PRESS RELEASE

GenePOC obtains FDA clearance for its GenePOC™ Carba test in the US

GenePOC announces FDA clearance of its molecular diagnostic test for the detection and differentiation of the five most frequent gene sequences associated with carbapenem-non-susceptibility.

Québec, Canada – May 16, 2019 – GenePOC Inc., member of the Debiopharm, announces the clearance by the FDA of its fourth test in the US, the GenePOC Carba assay, to be used with the revogene™ device.

About carbapenem-producing organisms (CPO)

CPO are known to be resistant to commonly used antibiotics and occasionally completely resistant to all available antibiotics. They are considered a serious global public health threat and are associated with significant morbidity, mortality and hospital costs[1]. In USA, the Centers for Disease Control and Prevention (CDC) recommends strong infection control measures for patients who are colonized or infected with CPO[2].

About the GenePOC Carba assay

The GenePOC Carba assay is a qualitative, *in vitro* diagnostic test designed for the detection and differentiation of the *bla*$_{KPC}$, *bla*$_{NDM}$, *bla*$_{VIM}$, *bla*$_{OXA-48-like}$, and *bla*$_{IMP}$ gene sequences associated with carbapenem-non-susceptibility. The assay can provide results from one up to eight samples in approximately 70 minutes using characterized carbapenem-non-susceptible pure colonies of *Enterobacteriaceae, Acinetobacter baumannii,* or *Pseudomonas aeruginosa.*

"There is an increasing number of CPO outbreaks which are difficult to control and overlap with spread to and within the community. The current diversity of carbapenemases that may be identified in a given geographical region underlines the need to possess methods that will identify a large spectrum of carbapenemases."

- Patrice Nordmann, Head of the Molecular Microbiology at the University of Fribourg, Switzerland

It is important to note that to prevent transmission from CPO-positive patients, hospitals should consider enhanced infection control measures such as contact precautions, isolation and dedicated nurses for patients who are confirmed CPO-positive[3].

"The FDA clearance for the GenePOC Carba assay represents a key milestone for GenePOC and shows how our technology is a key differentiator in the rapid diagnostics market. The flexibility of the technology will enable us to adapt to the constant evolution of this public threat by integrating more additional genes or subtypes as needed"

- Patrice Allibert, CEO of GenePOC

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[1] Borer A., Infect Control Hosp Epidemiol. 2009

[2] https://wwwnc.cdc.gov/eid/article/17/10/pdfs/11-0655.pdf

[3] https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/carbapenem-resistant-enterobacteriaceae-risk-assessment-april-2016.pdf

About revogene
The revogene is an automated and stand-alone device, enabling testing of single-use proprietary microfluidic cartridges with fluorescence-based real-time PCR technology to deliver an accurate diagnosis.

About GenePOC
GenePOC, member of Debiopharm Group, develops diagnostic devices which enable the prevention and detection of infectious diseases.
Further information: www.genepoc-diagnostics.com

About Debiopharm
Debiopharm aims to develop innovative therapies that target high unmet medical needs in oncology and bacterial infections by bridging the gap between disruptive discovery products and real-world patient reach. Further information: www.debiopharm.com.

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