



SpeedX Launching Line of Multiplex STI, Microbial Resistance Assays

Oct 07, 2015

|

[Madeleine Johnson](#)

Premium

NEW YORK (GenomeWeb) – Australian molecular diagnostics manufacturer SpeedX is developing a line of PCR-based *in vitro* diagnostics called PlexPCR using the firm's proprietary single-well multiplexing technologies. The initial tests are for certain sexually transmitted infections, and include one that can detect SNPs conferring antimicrobial resistance.

The firm has been "in technology development mode for five years," Colin Denver, vice president for sales and marketing at SpeedX, told GenomeWeb in an interview.

"We've worked a lot with our licensees and we've seen how good the technology is, so we've come to the point now where we want to commercialize it ourselves and apply it to areas where we think there is a real market need," Denver said.

A spinoff of J&J research, a Sydney-based entrepreneurial subsidiary of Johnson & Johnson, SpeedX was established with core technologies that include proprietary nucleic acid enzymes formerly called MNAszymes and unique primer and isothermal signaling technologies, including one named PassPriming. The firm has been using these to co-develop diagnostics with licensees and has also been nurturing its own fledgling IVD pipeline, as [previously reported](#).

As part of the new emphasis on making its own products, the firm recently rebranded these core technologies. The MNAszymes are now PlexZymes, and the PassPriming system is now named PlexPrime.

Last year the firm won ISO accreditation, which it said added value to the quality of SpeedX products but was also a first step in taking a suite of IVD products for CE marking. This will also be important if the firm decides to pursue clearance from the US Food and Drug Administration later on, Denver said.

The firm launched the first PlexPCR products at the [World STI and HIV Congress](#) in Brisbane last month.

These include what is believed to be the first nucleic acid amplification assay for drug resistance in *Mycoplasma genitalium*, called the *M. genitalium* ResistancePlus kit, and a single-well multiplex qPCR assay which detects herpes simplex viruses 1 and 2 as well as varicella zoster virus and an internal control, called the PlexPCR HSV-1&2, VZV kit.

The tests, which are compatible with existing PCR instruments, have launched as research-use-only kits in Australia at the moment. The firm is currently in the process of carrying out the clinical validations necessary for further regulatory approval.

"We're hoping to have CE mark within the next few months," Denver said. "We're planning to launch at the European Meeting for Molecular Diagnostics next week ... and we're looking to find clinical collaborators and potential distribution partners as well," he said.

The HSV test has been able to detect a number of co-infections that Denver said may have been missed previously.

And the *M. genitalium* test highlights one of the benefits of the technology. A standard six-channel real-time PCR detection system is usually limited to detecting six analytes, he said. "With our assay we can stack multiple analytes to report out on the same probe — our *M. genitalium* assay is only a three-channel assay but in the second channel we have five individual SNPs that may confer macrolide resistance, all stacked within a single channel," Denver explained.

This method can be useful for assays that need to report whether at least one mutation is present, rather than identify the exact mutation.

SpeedX is also pursuing antimicrobial resistance for future tests and the ResistancePlus name will be part of the PlexPCR branding, Denver said.

"With ResistancePlus, we're looking to create a line of products that provide more actionable information to clinicians about the resistance status of the bacteria that they're looking at, and with our technology we're able to provide a greater level of information in a shorter amount of time," he said.

The *M. genitalium* test may potentially be useful because that bacterium is purportedly quite difficult to grow in culture, and may take up to six weeks before it can be screened for resistance by standard methods. The SpeedX assay instead uses PCR to test for five SNPs associated with resistance to macrolide, a first-line antibiotic for the infection.

The emerging resistance of *M. genitalium* was described as a "moving target" in a recent [BMC Infectious Diseases](#) article, which also advocated that molecular methods for detection of macrolide resistance-mediating mutations be further developed, since this can help guide treatment decisions.

Jørgen Skov Jensen, a researcher at the Statens Serum Institut in Copenhagen, Denmark and an author on that study told GenomeWeb in an email that he is already familiar with the new SpeedX assay and has arranged to test it in his lab.

"To my knowledge, it is the first commercially available resistance test" for *M. genitalium*, Jensen said, adding, "The availability of a test that combines detection and treatment guidance would be a huge improvement in patient management." He noted that in many settings, nearly half of all patients carry macrolide-resistant strains that require a different, more expensive, treatment.

SpeedX also has a number of licensees at the moment, and is continuing these collaborations.

Denver described a cancer-based collaboration, two agricultural-based collaborations, and work with a few other diagnostics companies that is focused on menu expansion.

One collaborator has now advanced a product to market. The Idylla KRAS assay from Biocartis [received](#) CE-IVD marking in June and uses SpeedX technologies, Denver said. That firm is also developing assays for BRAF and NRAS as well, he noted.

Interestingly, Biocartis' collaboration with another company linked to Johnson & Johnson — subsidiary Janssen Diagnostics — has yielded three prototype infectious disease assays for the Idylla molecular diagnostics platform, [as reported by GenomeWeb](#).

SpeedX previously described a meningitis assay in development. Denver said that the HSV test came from that development process, since HSV is also an analyte in the meningitis test. "The herpes panel was of greater need to certain labs than meningitis at the time," he said.

SpeedX will continue to develop the meningitis assay — previously described as four panels of multiplex assays detecting a total of 10 common viral and bacterial causes of the infection — over the coming months and Denver said the firm believes it will ultimately offer significant benefits over other commercial assays.