Frequently Asked Questions About the OraQuick Rapid HIV-1 Antibody Test

What is the OraQuick Rapid HIV-1 Antibody Test, and how is it performed?

The OraQuick Rapid HIV-1 Antibody Test checks for HIV-1, the virus that causes AIDS, in a person's blood. The test detects antibodies to HIV-1 found in blood specimens obtained by fingerstick or venipuncture. As is true of all HIV screening tests, a reactive test result needs to be confirmed by an additional, more specific test.

When testing a fingerstick specimen, the fingertip is cleaned with alcohol and pricked with a lancet (needle) to get a small drop of blood. The blood is collected with a specimen loop and transferred to a small plastic vial containing a premeasured volume of developing solution, into which the sample is mixed. The testing process is the same for a whole blood specimen obtained by venipuncture. The specimen loop is inserted into the tube of blood after the tube has been inverted to ensure the blood is well mixed. The loop is then inserted into the test vial. Results of the test can be read in as little as 20 minutes.

How well does the test work?

In the clinical studies by the manufacturer (OraSure Technologies, Inc.), the OraQuick test correctly identified 99.6% of people who *were* infected with HIV-1 (sensitivity) and 100% of people who *were not* infected with HIV-1 (specificity). The Food and Drug Administration expects clinical laboratories to obtain similar results.

What are the limitations of the test? Does this test always give a correct result?

The limitations of this test are similar to the limitations of other HIV antibody tests, including

- **False-positive results:** Although no false-positive results were found in the clinical trial, statistical analysis of the data show that a very small number of people who *are not* infected with HIV-1 will have reactive test results (that is, tests that show HIV infection). As the test becomes widely used in outreach settings, false-positive results may occur. Reactive results should not be considered definitive until confirmatory testing has been done.

- **False-negative results:** A small number of people who *are* infected with HIV-1 will have negative test results.

- **Delayed detection of exposure:** OraQuick may not detect HIV-1 infection in people who were exposed within 3 months before being tested (it can take that long for antibodies to HIV-1 to be detectable in the blood).

- **Follow-up testing:** A reactive result is interpreted as preliminarily positive for HIV-1 infection. Another method should be used to confirm the initial test result.

Because of these limitations, all persons taking this test must receive counseling before being tested and after receiving their test results.

What type of counseling is provided to persons getting a rapid HIV test?

Counseling for rapid HIV tests includes

- Information about the importance of HIV testing
- Ways to reduce the risk of becoming infected with HIV
- Next steps for persons who have a reactive test result
- Need for additional testing of persons whose rapid test result is negative but who have had a recent exposure to HIV

CDC recently released revised guidelines for HIV counseling and testing. These guidelines, available at http://www.cdc.gov/mmwr/indrr_2001.html, include information about posttest counseling for persons tested with rapid HIV tests. The counseling includes information about HIV testing and its importance, as well as specific counseling to help reduce risks for HIV infection. A very important part of counseling persons who have a reactive rapid HIV test result is to make sure they understand that the test result is preliminary and that further testing must be done to confirm the result. Persons who have a negative rapid test result but have had a recent exposure to HIV are counseled to get another test at least 3 months after the possible exposure to account for the possibility of a false-negative test result. For more information on rapid testing, go to CDC's rapid testing Web site at: http://www.cdc.gov/hiv/rapid_testing.

Does this test detect antibodies to HIV-2?

The test is approved to detect antibodies to HIV-1. Data on the test's sensitivity to detect antibodies to HIV-2 have not been reviewed, and the Food and Drug Administration has not approved the test for this purpose. Because HIV-2 is very rare in the United States, CDC does not recommend routine screening for HIV-2 at this time.

Are blood donors allowed to be screened by use of the OraQuick test?

No. This test is approved to help diagnose HIV infection, not to screen blood donors.

I heard the rapid test received a CLIA waiver. What does this mean?

CLIA refers to the Clinical Laboratory Improvements Amendments of 1988, which established standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of test results regardless of where a test is performed.

The OraQuick Rapid HIV-1 Antibody Test was categorized as a waived test by the Food and Drug Administration on January 31, 2003. The OraQuick test is simple to use and accurate. Under the waived category, the OraQuick rapid test will face less strict federal controls and can

be used at a larger number of clinical and nonclinical testing sites. This categorization will allow nonclinical testing sites to provide the test by applying for a CLIA certificate of waiver or agreeing to work under an organization that has a certificate of waiver. For tests categorized as waived, less stringent guidelines apply. However, before offering testing, an organization that has received a certificate of waiver must have a quality assurance plan and must provide training to ensure that the manufacturer's instructions are followed. For more information on the CLIA waived category and other CLIA categories, go to: http://www.phppo.cdc.gov/clia.

What needs to be done before a site is permitted to purchase and use the test?

Any site offering the rapid HIV test is considered a laboratory under the Clinical Laboratory Improvements Amendments (CLIA) and must meet certain quality assurance requirements before purchasing OraQuick. Under CLIA, a laboratory is defined as any facility that performs examinations, including the OraQuick rapid test, on humans. A facility can be a clinic or hospital with an on-site lab, a voluntary counseling and testing site, or an outreach setting. Only staff of clinical laboratories may use the test. All customers will receive a letter indicating that their purchase of OraQuick means that they agree to meet these requirements.

Any organization or group conducting the OraQuick rapid HIV test must:

- Have a CLIA certificate of waiver or be covered under an exception for multiple sites or public health use (The exceptions involve working with a main location that has a CLIA certificate of waiver.)
- Ensure that persons administering the test follow the manufacturer's test instructions
- Have a quality assurance plan to ensure that certain requirements, such as performing testing correctly and providing staff with appropriate instructional materials, will be met
- Agree to allow inspections, announced and unannounced, by the federal Centers for Medicare and Medicaid Services
- Follow HIV testing requirements or guidelines from the state health department

How can I obtain a certificate of waiver?

The CLIA program is administered by the federal Centers for Medicare and Medicaid Services. For information on obtaining a certificate of waiver, go to: http://www.cms.gov/clia.

What does it mean to have an "adequate quality assurance system"?

An adequate quality assurance system consists of planned activities to ensure that testing is carried out correctly and that test results are as accurate and reliable as possible for all persons tested. CDC's recommendations for quality assurance systems for rapid HIV testing -- *Quality Assurance Guidelines for Testing Using the OraQuick® Rapid HIV-1 Antibody Test* -- are available at: http://www.cdc.gov/hiv/rapid_testing.

Can waived tests be performed at nonclinical sites?

All testing sites, clinical and nonclinical (e.g., mobile vans, health fairs, community clinics, pharmacies) are subject to applicable state requirements. Conducting HIV testing by using the OraQuick Rapid HIV-1 Antibody Test, which is categorized as waived under the Clinical Laboratory Improvements Amendments (CLIA), will allow nonclinical testing sites to participate in HIV screening activities.

How much does the test cost?

The manufacturer and the laboratory performing the test determine the fee for the test.

Reference

Kelen GD, Shahan JB, Quinn TC. Emergency department–based HIV screening and counseling: experience with standard and rapid serologic testing. *Annals of Emergency Medicine* 1999; 33:147-155.