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Genetic Signatures Launches Analyte-Specific Reagents in US; Eyes FDA Approval for MDx Panels

Jul 08, 2016 | Madeleine Johnson

NEW YORK (GenomeWeb) – Australian molecular diagnostics manufacturer Genetic Signatures recently launched a line of analyte-specific reagents in the US and collaborated with the University of California, Los Angeles to evaluate a multiplex panel assay for enteric protozoan infections with an eye toward regulatory approval and the US diagnostics market.

The firm has also established a US management team that includes Mike Aicher — former CEO and founder of National Genetics Institute and senior vice president of current NGI parent company LabCorp — as executive director of US operations.

Genetic Signatures filed an IPO in Australia in 2015. "The IPO was really about expansion of the product lines and also geographical expansion," CEO John Melki said in an interview with GenomeWeb this week.

The firm now has CE-IVD marking for a number of products and has continued to grow its distributor network. Specifically, its products are distributed by AstraFormedic in Italy, Argenta in Poland, Medical Supply Company in Ireland, and Addvansys in Israel.

Genetic Signatures also has direct representation in Europe, as earlier this year it appointed a full-time director of sales and support based in the Netherlands, "supporting our strategy of having a direct presence in Europe, supplying products directly in regions in which we don't have distributors, and also supporting our distributors," Melki said. The firm is also in the process of setting up a European distribution hub, he added.

The core technology underlying Genetic Signatures' products is a nucleic acid amplification strategy called 3base.

"We change the four-letter alphabet to a three-letter alphabet," Melki said. This is accomplished with standard bisulfite treatment of the sort typically used in epigenetic analyses, converting cytosines to thymines. The firm's CSO, Douglas Millar, was one of the original developers of the bisulfite method published about 25 years ago.

Using bisulfite-converted DNA for PCR-based molecular diagnostics is unique to Genetic Signatures. The firm came up with the method in a "eureka moment," Melki said, when Millar realized the technique creates homologies in genomes that could then be utilized to produce better assays.

"It gives us a number of advantages in real-time PCR assays that we design," Melki said, namely reducing complexity between subtypes or strains, making them more similar to each other without compromising specificity.

For diagnostics purposes, this enables development of assays that can detect many variants of a given pathogen. It also allows the firm to target different regions of genomes than other tests do. For example, typical human papillomavirus tests home in on the L1 portion of the HPV genome because it is less variable than other areas, but Genetic Signatures showed a number of years ago that its test, which targets different regions, is as sensitive as the Digene Hybrid Capture II from Qiagen.

And the method can still be used to detect small variations as well. "We don't lose all the information ... we just have a different landscape, so we can target regions that become more similar to each other after conversion or we can target regions which stay the same after conversion," Melki explained.

The 3Base method also allows the firm to include both DNA and RNA targets in its multiplex panels, and the tests are fluorescent probe-based, so there is no post-PCR manipulation required.

The firm's line of assays, called EasyScreen, uses the 3Base method. The menu currently includes tests for enteric bacteria, viruses, and protozoa. A number of the test kits are approved by the Therapeutic Goods Administration, an Australian equivalent to the US Food and Drug Administration, and are CE-IVD marked, and the firm is also selling into Canada at this time, Melki said.

In terms of the US, Genetic Signatures is planning to pursue FDA approval, but has not yet determined which test it will submit first. The firm's kit to detect protozoa that was recently evaluated in collaboration with UCLA is one possibility, as it detects a number of species that aren't easily detected by traditional methods and there may be a market need for additional targets, Melki noted. The kit as it is currently commercially available in Australia and Europe detects five targets — Cryptosporidium spp., Giardia intestinalis, Dientamoeba fragilis, Entamoeba histolytica, and Blastocystis hominis from stool samples.

In Australia, the financial full year is July to June, so the firm has not yet reported its most recent full year results. Melki said the firm exceeded $1 million in sales revenue for the first time in the prior fiscal year, but surpassed that within the first three quarters of the most recent year. Genetic Signatures also reported 72 percent growth year-over-year in diagnostic kit revenue.

To further fuel this growth, the firm is expanding, setting up trials and collaborations in Europe, particularly with respect to gastroenteritis and respiratory syndromic panels — each of which detects over 20 targets — as well as meningitis and sexually transmitted infection kits in development.

At the European Congress of Clinical Microbiology and Infectious Diseases this year, Genetic Signatures also presented preliminary data on a carbapenemase-producing and extended spectrum beta-lactamase (ESBL) organisms panel. An evaluation at an Australian hospital including 85 clinical CPO and ESBL isolates found total agreement between phenotypic data generated by the hospital lab with the Verigene Gram-Negative Blood Culture Test from Nanosphere compared to Genetic Signatures' three-hour molecular diagnostic test.

Relative to the vast competition in the molecular diagnostic multiplex assay space, Melki said, "Our 3base technology is very unique to us and allows us to have a wide array of targets in a multiplex form," adding that the throughput is a further potential differentiator. The tests are compatible with 384-well plates, with full coverage of up to 24 targets still allowing up to 48 patient specimens to be processed per plate.

"We have some very high-throughput laboratories doing screening with our technology that they can't do, really, with any other type of kit, and we are an open platform, so we are compatible on a number of purification and real-time PCR instruments," Melki said.

The ASR line in the US includes reagents that target bisulfite-converted nucleic acid sequences, Melki said. But "the ultimate goal would be FDA approval for all of our products," he said, adding that the firm is actively working on its pre-submission with the agency now.