BioWorld MedTech

Clarivate Analytics

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December 11, 2018
Volume 22, No. 239
Special Reprint

Chromacode looks to battle tick-borne pathogens with new assay

By Liz Hollis, Staff Writer

Although it is crucial to identify tick-borne diseases, including Lyme, early, many tests can be inaccurate or difficult to interpret. Chromacode Inc., of Carlsbad, Calif., is looking to help change that.

The company reported the commercial launch of its first multiplex test using its High Definition Polymerase Chain Reaction (HDPCR) technology. Chromacode said the HDPCR Tick-Borne Pathogen (TBP) panel is the only multiplex PCR test that detects nine of the most common tick-borne pathogens in a single test.

Eyeing a need

The need for better testing and treatment has caught the eye of U.S. regulators and other companies.

"The lack of a clear path for treatment of persistent symptoms in some patients with Lyme disease and other tick-borne diseases not only amplifies patient suffering but also significantly increases health care costs," according to the *Tick-Borne Disease Working Group 2018 Report to Congress*.

Part of the U.S. Department of Health and Human Services, the working group was established as part of the 21st Century Cures Act to provide expertise and review federal efforts related to all tick-borne diseases.

Although the incidence of tick-borne disease is growing, funding has been slow in coming.

"The U.S. National Institutes of Health (NIH) and the CDC spend $77,355 and $20,293, respectively, per new surveillance case of HIV/AIDS, and $36,063 and $11,459 per new case of hepatitis C virus, yet only $768 and $302 for each new case of Lyme disease," the report noted.

Companies already have shown that the need is great. This past summer, Quest Diagnostics Inc. helped put that in perspective after looking at more than 6 million de-identified laboratory test results over the past seven years and determining that the disease spiked between 2016 and 2017. (See *BioWorld MedTech*, Aug. 1, 2018.)

Limited options

Glen Hansen, director of clinical microbiology and molecular diagnostics, Hennepin County Medical Center in Minneapolis, noted that there are currently single-plex PCR options for detecting these pathogens. In addition, testing for tick-carrying pathogens often is done through serological assays for a small number of pathogens. However, there are limitations posed by the lack of immune system response in early infections.

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>
> Scott Powell
> Senior director, strategic marketing, Chromacode

For its part, the HDPCR multiplexing technology potentially could allow for early identification of a broader array of pathogens. It combines proprietary data science algorithms with chemistries to increase the multiplexing levels of common real-time PCR (qPCR) and digital PCR instruments for simultaneous detection of multiple targets in a single reaction. Data are analyzed on the secure Chromacode Cloud.

"What we're doing that's unique is that instead of qPCR where you're traditionally limited to one or two targets per reaction, we're now able to look at nine different relevant tick-borne pathogens for the U.S. population," Scott Powell, senior director, strategic marketing at Chromacode, told *BioWorld MedTech*. This is important because as a result of warmer winters, ticks are harboring multiple pathogens, rather than just one.

Focused on data science

"We are a data-science company, and that's one of the things that sometimes people miss," Chromacode CEO Greg Gosch told *BioWorld MedTech*, adding that many players in the space focus on hardware. "What we're doing instead is actually leveraging the hardware capabilities of the existing

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instrumentation, but applying a data analytics approach, a software approach to extract additional information from those technologies." As a result, entities do not have to purchase a new instrument, as the Chromacode can help the customer expand the capabilities of what it already has.

While the product is research-use only, it has multiple target audiences, such as public health labs, pharma, academic medical centers, those looking to build a laboratory developed test for their applications, Gosch said. "That is in our plans," he added when asked whether the company would pursue the CE mark or a green light from the FDA. He explained that the company would have to seek a partner for regulatory signoffs, as it does not currently offer instruments.

In terms of commercialization, the company has a two-pronged approach. "For large laboratories in the clinical research space, we'll have a direct sales force. The other key component as we march towards IVD/CE mark and that sort of thing, we are engaged in partnership discussions with a number of different qPCR vendors in both the diagnostic space as well as the research space."

He added that the company expects to report a number of partnerships over the next 18 months or so.

Under development

The company also is eyeing noninvasive prenatal testing through the ongoing development of a proposed multiplexed digital and droplet digital PCR test for the analysis of Trisomy 13, 18 and 21, and sex chromosome abnormalities from cell-free DNA.

It also is working on a test for multidrug resistance, which "is . . . a very big global problem. If we don't do anything collectively as a scientific community in the next 20 years, we're really looking at potentially going back to age before antibiotics," said Powell.

Findings

At the Association for Molecular Pathology (AMP) 2018 Annual Meeting & Expo, in San Antonio, the company noted there were three study presentations.

Blake Buchan, associate professor, department of pathology, Medical College of Wisconsin and senior author of one of Chromacode's AMP posters, explained some of the findings he had seen with the test. Specifically, the team looked at 175 people tested for Lyme disease.

"We wanted to see potentially what else these patients may have [and] how well it worked," he told *BioWorld MedTech*. "Specimens were sent to an independent lab that validated single-plex molecular test for all of these individual targets as a reference."

The study came in late September and October, so outside peak tick season. The team found some intriguing results, with two positives of organisms that were unexpected.

"Even in a relatively small sample set, we've got a couple of specimens that are positive for organisms that are not really on the radar of clinicians," Buchan explained. ♦