

Multiplex assay for the detection of syphilis and other pathogens associated with genital lesions using **PlexPCR™**

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Background

- > Syphilis, caused by *Treponema pallidum* subsp. *pallidum* (T. pal), is responsible for lesions at a variety of body sites
- > Herpes simplex virus 1 (HSV-1) & herpes simplex virus 2 (HSV-2) cause lesions at a variety of cutaneous and mucocutaneous sites
- > Primary infection with Varicella zoster virus (VZV) causes chickenpox, and reactivation later in life produces shingles
- > Skin & genital lesions have similar clinical presentation for all four organisms^{1,2}
 - In Australia, population estimates are 85% carrying HSV-1 and 20% carrying HSV-2³
 - Up to 3% of genital swab samples are VZV⁴
 - VZV requires different treatment/therapeutic intervention to HSV-1 & HSV-2⁴
 - After hitting lows in 2001, the rate of syphilis infections is increasing²

Identification of organism is crucial for correct clinical management of genital lesions

Clinical Evaluation

PlexPCR™ vs Westmead In-house Assay

- > The performance of the assay was evaluated using clinical samples obtained from Pathology West, Sydney, in a retrospective study comparing the SpeedX and in-house assays. Samples were from a range of anatomical sites, including genital lesions.

SpeedX	HSV-1 detection			HSV-2 detection		
	+	-	Total	+	-	Total
+	34	2	36	23	0	23
-	2	66	68	0	81	81
Total	36	68	104	23	81	104

Sensitivity 94.4% (95% CI 81.9-98.5%)
Specificity 97.1% (95% CI 90.0-99.2%)

SpeedX	VZV detection			T. Pal detection		
	+	-	Total	+	-	Total
+	40	1	41	87	0	87
-	1	33	34	5	11	16
Total	41	34	75	92	11	103

Sensitivity 97.6% (95% CI 87.4-99.6%)
Specificity 97.1% (95% CI 85.1-99.5%)

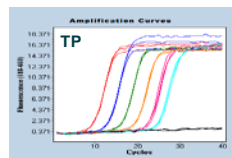
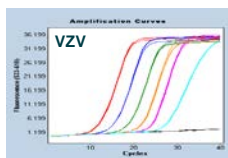
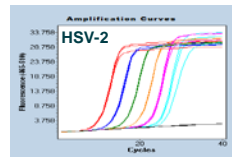
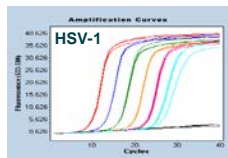
High sensitivity and specificity with clinical samples

Analytical Specificity

Organism	Conc	Organism	Conc
<i>Neisseria gonorrhoeae</i>	10 ⁴ copies per assay	<i>Haemophilus influenzae</i>	10 ⁶ copies per assay
<i>Mycoplasma hominis</i>		<i>Neisseria meningitidis</i>	
<i>Trichomonas vaginalis</i>		<i>Enterococcus faecalis</i>	
<i>Mycoplasma pneumoniae</i>		<i>Escherichia coli</i>	
<i>Ureaplasma parvum</i>		<i>Klebsiella pneumoniae</i>	
<i>Ureaplasma urealyticum</i>		<i>Pseudomonas aeruginosa</i>	
<i>Chlamydia pneumoniae</i>		<i>Streptococcus pneumoniae</i>	
Human herpes virus 6		<i>Haemophilus ducreyi</i>	
Epstein Barr virus		<i>Chlamydia trachomatis</i>	

No cross-reactivity with a wide range of organisms

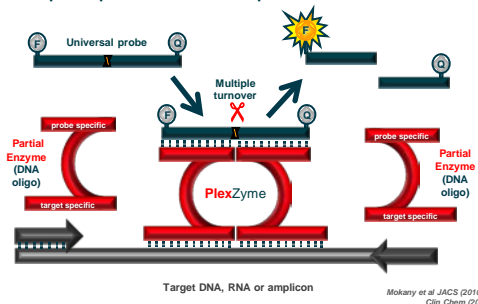
Analytical Sensitivity



Detection to 10 copies per assay

PlexPCR™ Technology for NAATs

- > **PlexZyme™** detection in qPCR is highly specific & sensitive
- > Superior performance in multiplex



Conclusions

- > The **PlexPCR™** HSV-1&2, VZV, Syphilis test (SpeedX) provides sensitive, specific and rapid detection of pathogens causing cutaneous and mucocutaneous lesions.
- > In response to the current emerging syphilis outbreak, the SpeedX assay could provide a rapid and effective method of determining the infectious agent responsible for genital lesions, supporting earlier detection at primary presentation and rapid treatment to reduce morbidity or worse outcomes.

References:

1. Simon HK, Steele DW. Ann Emerg Med. (1995);
2. CDC Syphilis fact sheet. <https://www.cdc.gov/std/syphilis/stdfact-syphilis-detailed.htm>.
3. http://www.sexualhealthaustralia.com.au/genital_herpes.html ; 4. Birch CJ et al. Sex Transm Infect (2003).

PlexPCR™ is a flexible, rapid & cost-effective technology for multiplexed detection of targets and genetic variants



If you are interested in multiplexing your assay and/or wanting to achieve specific single base discrimination contact info@speedx.com.au

or for more information about **PlexPrime™** & **PlexPCR™** technology visit www.speedx.com.au