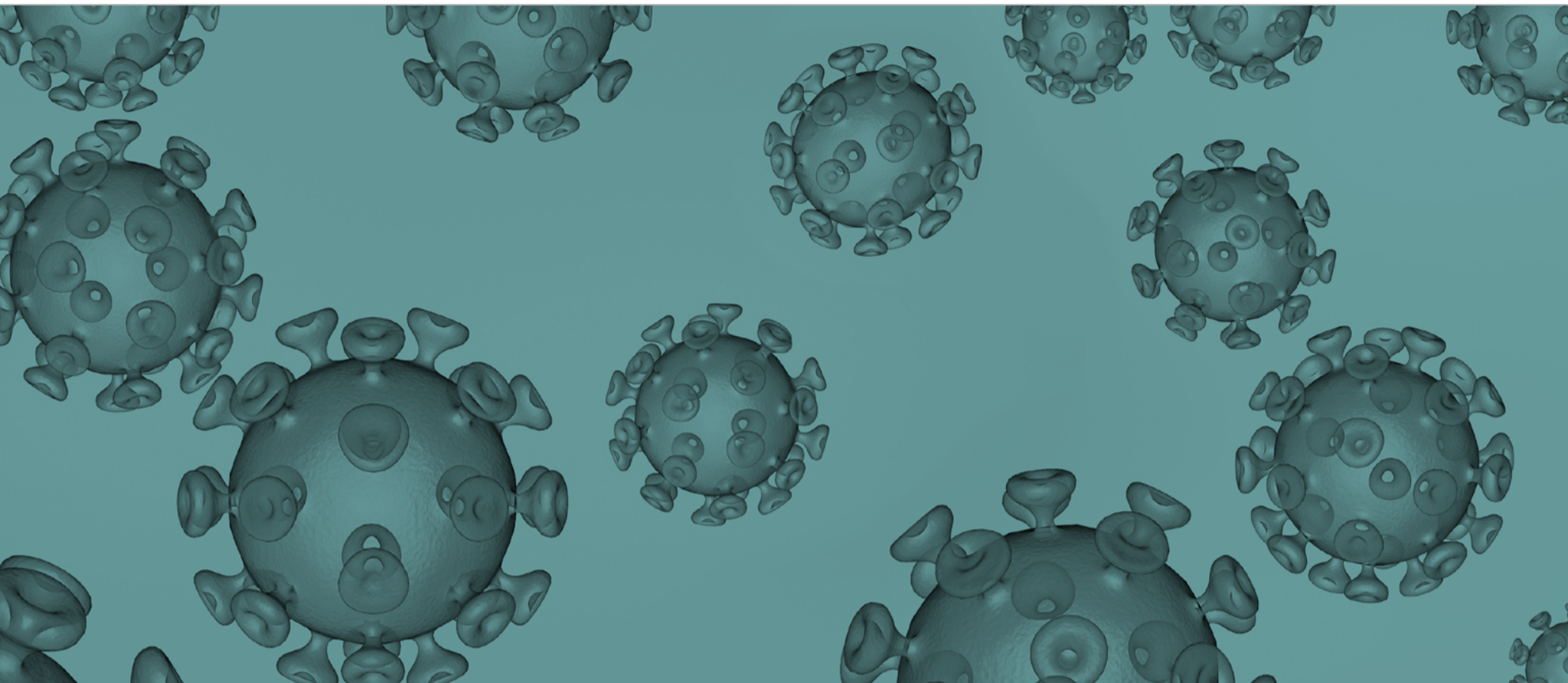




Alere Determine™ HIV-1/2 Ag/Ab Combo



HIV by the Numbers

14%
of people with HIV
don't know



the 14% unaware of their infection are responsible for **54-70%**
 of new HIV infections

- An estimated 1.2 million persons in the United States are currently living with HIV infection.
- Approximately 14% of individuals living with HIV infection are unaware of their positive status.¹
- In the U.S., approximately 50,000 people in the U.S. become infected with HIV each year.²
- 54-70% of new infections are transmitted by individuals who are unaware of their HIV positive status.³

TAP HERE TO SEE THE PRODUCT

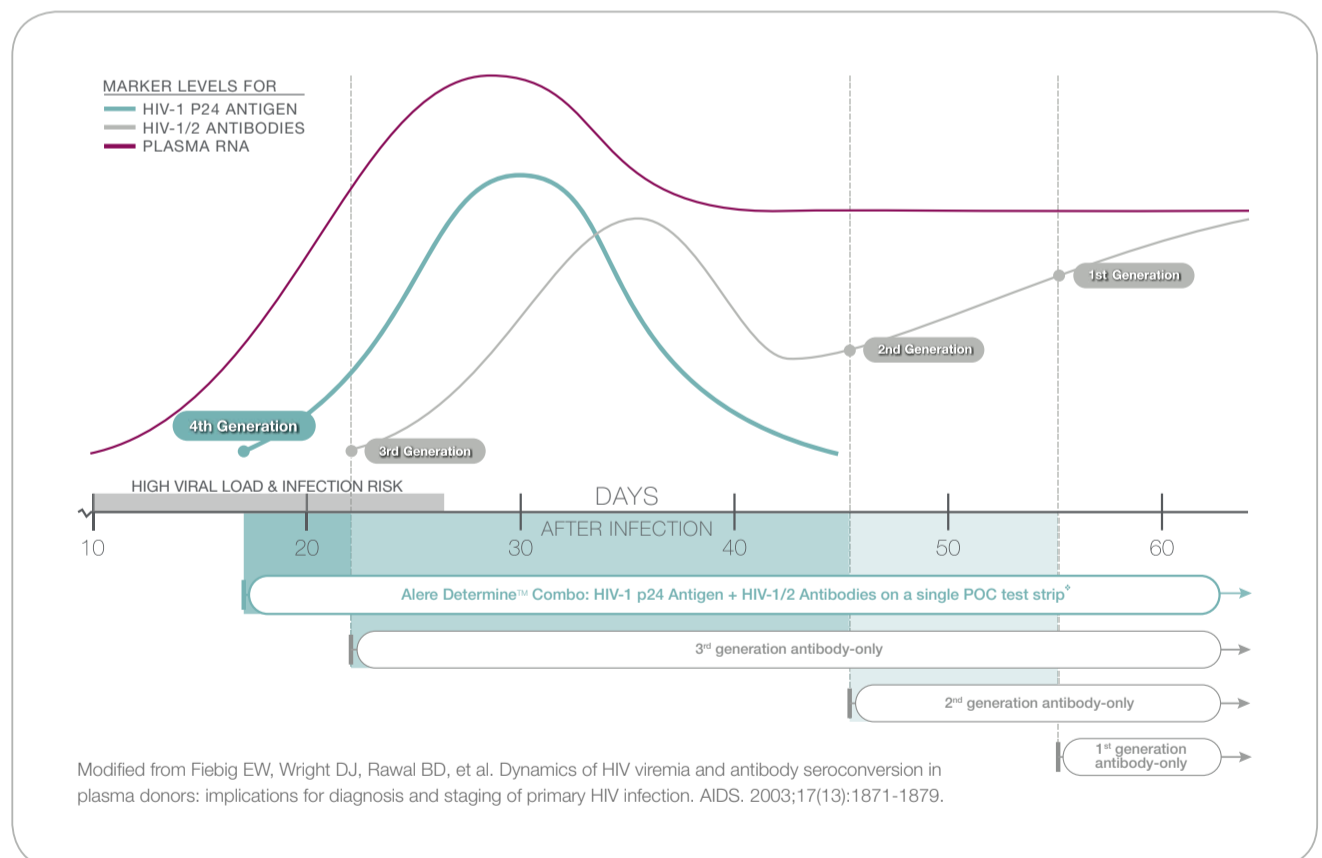


HIV Testing Guidelines

The overall benefits of screening for HIV infection in adolescents, adults, and pregnant women in the general population as well as high risk individuals are substantial.

- The United States Preventive Services Task Force (USPSTF) recommends that clinicians screen for HIV infection in adolescents and adults aged 15 to 65 years. Younger adolescents and older adults who are at increased risk should also be screened.⁴
- The USPSTF recommends that clinicians screen all pregnant women for HIV, including those who present in labor who are untested and whose HIV status is unknown.
- Earlier generation HIV tests detect the presence of antibodies produced by the body to fight HIV. Detectable antibodies usually develop within 2-8 weeks after infection, but may take longer; the period after initial infection with HIV before detectable antibodies develop is called the “window period”.⁵
- The CDC has proposed a new HIV diagnostic algorithm that recommends use of 4th generation EIA (Instrument-based) tests for screening for HIV as published studies have shown that the highest rate of HIV transmission occurs during a period of p24 antigenemia that precedes the development of detectable antibodies to HIV.^{6,7}

HIV Laboratory Markers⁸



Detecting HIV Earlier

In August 2013, the FDA approved Alere Determine™ HIV-1/2 Ag/Ab Combo and granted CLIA Waiver for fingerstick whole blood in December 2014. This is the first 4th generation rapid test approved to distinguish results for HIV-1 p24 antigen and HIV antibodies in a single test. Alere Determine™ HIV-1/2 Ag/Ab Combo is a 4th generation test that has the ability to detect HIV sooner than 2nd and 3rd generation tests. Identifying HIV infection early, during the most infectious stage offers significant benefits, particularly in high risk populations such as men who have sex with men and injecting drug users.



- Rapid detection helps to get patients into effective care and treatment earlier.
- Detecting HIV sooner enables health care providers to diagnose HIV infection earlier allowing individuals to seek medical care sooner.
- Individuals who are unaware of their infection are 3.5 times more likely to transmit the virus to someone else.⁹
- The USPSTF found convincing evidence that identification and treatment of HIV infection may significantly reduce risk for progression to AIDS, AIDS-related events, and death in individuals with immunologically advanced HIV.⁴
- The USPSTF found convincing evidence that the use of ART (antiretroviral therapy) is associated with a substantially decreased risk for transmission from HIV-positive persons to uninfected heterosexual partners.⁴
- Convincing evidence also shows that identification and treatment of HIV-positive pregnant women dramatically reduces rates of mother-to-child transmission.⁴

“This test helps diagnose HIV infection at an earlier time in outreach settings, allowing individuals to seek medical care sooner.”¹⁰

FDA Representative

Additional Background



1.1 Million

Since the first cases of AIDS were reported in 1981, more than 1.1 million persons have been diagnosed and nearly **650,000** have died from the condition in the United States.

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- More than half (54%) of U.S. adults, aged 18-64, reported ever having been tested for HIV, including 22% who report being tested in the last year.¹²
- Many people with HIV are diagnosed late in their illness; in 2010, 32% received an AIDS diagnosis within one year of testing HIV positive.¹²
- Two types of HIV have been identified, HIV-1 and HIV-2. HIV-1 is responsible for most HIV infections throughout the world. HIV-2 is found primarily in West Africa; however, cases of HIV-2 infection have been reported in North America and Europe.

For more information, visit AlereHIV.com/US or call 877.441.7440

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