Canada's GenePOC Expanding to Enter Lab and POC MDx Market Next Year

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Premium

NEW YORK (GenomeWeb) – Canadian firm GenePOC recently expanded its staff and intends to enter the molecular diagnostics market with a Group B *Streptococcus* assay at the end of the second quarter of 2016 and a *Clostridium difficile* assay in Q4 2016.

The company will initially launch the tests as CE-IVD products in Europe, and is aiming for US Food and Drug Administration approval of its platform and assays in late 2016.

To support these efforts, GenePOC received an undisclosed amount of private financing at the beginning of this year. Swiss development group Debiopharm Diagnostics is now the largest shareholder in GenePOC, with Montreal's Emerillon Capital also providing investment.

"Since then, the company is progressing very rapidly," Herbert Torfs, vice president of business development strategy, told GenomeWeb in an interview.

Torfs, who has been at the firm since September and was previously part of the European team at BD Diagnostics and BD Biosciences, said GenePOC has recently expanded from eight to 30 employees.

The majority of these new hires are involved in development as well as ramping up for manufacturing and quality control of the company's platform and assays, he said. All the assay development, as well as reagent, consumable, and instrument manufacturing, is done in-house in Quebec City.

The firm's platform is a fully automated real-time PCR device that uses a spinning disk format. It runs up to eight wedge-shaped tests, called PIEs, simultaneously in under an hour, requiring five processing steps and less than one minute of hands-on time.

The long-term development menu includes assays for respiratory, gastrointestinal, neonatal, and hospital-acquired infections, as well as sexually transmitted diseases, according to the company's website.

The firm had earlier intimated a launch of the product in 2014, as previously reported, but Torfs said this had to be pushed back due to availability of funding.

Now, "GenePOC got its series A funding completed in the first months of 2015, which allows us to complete the development of the instrument, set up manufacturing of consumables, and complete assay development and validation," he said.

In terms of development, the firm's efforts have been focused mainly around ease of use, flexibility, a short hands-on time, and producing relatively fast turn-around times, Torfs noted, adding that the company's current turnaround time is 51 minutes.

GenePOC's technology enables multiplexing of up to 12 targets, and the platform has the flexibility to run mixed batches of its tests with each consumable PIE having integrated sample lysis and real-time PCR capabilities.

The company will be initiating clinical trials of its GBS test in the first quarter of 2016, followed by *C. diff* trials. After obtaining CE-IVD status, the commercial launch of the platform in Europe should be at the end of the second quarter next year, with FDA clearance three to six months later, Torfs said.

"For the European market, we are targeting the laboratory and the point-of-care testing market, which we consider to be in the hospital environment, but outside of the lab," Torfs said.

In the US, for example, for GBS — which can cause morbidity and mortality of babies born to infected mothers, and for which all US women are screened at 35 to 37 weeks of gestation as per US Centers for Disease Control and Prevention recommendations — the GenePOC tests could be performed in the delivery department or the obstetrics and gynecology units of a hospital, Torfs said.

For the *C. diff* test, the firm also plans to have additional claims that "may promote or stimulate the use of the platform outside the laboratory environment," he said.

Pursuing CLIA waiver is also on GenePOC's development list, but not at launch for the GBS and *C. diff* tests. Torfs said the platform and workflow in its current configuration would most likely be considered moderately complex, but that the firm expects to have future discussions with the FDA about the best approach to go for full CLIA waiver.

The GenePOC platform is somewhat reminiscent of other disk-based devices on the market or in development, such as the LabDisk player being developed in collaboration by Hahn-Schickard and Qiagen.

It will also enter a POC molecular testing space that is in its infancy, with three players now becoming established but with apparently ample room to develop customers and market share, as reported by GenomeWeb.

For distribution, GenePOC plans to seek well-established partners in Europe that have inroads into both the laboratory and point-of-care testing markets. Torfs anticipated the company would disclose partners in various European countries in early 2016.

"For the US, we are in the process of deciding what our go-to-market model will look like," he said, adding it may be either be direct or employing a distribution network.

The next IVD assays in GenePOC's pipeline are tests for Group A Strep and carbapenem-resistant *Enterobacteriaceae*, Torfs said.

Interestingly, despite a number of molecular GAS tests currently commercially available, adoption

seems to be in a holding pattern, possibly due to a lack of clinical guidelines directing clinicians to use this method. And there has recently been some discussion around the need to reduce false positive results if molecular CRE tests are to be used for patient screening.

Although there are not yet any published studies describing the GenePOC platform, the firm is currently setting up beta testing, initially in Canada. "As soon as we get results out of those, we are planning to extend them to Europe as well," Torfs said, adding that the firm is planning a number of additional activities in European markets pre-launch.

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