

PRESS RELEASE

GenePOC[®] launches its GenePOC[®] CDiff test in Canada

GenePOC announces the Health Canada approval and launch of its molecular diagnostic test for the detection of Clostridium difficile in Canada

Québec, Canada – October 23, 2018 – GenePOC Inc., member of the Debiopharm Group, is proud to announce the approval by Health Canada and the launch of its GenePOC CDiff assay to be used with the revogene[™] instrument.

About the Clostridium difficile infection

C. difficile infection (CDI) in Canada is the main cause of infectious diarrhea in hospitals and long-term care facilities. In 2017, the INSPQ estimated that the incidence of *C. difficile* nosocomial infections had reached up to 6.08 cases per 10 000 days-attendance. The mortality rates at 10 and 30 days were 6.3% and 12.4%, respectively¹. Still today, CDI represents a major issue for many medical institutions and is associated with 260 million dollars in additional health care costs². The majority of CDI occurs for patients who received antibiotics in high doses or for a long period of time.

About GenePOC CDiff assay

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.

“The approval of our CDiff assay by Health Canada for the diagnostic of toxigenic *C. difficile* is in line with the objectives of control and prevention of this nosocomial infection,” said Patrice Allibert, PhD, CEO of GenePOC. “In one step and within only seventy minutes, a CDI can be identified. Our molecular tests, used with the revogene instrument, have demonstrated to provide specific, sensitive and timely identification of patients with toxigenic CDI. Moreover, they are easy to use and affordable, which aligns well to the current needs of our health care system” concluded Patrice Allibert.

It is important to mention that earlier this year, GenePOC received the Health Canada approval and launched its first rapid diagnostic assay for the detection of group B *Streptococcus* from LIM broth enrichments. Therefore, it is their second Health Canada approval this year.

Professor Michel G. Bergeron, M.D., added: “*C. difficile* kills approximately 3000 Canadians a year. Rapid diagnosis using GenePOC’s unique technology, initially developed in my laboratory at University Laval in Québec City, will save many lives while controlling its costly dissemination in hospitals.”

The GenePOC CDiff test has been developed with the financial support of the FPQIS (Fonds de partenariat pour un Québec en santé).

About the revogene instrument

The revogene is an automated and stand-alone instrument. It enables testing of single-use proprietary microfluidic cartridges, called PIEs, with its fluorescence-based real-time polymerase chain reaction platform to deliver an accurate diagnosis. In 2017, the revogene received the prestigious prize by *Frost & Sullivan for the New Product Innovation*³ as well as the *Red Dot Award Best of the Best – Product Design*⁴.

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 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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1. INSPQ Update July 24th 2017 (<http://www.inspq.qc.ca>)
2. Levy and al., *Open Forum Infect Dis* 2015; 2: 1-10
3. Frost & Sullivan European Molecular Diagnostics for Infectious Disease New Product Innovation Award, 201
4. 2017 Best of the Best RedDot Award, 2017