U.S. Food and Drug Administration Grants CLIA Waiver for Alere Determine™ HIV-1/2 Ag/Ab Combo Test

CLIA waiver expands screening opportunities, enabling healthcare providers to quickly and accurately diagnose HIV infection and initiate treatment

WALTHAM, Mass., Dec. 9, 2014 – Alere Inc. (NYSE: ALR), a global leader in rapid diagnostic tests, today announced that the U.S. Food and Drug Administration (FDA) has granted CLIA (Clinical Laboratory Improvement Amendments) Waiver for the Alere Determine™ HIV-1/2 Ag/Ab Combo test. Until now, the test has been available for sale in the United States to health facilities and laboratories licensed to conduct tests of moderate complexity. With this approval, the test will now be available for use in physician offices, clinics and other public health settings as well.

Alere Determine HIV 1-2 Ag/Ab Combo was FDA-approved in August 2013 as the first fourth-generation, rapid point-of-care test that detects both HIV-1/2 antibodies and free HIV-1 p24 antigen. Due to its capability to detect p24 antigen, which can appear in only days after infection and before the HIV antibody is detectable, Alere Determine HIV-1/2 Ag/Ab Combo may detect HIV infection earlier in the course of the disease. Earlier detection allows healthcare providers to improve clinical outcomes through earlier diagnosis and treatment of patients who test positive for HIV.

“CLIA Waiver of the Alere Determine HIV-1/2 Ag/Ab Combo will help facilitate accurate and early detection of HIV, which is critical to stemming the spread of HIV/AIDS in the United States, and will have a positive economic impact by bringing a critical healthcare service nearer to patients,” said Avi Pelossof, Global President of Infectious Disease at Alere. “Broadening the test’s availability to laboratories, physician offices, clinics and other public health settings, advances Alere’s commitment to delivering reliable and actionable information through rapid diagnostics.”

“I’m excited to learn that Alere Determine HIV-1/2 Ag/Ab Combo has been granted CLIA waiver and will be available for broader use in HIV screening,” said Eugene Martin, Ph.D., Professor of Pathology & Laboratory Medicine at Rutgers University – Robert Wood Johnson Medical School and the Co-Director of NJ HIV, the Rapid HIV Test Support Program. “The promise of a fourth-generation, rapid HIV test is one that we all look forward to since it will allow screening locations

to potentially identify early HIV infections, and to steer those who are most at risk of infecting others into treatment sooner."

According to the Centers for Disease Control and Prevention (CDC), there are approximately 1.1 million Americans living with HIV, and an estimated 180,900 (15.8%) whose infections have not been diagnosed. In 2011, the CDC estimated that there were 49,273 newly infected people with the virus in the United Sates, indicating that HIV remains a serious health problem. HIV testing is essential for healthcare and social services to improve the quality of life and survival for persons who have HIV.[i]

For more information, visit www.AlereHIV.com/US.

About Alere
Because **Knowing now matters™**, Alere delivers reliable and actionable information through rapid diagnostic tests, resulting in better clinical and economic healthcare 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 www.alere.com.

###

Media Contact:
Jackie Lustig
Director, Corporate Communications
Jackie.lustig@alere.com
781.341.4009

Investor Contact:
Juliet Cunningham
Vice President, Investor Relations
ir@alere.com
858.805.2232

[i] Centers for Disease Control and Prevention, HIV in the United States: *At A Glance,* http://www.cdc.gov/hiv/statistics/basics/ataglance.html.