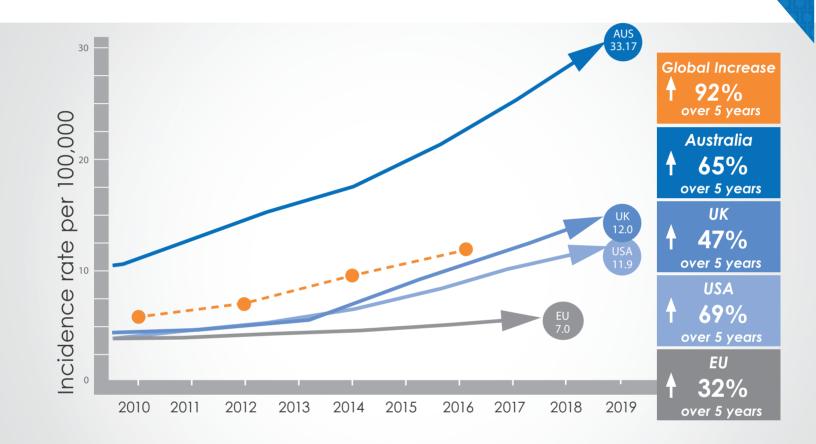
PlexPCR® VHS

Varicella, Herpes and Syphilis

Confident lesion testing to suit any population



Syphilis rates are on the rise¹⁻⁸

- Symptomatic/visual lesion diagnostics can have low accuracy (33-80%), 9-11 molecular testing is recommended 12-15,17-18
- Syphilis lesions can present atypically, be painful, and appear indistinguishable from herpes^{13,19,20}
- Atypical zoster (VZV) may account for 1-3%²¹⁻²³ 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
PlexPCR® HV (7500) PlexPCR® HV (LC480) PlexPCR® HV (CFX)	HSV-1 / HSV-2 / VZV
PlexPCR® VHS (7500) PlexPCR® VHS (LC480) PlexPCR® VHS (CFX)	HSV-1 / HSV-2 / VZV / T. pallidum

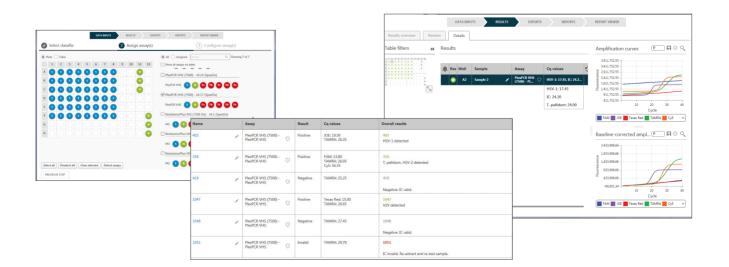
- Multiple analysis module options for flexible target analysis
- Choose all four targets or herpes and varicella only
- Modules analysed simulatenously to streamline workflow and data analysis

Fast and reproducible data analysis.

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

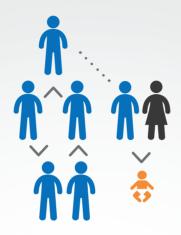
The complete **Plex**PCR® VHS solution includes:

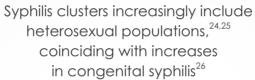
- Automated result calling
- Simple sample processing
- Validated, high security, GDPR compliance
- Multiple analysis modules with or without syphilis

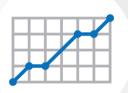


"We strongly believe in having a T. pallidum PCR as part of the routine test for any genito-anal ulcer. Several patients have been found to have syphilis where this was not originally suspected, and blood tests would never have been taken."

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



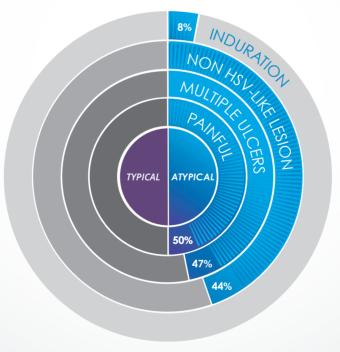




Syphilis at highest rates in decades, including rise in congenital syphilis cases^{1-3,9,16}



Molecular testing
from a syphilis lesion
is a direct detection
method—simplifying
diagnosis and enabling
timely partner
notification and
contact tracing²⁷



Atypical lesion presentation can complicate diagnosis^{13,19-23}



Surveillance or sentinal lesion screening can assist with early detection^{28,29}



Increased number of reported syphilis epidemics and outbreaks³⁰⁻³²



PlexPCR° VHS is a single-well, mulitplex qPCR test detecting common causes of genital and oral lesions. Detect Herpes simplex virus type-1 and -2 (HSV-1 and HSV-2), and Varicella zoster virus (VZV), with software analysis options to include *Treponema pallidum* (syphilis) detection. **Plex**PCR° VHS is powered by **Plex**PCR° proprietary technologies for improved multiplex performance compared with other probe-based methods.³³

Single-well **Plex**PCR® Test

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

Demonstrated clinical performance³⁴

	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, genital, non-genital, anal/rectal and oral swab specimens.³⁴

PlexPCR® VHS Flexible lesion diagnostics

Product	Compatible	Size	Cat #
PlexPCR® VHS*	7500 Fast	100 reactions	1123001
	LC480 II	100 reactions	1121001
	CFX	100 reactions	1125001

*CE-IVD, TGA cleared. Not for sale in the US

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. Sexually Transmitted Infections. [S.L.]: National Academies Press; 2021. 5. National Overview - Sexually Transmitted Disease Surveillance, 2020 [Internet]. Cdc.gov. 2021 [cited 2 August 2021]. Available from: https://www.cdc.gov/std/statistics/2020/overview.htm 6. Prochazka M, et al. Tracking the syphilis epidemic in England: 2010 to 2019. January 2021, Public Health England, London. 7. National syphilis surveillance quarterly report - July to September 2022 [Internet] https://www.health.gov.au/resources/publications/ national-syphilis-surveillance-quarterly-report-july-to-september-2022?language=en [Cited 8 March 2023] Available from: https://www.health.gov.au/sites/default/files/2023-03/national-syphilissurveillance-quarterty-report-july-to-september-2022.pdf 8. European Centre for Disease Prevention and Control, . (n.d.). (tech.). Syphillis Annual Epidemiological Report for 2018. Retrieved from https://www.ecdc.europa.eu/sites/default/files/documents/syphilis-aer-2018.pdf 9. Dangor Y et al. Sex Transm Dis 1990; 17:184-189. 10. O'Farrell N et al. Genitourin Med 1994; 70: 7-11 11. Ndinya-Achola JO et al. Int J STD & AIDS 1996; 7: 201-205 12. Workowski KA et al MMWR Recomm Rep 2015;64 (RR03); 25-48 13. Janier M et al. 2020 European auideline on the management of syphilis https://onlinelibrary.wiley.com/doi/10.1111/jdv.16946 14. Australian STI Management Guidelines 2023 [Internet] https://sti.guidelines.org.au/ [cited 8 March 2023] Available from: https://sti.guidelines.org.au/sexually-transmissible-infections/syphilis/ 15. Patel R et al. 2017 European guidelines for the management of genital herpes 16. Abara WE et al. PLOS ONE Published online 22 July 2016 17. Kingston M et al. UK national guidelines on the management of syphilis 2015 18. Grange et al 2021: Use of a Multiplex PCR Assay To Assess the Presence of Treponema pallidum in Mucocutaneous Ulcerations in Patients with Suspected Syphilis Print 2021 Jan 21 [Internet] https://pubmed.ncbi.nlm.nih.gov/33177120/ [Cited 15 March 2023] 19.Towns JM Sex Transm Infect. 2016 Mar; 92(2): 110-5 20. Hope-Rapp E et al. J Sex Transm Dis. 2010; 37: 153-8 21. Rübben A et al. Br J Dermatol. 1997; 137(2): 259-61 22. Granato PA et al. J Clin Virol. 2016 Nov;84:87-89 23. Birch C et al. Sex Transm Infect. 2003; 79:298-300 24. Cunningham S et al. Sex Transm Infect. 2006;82:444-445 25. Doherty IA et al. Sex Transm Dis. 2011 May; 38(5): 378–384 26. Slutsker JS et al. MMWR Morb Mortal Wkly Rep 2018;67:1088–1093 27. Goldstein et al. 2021 Diagn Microbiol Infect Dis. 2021 Feb;99(2):115221.doi: 10.1016/j.diagmicrobio.2020.115221. Epub 2020 Sep 21. https://pubmed.ncbi.nlm.nih.gov/33176262/28, Syphilis CDNA National Guidelines for Public Health Units v1.1, June 2018 29, Scott LJ Sex Transm Infect 2010 86:537-539 30, Victoria Government Department Health [Internet]. https://www.health.vic.gov.au/ [cited 4 March 2023] https://www.health.vic.gov.au/infectious-diseases/local-government-areas-surveillancereport 31. Bright A & Dups J, Communicable Diseases Intelligence Volume 40 No 1 - March 2016 32. Arizona Dept. Health & Services, Real-Time Syphilis Data 2018 33. Mokany E., Tan Y.L., Bone S.M., Fuery C., Todd A.V., 2013. MNAzyme qPCR with superior multiplexing capacity. Clin. Chem. 59(2); 419-426 34. PlexPCR® VHS Instructions for use

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