PRESS RELEASE

GenePOC obtains FDA clearance for its GenePOC™ Strep A test

GenePOC announces FDA clearance of its molecular diagnostic test for the detection of Streptococcus *group A in the US*

Québec, Canada – March 21st, 2019 – GenePOC Inc., member of the Debiopharm Group™, is proud to announce its third test cleared by the FDA, the GenePOC Strep A assay, to be used with the revogene™ device.

About Group A *Streptococcus (GAS) infection*

GAS is the most common bacterial etiology of pharyngitis accounting for 15 to 30% cases in children and 5 to 20% in adults[1]. It is estimated that 616 million people worldwide has a pharyngitis from a GAS infection annually and more than 18 million develop a severe GAS infection[2]. In USA, approximately 11,000 to 13,000 cases of invasive GAS disease occur each year. GAS infection can cause impetigo, scarlet fever, rheumatic fever or more severe infections such as pneumonia, rheumatic heart disease, streptococcal toxic shock syndrome and even death[3].

About the GenePOC Strep A assay

The GenePOC Strep A assay is a qualitative *in vitro* diagnostic test for the detection of *Streptococcus pyogenes* nucleic acids from throat swab specimens obtained from patients with signs and symptoms of pharyngitis. The GenePOC Strep A assay is intended for use as an aid in the diagnosis of Group A Streptococcus in humans. The GenePOC Strep A assay can provide results from up to eight samples as early as 42 minutes for positive specimens and in approximately 70 minutes for negative specimens, without the need for culture confirmation.

"The GenePOC Strep A assay demonstrated good performance during our evaluation and is a promising alternative to replace throat culture and Rapid Antigen Diagnostic Test (RADT). Improved detection and rapid results have the potential to improve antibiotic utilization in the emergency department".
- Amanda Harrington, Medical Director of Microbiology at the Loyola University in Chicago.

It is important to note that about 11 million patients are diagnosed with a pharyngitis in the emergency department in the USA[4]. More importantly, over 70% of pharyngitis have a viral cause[5]. The national guidelines for the treatment of pharyngitis endorsed by the Infectious Disease Society of America (IDSA) recommend antibiotic therapy only for streptococcal pharyngitis. A test done within the hour allows physicians to better manage patients.

"The GenePOC Strep A assay can provide "actionable" results without the need to confirm by culture. This is the third FDA cleared assay in the past 16 months, which demonstrates the commitment of GenePOC to developing important assays to complete its current offering and become a strong player in the field of rapid molecular diagnostics."
- Patrice Allibert, CEO of GenePOC

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[1] Bisno AL., and al., Clin Infect Dis. 2002; 35 (2): 113-125
[2] Carapetis JR., and al Lancet Infect Dis. 2005;5(11):685–94
[3] Centers for Disease Control and Prevention (CDC) www.cdc.gov/groupastrep/surveillance.html
[4] Hing E., and al., National Ambul Medical Survey: 2003 Summary. Adv Data. 2005; 365:1-48
[5] Bower JR. and al., Netter's Infectious Diseases 2012; 177-182

About the revogene
The revogene is an automated and stand-alone device. It enables testing of single-use proprietary microfluidic cartridges, called PIEs, with fluorescence-based real-time polymerase chain reaction technology to deliver an accurate diagnosis. In 2017, the revogene received the prestigious prize by *Frost & Sullivan for the New Product Innovation*[6] as well as the *Red Dot Award Best of the Best – Product Design.*[7]

About GenePOC
GenePOC is a company that specializes in the development of diagnostic devices which enable the prevention and detection of infectious diseases. The company aims to become the market leader in the rapid microbial testing. GenePOC is a member of the Debiopharm Group. GenePOC's revogene instrument is available in the US, EU and Canadian markets with a rapidly expanding test menu. Further information: www.genepoc-diagnostics.com

About Debiopharm Group ™
Debiopharm Group is a Swiss-headquartered global biopharmaceutical group including five companies active in the life science areas of drug development, GMP manufacturing of proprietary drugs, diagnostic tools and investment management. For more information, please see www.debiopharm.com

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[6] Frost & Sullivan European Molecular Diagnostics for Infectious Disease New Product Innovation Award, 201
[7] 2017 Best of the Best RedDot Award, 2017