Today, 1.2 million people are infected with the HIV virus, and nearly 250,000 don’t know it.

Introducing a major advance in the fight against HIV/AIDS.

The first in-home oral HIV test.
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OraQuick

The First In-Home Oral HIV Test
FDA Approved for Sale Over-the-Counter.

For the first time ever, individuals have over-the-counter access to the same oral HIV test healthcare professionals have relied on for years.

The OraQuick In-Home HIV Test offers people clinically proven results in just 20 minutes in the comfort and privacy of their homes. It empowers them to take the critical first step in learning their HIV status. OraQuick was approved by the FDA on July 3, 2012 for use by adults 17 years of age or older.

**Trusted**
- The OraQuick In-Home HIV Test is the same test used by healthcare professionals since 2004 under the name OraQuick ADVANCE® Rapid HIV-1/2 Test which:
  - Sold more than 20 million tests since 2004
  - Is FDA approved and the first CLIA waived HIV test

**Fast**
- Results in 20 minutes

**Oral**
- Oral fluid swab
- No blood required

**Confidential**
- In-home testing
- 24/7 Support Center
  - Bilingual (English/Spanish)
  - HIPAA-compliant

HIV: Human Immunodeficiency Virus

HIPAA: Health Insurance Portability and Accountability Act
A Support Center, staffed with a team of trained professionals available 24/7, provides information on HIV/AIDS, the OraQuick In-Home HIV Test, and referrals to follow-up care.

- Toll-free support available 24/7 at 1-866-436-6527.
- Staffed with representatives trained in accordance with CDC Guidelines for HIV Counseling, Testing and Referral Services.
- Provides information on HIV/AIDS and the OraQuick in-home test.
- Offers help to interpret and understand test results.
- Provides referrals to follow-up support and care.
- Bilingual: English and Spanish-language capability.

In addition to the toll-free Support Center, a comprehensive website provides another way to access information including:

- HIV/AIDS education.
- Access to extensive referral database to connect patients to local support and care including:
  - CDC NPIN (National Prevention Information Network) database with over 8,000 HIV testing, counseling and care centers throughout the United States.
  - Supplemented with resources from the HIV Medicine Association, an organization of medical professionals who practice HIV medicine. HIVMA promotes quality HIV care and advocates for policies that ensure a comprehensive and humane response to the AIDS pandemic.
- Option to purchase online through OraQuick.com or participating retailers.
OraQuick

Designed for Consumer Use.

Each test kit includes step-by-step instructions.

- People should carefully follow test directions provided with the test kit to get an accurate result.
- For further assistance with usage directions, a product demonstration video is available on OraQuick.com.

Prepare the Test Kit.

- Read Directions
- Open Test Tube
- Open Test Stick

Perform the Test.

- Swipe Gums
- Place the Test Stick in Test Tube & Start Timing
- Wait 20 Minutes

Read the Results.

- Negative
  - If there is ONE LINE next to the “C” and NO line next to the “T,” your test result is negative.
  - If test did not work or results are unclear, call OraQuick Support Center (1-866-436-6527)

- Positive
  - If there are TWO LINES, one next to the “C” and any line next to the “T,” even a faint one you may have HIV.

Follow Up if Needed.

- A positive OraQuick In-Home HIV Test result must be confirmed by a doctor, clinic or healthcare professional
- Questions? Call 1-866-436-6527 or go to OraQuick.com
Rather than standard blood testing, OraQuick uses an oral swab. Just like blood, oral fluid (mucosal transudate) collected by swabbing the gums, also contains antibodies produced in response to viral infection. If present, the OraQuick Test detects these HIV antibodies in the oral fluid.

The OraQuick test device operating principle.

Using a lateral flow process, a sample specimen is wicked up by the flat pad of the device and transferred to the cellulose membrane. Human antibodies and HIV antibodies (if present) bind to the colloidal gold particles.

Control and test lines designed to make interpretation of results easy.

Colloidal gold particles containing HIV antibodies bind to the HIV antigen "T" line forming a visible red band. Colloidal gold particles containing Human antibodies bind to the Anti-Human Antibodies "C" line forming a visible red band. Any remaining colloidal gold particles are captured and retained by the absorbent pad.
Preference and Benefit of Oral Testing.

OraQuick increases the number of people who benefit from knowing their HIV status.

Less than 54% of patients who took non-rapid tests in a professional setting actually followed up to receive their test results. The fast results and confidential in-home testing environment of the OraQuick test increased the receipt of HIV test results to 98.9%.

98.9% of people received test results with in-home rapid testing compared to 54% who were tested using non-rapid laboratory tests.


Awareness is Critical in the Fight Against HIV.

In the U.S. HIV infection continues to be a significant health issue.

- 1.2 million people are infected with HIV (prevalence).
- More than 47,000 diagnosed with HIV infection each year (incidence).
- More than 236,000 people infected with HIV are unaware of their HIV status.
- These individuals are responsible for up to 70% of new HIV infections each year.¹

Access to HIV testing helps reduce the spread of HIV.

- Testing identifies more HIV-positive individuals who are unaware of their HIV status.
- Increased awareness helps prevent transmission from these individuals to uninfected individuals.²

Since 2006 CDC has recommended HIV testing annually for all Americans, and more often for those at higher risk.

"With an estimated one out of five HIV-positive Americans unaware of their infection, increased opportunities for testing are critical."

– Department of Health & Human Services, Centers for Disease Control and Prevention, Rapid HIV Testing


Individuals in the U.S. Unaware of Their Status (Thousands)

1. Hall HI, Holtgrave D, Maulsby C. HIV transmission rates from persons living with HIV who are aware and unaware of their infection. AIDS. 2012;26(7):893-896.
OraQuick Helps Generate Awareness and Overcome the Barriers to Testing.

### Common barriers to testing.
- Fear of a positive HIV result.
- Complacency to test for HIV given advancements in drug treatments extending life expectancy.
- Lack of privacy and confidentiality are additional deterrents to seeking HIV testing from healthcare professionals.
- Busy lifestyles are often an excuse for not getting tested.
- Denial that an individual behavior could increase the risk of acquiring HIV.

### OraQuick In-Home HIV Test addresses the unmet need to reach more people.

OraQuick is designed to address many of the key barriers that discourage individuals from getting tested. This should impact both the total number of people who undergo testing, and the total number of new HIV positive people who are identified as a result.

- 8,391 HIV-positive individuals projected to be identified for every 1 million tested in a risk-benefit analysis of the OraQuick In-Home HIV Test.\(^1\)\(^2\)

### Early detection and intervention provide life-saving benefits.
- Early detection enables HIV-infected individuals to live longer, healthier lives enabling the start of antiretroviral therapy before symptoms develop.
- Knowledge of one’s HIV status enables infected individuals to take the necessary precautions to guard against spreading the disease to their sexual partners.

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1. OraQuick® In-Home HIV Test Package Insert.
OraQuick

Thoughtfully Designed and Carefully Evaluated.

Performance validated in clinical studies.

In a clinical study, 4,999 people who were unaware of their HIV status were given the OraQuick In-Home HIV Test to take home and use. The researchers compared the OraQuick In-Home HIV Test results with laboratory test results performed by a trained professional. The laboratory based results showed that 96 people were HIV-positive and 4,903 people were HIV-negative. The comparison of results was as follows:

- 99.98% of HIV-negative subjects (4902 out of 4903) were able to obtain a correct test result.
- 91.67% of HIV-positive subjects (88 out of 96) were able to obtain a correct test result.
- 98.9% of all subjects completed the test and obtained a valid result.

Proven performance by untrained users:

- Specifically designed and validated for in-home use
  - 99.9% specificity (4902/4903 [95% CI: 99.89%-100.00%])
  - 91.67% sensitivity (88/96 [95% CI: 84.24%-96.33%])

Studies show our product labeling demonstrates high rates of comprehension for all messages across a broad range of literacy levels.

2010 Label Comprehension Study:

- Questions on self-selection: 98.8%
- Questions on performing the test: 97.2%
- Questions on interpretation of the test results: 97.2%

1. OraQuick® In-Home HIV Test Package Insert.

HIPAA: Health Insurance Portability and Accountability Act
Warnings and Precautions.

- A positive result with this test does not mean that you are definitely infected with HIV, but rather that additional testing should be done in a medical setting.

- A negative result with this test does not mean that you are definitely not infected with HIV, particularly when exposure may have been within the previous 3 months.

- If your test is negative and you engage in activities that put you at risk for HIV on a regular basis, you should test regularly.

- This product should not be used to make decisions on behavior that may put you at increased risk for HIV.

Please direct your patients to OraQuick.com or our Support Center (1-866-436-6527) for complete resources and information.