Alere Receives FDA Clearance for Alere™ i Influenza A & B 2 Rapid Molecular Test

Latest testing application on innovative Alere i molecular diagnostic platform detects influenza infections in as little as 5 minutes

WALTHAM, Mass., October, 2, 2017 – Alere Inc. (NYSE: ALR), a global leader in rapid diagnostics, today announced that its Alere™ i Influenza A & B 2 test has received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) for the detection of influenza A and B infection in children and adults.

Alere i Influenza A & B 2 is a second-generation rapid molecular assay, which delivers lab accurate results in less time, with the ability to report a positive result in as little as 5 minutes. This test will provide greater convenience with the addition of room temperature storage and reduced warm-up time for transport media samples. Alere i Influenza A & B 2 also offers increased sample flexibility with nasopharyngeal swabs now validated for direct use, as well as, in transport media.

Alere will shortly submit an application for CLIA (Clinical Laboratory Improvement Amendments) waiver of the Alere i Influenza A & B 2 test. Alere i testing applications have previously been CLIA-waived for Influenza A & B, Strep A and RSV.

“Our innovative Alere i platform leads the way in the rapid molecular segment with thousands of placements in hospitals, clinics, physician offices and other point of care settings. With this latest enhancement we now can offer ‘early call out’ of positive results on all three available applications, Alere i Influenza A & B 2, Alere i Strep A and Alere i RSV. In acute care settings, every minute counts when assessing symptomatic patients. 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 2 was established in a multi-center, prospective clinical study conducted at ten US trial sites during the 2016-2017 respiratory season, in which 1074 prospective nasal or nasopharyngeal swab specimens, collected from patients with influenza-like symptoms, were evaluated with Alere™ i, and compared to an FDA-cleared real-time Polymerase Chain Reaction (RT-PCR) test.

Alere has also expanded some of the features on the Alere i instrument with the introduction of bi-directional connectivity and an optional QC lockout function, to prevent testing of patient samples if QC testing requirements are not met, enhancing overall quality assurance.

The Alere i molecular platform was initially cleared for marketing by the FDA for the detection and differentiation of influenza A and B virus in June 2014, with Alere i Strep A receiving FDA clearance in March 2015 and Alere i RSV receiving clearance in October

2016. The Alere i Influenza A & B 2 test will be available for use in hospitals in time for the 2017-2018 respiratory season.

For more information on Alere i Influenza A & B 2, go to www.alere.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

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 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.