



Alere Receives FDA CLIA Waiver for Alere™ i Influenza A & B Test

*First-ever CLIA-waived molecular flu test delivers lab-accurate results
at the point of care in less than 15 minutes*

WALTHAM, Mass., Jan. 7, 2015 – 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 waiver for the Alere™ i Influenza A & B test, the only molecular test to detect and differentiate influenza A and B virus in under 15 minutes. Alere i Influenza A & B is the first-ever molecular test to receive a CLIA (Clinical Laboratory Improvement Amendments) waiver, which allows for broad use by healthcare providers, ranging from hospitals and physician offices to clinics and other healthcare settings.

“This milestone greatly expands the availability of molecular testing to a wide range of healthcare settings during this influenza season,” said Avi Pelossof, Global President of Infectious Disease at Alere. “By making lab-accurate, actionable results available at the point of care, Alere i empowers healthcare providers to quickly identify and treat people with influenza – improving patients’ clinical outcomes, protecting their communities, and reducing healthcare costs.”

The Alere i test was cleared for marketing by the FDA in June 2014, and was made available in September for health facilities and laboratories licensed to conduct tests of moderate complexity under the CLIA program. With CLIA waiver, the test will be available in a significantly broader range of healthcare settings.

About the Alere i Influenza A & B test

Molecular testing involves the extraction and analysis of DNA or RNA strands to detect sequences associated with viral and bacterial causes of infections. Alere i Influenza A & B is the first molecular diagnostic test that delivers actionable, lab-accurate results in less than 15 minutes on a user-friendly platform. Unlike polymerase chain reaction (PCR) testing, Alere’s proprietary Molecular. In Minutes™ (MIM) isothermal nucleic acid amplification technology (iNAT) does not require lengthy and complex thermo cycling or DNA purification, and can therefore deliver PCR-caliber results more quickly – and in a broad range of settings.

The clinical performance of Alere i Influenza A & B was established in a multi-center study conducted in the U.S., in which 630 nasal swab specimens, were evaluated with Alere i, and compared to an FDA cleared Real-Time PCR (RT-PCR) assay.

Additional tests on the Alere i platform are currently in development. Alere recently filed a 510k application for Strep A, and the company is planning to initiate clinical trials for a respiratory syncytial virus (RSV) test during the current respiratory season.

More information about the Alere i test and flu diagnosis is available at <http://alere-i.com/us/>.

About Influenza

Each year, a combination of influenza A and B virus strains circulate within the United States. The burden of influenza is currently estimated to be 25-50 million cases per year. The disease and its complications cause as many as 150,000 hospitalizations and 3,000 - 49,000 deaths annually. Influenza also poses a significant economic burden including medical care expenses and loss of productivity. Rapid diagnostics with increased sensitivity are essential for the reliable detection of influenza A and B, enabling healthcare professionals to make immediate, effective treatment decisions and prevent unnecessary prescribing of antibiotics and antiviral medications. Rapid diagnosis of influenza can help reduce length of hospital stays, secondary complications and the cost of hospital care, and allow effective implementation of infection control measures.^{1,2,3}

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.

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¹ U.S. Centers for Disease Control and Prevention (CDC). Key facts about influenza (flu) & flu vaccine. <http://www.cdc.gov/flu/keyfacts.htm>.

² World Health Organization. Influenza. <http://www.who.int/immunization/topics/influenza/en/index.html>.

³ Rapid influenza diagnostic tests increased antiviral use. *J Ped Infect Dis* (2013) doi: 10.1093/jpids/pit071. First published online: November 13, 2013.