



Alere Receives FDA Clearance for Alere™ i Strep A Rapid Molecular Test

Newest testing application on innovative Alere i molecular diagnostic platform detects Group A Streptococcus infections in 8 minutes or less

WALTHAM, Mass., April 2, 2015 – Alere Inc. (NYSE: ALR), a global leader in rapid diagnostic tests, today announced that its Alere™ i Strep A test has received marketing clearance from the U.S. Food and Drug Administration (FDA). Alere i Strep A is the first molecular test that detects Group A *Streptococcus* (GAS) bacteria in throat swab specimens in 8 minutes or less.

Upon receipt of this clearance from the FDA, Alere submitted an application for CLIA (Clinical Laboratory Improvement Amendments) waiver of the Alere i Strep A test. Other assays currently in development on the Alere i platform include respiratory syncytial virus (RSV), *C. difficile* and *Chlamydia/Gonorrhoea*.

“This FDA clearance brings the power of our Alere i molecular platform to the detection of Strep A. The speed and accuracy of the Alere i Strep A test empower healthcare professionals to initiate the right treatment in an actionable timeframe, which is a critical step in reducing unnecessary prescription of antibiotics and enhancing operational efficiency,” said Avi Pelossof, Global President of Infectious Disease at Alere.

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. In January 2015, Alere i Influenza A & B became the first-ever molecular test to receive CLIA waiver, which allows for broad use by healthcare providers, ranging from hospitals and physician offices to clinics and other healthcare settings. Expanding the menu on the Alere i platform to include Strep A and potentially other assays increases the utility of the platform for a wider range of users. Furthermore, given the less seasonal nature of Strep A, its addition enhances the value of the platform for users on a year-round basis.

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.

The clinical performance of Alere i Strep A was established in a multi-center study conducted in the U.S., in which 481 throat swab specimens were evaluated with Alere i and compared to standard bacterial culture. The overall sensitivity and specificity of the Alere i Strep A was 95.9% (141/147; 95% CI=91.4%, 98.1%) and 94.6% (316/334; 95% CI=91.6%, 96.6%), respectively. All samples generating discordant results between Alere i Strep A and bacterial culture were evaluated by a laboratory developed real-time PCR assay. Of the 6 samples negative by Alere i Strep A and positive by bacterial culture, 4 were also negative for Group A Strep by the real-time PCR assay. Of the 18 samples positive by Alere i Strep A and negative by bacterial culture, 13 were also positive for Group A Strep by the real-time PCR assay.

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

Because **Knowing now matters™**, Alere delivers reliable and actionable information through rapid diagnostic tests, resulting in better clinical and economic healthcare 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 CDC. Group A Streptococcal (GAS) Disease – For Clinicians. Available at <http://www.cdc.gov/groupastrep/clinicians.html>.

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