PRESS RELEASE

GenePOC Launches its GenePOC™ CDiff test in the United States

GenePOC announces the launch and FDA clearance of its *Clostridium difficile* molecular test in US.

Québec, Canada – November 28, 2017 – GenePOC Inc. (GenePOC), a member of the Debiopharm Group™, is proud to announce the launch of its 2nd FDA cleared assay in less than 6 months, GenePOC™ CDiff, for use on the revogene™ instrument. The GenePOC CDiff test targets the toxin B gene of toxigenic *C. difficile* strains in unformed stool specimens obtained from patients suspected of having *C. difficile* infection (CDI). The test provides a novel and highly flexible alternative to assist clinicians in rapidly identifying, isolating and treating patients having CDI. Consequently, rapid management of patients having CDI will aid in preventing the spread of the bacteria - identified as an urgent threat in healthcare settings by the center for disease control (CDC).

About *C. difficile* infection in the US

In the United States, CDI is the leading cause of infectious antibiotic-associated diarrhea with 293 000 infections per year[i] representing $4.8 billion in additional healthcare cost per year[ii]. CDI poses many challenges to health institutions, among which is being able to efficiently test the patients at risk.

Traditional testing methods for identification of toxigenic *C. difficile,* such as toxigenic culture and enzyme immunoassays (EIA), have been found to be labor intensive, to increase delays and, to have limited sensitivity[iii].

There exists a need for a faster and simpler testing algorithm. According to the 2010 guidance from the American Society for Microbiology, nucleic acid amplification tests detecting *C. difficile* toxin genes may be used as a stand-alone test[iv]. In fact, those molecular tests provide sensitive, specific and timely identification of patients with toxigenic *C. difficile* infection, and exhibit better performance than toxin EIAs[v].

According to Dr Nathan Ledeboer from the Medical College of Wisconsin, in Milwaukee: “It all starts with timely diagnosis of *C. difficile* infections to critically impact patient management and ensure proper implementation of infection control practices”. Dr Nathan Ledeboer participated in a multicentric clinical trial, evaluating GenePOC CDiff test for use on the revogene instrument.

About GenePOC CDiff test

The GenePOC CDiff assay is a qualitative in vitro diagnostic test to detect the toxin B (tcdB) gene of toxigenic *C. difficile* in unformed (liquid or soft) stool specimens obtained from patients suspected of having CDI. Performing this test enables healthcare professionals to detect the presence of toxigenic *C. difficile* within 70 minutes after loading the patient sample in the test cartridge or PIE. Early and accurate detection can lead to better control and management of CDI, which in turn can improve patient management and reduce the risk of transmission.

“A simple one-step algorithm to detect toxigenic *C. difficile*, using a clinical test with excellent performance, will inevitably contribute to better control the spread of CDI and reduce outbreaks” says Dr Patrice Allibert, CEO of GenePOC. “What makes our assay so unique is its right balance between sensitivity and specificity. This translates into the ability to identify patients with CDI from a single GenePOC CDiff test, a molecular test with less than 1% unresolved rate according to clinical trial results. Our test is performed on the affordable, user-friendly revogene instrument which can be directly connected to the hospital and laboratory information systems (LIS/HIS), for seamless transmission and communication of actionable results”, Patrice Allibert continued.

About revogene™
The revogene is an automated and stand-alone instrument. It enables testing of single-use proprietary microfluidic cartridges, called PIEs, with fluorescence-based real-time polymerase chain reaction platform to deliver an accurate diagnosis. revogene, has been award winning for its innovative technology and design[vi,vii].

The revogene instrument is both CE-Marked and FDA cleared.

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 at the point of care (POC).
GenePOC is a member of the Debiopharm Group.
GenePOC's revogene instrument is available in the US and EU 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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