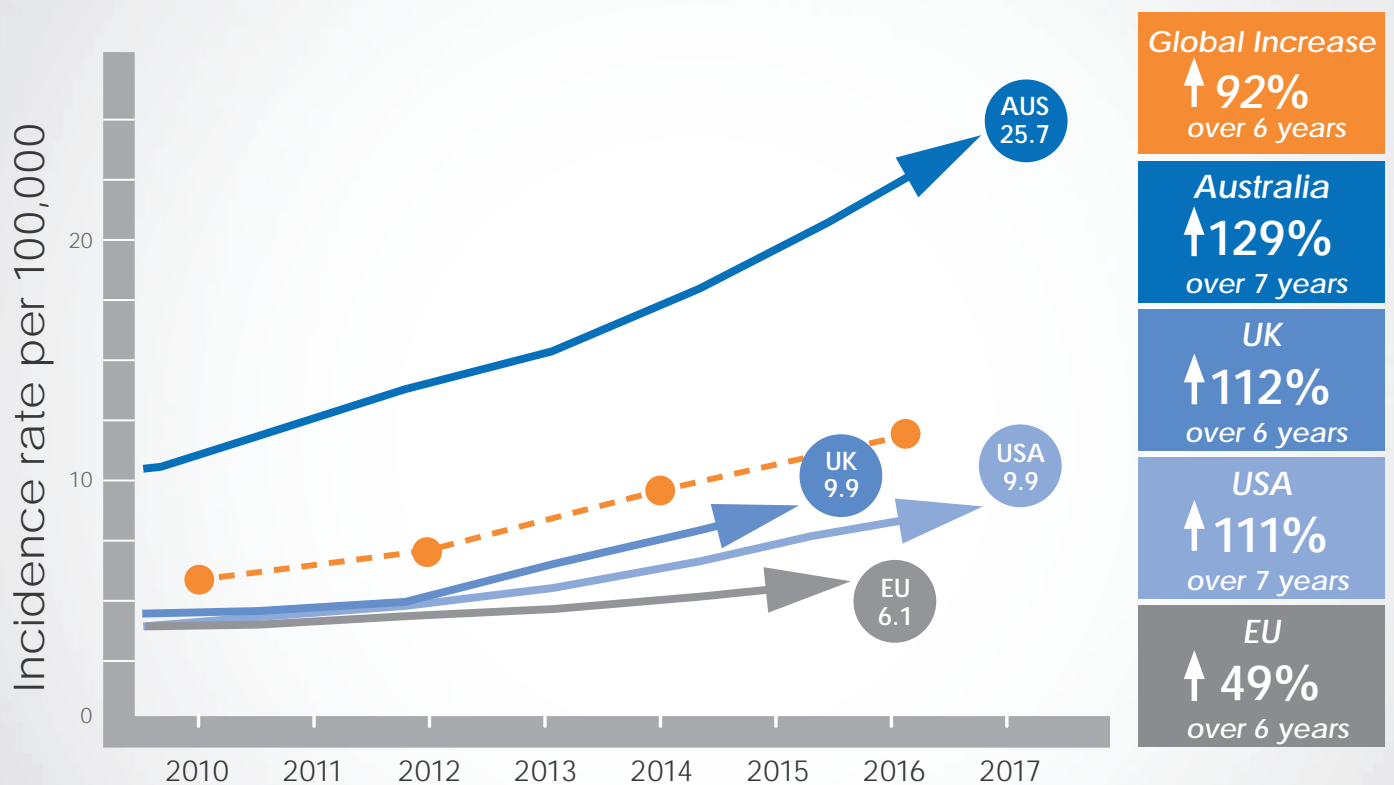


PlexPCR[®] VHS

Varicella, Herpes & Syphilis

Confident lesion testing to suit any population



Syphilis rates are on the rise¹⁻³

- ▶ Symptomatic/visual lesion diagnostics can have low accuracy (33-80%),⁴⁻⁶ molecular testing is recommended.⁷⁻¹²
- ▶ Syphilis lesions can present atypically, be painful, and appear indistinguishable from herpes.^{8,13,14}
- ▶ Atypical zoster (VZV) may account for 1-3%¹⁵⁻¹⁷ of genital lesions, misdiagnosis can affect patient psychological wellbeing.

One kit. Two tests.

Individual software modules provide two tests for one validation/verification. The automated analysis is included with the **PlexPCR® VHS** lesion diagnostics solution.

SpeedX Software Module	Targets
SpeedX Analysis PlexPCR® HV	HSV-1 HSV-2 VZV
SpeedX Analysis PlexPCR® VHS	HSV-1 HSV-2 VZV <i>T. pallidum</i>

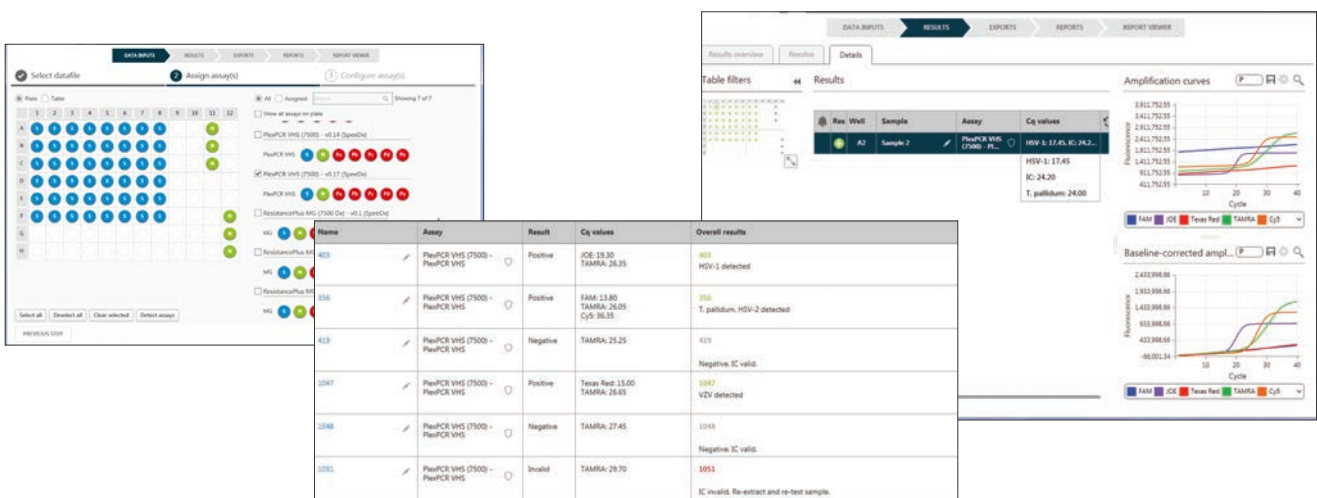
- ▶ Suitable for high or low risk population testing
- ▶ Multiple analysis module options for flexible target analysis
- ▶ Choose all four targets or herpes and varicella only
- ▶ Modules analysed simulatenously to streamline workflow and data analysis

Fast and reproducible data analysis.

Streamline your workflow and minimise time spent with subjective amplification curves with SpeedX Analysis software.

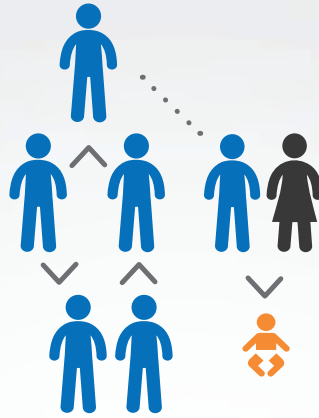
The complete **PlexPCR® VHS** solution includes:

- ▶ Automated result calling
- ▶ Simple sample processing
- ▶ Validated, high security, GDPR compliance
- ▶ Multiple analysis modules with or without syphilis

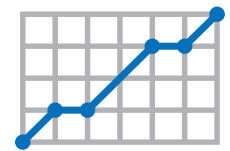


“We strongly believe in having a *T. pallidum* PCR as part of the routine test for any genito-anal ulcer. Several patients have been found to have syphilis where this was not originally suspected, and blood tests would never have been taken.”

Dr. Andrew Winter, Consultant in Sexual Health and HIV Medicine, NHS Greater Glasgow and Clyde, UK.



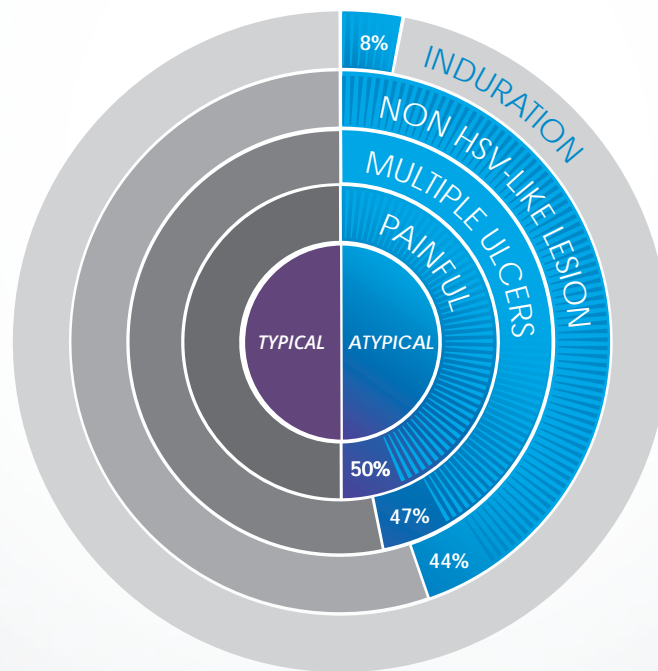
Syphilis clusters increasingly include heterosexual populations,^{18,19} coinciding with increases in congenital syphilis.²⁰



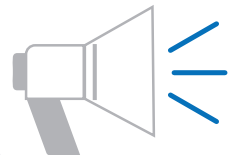
Syphilis at highest rates in decades, including rise in congenital syphilis cases.^{1-4,11}



Molecular testing from a syphilis lesion is a direct detection method—simplifying diagnosis and enabling timely partner notification and contact tracing.²¹



Atypical lesion presentation can complicate diagnosis.^{8,13-17}



Increased number of reported syphilis epidemics and outbreaks.²⁴⁻²⁶



Surveillance or sentinel lesion screening can assist with early detection.^{22,23}

PlexPCR[®] VHS is a single-well, multiplex qPCR test detecting common causes of genital and oral lesions. Detect Herpes simplex virus type-1 & -2 (HSV-1 & HSV-2), and Varicella zoster virus (VZV), with software analysis options to include *Treponema pallidum* (syphilis) detection. **PlexPCR**[®] VHS is powered by **PlexPCR**[®] proprietary technologies for improved multiplex performance compared with other probe-based methods.²⁶

Single-well **PlexPCR**[®] Test

Channel	Target
1	HSV-1
2	HSV-2
3	VZV
4	<i>T. pallidum</i> (optional analysis)
5	Internal Control

Demonstrated clinical performance²⁸

	HSV-1	HSV-2	VZV	TP
Sensitivity	97.7%	100%	100%	100%
Specificity	99.7%	99.7%	99.7%	100%

Validated with non-genital and genital swabs.²⁸

PlexPCR[®] VHS

Flexible lesion diagnostics

Product	Compatible	Size	Cat #
PlexPCR [®] VHS*	ABI 7500/7500 Fast/Dx	100 reactions	1123001
	LC 480 II	100 reactions	1121001
	CFX IVD, CFX Touch	100 reactions	1125001

References: 1. Australian Institute of Health and Welfare 2018. Australia's health 2018. Australia's health series no. 16. 2. ECDC surveillance atlas of infectious diseases, syphilis 2015 3. CDC Sexually Transmitted Disease Surveillance 2017 4. Dangor Y et al. Sex Transm Dis 1990; 17:184-189. 5. O'Farrell N et al. Genitourin Med 1994; 70: 7-11 6. Ndinya-Achola JO et al. Int J STD & AIDS 1996; 7: 201-205 7. Workowski KA et al. MMWR Recomm Rep 2015;64 (RR03): 25-48 8. Janier M et al. 2014 European guideline on the management of syphilis 9. Australian STI Management Guidelines 10. Patel R et al. 2017 European guidelines for the management of genital herpes 11. Abara WE et al. PLOS ONE Published online 22 July 2016 12. Kingston M et al. UK national guidelines on the management of syphilis 2015 13. Towns JM Sex Transm Infect. 2016 Mar;92(2):110-5 14. Hope-Rapp E et al. J Sex Transm Dis. 2010;37:153-8 15. Rubben A et al. Br J Dermatol. 1997;137(2):259-61 16. Granato PA et al. J Clin Virol. 2016 Nov;84:87-89 17. Birch C et al. Sex Transm Infect. 2003; 79:298-300 18. Cunningham S et al. Sex Transm Infect. 2006;82:444-445 19. Doherty IA et al. Sex Transm Dis. 2011 May; 38(5): 378-384 20. Slutsker JS et al. MMWR Morb Mortal Wkly Rep 2018;67:1088-1093 21. Syphilis CDNA National Guidelines for Public Health Units v1.1, June 2018 22. Acquah R et al. Sex Transm Infect 2017;93:326 23. Scott LJ Sex Transm Infect 2010 86:537-539 24. <https://www.dhhs.nh.gov/media/pr/2017/06222017syphilis.htm> 25. Bright A & Dups J, Communicable Diseases Intelligence Volume 40 No 1 - March 2016 26. Arizona Dept. Health & Services, Real-Time Syphilis Data 2018 27. Mokany E et al. Clin. Chem. 2013; 59(2): 419-426 28. **PlexPCR**[®] VHS Instructions for use *Not for sale in USA. **PlexPCR**[®] VHS kits are developed and manufactured by **SpeedX** Pty Ltd, Sydney. **PlexPCR**[®] & **SpeedX**[®] are registered trademarks of **SpeedX** Pty Ltd. Other copyright and trademarks are the property of the respective owners. **SpeedX** Pty Ltd products may be covered by one or more local or foreign patents. Visit www.plexpcr.com/patents for comprehensive patent information.

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