Australia's Genetic Signatures Plans Global Market Rollout of STI, Flavivirus/Alphavirus Panels

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Premium

NEW YORK (GenomeWeb) – Australian firm Genetic Signatures is parlaying its 3base technology into a number of new multiplex panel tests in addition to its existing enteric and respiratory product suite, including ones for sexually transmitted infections and an assay that tests for all flaviviruses and alphaviruses. The firm recently presented data on these first products while continuing its plans for global expansion.

The proprietary 3base method uses an initial bisulfite treatment to convert cytosines to thymines. Thus, all of the firm's PCR-based molecular diagnostics are designed for a simplified code. According to the firm, this technique reduces complexity between subtypes or strains, but also allows it to target other regions of genomes than those typically chosen for diagnostics, and to include both DNA and RNA targets in its multiplex panels.

The firm's first kit can rapidly detect 12 of the most common sexually transmitted infections and was launched at the end of March, CEO John Melki said in an interview.

The STI kit was also recently evaluated by SydPath, the pathology service of St. Vincent's Hospital in Sydney. In a presentation at a National Reference Laboratory conference in Australia late last year, SydPath microbiologist Damien Stark described the lab's previous workflow for sexually transmitted infections.

"A lot of the targets that we detect in the kit [physicians] were either not testing [for] or they were testing weekly by sending off to a reference lab," Melki said. "So, if the doctor suspected something, they would send it off and get the results in days, or weeks, depending on what the service was."

The SydPath workflow included in-house weekday testing for chlamydia and gonorrhea using the Roche Cobas 4800, three times per week testing for herpes simplex 1/2 using Focus Diagnostics' Simplexa assay, as well as daily testing using microscopy for *Trichomonas vaginalis*. The remaining common targets, such as candida species or mycoplasma genetalium, the lab would either send away or culture for up to 48 hours.

The SydPath evaluation demonstrated a time to results of between four and five hours with minimal hands-on time. And, by bringing more molecular testing into the hospital, the lab was able to detect

692 cases of STIs from 729 specimens in-house, as compared to 247 cases using their previous outsourced workflow. The as-yet unpublished evaluation also showed 100 percent specificities and sensitivities for almost all targets using a variety of specimen types. Importantly, it also showed that about a quarter of patients actually had mixed infections.

Based on the results of its evaluation, SydPath has become Genetic Signatures' first customer for the STI test. "They like the results that they receive, they like the fact that they can screen for multiple targets simultaneously, and they're quite excited to announce this new service," Melki said.

He also noted that this test was the first the firm has launched since its IPO. It has been launched as a research-use-only product for the time being, but, "we are expecting regulatory approvals both in Australia and a CE-IVD mark in the coming months," he said.

A second kit, to detect viruses commonly transmitted by mosquitoes and ticks, was also recently evaluated, and data was presented this week at the European Congress of Clinical Microbiology and Infectious Diseases.

The test uses the 3base technology to enable screening for all flaviviruses and alphaviruses in a single assay. Flaviviruses include West Nile, dengue, tick-borne encephalitis, yellow fever, Zika, and others, while alphaviruses include things like chikungunya, Ross River virus, and O'nyong'nyong.

"Our technology has allowed us to develop a test, which we call a screening component, that's a world-wide test that can tell you if you have any form of flavivirus or any form of alphavirus," Melki said.

"We can then do a reflex test, and we can make those regionally specific. For the US, Australia, Europe or for Africa, the targets that you would choose as your secondary test would make sense geographically because they are the organisms that are of interest or are prone to outbreak in those regions."

The data presented at ECCMID described a trial in Vanuatu conducted during what was suspected to be dengue type II outbreak in the Pacific island nation that began in 2016.

"Using our technology we were able to do a pan-flavivirus, a pan-alphavirus, and a pan-dengue to pick up all four types of dengue, and we were also able to include a dengue II specific assay right there in the initial screen," Melki said.

For almost 200 samples evaluated, 116 were dengue type II positive, and the firm was able to identify that subtype right from the initial screen, he added.

In addition to the two kits, Genetic Signatures is now also pushing ahead with expansion plans in the US. It is currently offering its 3base technology as analyte-specific reagents, and is also collaborating with a lab at the University of California, Los Angeles on detection of enteric protozoan infections. That work is expected to be presented at the Clinical Virology Symposium in Savannah, Georgia next month.

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