

PRESS RELEASE

GenePOC Launches its new GenePOC™ GBS DS test

GenePOC announces the launch of its Group B Streptococcus Direct Swab (DS) molecular test in Europe

Québec, Canada—October 12, 2017 – GenePOC, Inc. (GenePOC), a member of the Debiopharm Group, is proud to announce the launch of its 2nd assay this year, GenePOC™ GBS DSⁱ, for use on the revogene™ instrument. GenePOC GBS DS at *intrapartum* will aid to minimize the risk of GBS transmission from the mother to their newborn and will help to optimize antibiotic stewardship.

About GBS screening in Europe

Still today, GBS is the leading cause of infection in infants worldwide with a fatality rate between 4-6%ⁱⁱ. There is an unmet clinical need as many countries have introduced guidelines to prevent early onset disease in newborns while other countries do not follow any guidelines yet.

In the current clinical strategy, the detection of Group B *Streptococcus* colonization in pregnant women is performed between 35 and 37 weeks of gestation and, if a positive result is obtained, an *intrapartum* antibiotic prophylaxis (IAP) is administrated to the mother. However, studies have shown that up to 61, 4% of term infants with GBS disease are born to women who have been falsely diagnosed negative or whose colonization status has changed from the time of antenatal testing to the time of deliveryⁱⁱⁱ.

“Intrapartum GBS testing is superior to antenatal testing at week 35-37. However, this requires very fast and easy methods. The GBS DS assay from GenePOC allows sensitive diagnosis of GBS just prior to delivery, making intrapartum GBS screening possible and resulting in optimized detection of patients at risk” said Prof. Dr. med. Lutz von Müller from Christophorus-Kliniken, Coesfeld, Germany. Dr Von Müller studied the detection of Group B Streptococcus (GBS) colonization before delivery and compared the new GenePOC molecular system to culture.

“What we are passionate about at GenePOC is to eliminate the highly debilitating effects of early onset diseases which include meningitis, pneumonia and in some cases death. In launching our new GenePOC GBS DS assay, we will be directly addressing that unmet clinical need. Our goal is to work closely with our distribution partners to improve the standard of care while decreasing the occurrence of early onset Group B Streptococcal disease in infants.” said Patrice Allibert, PhD, CEO of GenePOC. “The GenePOC offer is a breakthrough solution for testing GBS carriage while the mother is in labor. Compared to alternatives already on the market, we excel in providing actionable and highly reliable results to clinicians and women”, Patrice Allibert continued.

About revogene

The revogene is an automated and standalone instrument. It enables testing of single-use proprietary microfluidic cartridges, or 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^{iv,v}.

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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ⁱ GenePOC GBS DS is not available in all geographies. It is not currently approved for sales in the USA and in Canada.

ⁱⁱ Edmond et al., The Lancet, 2012; 379; p.547-557

ⁱⁱⁱ Van Dyke, et al., NEJM, June 18, 2009; 360(25):2626-36

^{iv} 2017 Best of the Best RedDot Award, 2017

^v Frost & Sullivan European Molecular Diagnostics for Infectious Disease New Product Innovation Award, 2017