Applied BioCode Developing Multiplex, Bead-Based Gastrointestinal Pathogen Detection Panel

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NEW YORK (GenomeWeb) — Applied BioCode is developing a new test for gastrointestinal pathogens that it hopes to sell to high-volume hospital laboratories and that will compete directly with Luminex's US Food and Drug Administration-cleared Gastrointestinal Pathogen Panel.

The Santa Fe Springs, Calif.-based company is also working on a high-throughput, 96-well platform to support the assay, according to company executives.

Applied BioCode CEO Winston Ho and Bob Wessel, a marketing and business development consultant for the firm, discussed the new test and platform with *BioArray News* this week. They also provided a poster about the assay that the firm intends to present at the upcoming Annual Clinical Virology Symposium, which will be held later this month in Daytona Beach, Fla.

Applied BioCode's panel contains 16 targets associated with gastroenteritis, including 10 bacteria, three viruses, and three parasites. The panel is run using the company's barcoded magnetic beads technology, where targets are coupled to barcoded beads, providing a high-contrast transmitted signal, no fluorescence background, and nearly 100 percent decoding accuracy, according to the firm.

Though the company sells two analyzers for decoding its beads, it is developing a 96-well format, high-throughput system to support the new panel, which, if cleared by the FDA, will be its first *in vitro* diagnostic.

"Molecular diagnostics is a rapidly growing area and a GI panel is an offering where we feel we can add value with our technology," said Wessel.

He noted that the company has decided to focus on high-throughput labs, which will differentiate it from assays and systems sold by Nanosphere, bioMérieux's BioFire Diagnostics, and other firms that offer cartridge-based tests. And in addition to making it possible to analyze up to 96 samples at a time, the firm is also looking to integrate thermocycling, hybridization, and detection processes within one system, attributes that could distinguish it from Luminex's Gastrointestinal Pathogen Panel.

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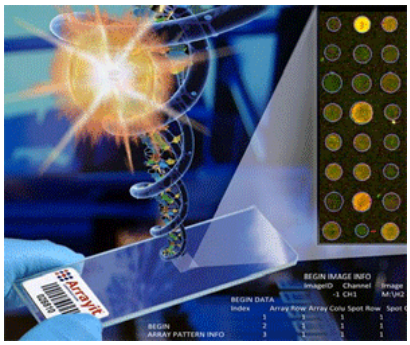

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According to Wessel, it is Applied BioCode's goal to deliver a system to market that is has a number of advantages over other offerings in the market.

"The main issue for us is providing a system that is more user friendly and suffers less from sample contamination," Wessel said. It will also benefit from the firm's technology platform, he maintained, as each bead will have its own barcode, making it "easier to differentiate the targets" via direct microplate imaging.

Ho, the CEO, characterized Applied BioCode's technology is a "digital multiplex bead platform" that is "very reproducible and very stable," noting that the semiconductor process the firm uses to produce its beads results in "no variation" between assays. Ho also said that it is possible that the company's new 96-well system could be available for research in the future, though he declined to elaborate

FDA clearance will be paramount for the launch of Applied BioCode's new test. The agency cleared Luminex's GPP for use on its high-throughput LX 200 system in January 2013 and again for use on its MagPix benchtop instrument last April. The test is based on Luminex's bead array technology and enables users to detect 11 gastrointestinal pathogens in a single, five-hour assay. The company has predicted that its GPP will be a "key growth driver" this year.

Wessel said that Applied BioCode hopes to be able to submit its assay to the FDA for review early next year.

In terms of challenging Luminex in the global market place, Wessel said that Applied BioCode will price the system competitively, and will work with distribution partners to make it available worldwide.

Applied BioCode also has some partners who are developing somewhat related tests. Oslo, Norway-based Genetic Analysis announced earlier this year that it had achieved a CE IVD marking for its GA-map IBS Dysbiosis test, which targets dysbiosis — an imbalance of gut microbacteria that can lead to the development of irritable bowel disease and other gastrointestinal aliments is now CE marked and available for use on clinical samples in European labs. The company also announced at the time that it had signed a license and supply agreement with Applied BioCode for its barcoded magnetic bead technology for multiplex array analysis.

Wessel acknowledged Applied BioCode's relationship with Genetic Analysis, but noted that its internal GI assay differs from its partner's assay in terms of indication and platform.

Justin Petrone is the editor of GenomeWeb's *BioArray News* and covers the microarray and biochip sector of the genomics market. E-mail Justin Petrone or follow his GenomeWeb Twitter account at @BioArrayNews.

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