SpeeDx receives FDA listing for *Mycoplasma genitalium* product

SYDNEY, AUSTRALIA – (April 19, 2018). SpeeDx's ***Resistance****Plus*® MG Positive Control kit has now been listed with the US Food and Drug Administration (FDA) for sale in the United States through the company's recently incorporated US entity, SpeeDx Inc. The announcement coincides with the FDA registration of the Australian parent company – SpeeDx Pty Ltd – as a Medical Device Manufacturing Establishment, and clinical trials remain on-track for the ***Resistance****Plus* MG assay.*

The ***Resistance****Plus* MG Positive Control kit contains synthetic DNA to simulate *Mycoplasma genitalium*, as well as five mutations known to confer resistance to macrolide antibiotics. Macrolide-resistant *M. genitalium* is a challenging sexually transmitted infection (STI), and global management guidelines are currently being adapted to deal with the rise in resistance. "This is an important product in our portfolio," said Elisa Mokany, Chief Technology Officer for SpeeDx. "*M. genitalium* is very difficult to culture, and positive material for quality control can be hard to come by."

SpeeDx's ***Resistance****Plus* MG assay is the first commercially available diagnostic test that simultaneously detects *M. genitalium* and genetic markers for antimicrobial resistance, and has been widely adopted across Europe, Australia and New Zealand since gaining CE marking in 2016. "We have a strong focus on tackling the global antimicrobial resistance problem," said Colin Denver, CEO of SpeeDx. "STIs are set to become the first incurable bacterial infections, and our ***Resistance****Plus* line of diagnostic tests empowers clinicians to make informed treatment decisions."

About *Mycoplasma genitalium*

M. genitalium can cause symptoms such as urethritis, cervicitis, endometritis and pelvic inflammatory disease. In recent studies, it has been found to have a higher prevalence than gonorrhoea. Like gonorrhoea, *M. genitalium* is evolving into a so-called STI superbug that is becoming resistant to many antibiotic treatments, leading to exceedingly difficult-to-treat infections and threatening global public health.

Macrolide antibiotics, specifically azithromycin, are the first-line treatments for the rapidly growing problem of *M. genitalium* STIs, but resistance to these antibiotics has increased by up to 60 percent in several countries. This development led guidelines on *M. genitalium* infections in Europe and Australia recommending the molecular detection of *M. genitalium* be complemented with an assay capable of detecting macrolide resistance-associated mutations.

About SpeeDx

Founded in 2009, SpeeDx is an Australian-based private company with offices in London and the US, and distributors across Europe. SpeeDx specializes in molecular diagnostic solutions that go beyond simple detection to offer comprehensive information for improved patient management. Innovative real-time polymerase chain reaction (qPCR) technology has driven market-leading multiplex detection and priming strategies. Product portfolios focus on multiplex diagnostics for sexually transmitted infection (STI), antibiotic resistance markers, and respiratory disease. Currently, SpeeDx markets the only CE-marked and TGA approved commercial molecular test for the STI *M. genitalium* (ResistancePlus® MG*) that combines detection of the disease with detection of markers for antibiotic resistance.
For more information about SpeeDx please see: http://plexpcr.com

* Not available in the US