Genedrive Validates Near-Patient HCV Assay With Eye to European, Sub-Saharan Africa Markets

May 02, 2018 | Madeleine Johnson

NEW YORK (GenomeWeb) – Genedrive plc, a Manchester, UK-based company formerly known as Epistem, has completed validation studies of its point-of-care molecular diagnostics system and assay for hepatitis C virus. The studies were conducted in Europe as well as South Africa to demonstrate the assay works on genotypes predominate in different global regions.

Genedrive has miniaturized molecular HCV testing onto a hand-held, portable device that weighs approximately 600 grams, or a little more than 21 ounces. In a validation of the instrument and CE-marked assay published last month in *BMJ Gut*, the firm showed 98 percent sensitivity and 100 percent specificity across all major HCV genotypes. It also demonstrated proof of concept for a semi-quantitative assessment of HCV viral load using melting peak ratiometric analysis.

There are six main genotypes of HCV, with two predominating in Europe, said Gino Miele, the firm's director of research and development, in an interview. The South African site was included "to reflect genotypes that are more prevalent in Africa and Sub-Saharan countries," he said. Additionally, the European sites, located in the UK and France, were more laboratory-based, while the African site was more oriented towards the firm's intended user scenario of decentralized settings, Miele said.

In South Africa, the HCV test was validated on 130 clinical plasma and serum samples across three Genedrive instruments and four operators, according to the study. Samples were collected from various African countries — including Ghana, Kenya, Mauritius, Mozambique, Nigeria, South Africa, Uganda, and Zimbabwe — as part of routine HCV diagnostic testing using the Abbott RealTime HCV Genotype II on the Abbott m2000.

Genedrive included a site in South Africa in the validation for scientific and strategic reasons. "We target our products currently towards low- and middle-income countries (LMICs)," explained David Budd, the firm's CEO.

Budd said that potential customers want to see how the product works on real-world samples in the field, as these tend to be less well-controlled than the lab specimens used for development work.

While there are other qualitative and quantitative HCV tests available in LMICs, such as the Abbott test and platform, they are mostly concentrated in large hospital environments. "We are the very first people to bring a decentralized HCV molecular test to the market," Budd asserted.

"The four big pillars of global health problems are tuberculosis, HIV, malaria, and hepatitis," Budd said, adding that, based on the firm's technology and route to market, "HCV and TB are the ones that are most tangible for us right now." This is also because these are diagnostics opportunities where the number of solutions in the market is limited.

On the TB side, Genedrive had a product launched in India, but after signing a distribution deal with Sysmex it determined that the test it had developed would not suit all of the geographies it gained access to in the deal. The firm is now re-engineering the TB product to drive the cost down. "We recognize that in all of these markets, while you need the right level of performance and people like their bells and whistles like everywhere in the world, it absolutely has to be affordable."

The firm also recently received funding to develop a more automated sample prep method for the TB test in order to improve user experience and potentially increase the sensitivity of the test. The ultimate goal for the TB test is to have higher sensitivity than microscopy but also to report some drug resistance information, particularly rifampacin resistance.

The HCV test, meanwhile, meets the World Health Organization and FIND target product profile for decentralized HCV testing. Genedrive plans to apply for WHO pre-qualification, but Budd noted that there are also other routes into markets in the developing world.

"The easiest and most immediate way is actually to go into the private laboratories and healthcare infrastructure in a country," Budd said. The WHO PQ process, on the other hand, is quite rigorous, but he said PQ will likely be important to fully realize the commercial and distribution opportunities in areas that need subsidy or financial support.

According to the WHO, HCV caused more than 1.3 million deaths in 2015. There were also 1.75 million new infections, bringing the total number of people infected worldwide to 71 million. And, unlike tuberculosis and HIV, which have comparable, but declining, mortality rates, HCV mortality is on the rise. The WHO has called for the elimination of HCV as a public health threat by 2030, aiming to reduce new infections by 90 percent and mortality by 65 percent.

In the past, treatment required HCV genotyping and viral load testing, with additional viral load testing to determine treatment response. The current treatment algorithm involves screening with an antibody-based test, followed by confirmation of infection with a molecular test prior to therapy. "That's where we come in," Budd said. The newest therapies — which involve direct-acting anti-virals that can cure infections in about 12 weeks, as opposed to genotype-specific drugs that could take up to 48 weeks of treatment — only require a simple pan-genotype molecular test to diagnose HCV infection, plus one after therapy to confirm the cure.

Genedrive's miniaturized system will be offered to hospitals and clinics that are closer to patients than big hospitals and that can prescribe drugs and follow up with patients quickly, Budd said.

The cost of the Genedrive instrument and cartridges is expected to be lower than the firm's main competitors in the LMIC diagnostics market, particularly Cepheid. "Our target is to be able to deliver something into the market at the same end price that Cepheid currently gets at a subsidy," Budd said.

The portable Cepheid Omni platform, which has been estimated to cost around $3,000 would perhaps be most equivalent to the Genedrive platform, but it's launch has been delayed. "I'm sure it will come, and frankly their products work well, but I think the thing we recognize is that it uses the same cartridges as the other [Cepheid GeneXpert] systems use, and we know there are huge manufacturing and distribution costs to those," Budd said.

While the Genedrive platform will be unlikely to exceed the performance of the currently-available Cepheid instruments, which cost tens of thousands of dollars without subsidies, it will have higher sensitivity than smear microscopy and could potentially serve as a replacement technology.

Budd said the low cost of the system due to the fact that it is simpler in its design than other commercial molecular systems, in that it is not fully integrated, so the user must do some manual sample prep upfront. However, the instrument is also essentially disposable, obviating the need for any maintenance contracts or service network. "If it breaks, when it breaks, you throw it out and we'll send you another one in the mail," Budd said.

The device itself has an end-user list price of around $4,000, but it is likely that many instruments will be placed as part of a reagent rental model as well, Budd said.