017).

At a minimum, informed consent must be obtained verbally at the testing site. Public sector testing sites are advised to document clients' verbal consent with a signature by the person conducting the test (not the patient or client) on the Oregon State Public Health Lab HIV Test Request Form. As with the standard HIV test, Oregon law requires that providers conducting HIV tests obtain or ensure explicit verbal or written informed consent for HIV testing.

This verbal or written consent:

- must be obtained **prior** to performing the test, and
- should be **documented** (Kept in medical record for private sector testing. Documented on Test Request Form for public sector test sites).

Note: Oregon law does not require that consent for HIV testing be in writing, signed by the client or patient.

Because consent must be obtained *prior* to ordering or prescribing the test, counselors must obtain consent *before* they conduct the fingerstick or collect the oral fluid specimen and initiate the rapid test.

The following informational areas must be covered with a client or patient prior to getting a verbal (or written) informed consent for HIV testing:

BASIC INFORMATION ABOUT THE TEST

Ask patient or client to share what they already know about the HIV test. Clear up major misconceptions and fill in the gaps with the following information:

- The HIV Antibody test shows if you have been infected with HIV, the virus that causes AIDS.
- This test shows if your body has made antibodies to the HIV virus. If a person's body has made antibodies to HIV, the test will show a positive result. A person who tests positive for HIV is infected with the virus.
- This is not a test for AIDS. After a positive HIV result with this test, only a doctor can determine through medical examination, other tests, and your history of risk, the presence of AIDS or any other HIV related illnesses.
- A negative HIV test does not always mean that you are free from the virus. Antibodies to HIV can take up to 3 months to develop. This test may not detect exposures to HIV within the last 3 months.

DISADVANTAGES & ADVANTAGES TO TESTING

Ask patient or client to share their perspectives.

Some Disadvantages Commonly Mentioned:

- May have to be retested to confirm results.
- Can cause anxiety and/or depression.
- Can provide a false sense of security if results are negative and there has been risk for HIV.
- May affect ability to get a new life or health insurance policy if test is positive and it becomes part of a medical record.

- HIV reporting rules can be scary and confusing.
- Informing partners of a positive result can be difficult.

Some Advantages Commonly Mentioned:

- Can help to inspire positive changes in behavior to lower risk of getting infected or infecting someone else.
- Can reduce the anxiety that comes from not knowing.
- Early medical treatment is important to long term health and wellbeing.
- If the test result is positive, we can help you with the process of informing your partners by connecting you with voluntary Partner Counseling & Referral Services (PCRS).

CONFIDENTIALITY

The following information reflects new HIV reporting rules effective April 15, 2006.

- Your HIV testing information and the test results can't be released to anyone without your written consent *except as required by reporting laws*.
- If you test confidentially and are found to be HIV positive, information about a positive test, **including your name**, must be reported to the Oregon Department of Human Services. Once reported, this information is kept extremely confidential, and the name of a person with HIV or AIDS will never be released to other agencies or individuals.
- If you are found to be HIV-infected, you are not required to personally tell anyone about this diagnosis. However it is very important to notify your sexual partners and those that might have been exposed to your blood. County health departments or the Oregon Department of Human Services staff can assist you with this procedure. Again, your name will never be used during this partner notification and referral procedure.
- Anonymous HIV testing is available through at least one public testing site in most counties in Oregon. Additional information about the HIV test is available through your local health department, by calling the Oregon AIDS Hotline at 1-800-777-AIDS, or by calling the Oregon Department of Human Services HIV/STD/TB program at 971-673-0153.

Age of Consent

The same rules regarding age of consent for standard HIV testing apply for rapid HIV testing. In Oregon, there is no minimum age to be able to provide independent consent to be tested for HIV.

Note: it is not recommended to use OraQuick® ADVANCE on persons under the age of 12, as no clinical data is available demonstrating the performance of OraQuick® ADVANCE on persons under the age of 12.

HIV COUNSELING

Pre-test Counseling

The State of Oregon HIV Prevention Program requires programs receiving State HIV Prevention Program funding for HIV Counseling, Testing and Referral Services (CTRS) to offer pre-test counseling to all persons at increased risk for HIV and to any person requesting it.

The person conducting the HIV test may provide the counseling or refer the client for counseling to another provider. Those providing pre-test counseling must assess the individual's risk of acquiring and transmitting HIV by evaluating the individuals' risk behaviors and unique circumstances, and as appropriate:

- Base counseling on the Centers for Disease Control and Prevention's Revised Guidelines for HIV Counseling, Testing and Referral, November 2001;
- Assist individuals in setting realistic behavior change goals and establish strategies for reducing their risk of acquiring or transmitting HIV;
- Provide appropriate risk reduction skills-building opportunities to support behavior change goals; and,
- Provide or refer for other appropriate prevention, support, or medical services.

Note: a person's refusal of pre-test counseling is not grounds for denying HIV testing.

Bear in mind that not all public sector testing programs are funded with State of Oregon DHS HIV Prevention Program funds. For those programs that are not supported with these funds, pre-test counseling is a strongly encouraged, but not required, element of an HIV testing process, especially with individuals at high-risk for HIV transmission or acquisition.

Post-test Counseling

All programs receiving State HIV Prevention Program funding must offer post-test counseling. The provider testing the client can provide the post-test counseling or arrange for such counseling. Post-test counseling must be consistent with the 2001 CDC's Revised Guidelines for HIV Counseling, Testing and Referral. In addition to the provision of HIV test results and appropriate confirmatory testing as recommended earlier in this document, those providing post-test counseling must also, as appropriate:

- Remind the individual of HIV reporting requirements;
- Revisit behavior change goals and strategies for reducing risk;
- Discuss and offer Partner Counseling and Referral Services (PCRS) and other support services if result is reactive;
- Offer referrals to needed services as prioritized by the client.

Bear in mind that not all public sector testing programs are funded with State of Oregon DHS HIV Prevention Program funds. For those programs that are not supported with these funds, post-test counseling is a strongly encouraged, but not required, element of an HIV testing process, especially with individuals at high-risk for HIV transmission or acquisition.

HIV REPORTING

In Oregon, AIDS name-based reporting has been in effect since 1984. HIV name-to-code reporting began in 2001 and transitioned to HIV name-based reporting in 2006.

Agencies providing confidential HIV testing should develop policies and procedures (including roles and responsibilities) to ensure the timely reporting of HIV cases to the local and state health departments.

Oregon Administrative Rules: 333-019-0223

(1) Reporting of AIDS:

- Each case or suspected case of AIDS shall be reported to the local health department (where specified) and to State DHS within one week from the time of identification;

(2) Reporting of HIV:

- Each case or suspected case of HIV infection shall be reported to the local health department (where specified) and to State DHS within one day from the time of identification;

Note: Positive HIV results obtained through anonymous testing are not reportable.

Therefore, if an agency provides **only** anonymous testing, reporting is not required. However, it is recommended that agencies offer and encourage confidential confirmatory testing in order to ensure that clients receive confirmatory results, an offer of PCRS services, and referral into appropriate case management and care services.

DHS has safely guarded the names of people with AIDS in over 20-years of name-based reporting. In addition, there have had no breaches of confidentiality in the collection and retention of HIV case reports since mandatory HIV reporting began in 2001.

The HIV and AIDS case reporting systems operate under particularly rigorous confidentiality standards:

- A limited number of public health personnel have access to HIV and AIDS data.
- Data are kept in a locked facility on a computer that cannot be linked to other computer networks.
- Removal of identifiable data from the facility is forbidden.
- Staff must review security procedures and sign strict confidentiality statements annually.

In addition, public health officials who improperly disclose the identity of any person with a reportable health condition, knowingly misuse confidential information or fail to adhere to established policies on information security are subject to criminal prosecution and fine. Furthermore, health care providers, health plans, billing companies and the people who work for them are subject to substantial fines and imprisonment for improper use or disclosure of identifiable health information under the Federal Health Insurance Portability and Accountability Act (HIPAA) of 1996.

APPENDICES

- APPENDIX A: Implementation Sequence
- APPENDIX B: Organizational Readiness Assessment Worksheets
- APPENDIX C: Quality Assurance Guidance
- APPENDIX D: Sample Quality Assurance Protocol
- APPENDIX 1: Documents & Record Sample Forms

APPENDIX A

SUGGESTED IMPLEMENTATION SEQUENCE

- 1) **Determine if agency has capacity to implement rapid testing.**
- 2) **Determine if rapid testing is right for proposed clients.**
- 3) **Determine if rapid testing is right for the proposed venue.**
- 4) Apply for CLIA Certificate of Waiver.
- 5) Obtain a Standing Order to Perform Tests from an authorized individual.
- 6) Set-up monitoring systems:
 - test processing logs
 - controls processing logs
 - temperature logs (test kit storage, control kit storage, testing environment)
- 7) Set-up records systems:
 - Confidential client charts;
 - Anonymous test tracking system
- 8) Set-up materials procurement, tracking, monitoring:
 - test kits and control kits
 - confirmatory specimen collection, labeling, and shipping
 - biohazardous waste storage
- 9) Set-up material storage:
 - dedicated refrigerator for controls (No lunches allowed!)
 - kits and other materials
- 10) Set-up biohazardous waste management and disposal system.
- 11) Set up blood borne exposure management plan.
- 12) Set-up procedure for confirmatory testing and ensure formalized relationship with a laboratory with appropriate documentation.
- 13) Set-up procedure to offer Partner Counseling and Referral Services (PCRS) and other support services for persons with reactive results.
- 14) Set-up linkages and interagency agreements for appropriate medical and social referrals for comprehensive follow-up care of persons who have HIV infection.
- 15) Identify & train appropriate staff:
 - test kit technique
 - finger-stick and/or oral fluid specimen collection for rapid testing; whole blood venipuncture and/or OraSure oral fluid specimen collection for confirmatory testing
 - client-centered counseling

See Appendix B for
Organizational Readiness
Assessment Worksheets

- 16) Set-up staff QA & supervision.
- 17) Prior to beginning a State-supported rapid testing program (programs receiving HIV Prevention funding for HIV testing and free or discounted test and control kits from the State HIV Program), eligible organizations must comply with and demonstrate the following:
- **Staff who will perform rapid HIV testing have completed training in *Client-Centered Counseling AND Rapid HIV Testing using the OraQuick® Advance HIV 1/2 Test, provided by DHS or CDC (delivered by DHS or a State-certified rapid testing trainer)*. Provide names and titles of persons who will perform the rapid test to DHS for confirmation of training completion.**
 - **Organization is enrolled in CLIA, has their own CLIA certificate covering rapid testing sites, and has a copy of the certificate at all sites when performing rapid testing.** Provide DHS a copy of the certificate and the locations of each site where the rapid test will be offered.
 - **Organization has a Standing Order to Perform this test from an authorized individual, and has a copy of that order at all sites when performing rapid testing.** Provide DHS a copy of the order.
 - **Quality Assurance Protocols are established following the Quality Assurance Guidance in Appendix C of this document, and are followed at all rapid testing sites.** Policies, procedures and protocols addressing each of the five basic elements of a QA program for OraQuick Rapid Testing must be addressed, including samples of appropriate documentation, and policies and procedures ensuring confidentiality and HIPPA compliance.
- See Appendices C & D for Quality Assurance Program Guidance.
- **Organization understands and complies with reporting and laboratory form requirements.** Evidence of this should be demonstrated in the written procedures that are part of the QA protocols.
 - **Submit documentation of the above items to DHS HIV Prevention Program for approval prior to performing state-sponsored rapid HIV testing.**

Submission may occur in one of the following ways:

Mail To: Julie Yu, HIV CTRS Program Coordinator
 800 NE Oregon Street, Suite 1105
 Portland, OR 97232
 (971) 673-0153

Email To: julie.yu@state.or.us

Fax To: (971) 673-0178

Please expect at least 2 weeks for review of the materials and notification of approval to begin rapid HIV testing.

APPENDIX B

Organizational Readiness Assessment Worksheets

Because implementation of rapid testing presents significant challenges, agencies should carefully consider whether or not this technology is appropriate for their agency; their clients; and, the venues in which they propose to use waived rapid testing.

When considering whether or not to implement rapid testing, agencies should ask the following questions:

- 1) Capacity: **Does our organization have the capacity to provide rapid testing?**
- 2) Client Appropriateness: **Is rapid testing appropriate for the clients we plan to serve?**
- 3) Venue: **Is rapid testing appropriate for the venue we plan to use?**

The following worksheets are designed to assist organizations in answering the above questions.

Worksheet 1:

Does our organization have the capacity to provide rapid testing?

The following tool is designed to help organizations assess their capacity to provide rapid testing.

The table is split into two columns. The first column (on the left) lists elements that are critical to the implementation of rapid testing. The second (empty column) on the right is for agencies to fill out with either a "Yes" or a "No". Use a "Yes" if your organization has the capacity to accomplish the element as described on the referenced page in this document. Use a "No" if your organization does not have the ability to accomplish the element.

Each of the following organizational capacity elements is critical to successful implementation of rapid testing. Therefore, an organization should only consider implementing rapid testing if they can fill out this table with a "Yes" for all of the following elements:

ELEMENT	YES/NO
<i>1. The organization already has a CLIA Certificate or is able to obtain a CLIA Certificate of Waiver.</i>	
<i>2. Counseling & Testing personnel are already trained to conduct the counseling and administer the OraQuick Advance test or the organization has plans for having them trained before the implementation of a rapid testing program.</i>	
<i>3. The organization already has or is able to put together a comprehensive Quality Assurance containing all of the required elements.</i>	
<i>4. Organization has an established relationship or can establish a relationship with a laboratory for confirmatory testing.</i>	
<i>5. Organization understands and is able to comply with data submittal requirements for each rapid test that is performed and the disease reporting requirements.</i>	
<i>6. Organization has staff that are willing and able to counsel with the additional challenges posed by a single session testing process and delivery of results in 20 minutes.</i>	
<i>7. Organization has staff who are willing and able to comply with additional recordkeeping requirements.</i>	
<i>8. Organization has staff who understand and are willing to adhere to the additional quality assurance procedures required to function essentially as a laboratory worker while conducting this test.</i>	
<i>9. Organization has a supervisory structure with skills and capacities to ensure quality control.</i>	
<i>10. Organization has formalized linkages or can formalize linkages with referral agencies for PCRS and other support services for persons whose results are HIV-positive.</i>	
<i>11. Organization has the storage space and refrigeration capacity to accommodate test kits, control kits and other supplies necessary to perform this test.</i>	
<i>12. Organization can provide a controlled environment for the transport of test kits and at outreach testing venues.</i>	
<i>13. Organization has the fiscal capacity to purchase test kits, control kits</i>	

<i>and other supplies and/or has identified their eligibility for other sources of support (e.g. State-sponsored rapid test and control kits).</i>	
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Worksheet 2:

Is rapid testing appropriate for the clients we plan to serve?

The following tool offers questions that can guide an agency in assessing whether or not rapid testing is appropriate for the clients they plan to serve. The five elements in this chart are not critical for the successful implementation of rapid testing. However, in terms of serving client needs, they suggest where it would be most appropriate to implement.

Therefore, while an agency could choose to implement rapid testing even if its answers are all "No" for this chart, agencies should **only consider implementing rapid testing if they have at least one "Yes" on this chart.**

ELEMENT	YES/NO
<i>1. Target client population has substantial non-return rates for HIV test results, especially if non-return rate is high for clients who test positive.</i>	
<i>2. The conventional 1-2 week waiting period for results is a barrier to testing for a substantial number of the target population.</i>	
<i>3. Conventional venipuncture is a barrier to testing for a substantial number of the target population.</i>	
<i>4. In clinics where blood specimen collection for STDs (including HIV) is in place, client would prefer to have an additional fingerstick or oral fluid test done in order to receive same day results.</i>	
<i>5. Target population has requested rapid HIV testing.</i>	

Worksheet 3:

Is rapid testing appropriate for the venue we plan to use?

The following tool offers questions that can guide an organization in assessing whether or not rapid testing is appropriate for use in a particular venue. The last two elements in this table are not critical and necessary for the successful implementation of rapid testing.

Therefore, an organization could choose to implement rapid testing even if it answers “No” to these last two elements (13 and 14). However, elements 1-12 are critical and necessary for the successful implementation of rapid testing.

Organizations should only implement rapid testing in sites where they are able to fulfill each of the elements numbered 1 thru 12.

ELEMENT	YES/ NO
<i>1. There is an ability to maintain confidentiality of client services & records.</i>	
<i>2. The site has the capacity to handle client flow & potential increase in demand.</i>	
<i>3. The site has a place for clients to wait and/or sign up prior to testing, and, where applicable, there is a place for client to wait for results.</i>	
<i>4. There is adequate private space for testing and counseling.</i>	
<i>5. There is an ability to maintain stable temperatures for testing (59°-99°).</i>	
<i>6. The site has an appropriate level of qualified trained staff.</i>	
<i>7. There is adequate lighting & availability of flat surfaces for running and reading the results of the test.</i>	
<i>8. The venue is appropriate for delivering preliminary positive results.</i>	
<i>9. Confirmatory specimen collection, storage & transport is possible at this site or agency has an arrangement to refer out for confirmatory testing.</i>	
<i>10. Biohazardous waste collection, storage and transport for disposal is possible at this site.</i>	
<i>11. The site adheres to OSHA/OR-OSHA standards and has the capacity to handle blood borne pathogen occupational exposures.</i>	
<i>12. Members of the target population remain at the venue long enough to receive counseling, testing and results.</i>	
<i>13. The venue serves a high-prevalence population (MSM, IDU, Partners of PLWH).</i>	

14. There is evidence of substantial under-screening of this particular target population.	
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APPENDIX C

Quality Assurance Guidance

Quality Assurance

Quality assurance (QA) refers to planned, step-by-step activities that let one know that testing is being carried out correctly, results are accurate, and mistakes are found and corrected to avoid adverse outcomes. Quality assurance is an ongoing set of activities that help to ensure that the test results provided are as accurate and reliable as possible for all persons being tested. Quality assurance activities should be in place during the entire testing process; this means from the time a person asks to be tested using the rapid HIV test to providing the test result.

Basic Elements of a QA Program for OraQuick Advance

Even though the OraQuick Advance test is simple to use, things can go wrong. To help find and prevent problems, the basic elements of a QA program should be in place before offering testing. These basic elements are the building blocks of a QA program and are listed below. More detail on these five elements is provided in this document.

1. Organization of the QA program
2. Testing personnel
3. Process control
 - a. Before testing
 - b. During testing
 - c. After testing
4. Documents and records
5. Troubleshooting

1. ORGANIZATION OF THE QA PROGRAM

Overview

Resources are needed to establish and maintain a QA program, no matter how simple. Someone must oversee the program and ensure the necessary staff and supplies are available. Each organization must:

- Identify the person(s) responsible for managing the QA program (this could be a senior staff member, outside consultant or a network of individuals who oversee different aspects of the QA program).
- Write procedures (step-by-step instructions) and make them available to all staff involved in testing (see the list of recommended procedures below).
- Verify the testing process (see below). Ensure staff knows how to perform processes and procedures.
- Create mechanisms for communication so that those who need to know are informed about QA issues, as well as all staff, when appropriate.

- Develop and implement mechanisms to ensure the site meets all applicable Federal, State, and other regulatory requirements.
- Each site offering testing must have a CLIA Certificate.
- Each site must also meet Federal requirements for biohazard safety, as well as applicable State rules. See Appendix A for more information on regulatory requirements.

Verifying the Testing Process

Before offering the test to clients or patients, each site should make sure (verify) that the testing process works as planned. This verification should be completed before testing is offered. Verification includes ensuring that staff have been trained and are able (competent) to perform their assigned tasks, the test kits work as expected (e.g., make sure the test gives accurate results for a referenced panel of non-reactive, weakly reactive and reactive specimens), and the logistics for providing confirmatory testing (if a person tests positive, he or she still has to have a test to confirm the finding) and biohazardous waste handling are in place.

Providing Written Procedures

It is strongly recommended that step-by-step, written instructions be made available to all staff performing testing. This will help to ensure that personnel know how to perform specific tasks and testing success is not left to chance. Testing personnel must follow instructions provided by the manufacturer. Additional procedures, as listed below, should be provided along with the manufacturer's instructions. Text from the current OraQuick Advance package insert may be used for some of the items denoted by an asterisk (*) in the list below. Written instructions should describe how to:

- Train new employees, assess their ability to do the testing and document training.
- Provide information to persons being tested before testing.
- Use gloves and other personal protective equipment.
- Safely dispose of biohazardous waste, including used lancets.
- Maintain sufficient supplies and unexpired test and control kits, follow the manufacturer's instructions for storage, and check performance of new test kit lots and shipments with external controls.
- Maintain and document the temperature of the room and refrigerator where the tests and controls are stored and testing is performed.
- Perform quality control testing and take action (e.g., contact the manufacturer) if controls don't work.
- Collect the OraQuick® Advance specimen.
- Perform steps in the test procedure.
- Report results.
- Refer specimens or persons being tested for confirmatory testing and manage confirmatory test results.
- Record test and quality control results.
- Conduct external quality assessment.
- Review records and store and destroy them when they are outdated (how long test result records are kept as part of a medical record may be subject to State or other requirements).
- Troubleshoot and take corrective action when things go wrong.

2. TESTING PERSONNEL

Overview

Having qualified, trained staff to perform and supervise OraQuick® Advance testing and the various activities in the QA program is one of the most important factors for ensuring accurate and reliable results. Key aspects of this element include:

- Qualifications
- Training
- Competency assessment (i.e., how well they are doing their job)

Personnel Qualifications

Since the OraQuick Advance test is waived under CLIA, there are no specific Federal requirements on who can perform the test. Beyond any regulatory requirements, it is recommended that certain qualities be considered when selecting personnel to perform the OraQuick® Advance test. The following list of qualities resulted from practical considerations and expert opinion:

- *Sincerity and commitment* – A dedication to performing testing according to defined procedures.
- *Literacy* – The ability to read instructions and record results is critical.
- *Organizational skills* – The need for this quality will depend on the number and complexity of tasks an individual performs in the testing process. If test volume is high and the individual performing testing is doing several tests or managing several other tasks simultaneously, organizational skills can be critical.
- *Decision-making skills* – Testing personnel should be able to interpret results and be able to recognize and handle problems that might come up.
- *Communication skills* – If the person performing the test also is the one who shares results or other information with the person being tested, being able to communicate clearly is important.

Components of Training

Training is crucial to ensuring quality testing. Training is also required to be able to purchase the OraQuick® Advance test kit. Staff should be fully trained on how to perform their assigned tasks and responsibilities. Training should be documented for each staff member; using training checklists is one way to handle this documentation.

The key components of a training program are:

- How to perform the test, including procedures performed before, during and after testing.
- How testing is integrated into the overall counseling and testing program.
- The importance of QA and the elements of the site's QA program.
- The use and importance of Universal (or Standard) Precautions/biohazard safety.

A training method should optimally include the following activities:

- Read the instructions for performing the test.
- Watch someone perform the test or view a video of someone performing the test.
- Practice performing the test with positive and negative control materials.
- Practice performing the specimen collection procedure.
- Review the procedures and forms on how to document testing.

Competency Assessment

Before a trainee is permitted to perform testing alone for the first time, his or her ability to conduct the test should be demonstrated and documented. This assessment should also be carried out at periodic intervals after training, such as every six months or other interval as determined by the testing site. This assessment can be carried out in many ways, but regardless of the method, every task for which a staff member is responsible should be evaluated. A supervisor or trainer should perform the assessment, using a combination of methods to determine competency. Examples of these methods are presented below.

To assess the task performance before testing, staff should be observed as they:

- Check and record the temperatures of the testing and storage areas.
- Set up the testing area, label the device and prepare control and test results log sheets.
- Run the external controls and record results.

To assess staff's ability to perform the test and interpret results:

- Observe the staff member performing the finger-stick, collecting the blood on a test loop and placing it into the testing vial.
- Observe how the test is performed on a client/patient. If such observation will interfere with actual client-provider interactions, observe test performance on a volunteer.
- Evaluate the use of Universal or Standard Precautions and procedures for biohazard and sharps (e.g., lancets, needles) waste disposal.
- Review results obtained on a panel of referenced specimens that show a range of results, such as five specimens that include non-reactive, weakly reactive and reactive results. Control materials supplied by the manufacturer may be used as a source of specimens in the panel.
- Appraise the individual's ability to interpret results. This might include using previously used test devices or pictures of devices that show non-reactive, weakly reactive, reactive and invalid results.

To assess task performance after testing:

- Review test records and quality control results documentation.
- Observe oral reporting of results to a test subject (if trainee's responsibility).
- Observe venous blood and/or oral fluid specimen collection and handling for confirmatory testing. If the frequency of OraQuick Advance reactive results is low, the trainee should be observed collecting blood and/or oral fluid from a staff volunteer and demonstrate how it is processed for confirmatory testing.
- Verify that confidentiality is maintained.

3. PROCESS CONTROL

Overview

Process control refers to the activities and techniques that are carried out to ensure that the testing procedures are performed correctly, the environment is suitable, and the test kit works as expected to produce accurate and reliable results.

Steps in the Testing Process

Steps in the testing process follow the path of workflow beginning with tasks before testing, followed by those conducted during and after testing. This path of workflow and the associated steps are shown below. Detailed descriptions about each of the steps listed below should be provided in a QA manual and can be found in the test kit and control kit inserts.

Before testing	During testing	After testing
<ul style="list-style-type: none">• Check storage and room temperatures daily• Check inventory and test kit lots, as needed• Provide HIV/AIDS information to the test subject• Set up test area, label test device• Perform external quality control according to the manufacturer's and the site's instructions	<ul style="list-style-type: none">• Follow biohazard safety precautions• Collect the finger-stick or oral fluid specimen• Perform the test• Interpret test results	<ul style="list-style-type: none">• Clean up and dispose of biohazardous waste• Report results to client• Document results• Collect, process and transport confirmatory test specimens• Manage confirmatory test results

4. DOCUMENTS & RECORDS

Overview

One of the hallmarks of a QA program is comprehensive documentation. Sites using the OraQuick® Advance test should have policies and procedures describing what QA records are required and how and when they are reviewed, stored and destroyed. Having a supervisor review records periodically is recommended. State regulations or other governmental or accrediting agencies may require facilities to have specific record retention policies (2 years in Oregon).

QA records should include the following:

- Training documentation Records
- Temperature logs: should include a daily record (or nearly daily) of the refrigerator temperature in which controls are stored, the temperature where test kits are stored and the temperature of the testing area. Thermometers should be placed in each location. Laboratory grade thermometers (can be purchased from medical or laboratory supply houses) are recommended and their accuracy checked periodically (e.g., every six months) by comparison with another thermometer.

- External control result logs: should include the date and time of control testing, lot number and expiration of the test kit, lot number and expiration date of the controls, control results, and corrective action taken if control results are unacceptable. Control records should be kept in the order in which they were completed so they can be easily compared with the test records. This will help find answers if there are questions about testing performed within a specific time frame.
- Test result logs: should include the date and time of testing, an identifier for the person being tested, a test kit lot number and expiration date, test result, action taken if the result was invalid, identification of the person who performed the test, whether confirmatory testing was requested, including the type of specimen sent for confirmation (e.g., oral fluid, blood), and the confirmatory test results when they are available. If more than one person is conducting testing, there should be a mechanism to chronologically link the test record log sheets to detect problems, such as invalid results occurring repeatedly with the same kit lot number.

5. TROUBLESHOOTING

Overview

Each site should have a method to detect and resolve 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.

Procedures

Procedures should be available to all testing personnel for the following:

- When to discontinue testing, e.g., when the external control results are unacceptable as described in the package insert.
- How to take corrective action, or an action taken in response to a problem, such as contacting the manufacturer when the external control results are unacceptable and following the advice provided.
- How to document problems and actions taken, such as a logbook where problems and corrective actions taken can be recorded.
- How to verify the corrective actions taken addressed the problem.

APPENDIX D

Sample Quality Assurance Protocol

Notice

This document is for sample purposes only. It describes a fictitious rapid testing program in a fictitious Oregon county. Underlined areas exist to demonstrate where your organization should customize this document to fit the needs of your program. Not all sections of this document will fit the needs of all programs. Organizations may need to add, edit or delete sections to accurately describe the quality assurance protocols of their unique rapid testing programs.

Cascadia County Quality Assurance Program For OraQuick® Advance Rapid HIV- 1 / 2 Antibody Testing Program

Cascadia County's HIV Rapid testing program is conducted by standing order of **Authorized Individual** using the policies and procedures approved by this **health department** and with oversight by the **Cascadia County HIV Prevention Program** Quality Assurance team. Written procedures are available to all staff conducting tests or overseeing test sites. These procedures are accessible on the **Cascadia County** shared drive under **Cascadia\QualityAssurance\HIVPolicy&Procedure**. Policies and procedures are also available in hardcopy at all testing sites.

This document will provide detailed protocols and documentation forms for each of the following five areas:

- **Organization of the QA Program**
- **Testing Personnel**
- **Process Control**
- **Documents and Records**
- **Troubleshooting**

Organization of the QA Program

The **Cascadia County** Quality Assurance Team, made up of the **Quality Assurance Program Coordinator** and the **Quality Assurance Assistant**, is responsible for maintaining the policy and procedure manual for OraQuick® Advance Rapid HIV-1/2 antibody testing as well as assuring compliance with all County, State, and Federal regulatory requirements. Communication regarding changes in regulatory requirements or testing practices will be communicated to and by the QA program to the appropriate staff. All notices from OraSure Technologies Inc. and Oregon Department of Human Services HIV Prevention Program shall be communicated to the QA program and disseminated as appropriate.

Oversight for staff training including initial OraQuick® Advance Rapid HIV-1/2 antibody testing training and all subsequent competency training is assigned to the QA program. Training documentation will be maintained by the QA team.

The QA Team will be responsible for maintaining an appropriate inventory of unexpired controls and test kits and monitoring and documenting the storage temperatures for those kits according to CLIA requirements and the recommendations of the manufacturers of OraQuick®. Documentation of storage temperatures will be maintained by the QA Team.

The QA Team will monitor all documentation and review all logs **at least quarterly** to ensure appropriate monitoring and documentation.

Testing Personnel

All **Cascadia County** staff conducting OraQuick® Advance Rapid HIV-1/2 antibody testing must first complete Client-Centered Counseling Training offered by the DHS HIV Program. This two-day training, designed to provide participants with skills and techniques for providing HIV risk-reduction counseling, must be completed prior to Rapid HIV Testing training.

Staff members conducting testing are also required to attend the Rapid HIV Testing training offered by the DHS HIV Prevention Program or a **Cascadia County** DHS-certified rapid testing trainer prior to performing tests at any site. This 5-hour training provides participants guidance on implementing a rapid HIV testing program and practical skills and experience to perform the rapid HIV test using the OraQuick® Advance Rapid HIV-1/2 Antibody Test.

All staff newly trained by DHS will be assessed through observation by a trained and experienced staff member for performance of tasks done before, during, and after testing. Training records are maintained by the **Cascadia County** QA Program.

Process Control

All activities and techniques carried out to ensure that testing procedures are performed correctly, the environment is suitable, and the test kit works as expected to produce accurate and reliable results are recorded in this section of the document.

Before Operation of Tests or Controls

Inventory: Check inventory of test kits and materials at the first of each month. Assure that appropriate stock of test kits, control kits and necessary associated test materials are available. Materials to maintain in inventory:

- Test Kits
- Control Kits
- Timers
- Thermometers for monitoring testing environments
- Antiseptic wipes
- Sterile lancets
- Gauze pads
- Latex, vinyl or Nitrile disposable gloves
- Clean, disposable, absorbent workspace covers
- Biohazard waste containers
- Bandages
- 10% bleach solution and paper towels for spills

Storage & Temperatures: Unused OraQuick® test kits will be stored unopened at 35°F - 80°F, and will not be opened until ready to perform the test. If test kits are stored refrigerated, the unopened test kits pouch will be brought to operating temperature (59°F - 99°F) before use.

External controls will be stored in a refrigerator at 35°F - 46°F. Kit control vials will remain closed until performing kits controls. Vials will be recapped and stored in their original container after use, and promptly re-refrigerated. Unused portions of open kit control vials will be disposed of 8 weeks after the date of first opening. Test kits and control kits will not be used after the last day of the month in which they expire.

Set-Up & Labeling:

- Package inserts (testing and controls) must be read completely before using the product.
- Needed materials will be gathered prior to performing controls and/or testing individuals. The test will be brought to room temperature.
- The workspace will be covered with a clean, disposal workspace cover. An OraQuick® reusable test stand will be placed upon the workspace cover.
- When running controls, test devices will be labeled with the expected results.

Safety:

- Specimens and materials contacting specimens will be handled as if capable of transmitting infectious agents.
- Drinking, eating and smoking will not be tolerated in areas where specimens are being handled.
- Disposable gloves will be worn when testing with all specimens (controls, oral fluid, and blood).
- Used lancets must be disposed of in a sharps container.
- Used test kit materials and specimen collection devices and any other biohazardous waste must be disposed of in a biohazard waste container.
- A 10% bleach solution or other germicidal solution will be used to clean up any spills.

During Operation of Tests & Controls

Set-up:

- Subject Information Pamphlets will be readily available to offer to persons being tested (required).
- Testing environment temperature will be monitored for appropriate testing range of 59° F -99° F.
- The two sides of the divided test kit pouch will be opened by tearing at the notches on the top of each side.
- To prevent contamination, the test device will be left in the pouch until ready for use.
- Tester will feel for absorbent packet in the test device portion of the pouch. If no packet is present, the device and developer solution will be discarded and a new pouch will be obtained for testing.
- When testing individuals, test device will be labeled with a **unique client identifier sticker**. When running controls, each test device (there will be 3) is labeled by permanent marker or sticker with the expected result (HIV-1+, HIV-2+, or HIV-).
- The holes on the back of the test device will not be covered as this will affect the flow of fluid from the developer solution vial to the result window.
- Developer solution vial will be removed from the pouch.
- Holding firmly in one hand, the cap of the developer solution vial will be removed by gently rocking the cap back and forth with the other hand. The cap will be set on the workspace cover.
- The developer solution vial will be slid into one of the slots of the test stand.
- When running controls, each developer solution vial (there will be 3) will be labeled by permanent marker with the corresponding reagent that is introduced into the developer solution (HIV-1+, HIV-2+, or HIV-).

External Controls: The positive and negative external test controls are used to verify the correct functioning of the test kit and the ability of the tester to perform the test and interpret the result. Controls must be run at the following times:

- Testing personnel before the first time they perform the tests on individuals;
- Upon opening a new shipment of test kits;
- Upon beginning a new test kit lot;
- If the temperature of the test kit storage area falls outside of 35° F -80° F;
- If the temperature of the testing environment falls outside of 59° F -99° F;
- **At periodic intervals as determined by the QA Program Coordinator.**

Protocol to run controls is similar to the protocol for testing fingerstick whole blood in human specimens, except that control reagents are used, not blood. Three test kits pouches, one for each expected result, are required each time controls are run.

- An unused specimen loop will be handled by the non-loop end. The loop will be dipped into a control vial and then the loop will be checked visually for its containment of the control fluid.
- The fluid-filled end of the loop will be inserted into the appropriately labeled developer solution vial, and gently stirred for a few seconds.
- The used loop will be removed and immediately discarded in a biohazard waste container.
- This process will be completed with a new loop, new test device and new developer solution for each of the control kits vials (there are three).
- The tester will start timing the test.
- Results will be read after 20 minutes but not more than 40 minutes.

Once vials have been opened, do not use the controls past the updated written expiration date on the outer carton which reflects a date 8 weeks after opening. Do not use controls if reagents appear cloudy or discolored (normal color range is from clear to light straw color). Unopened, do not use controls past the expiration date preprinted on the outer carton (typically up to one year from date of manufacture).

Open kit control vials only when you are running the controls. Recap and store the vials in their original container. The positive HIV-1 and positive HIV-2 vials have been manufactured to produce a very faint "T" line. The negative control will produce a non-reactive test result.

Control results and any corrective action taken will be documented on the External Control Log when the control results are not as expected.

Oral Fluid Procedure:

- The person being tested will be asked to remove the test device from its pouch. S/he will be instructed not to touch the flat pad of the device.
- The person being tested will be instructed to place the flat pad of the device above the teeth against the outer gum. S/he will be instructed to swab completely around the outer gums, both upper and lower, once around, free to use both sides of the flat pad. S/he will be instructed not to swab the roof of the mouth or inside of the cheek or the tongue.
- The person being tested will be instructed to insert the flat pad of the device all the way into the vial, making sure that it touches the bottom of the vial. The result window will be facing forward.
- The tester will start timing the test.
- Results will be read after 20 minutes but not more than 40 minutes.

Fingerstick Whole Blood Procedure:

- Using an antiseptic wipe, the tester will clean the finger of the person being tested.
- The finger will be allowed to air dry or it will be wiped dry with a sterile gauze pad.
- Using a sterile lancet, the tester will puncture the skin just off the center of the finger pad of the middle or ring fingers.
- The finger will be held downward, applying gentle pressure beside the point of puncture.
- The first drop of blood will be wiped away. A new drop of blood will be allowed to form.
- An unused specimen loop will be handled by the non-loop end. The loop will be placed just on the surface of the droplet of blood until it is completely filled.
- The blood-filled end of the loop will be inserted into the developer solution vial, and gently stirred for a few seconds.
- The used loop will be removed and immediately discarded in a biohazard waste container.
- The tester will start timing the test.

- Results will be read after 20 minutes but not more than 40 minutes.

Reading & Interpreting Results:

- **Validity:** A reddish-purple line in the “C” (Control) area of the result window, within the borders of the triangle next to the “C” area, indicates that a specimen was added and that the fluid migrated appropriately through the test device. The control line appears in both non-reactive (negative) and reactive (preliminary positive) results. There must be a reddish-purple line in the “C” area for the test to be valid.
- **Non-reactive (negative):** A non-reactive result appears as a reddish-purple line in the “C” area and NO line in the “T” area of the result window.

A non-reactive test result means that NO antibodies for HIV-1 or HIV-2 were detected in the specimen. The result is interpreted as negative for HIV-1 and HIV-2 antibodies. Almost all individuals with a non-reactive result are not infected with HIV. The exceptions are those who may have had a recent exposure to HIV (within the last three months). A recent exposure may or may not have been accurately evaluated by the test. Therefore, for clients with recent exposures, retest is recommended at three months from the last possible exposure.

- **Reactive (preliminary positive):** A reactive result appears as a reddish-purple line in the “C” area and a reddish-purple line in the “T” area. One of the lines may be darker than the other.

A reactive test result means that HIV-1 and/or HIV-2 antibodies have been detected in the specimen. The test result is interpreted as preliminary positive for HIV-1 and/or HIV-2 antibodies.

Further conventional testing (venipuncture or OraSure oral fluid collection—sent to lab) is always required to confirm a reactive result with a screening test (like OraQuick®). It is essential to explain:

- The meaning of a reactive screening test result in simple terms, avoiding technical jargon.
- Emphasize the importance of confirmatory testing, arrange to conduct the confirmatory test and schedule a return visit for confirmatory test results or refer out for confirmatory testing if appropriate.
- Underscore the importance of taking precautions to prevent transmitting infection to others while awaiting the results of the confirmatory test.
- **Invalid results:** Invalid results appear as:
 - No line next in the “C” area of the result window;
 - A red or pink background makes it difficult to read the result after 20 minutes; or
 - Any of the lines and NOT inside the “C” or “T” triangle areas.

If the test result is invalid, a new test must be conducted with a new test kit pouch and new oral fluid or fingerstick whole blood specimen. If an invalid result appears with this additional test, contact OraSure® Technologies Customer Service at 800-672-7873.

Counseling Protocols: Counseling protocols during the administration of rapid HIV tests are not different than counseling protocols followed during conventional specimen collection for laboratory HIV testing. At a minimum, the six steps of Client-Centered Counseling, as prescribed by the CDC, will be followed:

1. Introduce and orient individual to the session.
2. Help individual identify personal risk behaviors and circumstances that contribute to risk behaviors.
3. Help individual identify safer goal behavior(s).
4. Assist individual in developing an action plan with specific, incremental steps for reaching safer goal behavior(s).

5. Offer referrals and provide support.
6. Summarize and close the session.

After Testing

Documenting Results: Test results must be documented carefully on the test result log. Because timing is critical for reading results (as results are accurate only during the time period of 20 minutes to 40 minutes after the test begins development), the time the result is read should also be recorded.

Clean-up: At all times, staff will adhere to OSHA and OR-OSHA standards for handling biohazardous materials.

- Used lancets must be disposed of in a sharps container.
- Used test kit materials and specimen collection devices and any other biohazardous waste must be disposed of in a biohazard waste container.
- A 10% bleach solution or other germicidal solution will be used to clean up any spills.
- A new absorbent workspace cover, new gloves new testing materials will be prepared for the next client if appropriate.
- Supplies will be returned to appropriate storage locations.

Documents and Records

As documented in the OraQuick® Advance Rapid HIV 1 / 2 Antibody Testing Protocol adopted by the **Cascadia County health department**, the following documentation and forms are maintained for rapid HIV testing. Samples are available at the end of this document in Appendix 1:

- Training documentation
 - Training Checklist
 - Verification of training at DHS or CDC approved training
- Temperature log
 - Kit Storage temperature
 - Testing room temperature
 - Control refrigerator temperature
- External Control Log
 - Date
 - Time
 - Lot number
 - Expiration date of controls
 - Control results
 - Corrective action if applicable
- Test Result Log (maintained as part of clinic and outreach lab log)
 - Date
 - Time
 - Serology #
 - Test kit lot number and expiration
 - Test result
 - Identification of the CTR performing the test
 - Type of specimen sent for confirmation if preliminary positive
 - Corrective action taken if applicable

- Confidential Test Results for Client Form

Errors made by entering incorrect information or placing information in the wrong area should be corrected by drawing a single line through the error and initialing in the margin. Do not scribble over errors or use white-out to cover them up.

Laboratory and other State-required data collection procedures will be followed in accordance with the most current protocols and procedures. **(Attach the most current protocols and procedures to this QA manual).**

Data collection forms and Test Request Forms with documentation of results will be maintained **in a locked filing cabinet for anonymous testing and in the client chart for confidential testing**. Confidential testing records will be kept for seven years. Anonymous testing records will be kept for two years. Clients who test confidentially may receive a copy of their test results after signing the HIPPA-compliant Release of Information Form.

Troubleshooting

The preceding *OraQuick* Advanced Rapid HIV-1 & HIV-2 Antibody Testing Protocol adopted by **Cascadia County Health Department** addresses when to discontinue testing, corrective actions to take in the event of equipment failure or an inadequate testing environment, and documentation.

Additionally, the **Cascadia County** Quality Assurance Program conducts **monthly** reviews of every rapid HIV antibody test and result. All results are verified by review of the lab result log and test result data available on the Oregon State Public Health Laboratory WebRad site. Disposition forms are collected and reviewed before being sent and all forms are reviewed before being mailed. Anomalies, questions, and errors found during this process are addressed by the QA program and corrective action is taken. All corrective actions are documented.

APPENDIX 1

Documents & Records Sample Forms

This appendix includes samples of the following forms:

Training documentation

Temperature logs

External Control Result Log

Test Result Log

Confidential Test Results for Client Form

Training Checklist for OraQuick® Advance Rapid HIV-1 & HIV-2 Antibody Testing

Employee: _____

Instructions: Complete table with dates as trainee performs each objective or procedural step. The trainee should initial and date each field she or he feels they have mastered. The trainer will initial each field after verifying the trainee is able to perform the specific objective or procedure being evaluated. Completed checklists should be submitted to the Quality Assurance Program for recording.

Objective/Procedural Step	Date observed	Date performed	Trainee's initial/date	Trainer's initial/date
Read <i>OraQuick</i> ® Advance Rapid HIV-1 & HIV-2 Antibody Testing Protocol	N/A			
Read Exposure Control Plan (or Blood borne Pathogen training completed)	N/A			
Evaluate environment for testing parameters (e.g., temperature, light, work space)				
Practice test with negative and positive controls				
Give person being tested the "Subject Information" brochure				
Assemble correct test device components and paperwork and demonstrate appropriate labeling and documentation				
Collect specimen and immerse in vial, mixing correctly				
Insert test device, time test, read result, document result in chart and on all appropriate paperwork				
Dispose of lancet and other biohazardous waste correctly				
Record internal and external controls				
Report test result to the person being tested				
Collect specimen for confirmatory testing (if applicable)				
Send confirmatory test specimen to laboratory with proper documentation.				
Receive results and record results properly				
Explain what to do if QC results show a problem				
Explain proper reporting and documentation of any failure or error in Rapid HIV testing process				

OraQuick® Advance HIV-1/2 Test Kit Storage Temperature Record

- Store unopened kits at 35°F - 80°F
- If test kits are stored at temperatures outside of ambient temperature 59°F– 80°F or used outside of the operating temperature 59°F – 99°F, use the Kit Controls to ensure performance of test.
- If stored refrigerated, be sure pouch is brought to operating temperature before performing test 59°F – 99°F
- Note identified temperature issues & solutions on the back of this form.

Date	Jan	Feb	Mar	April	May	June	July	Aug	Sept	Oct	Nov	Dec
1												
2												
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Identified Temperature issues & solutions

Date	Description of Issue & Solution	Need to Report to Manager? If yes, include comments here.	Staff Initials

OraQuick® Advance HIV-1/2 Control Kit Storage Temperature Record

- Store opened and unopened kits at 35°F - 46°F
- Upon opening vials, update expiration date by writing on the outside of the box a date 8 weeks from date of opening vials.
- Unopened vials are good until the preprinted expiration date on the front of the box.
- Note identified temperature issues & solutions on the back of this form.

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Identified Temperature issues & solutions

Date	Description of Issue & Solution	Need to Report to Manager? If yes, include comments here.	Staff Initials

OraQuick® Advance HIV-1/2 Testing Environment Temperature Record

- Testing environment must be between 59° F – 99°F.
- If testing environment goes outside acceptable range, all testing on human specimens must cease.
- Controls must immediately be run to ensure the validity of the tests conducted between the most recent run of controls and the last time controls were run.
- Note identified temperature issues & solutions on the back of this form.

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Identified Temperature issues & solutions

Date	Description of Issue & Solution	Need to Report to Manager? If yes, include comments here.	Staff Initials

When to Run Test Controls

- Each new test operator prior to performing testing on patient specimens
- If the temperature of the testing area falls outside of 15° – 37°C (59° – 99°F)
- When opening a new test kit lot
- Whenever a new shipment of test kits is received
- If the temperature of the test kit storage area falls outside of 2° - 27° C (35° – 80°F)
- At periodic intervals as dictated by the user facility

Control Shelf Life

- 1 year from date of manufacture or 8 weeks after initial opening of packaging

		Date	Date	Date	Date	Date	Date
Control Information	Test Control Lot #						
	Test Control Expiration						
	Date Test Control Opened						
Positive HIV-1	Expiration of Test Kit						
	Lot Number						
	Result of Positive Control						
Positive HIV-2 Control	Expiration of Test Kit						
	Lot Number						
	Result of Positive Control						
Negative Control	Expiration of Test Kit						
	Lot Number						
	Result of Negative Control						
Room Temp	Room Temperature (note temp)						
Room Light	Room Lighting Adequate?	Y N	Y N	Y N	Y N	Y N	Y N
	Tester's Initials						
	NOTES						

OraQuick® Advance HIV-1/2 Test Result Record

Site:

		Date of Test	Date of Test	Date of Test	Date of Test	Date of Test	Date of Test
Test Kit Information	Test Kit Lot #						
	Test Kit Expiration Date	Month Year	Month Year	Month Year	Month Year	Month Year	Month Year
	Specimen Type: (circle one)	Oral Finger	Oral Finger	Oral Finger	Oral Finger	Oral Finger	Oral Finger
Client Info.	Serology #						
	Client ID number (if applicable)						
		Check one	Check one Box	Check one Box	Check one Box	Check one Box	Check one Box
Results	NON REACTIVE						
	REACTIVE						
	INVALID						
IF REACTIVE	Confirmatory Test Done?	Y N	Y N	Y N	Y N	Y N	Y N
	If No, Reason						
	If Yes, Result Delivered to Client?	Pos. Neg Ind Y N	Pos. Neg Ind Y N	Pos. Neg Ind Y N	Pos. Neg Ind Y N	Pos. Neg Ind Y N	Pos. Neg Ind Y N
Room Temp	Room Temperature (note temp)						
Room Light	Room Lighting Adequate?	Y N	Y N	Y N	Y N	Y N	Y N
	Tester's Initials						
	NOTES						

CASCADIA COUNTY HEALTH DEPARTMENT

9999 Cascadia Road
Cascadia, Oregon 99999
(999) 999-9999

Rapid HIV Antibody Test Results

The following individual for which these test results are linked has signed a HIPPA-compliant Release of Information Form granting the release of this written verification of his/her HIV antibody test result to the individual. The signed Release of Information Form is located in the individual's medical records at this facility.

Name: _____

Oregon HIV ID Number: _____

Date of Birth: _____

Specimen Type: Oral Fluid Fingertick

Testing: Confidential*

**Anonymous Testing does not involve an name and, therefore, cannot be linked with a specific individual. Written verification of results is not available for anonymous testing.*

RESULTS

- Negative for HIV-1 and HIV-2 Antibodies**
It may take up to three months post-exposure to develop antibodies that are detectable by this testing process. If exposure occurred within the past three months, it is recommended that this test be repeated between three months past the date of exposure and three months past the date of this test.

- Preliminary Positive for HIV-1 and/or HIV-2 Antibodies**
This test (OraQuick® Advance Rapid HIV 1 / 2 Antibody Test) is a screening test for HIV-1 and/or HIV-2 Antibodies. A screening test cannot confirm an HIV-positive diagnosis. To confirm this diagnosis, another specimen must be collected at this or another facility to send to a laboratory for conventional HIV Testing with results available in 1-2 weeks.

Signature of Person who Performed Test

Date