



SpeedX Opens European Offices to Launch HSV, Antibiotic Resistant Mycoplasma Genitalium Tests

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Premium

NEW YORK (GenomeWeb) – With a new European toehold in London, Australian firm SpeedX is focusing on filling an unmet need for antibiotic-resistant *Mycoplasma genitalium* testing.

In general, the firm is developing its core enzyme and primer technologies in two product lines — PlexPCR and Resistance Plus — with a planned menu of infectious disease assays. And with an eye on increasing its presence in the European market, SpeedX signed a [distribution agreement](#) with Netherlands-based Goffin Molecular for these products in April.

The company also recently received the CE mark on a test to detect and distinguish herpes simplex 1 and 2 and varicella viruses, Colin Denver, vice president of sales and marketing at SpeedX, told GenomeWeb in an interview.

SpeedX sees its [previously described](#) *M. genitalium* resistance test as filling an unmet need in the diagnostics market. It will now bring that test into Europe, aiming for CE-IVD marking at the end of July. After obtaining the CE mark, SpeedX will take the test through the Therapeutic Goods Administration, an Australian equivalent to the US Food and Drug Administration, and plans to seek US FDA approval in 2017.

The SpeedX *M. genitalium* assay is single-tube test on the firm's Resistance Plus line and detects five SNPs in the 23s rRNA gene that can confer resistance to the macrolide drug azithromycin, Denver said.

A study published in [PLoS One](#) this month evaluated the *M. genitalium* resistance test on 254 patient samples, showing a sensitivity and specificity for *M. genitalium* detection of 99 and 97 percent, with a sensitivity of antibiotic resistance detection of 99 and 100 percent.

In addition to the *M. genitalium* resistance test, SpeedX has an antibiotic-resistance test for gonorrhea in its research pipeline, as well as one for carbapenem resistant-enterobacteriaceae. On the PlexPCR line, the firm is developing a respiratory virus detection kit that includes influenza A and B, respiratory syncytial virus, human metapneumovirus, adenovirus, rhinovirus, and parainfluenza virus, Denver said.

The PlexPCR line debuted in Australia in October, and the firm currently has some customers and active evaluations for the HSV product, as well as a number of research and collaborative links for the *M. genitalium* product, he said.

All tests are being developed with an "open-platform approach," he added, but SpeedX is also open to future strategic platform collaborations.

Targeting an unmet need

The *M. genitalium* bacteria is very difficult to culture, so treatment failure is currently the typical way resistant strains are detected, Denver said.

Lisa Manhart, an epidemiologist at the University of Washington's School of Public Health specializing in *M. genitalium*, told GenomeWeb that *M. genitalium* infects between 1 and 3 percent of people in the general population per year, but in groups engaged in risky sexual behavior the prevalence can be as high as 20 percent.

By comparison, gonorrhea affects about 0.6 percent of the general population, while trichomonas and chlamydia affect 3 percent and 4 percent, respectively.

Manhart helped draft the *M. genitalium* section of the US Centers for Disease Control and Prevention [guidelines](#) for treatment of sexually transmitted diseases in 2015, the first time the agency included a section with specific guidance on this pathogen. She noted that the CDC cannot recommend diagnostic tests until they have FDA approval, and currently there are no FDA-approved diagnostic assays to test patients for *M. genitalium*, let alone for antibiotic-resistant strains.

At the time the CDC guidelines were being prepared, the effects of the infection on males were well understood. But her group has since completed a [meta-analysis](#) that showed "strong, significant effects" of *M. genitalium* infection on women as well. These include increased risk of cervicitis, pelvic inflammatory disease, preterm birth, spontaneous abortion, and a trend toward a relationship to infertility.

A handful of firms provide molecular tests for *M. genitalium*, Manhart said. The few in-house, lab-developed tests offered by research and commercial labs often don't publish test performance characteristics. The sole commercial test is available from Hologic on its Aptima platform as an analyte-specific reagent.

Manhart said her impression is that the Hologic test — which she described as "excellent" — has been picked up quickly, particularly among researchers. However, that test is only for detection of the bacterium and does not detect resistance markers.

And measuring resistance is "super important," Manhart said. The pathogen's resistance to azithromycin, a macrolide antibiotic, has emerged rapidly and is a big problem in some areas. Alternative drugs are effective but more toxic to patients. If there were a resistance test readily available, then azithromycin could still be used in patients without resistance, and clinicians could use the alternative drugs that have greater side effects only when needed, she said.

Luckily, the known resistance mechanisms in *M. genitalium* are "pretty simple," she said, compared to antibiotic resistance in gonorrhea or tuberculosis, for example.

The five SNPs that the SpeedX test detects are in the same gene, which could complicate multiplexing. However, this type of multiplexing is aided by the firm's proprietary enzymes and primers as [previously reported](#), which also bear some similarities to [recently described](#) 'SuperSelective' primers.

There have been reports of certain communities in which incidence of resistance has become very high, Manhart said. For example, a study [in Greenland](#) showed an *M. genitalium* prevalence of almost 10 percent, with 100 percent of strains carrying macrolide-resistance genes that were detected by sequencing.

A 2011 study of non-gonococcal urethritis (NGU) [in Seattle](#) showed a low cure rate for *M. genitalium* using standard drug treatments. The authors, of whom Manhart was one, concluded, "The absence of a

commercially available assay for *M. genitalium*, along with treatment failure up to 70 percent, presents substantial challenges for the clinical management of NGU."

Compared to the potential [gonorrhea "superbug."](#) Manhart said antibiotic-resistant *M. genitalium* could be even more of a concern. "We know through history that gonorrhea can develop resistance to most drugs, but right now [resistance](#) to the CDC-recommended therapy is 0.5 to 1 percent," she said. *M. genitalium*, on the other hand, has resistance from 40 to 60 percent in some areas, Manhart said, while incidence of *M. genitalium* is up to four times that of gonorrhea in the general population.

Manhart speculated that people tend to focus more on gonorrhea because of the history of that infection in the US, and also because the bacteria has been studied for a longer time.

Although *M. genitalium* may have been a cause of inflammation of the urethra and cervix for ages, the bacteria was only first described in 1980 when it was cultured from specimens of a handful patients with urethritis. There followed a "fallow period" of about 10 years in which many labs failed to replicate the results, according to one [comprehensive review](#), because the bacteria is "tiny, and really hard to grow," Manhart said.

In fact, she noted that there are only about four labs in the world that can grow *M. genitalium*, and culturing can take up to six months. So, epidemiological studies were really only able to begin when nucleic acid amplification tests were developed, and, "It takes a long time for enough consistent scientific evidence to build up," she said.

Since the bacteria is not routinely tested for, it is difficult to know what the potential market could be. Uptake of the detection-only Hologic TMA Aptima test could provide some insights. The company reported in its second quarter [earnings](#) that the test was recently CE-marked but it did not provide further details.

SpeedX's Denver said *M. genitalium* has about half the prevalence of chlamydia, and currently the chlamydia testing market would include about 1.4 million reported infections last year in the US. But, "It's a tough one to project — I think the market is extremely fast growing in terms of the awareness of *M. genitalium*, and it is something I think you would see in the near future ... requested routinely."

The company will now launch the test in Europe from its new offices in the [London Bioscience Innovation Center](#), a biotech and life science incubator near Kings Cross Station. "Incubator spaces make it easy to make connections in markets that you've not got a lot of experience in," said Denver. The center is also connected to the Royal Veterinary College and offers lab space, providing an opportunity for expansion of services beyond the firm's labs in Sydney.

But the potential market size remains somewhat of a chicken and egg question, UW's Manhart said.

"In many cases people won't test for something unless it is recommended, and people won't recommend a test unless it is FDA approved, and companies don't want to go for FDA approval unless they know that there is a market for their test," she said, adding that more data might support use of a test, but without a test it is hard to generate data.

"It requires someone to take a deep breath and jump off the cliff, and say, 'I believe the scientific community is taking this seriously, people would use this test,' and move forward with it."

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