



SpeedX Receives TGA Approval for PlexPCR™ HSV-1&2, VZV

A simple multiplexed solution for herpes viral detection

SYDNEY, AUSTRALIA--(October 5th, 2016). SpeedX Pty. Ltd. announced it has received TGA approval for its PlexPCR™ HSV-1&2, VZV multiplex qPCR kit. The test offers a single-well solution to cover the detection and differentiation of three herpes viruses (HSV-1, HSV-2, VZV) in addition to an internal control. Validated for use on multiple lesion specimen types, the test is designed to streamline herpes testing workflows and support appropriate clinical and therapeutic management for infections that present similarly.

Dr. Tim Read, a Sexual Health Physician at Melbourne Sexual Health Centre has validated the need for a more inclusive approach to herpes diagnostics, saying: “Our study highlights that a small but significant number of cases of presumed genital HSV infection are caused by VZV, and that zoster needs to be considered as a differential diagnosis for genital herpetic lesions.¹”

The SpeedX portfolio is based on market-leading multiplex technology and the PlexPCR™ HSV-1&2, VZV kit is the first to receive TGA approval from a range of infectious disease and antibiotic resistance detection kits in the pipeline.

“We are delighted to receive TGA approval for this new high-performance benchmark for multiplex qPCR HSV and VZV testing,” said Colin Denver, CEO for SpeedX. “This is the first test of many that we are excited to offer to the Australian market, following targeted and collaborative development with leading sexual health clinicians and researchers both here and around the world.”

About herpes simplex virus types 1 and 2 (HSV-1&2) and varicella zoster virus (VZV)

HSV is a contagious infection spread through oral or sexual contact, causing a life-long infection, although treatment can reduce symptoms. VZV is a commonly occurring virus causing chickenpox in children, teens, and young adults as well as herpes zoster (shingles) typically in adults and aged populations. All three viruses present with clinically similar symptoms appearing as lesions or ulcers on the skin, mouth (“cold sores”), or genital area. Due to the similarities in clinical presentation, molecular-based tests have become the gold standard to detect and differentiate the cause of infection. Treatment of HSV-1&2 and VZV includes acyclovir, famciclovir, and valacyclovir, however appropriate dosage requires correct identification of the causative virus.

About SpeedX

Based in Sydney, Australia and founded in 2009, SpeedX is a privately owned company specializing in innovative multiplex real-time polymerase chain reaction (qPCR) solutions for clinical diagnostics. SpeedX has a portfolio of market leading detection and priming technologies to enable new healthcare paradigms based on improved delivery and reduced costs. SpeedX has a proven track record of scientific discovery and strives to provide cutting edge clinically relevant tools for the clinical diagnostic market. For more information on SpeedX please see: <http://www.speedx.com.au/>

About PlexPCR™ and ResistancePlus™

PlexPCR™ and ResistancePlus™ constitute multiplex qPCR kits for detection of infectious disease pathogens and antimicrobial resistance markers, respectively. Powered by the company’s proprietary PlexZyme™ and PlexPrime™ technologies, both product lines offer high multiplexing capability for better, more streamlined infectious disease management. With increased ability to



detect more pathogens as well as multiple genetic markers, every PlexPCR™ and ResistancePlus™ test provides more actionable information for laboratories and clinicians alike.

1. C J Birch, J D Druce, M C Catton, L MacGregor, T Read. Detection of varicella zoster virus in genital specimens using a multiplex polymerase chain reaction. **Sex Transm Infect.** 2003;79:298–300