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Roche Receives FDA Clearance for Strep A Test on cobas Liat System

The cobas Strep A test is the first molecular point of care test to provide a result in 15 minutes for this common infection

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has provided 510(k) clearance for the cobas[®] Strep A test for the detection of group A streptococcus bacterial (Strep A) DNA in throat swab specimens. The cobas Strep A test runs on the cobas Liat System, a molecular point of care diagnostic system, which will be launched later this year. With a time to result of just 15 minutes, the cobas Strep A test achieves outstanding sensitivity aiding healthcare professionals to make immediate, informed treatment decisions in a variety of testing locations.

Strep A is the cause of strep throat, as well as certain skin infections, scarlet fever, and toxic shock syndrome. About 37% of sore throats among children¹ and 5-15% in adults² are caused by Strep A and infection is most common between the ages of 5 and 15³.

“The cobas Strep A test is easy to use and provides accurate results to support a treatment decision in just 15 minutes, much faster than current technologies,” said Roland Diggelmann, COO of Roche Diagnostics. “It also provides a significant improvement over conventional methods such as culture testing, where patients can wait up to 2 days to receive their result, or rapid antigen testing where confirmation with culture is needed due to significantly lower sensitivity.”

The new cobas Strep A test adds to the growing portfolio of assays designed for use with the cobas Liat System, enabling healthcare professionals to perform molecular PCR testing in a variety of settings with speed, accuracy, reliability and minimal training. The analyzer and two initial assays (cobas Influenza A/B and cobas Strep A) are both CE Marked and FDA cleared. Roche expects to begin sales of the system and assays later this year.

About the cobas Strep A assay

Utilizing polymerase chain reaction (PCR) technology, the cobas Strep A test can detect Strep A DNA obtained from throat swab specimens in 15 minutes with the cobas Liat System. The cobas Strep A test is CE Marked and FDA cleared.

About the cobas Liat System*

The Roche cobas Liat is a compact, fast and easy to use molecular diagnostic system designed for on-demand testing in physician clinics, pharmacy, and hospital lab settings. The system includes the cobas[®] Liat Analyzer and growing portfolio of assays, including cobas Influenza A/B and cobas Strep A.

*The cobas Liat System is not currently CLIA Waived in the United States

About Strep-A

Streptococcus pyogenes (Strep A) is a ubiquitous pathogen that causes a wide range of human infections, including pharyngitis, sinusitis, lymphadenitis, pyoderma, endocarditis, meningitis, septicemia, tonsillitis, impetigo, and upper respiratory tract infections. Strep A is capable of initiating two nonsuppurative complications – acute rheumatic fever and post-streptococcal acute glomerulonephritis – which can have severe negative consequences on the health and well-being of infected patients. Accurate diagnosis of acute infection is necessary to properly treat the disease using appropriate antibiotic therapy. If left untreated, Strep A infections can lead to other serious, sometimes life-threatening conditions, including rheumatic fever, scarlet fever, peritonsillar abscess, necrotizing fasciitis, and streptococcal toxic shock syndrome.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-four medicines developed by Roche are included in the World Health Organisation Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2013 the Roche Group employed over 85,000 people worldwide, invested 8.7 billion Swiss francs in R&D and posted sales of 46.8 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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References

¹ Shaikh N, Leonard E, Martin JM (September 2010). "Prevalence of streptococcal pharyngitis and streptococcal carriage in children: a meta-analysis". *Pediatrics* **126** (3): e557–64. doi:10.1542/peds.2009-2648

² Shulman, ST; Bisno, AL; Clegg, HW; Gerber, MA; Kaplan, EL; Lee, G; Martin, JM; Van Beneden, C (Sep 9, 2012). "Clinical Practice Guideline for the Diagnosis and Management of Group A Streptococcal Pharyngitis: 2012 Update by the Infectious Diseases Society of America.". *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America* **55** (10): e86–102. doi:10.1093/cid/cis629.

³ <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001663>