Rapid results and early detection

IgM HIV testing from OraQuick®, made easy

Early and accurate detection is the first line of defense in the fight against HIV and is a key strategy for Ending the HIV Epidemic by 2030.

The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is capable of detecting IgM antibodies as early as day 20 post-infection, comparable to 3rd generation lab-accurate results.

Identifying HIV from early IgM antibodies[1]

The CDC recommends using "tests that can detect HIV infection biomarkers within 30 days of infection, when initial immune responses are mounted." The IgM response of an infected patient is often used as a biomarker of an acute infection within a 20-25 day window following infection. This window requirement applies to "lab-based testing with automated analyzers and rapid, point of care (POC) testing used for screening in a non-clinical setting."

OraQuick and IgM performance data[2]

Predominantly anti-HIV-1 IgM Seroconverters Sample	OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Test Line Response
914-01	R
914-02	R
914-03	R
924-08	R
925-05	R
925-06	R
927-03	R
928-02	R
934-02	R
934-03	R
938-03	R
940-04	R
940-05	R
943-06	NR
944-05	R
950-04	NR

Red denotes *IgM only* samples

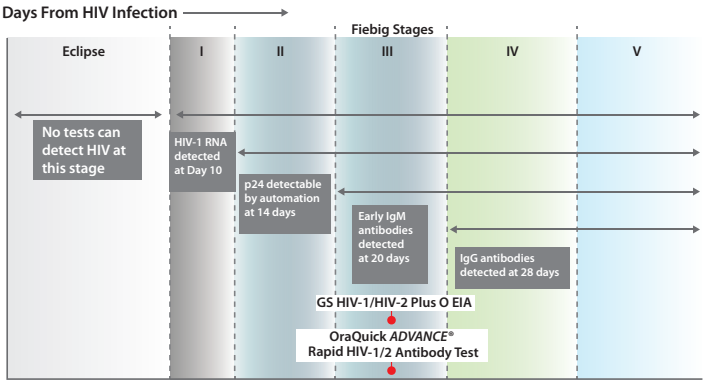
- ✓ **OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test** uses colloidal gold Protein A conjugate, which binds to human antibodies.
- ✓ The **OraQuick *ADVANCE*® Test** identified 14 out of 16 IgM/IgG reactive seroconversion panel members.
- ✓ The **OraQuick *ADVANCE*® Test** demonstrates 3rd generation performance equivalency with detection of IgM and IgG antibodies.
- ✓ The CDC recognizes the ability of the **OraQuick *ADVANCE*® Test** to detect IgM antibodies.[3]

"The OraQuick *ADVANCE*® Test can detect IgM antibodies during an acute infection window period. ... and is therefore suitable for use in testing environments requiring adherence to the CDC and APHL recommendations." [1]

Proven sensitivity and reliability

Following acute infection of HIV virus in a patient, tests can detect certain biomarkers to suggest the presence of the virus at different stages of the infection.

These biomarkers include the p24 antigen, viral RNA and the patient's IgM and IgG antibody response.



Stages of HIV infection chart adapted from: Fiebig EW, Wright DJ, Rawal BD, et al. Dynamics of HIV viremia and antibody seroconversion in plasma donors: implications for diagnosis and staging of primary HIV infection. *AIDS* 2003;17(13):1871-1879.
The comparative OraQuick *ADVANCE*® data to GS HIV-1/HIV-2 Plus O EIA has been extracted from the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Package Insert.

To provide the most accurate results to patients, the CDC recommends that sites use the most sensitive, cost-effective and feasible HIV testing technologies available to them.

Although there is a 4th generation POC p24 antigen detection test available, the CDC recommends it be used with serum or plasma.[4]

In the absence of a reliable 4th generation POC test, tests such as the OraQuick *ADVANCE*® should be used due to their proven sensitivity and reliability.

HIV testing — anytime, anywhere, made easy

Proven

- Results in as little as 20 minutes with greater than 99% specificity and sensitivity
- Able to detect seroconversion approximately 20-25 days after infection
- IgM reactivity consistent with 3rd generation EIAs

Trusted

- More people learn their results with OraQuick[5]
- 58 million tests used worldwide[5]
- Faster linkage to care

Easy

- Multiple specimens supported, including oral fluid, fingerstick whole blood, venipuncture whole blood and plasma
- Easy 3-step process, with less than 1 minute hands-on time
- Walk-away procedure allows providers to batch tests

OraQuick ADVANCE® Rapid Antibody Test HIV-1/2

OraSure Technologies

www.orasure.com

1 Guillon G, Yearwood G, Snipes C, Boschi D, Reed MR. Human anti-HIV IgM detection by the OraQuick *ADVANCE*® Rapid HIV 1/2 Antibody Test [published correction appears in PeerJ. 2018 Jun 22;6:]. *PeerJ*. 2018;6:e4430. https://doi.org/10.7717/peerj.4430
2 IgM antibody panels identified from: Moshgabadi, N, et al. Sensitivity of a rapid point of care assay for early HIV antibody detection is enhanced by its ability to detect HIV gp41 IgM antibodies. Data presented at 2017 NMA Conference, Philadelphia, PA. Complete data found in OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Package Insert.
3 Advantages and disadvantages of FDA-approved HIV assays used for screening. https://www.cdc.gov/hiv/pdf/testing/hiv-tests-advantages-disadvantages_1.pdf.
4 Centers for Disease Control and Prevention. 2017. Technical Update: Use of the Determine HIV 1/2 Ag/Ab combo test with serum or plasma in the laboratory algorithm for HIV diagnosis.
5 Centers for Disease Control and Prevention. CDC-Funded HIV Testing: United States, Puerto Rico, and the U.S. Virgin Islands, 2017. https://www.cdc.gov/hiv/pdf/library/reports/cdc-hiv-funded-hiv-testing-report-2017.pdf.