



Alere Receives FDA CLIA Waiver for Alere™ i Strep A Rapid Molecular Test

Molecular diagnostic platform that detects Group A Streptococcus infections in 8 minutes or less now widely available in broad range of healthcare settings

WALTHAM, Mass., July 16, 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 Strep A test. The test, which was cleared for marketing by the FDA in April 2015, is the first molecular platform that detects Group A *Streptococcus* (GAS) bacteria in 8 minutes or less.

With CLIA waiver, the Alere i Strep A test will be available in a broad range of healthcare settings, including physician offices, hospital emergency rooms, and retail and walk-in clinics in the United States.

“Strep A is highly transmissible, and prompt treatment is critical to reducing the spread of the infection to others. With CLIA waiver for the Alere i Strep A test, we can help link more people to early treatment by bringing rapid molecular diagnosis to even more settings where they seek health care,” said Avi Pelossof, Global President of Infectious Disease at Alere.

The Strep A test is the second assay on the Alere i molecular platform, which initially received 510(k) clearance for the detection and differentiation of influenza A and B virus in 2014. In January 2015, Alere i Influenza A & B became the first-ever molecular test to receive CLIA waiver.

About the Alere i Strep A test

Alere i Strep A detects Group A *Streptococcus* (GAS) bacteria in throat swab specimens using Alere’s proprietary Molecular In Minutes™ (MIM) isothermal nucleic acid amplification technology (iNAT). Unlike polymerase chain reaction (PCR) tests, iNAT does not require lengthy and complex thermocycling or DNA purification and can therefore deliver PCR-caliber results more quickly – and in a broad range of settings.

Other assays currently in development on the Alere i platform include respiratory syncytial virus (RSV), *C. difficile* and *Chlamydia/Gonorrhoea*.

About Strep A

Group A *Streptococcus* (Group A Strep, or GAS) bacteria spread through contact with droplets from an infected person's cough or sneeze, and live in a person's nose and throat. Most GAS infections cause relatively mild (noninvasive) illnesses such as strep throat, scarlet fever, and impetigo (a skin infection). More than 10 million non-invasive GAS

infections (primarily throat and superficial skin infections) occur annually in the U.S.¹ Occasionally, these bacteria can cause severe and even life-threatening (invasive) diseases. Cases of invasive GAS infections, such as necrotizing fasciitis and streptococcal toxic shock syndrome, occur less frequently but are associated with higher rates of deaths.²

About Alere

Alere believes that when diagnosing and monitoring health conditions, **Knowing now matters™**. Alere delivers on this vision by delivering 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.

#

Media Contact:

Jackie Lustig
Senior Director, Corporate Communications
pr@alere.com
781.314.4009

Investor Relations

Juliet Cunningham
Vice President, Investor Relations
ir@alere.com
858.805.2232

¹ CDC. Group A Streptococcal (GAS) Disease – For Clinicians. Available at <http://www.cdc.gov/groupastrep/clinicians.html>.

² CDC. Group A Streptococcal (GAS) Disease – For Clinicians. Available at <http://www.cdc.gov/groupastrep/clinicians.html>.