Alere Receives FDA Clearance for Alere™ i Influenza A and B Test

First-ever Platform to Deliver Highly Accurate, Molecular Results in Under 15 Minutes

WALTHAM, Mass., June 16, 2014 – Alere Inc. (NYSE: ALR), a leading global provider of point-of-care rapid diagnostic and health information solutions, today announced that it has received clearance from the U.S. Food and Drug Administration (FDA) for the Alere™ i Influenza A & B test, the first and only molecular test to detect and differentiate influenza A and B virus in less than 15 minutes.

"By providing the speed of a rapid test with molecular technology, Alere i delivers clinically meaningful and actionable results to clinicians – enabling them to treat patients more quickly and appropriately," said Avi Pelossof, Alere Global President of Infectious Disease.

The clinical performance of Alere i Influenza A & B was established in a multi-center, prospective study conducted at eight U.S. trial sites during the 2012-2013 flu season, in which 585 prospective nasal swab specimens, collected from patients presenting with influenza-like symptoms, were evaluated with Alere i, and compared to viral culture. All specimens generating discrepant results between the Alere i Influenza A & B test and viral culture were tested using an FDA cleared RT-PCR assay to confirm influenza status.

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. Alere i tests for Strep A, *C. difficile*, respiratory syncytial virus (RSV) and chlamydia / gonorrhea are currently in development.

Alere i Influenza A & B was launched earlier this year in Europe. Clinical trials for CLIA waiver of Alere i Influenza A & B have been completed and the Company expects to submit a CLIA waiver filing to the FDA in early Q3 2014. Clinical trials for Strep A have also been completed and the Company expects to file for 510k clearance in Q3 2014.

For more information on Alere i Influenza A & B, go to www.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, and 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

By developing new capabilities in near-patient diagnosis, monitoring and health information technology, Alere enables individuals to take charge of improving their health and quality of life at home. Alere's global leading products and services, as well as its new product development efforts, focus on infectious disease, toxicology, cardiology and diabetes. Alere is headquartered in Waltham, Massachusetts. For more information regarding Alere, please visit www.alere.com.

# # #

Media Contact:
Jackie Lustig
Director, Corporate Communications
Jackie.Lustig@alere.com
781.314.4009

[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.