



FDA Clears the Simplexa™ Group A Strep Direct Test from Focus Diagnostics, a Quest Diagnostics Business

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CYPRESS, Calif. and MADISON, N.J., April 15, 2015 /PRNewswire/ -- Focus Diagnostics, the clinical-laboratory products business of Quest Diagnostics (NYSE: DGX), today announced the FDA 510(k) clearance and CLIA moderate-complexity categorization for its Simplexa Group A Strep Direct Kit. Simplexa Group A Strep Direct is a real-time polymerase chain reaction assay for the detection of Group A *Streptococcus* bacteria directly from throat swabs.

The most prevalent form of Group A *Streptococcus* (GAS) is strep throat (pharyngitis), a condition most common in children aged 5-15. More than 600 million cases of strep pharyngitis are estimated to occur worldwide each year. Sore throat, a common symptom of strep pharyngitis, is responsible for 7.3 million pediatric out-patient visits in the United States.

"Fast, reliable diagnosis of strep can make a world of difference in the effectiveness of treatment for this highly prevalent and painful bacterial infection," said Hollis (Holly) J. Batterman, MD, medical director, infectious diseases, Focus Diagnostics. "Our Simplexa Direct Strep test uses a proprietary technique to provide results in as quickly as an hour, compared to up to two days for culture, and has better specificity than rapid antigen tests, which are prone to false negatives. Faster diagnosis and subsequent treatment can minimize the risks of infection of others, inappropriate use of antibiotics and progression to more advanced and potentially life-threatening disease."

"Simplexa Direct Strep reflects our vision to provide diagnostic insights that help physicians and patients take prompt, well informed actions to achieve a favorable outcome," Dr. Batterman added.

Simplexa tests, designed for use on the 3M™ Integrated Cycler, employ real-time polymerase chain reaction (PCR) technology to detect DNA or RNA in viruses, bacteria, and other analytes. Using a proprietary chemistry technique that eliminates the nucleic acid extraction process typical of molecular diagnostics, Simplexa tests can produce results in as quickly as an hour.

The Simplexa Group A Strep Direct test is intended for the *in vitro* qualitative detection of group A *Streptococcus* from throat swabs collected from human patients with signs and symptoms of pharyngitis, such as sore throat. Simplexa Group A Strep Direct showed strong performance in clinical studies, with 97.4% sensitivity and 95.2% specificity compared to culture.

The test is also categorized as moderate complexity, enabling some physician offices, community hospitals, health clinics and integrated delivery networks to perform the test directly. Molecular tests are typically categorized as high-complexity, under the Clinical Laboratory Improvement Amendments, and can only be performed in certain reference and complex hospital labs.

"With moderate complexity classification and a streamlined workflow, our Simplexa Direct Strep test could potentially benefit a large number of the many millions of people suspected of strep each year," said Michelle Tabb, PhD, Vice President of Research and Development for Focus Diagnostics. "That's a major advantage over other molecular methods of diagnosing Group A Strep, which may be more labor intensive to perform."

The test was CE marked for distribution in the European Union in February 2015. The test kit is now available directly in the United States and internationally through the global distribution network of Focus Diagnostics.

About Strep Throat

Group A *Streptococcus* (GAS) is a gram-positive bacterium responsible for a wide range of infections. The most prominent of these infections are known as strep throat (pharyngitis), which occur when the bacteria colonizes in the throat. Strep throat is most common in children between ages 5 and 15. Because it shares symptoms, such as painful sore throat and fever, in common with the flu and other respiratory conditions, laboratory testing is an important aid in diagnosis. Untreated strep infections can lead to serious conditions, including Rheumatic fever and Scarlet fever. Strep is typically treated with a course of antibiotics.

About Focus Diagnostics and Simplexa

Focus Diagnostics, Inc., a business of Quest Diagnostics, develops and manufactures the Simplexa line of molecular test products operating on the Integrated Cycler, a compact, portable testing platform, as part of a global collaboration with 3M. Simplexa was the first test kit to be FDA cleared for aiding in the detection and differentiation of the 2009 H1N1 influenza virus in May 2010. Additional Simplexa tests aid in the detection and differentiation of influenza A, influenza B and RSV, *Clostridium difficile* and HSV 1 & 2. The Simplexa/3M technology has won several industry awards for medical innovation, including twice winning the prestigious Medical Design Excellence Award. In addition to Simplexa, Focus Diagnostics' products sold worldwide include HerpeSelect™ type-specific HSV serology and West Nile Virus DxSelect™. To learn more or to order Simplexa and other Focus Diagnostics tests, please contact Focus Diagnostics at 800-838-4548 or visit www.Focusdx.com.

About Quest Diagnostics

Quest Diagnostics is the world's leading provider of diagnostic information services needed to make better healthcare decisions. The company offers the broadest access to diagnostic testing services through its network of laboratories and patient service centers, and provides interpretive consultation through its extensive medical and scientific staff. Quest Diagnostics is a pioneer in developing innovative diagnostic tests and advanced healthcare information technology solutions that help improve patient care. Additional company information is available at www.QuestDiagnostics.com.

About 3M

3M is a science-based company with a culture of creative collaboration that inspires powerful technologies, making life better. With \$32 billion in sales, 3M employs 90,000 people worldwide and has operations in more than 70 countries. For more information, visit www.3M.com or follow @3MNewsroom on Twitter.

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