



## **Alere Receives FDA Clearance for Alere™ i RSV Rapid Molecular Test**

*Latest testing application on innovative Alere i molecular diagnostic platform detects RSV infections in 13 minutes or less*

**WALTHAM, Mass., August 19, 2016** – Alere Inc. (NYSE: ALR), a global leader in rapid diagnostics, today announced that its Alere™ i RSV test has received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) for the detection of RSV infection in children and adults. Following Alere™ i Influenza A & B and Alere™ i Strep A, Alere i RSV is the latest testing application on the Alere i platform and is the first molecular test that can be used at the point-of-care to detect RSV in 13 minutes or less.

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

“Our innovative Alere i platform now allows for the rapid molecular detection of RSV, Influenza A & B and Strep A,” said Avi Pelossof, Alere Global President of Infectious Disease. “The availability of clinically meaningful results in an actionable timeframe empowers clinicians to deliver prompt and appropriate patient care. We are excited to continue our ground-breaking innovation on this platform with multiple new analytes progressing well through product development.”

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 this highly contagious and potentially life-threatening infection.

### **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. The Alere i RSV test will be available for use in hospitals in time for the 2016-2017 respiratory season.

### **About Respiratory Syncytial Virus (RSV)**

RSV is a respiratory virus that infects a person's lungs and breathing passages.<sup>1</sup> 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.<sup>2</sup> In the U.S., almost 58,000 children under the age of five with RSV infection are hospitalized annually.<sup>3</sup> 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.<sup>4</sup> 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.**<sup>TM</sup> 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](http://www.alere.com).

# # #

### **Media Contact:**

Jackie Lustig  
Senior Director, Corporate Communications  
[pr@alere.com](mailto:pr@alere.com)  
781 314 4009

### **Investor Relations Contact:**

Juliet Cunningham  
Vice President, Investor Relations  
[ir@alere.com](mailto:ir@alere.com)  
858 805 2232

---

<sup>1</sup> U.S. Centers for Disease Control and Prevention (CDC). Respiratory Syncytial Virus Infection (RSV). December 2014. Available at: <https://www.cdc.gov/rsv/>.

<sup>2</sup> CDC. Respiratory Syncytial Virus Infection (RSV). Infection and Incidence. December 2014. Available at: <https://www.cdc.gov/rsv/about/infection.html>.

<sup>3</sup> CDC. Respiratory Syncytial Virus Circulation in the United States, July 2012–June 2014. *MMWR*. 2014;62:141-4.

<sup>4</sup> CDC. Respiratory Syncytial Virus Infection (RSV). Infection and Incidence. December 2014. Available at: <https://www.cdc.gov/rsv/about/infection.html>.