Alere Receives FDA CLIA Waiver for Alere™ i RSV Rapid Molecular Test

First molecular test to detect RSV infection in 13 minutes or less now widely available in a broad range of healthcare settings

WALTHAM, Mass., March 7, 2017 – Alere Inc. (NYSE: ALR), a global leader in rapid diagnostics, today announced that its Alere™ i RSV test has been granted CLIA (Clinical Laboratory Improvement Amendments) waiver by the U.S. Food and Drug Administration (FDA) for the detection of RSV (*respiratory syncytial virus)* infection in children and adults. The Alere i RSV test, which was cleared for marketing by the FDA in August 2016, is the first molecular test that can be used at the point-of-care to detect RSV in 13 minutes or less.

With CLIA waiver, the Alere i RSV test will be available in physician offices, hospital emergency rooms and walk-in clinics throughout the United States.

“Our innovative Alere i platform now offers the key trio of respiratory assays for rapid molecular detection of RSV, Influenza A & B and Strep A in a broad range of healthcare settings,” said Avi Pelossof, Alere Global President of Infectious Disease. “Healthcare providers can now deploy the power of rapid molecular testing to quickly and accurately differentiate these potentially serious infections and link patients to the appropriate treatment.”

In acute care settings, every minute counts when assessing symptomatic patients. Arming healthcare personnel with a simple-to-use, point-of-care RSV test that offers speed and molecular accuracy facilitates early and appropriate supportive care, the avoidance of unnecessary antibiotic treatment, and the rapid initiation of infection control measures to help control the spread of RSV, a highly contagious and potentially life-threatening infection.

“As of February 28, 2017, we have installed approximately 7,500 Alere i instruments across the globe. Achieving a third CLIA-waived assay on the platform demonstrates our ability to successfully bring transformational new technology to market and we look forward to further expanding the assay content and disease states of the Alere i platform,” said Pelossof.

About the Alere i RSV test

Alere i RSV detects the RSV virus in nasopharyngeal (NP) swab samples using Alere’s proprietary Molecular In Minutes™ isothermal nucleic acid amplification technology (iNAT). Alere i RSV is significantly faster than conventional polymerase chain reaction (PCR) tests delivering results in 13 minutes or less.

In clinical performance studies, the overall sensitivity and specificity of Alere i RSV using direct NP swab samples was 98.6% and 98.0%, respectively, versus PCR. With Viral Transport Media (VTM) samples, the sensitivity and specificity of Alere i RSV was 98.6% and 97.8%, respectively, versus PCR.

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.

About Respiratory Syncytial Virus (RSV)
RSV is a respiratory virus that infects a person's lungs and breathing passages.[1] It is the most common cause of bronchiolitis (inflammation of the small airways in the lung) and pneumonia in children under one year of age.[2] In the U.S., almost 58,000 children under the age of five with RSV infection are hospitalized annually.[3] Premature infants and young children with congenital heart or chronic lung disease or with compromised immune systems due to a medical condition or medical treatment are at highest risk for severe cases of RSV, and may require mechanical ventilation.[2,4] Adults aged 65 and older are also at increased risk of severe disease.[2] In the U.S., RSV leads to 177,000 hospitalizations and 14,000 deaths among adults older than 65 years annually.[5,6]

Because there is currently no treatment for RSV, infection control strategies are focused on reducing transmission.

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.

Cautionary Statement Regarding Forward-Looking Statements

This communication contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding: the expected benefits of the Alere™ i RSV test, such as facilitation of supportive care, avoidance of unnecessary treatments and rapid initiation of infection control measures to help control the spread of RSV; the further expansion of the assay content and disease states of the Alere I platform. Readers can identify these statements by forward-looking words such as "may," "could," "should," "would," "intend," "will," "expect," "anticipate," "believe," "estimate," "continue," "goal" or similar words. A number of important factors could cause actual results of Alere and its subsidiaries to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, (i) the anticipated benefits of the Alere i platform may not be realized, (ii) the Company may be unable to expand the assay content and disease states of the Alere i platform due to research and development challenges, failure to obtain the required regulatory approvals or other reasons; and (iii) the risk factors detailed in Part I, Item 1A, "Risk Factors," of our Annual Report on Form 10-K for the fiscal year ended

December 31, 2015 (as filed with the SEC on August 8, 2016) and other risk factors identified herein or from time to time in our periodic filings with the SEC. Readers should carefully review these risk factors, and should not place undue reliance on our forward-looking statements. These forward-looking statements are based on information, plans and estimates at the date of this communication. We undertake no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes.

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[1] U.S. Centers for Disease Control and Prevention (CDC). Respiratory Syncytial Virus Infection (RSV). December 2014. Available at: https://www.cdc.gov/rsv/.
[2] CDC. Respiratory Syncytial Virus Infection (RSV). Infection and incidence. December 2014. Available at: https://www.cdc.gov/rsv/about/infection.html.
[3] CDC. Respiratory Syncytial Virus Circulation in the United States, July 2012–June 2014. *MMWR*. 2014; 62:141-4.
[4] CDC. Respiratory Syncytial Virus Infection (RSV). Symptoms and care. December 2014. Available at: https://www.cdc.gov/rsv/about/symptoms.html.
[5] Falsey AR, Hennessey RN, Formica MA, Cox C, Walsh EE. Respiratory syncytial virus infection in elderly and high-risk adults. *New Engl J Med*. 2005;352(17):1749-59.
[6] CDC. Respiratory Syncytial Virus Infection (RSV). Trends and Surveillance. March 2016. Available at: https://www.cdc.gov/rsv/research/us-surveillance.html.