



## **Alere™ HIV Combo Test Receives WHO Prequalification**

*Broadened Access to a New 4<sup>th</sup>-generation Test in Resource-limited Countries Increases Opportunities to Meet Ambitious New Goals for Screening and Linkage to Care*

**WALTHAM, Mass.**, July 13, 2016 – Alere (NYSE: ALR), a global leader in rapid diagnostics, today announced that its Alere™ HIV Combo, a rapid point-of-care fourth-generation test that detects both HIV-1/2 antibodies and the HIV-1 p24 antigen, has been awarded World Health Organization (WHO) prequalification, making it available for public sector procurement in resource-limited countries.

Conventional second- and third-generation HIV rapid tests can only detect antibodies against HIV which may not appear until three weeks after infection.<sup>1</sup> Alere HIV Combo detects not only these antibodies but can also detect free HIV-1 p24 antigen which can appear up to 7.7 days earlier.<sup>1</sup> For global HIV programmes this means the potential to increase case finding particularly in key high risk populations that have been disproportionately affected by HIV.

“WHO’s prequalification of the Alere HIV Combo reflects our commitment to making high-quality point-of-care HIV diagnostics available in areas with the greatest burden of HIV infection,” said Avi Pelossof, Alere Global President of Infectious Disease. “The first step in eradicating AIDS is identifying as many individuals as possible infected with HIV and linking them to care. Now, even more healthcare workers will be able to accomplish this with a new 4<sup>th</sup> generation HIV point-of-care test available today.”

“We can’t meet UNAIDS’ 90-90-90 target unless we achieve the first goal of ensuring that people with HIV know their status, and this requires helping healthcare workers in developing countries make every testing opportunity count,” said Collins Odhiambo, Ph.D., who evaluated the Alere HIV Combo at the Kenya Medical Research Institute (KEMRI). “The Alere HIV Combo brings point-of-care diagnosis directly to people at greatest risk for infection – including those in remote areas – and makes screenings as impactful as possible by enabling healthcare workers to identify highly infectious individuals, and link them to treatment.”

### **About UNAIDS’ 90-90-90 Goals**

In 2014, the Joint United Nations Programme on HIV/AIDS (UNAIDS) established an ambitious target designed to drive progress towards ending the AIDS epidemic: by 2020, 90 percent of all people living with HIV will know their HIV status, 90 percent of all people with diagnosed HIV infection will receive sustained antiretroviral therapy, and 90 percent of all people receiving antiretroviral therapy will have viral suppression.<sup>2</sup> Alere supports these important goals with a portfolio of diagnostic solutions for the complete cascade of HIV care

from initial screening and diagnosis to staging and ongoing monitoring. For more information on Alere's HIV solutions, please visit <http://www.alerehiv.com>.

Prior to WHO prequalification, the product received CE certification on January 29, 2015. For more product information, please visit <http://www.alerehiv.com/ww/home/hiv-screening/alere-hiv-combo/introduction.html>.

Note: The Alere HIV Combo is not approved for sale in the U.S. Alere Determine™ HIV-1/2 Ag/Ab Combo is CLIA-waived and available in the U.S.

### **About the Alere HIV Combo**

The Alere HIV Combo is a new 4<sup>th</sup> generation HIV point-of-care test that detects both free HIV 1-p24 antigen and HIV 1/2 antibodies in 20 minutes. HIV-1 p24 can appear up to 7.7 days before the appearance of antibodies and can help further reduce the window period. By detecting HIV infection earlier, the Alere HIV Combo enables increased case finding at a time when individuals are up to 10 times more likely to transmit HIV than individuals with established infection.<sup>3</sup>

### **About Alere**

Alere believes that when diagnosing and monitoring health conditions, **Knowing now matters.**™ Alere delivers on this vision by providing reliable and actionable information through rapid diagnostic tests, enhancing clinical and economic health outcomes globally. Headquartered in Waltham, Mass., Alere focuses on rapid diagnostics for infectious disease, cardiometabolic disease and toxicology. For more information on Alere, please visit <http://www.alere.com>.

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<sup>1</sup> 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 2003.

<sup>2</sup> The Joint United Nations Programme on HIV/AIDS (UNAIDS). 90-90-90: An ambitious treatment target to help end the AIDS epidemic. Available online at [http://www.unaids.org/sites/default/files/media\\_asset/90-90-90\\_en\\_0.pdf](http://www.unaids.org/sites/default/files/media_asset/90-90-90_en_0.pdf).

<sup>3</sup> Wawer MJ, Gray RH., Sewankambo NK et al. Rates of HIV-1 transmission per coital act by-stage of HIV-1 infection in Rakai, Uganda. Journal of Infectious Disease 2005;191: 1403-9.