



T. Pallidum/HSV-1/HSV-2 Nucleic Acid Detection Kit (Real-Time PCR)

Early Detection and Differential Diagnosis of Syphilis
and Genital Herpes

NMPA registration number: 20253400805

Background



Syphilis (TP)

Syphilis remains a significant global health concern. According to World Health Organization (WHO) estimates, approximately 12 million new cases occur globally each year. WHO has identified syphilis as one of the four priority sexually transmitted infections (STIs).



Herpes Simplex Virus (HSV)

Herpes simplex virus infection is also highly prevalent in the general population. According to data published by the WHO, approximately 3.7 billion people under the age of 50 (67%) are infected with HSV type I, and about 491 million people aged 15-49 (13%) are infected with HSV type II worldwide.






Official recommendation

In the 2021 WHO Guidelines for the Management of Symptomatic Sexually Transmitted Infections^[1], it is strongly recommended that individuals with genital ulcers (including anorectal ulcers) undergo molecular testing (such as nucleic acid amplification tests) to confirm or rule out infections with herpes simplex virus and syphilis.

Diagnostic value

1. Confirming or ruling out syphilis and herpes infections in patients with genital ulcers to guide precise medication and reduce the risk of drug resistance.
2. Early identification of suspected syphilis infections to enable early diagnosis, prompt treatment, and faster recovery.

Product features

 Efficient Triple detection in a single tube for rapid and effective diagnosis of <i>Treponema pallidum</i> , Herpes Simplex Virus Type I (HSV-1), and Type II (HSV-2).	 Accurate The limit of detection for <i>Treponema pallidum</i> , Herpes Simplex Virus Type I (HSV-1), and Type II (HSV-2) is as low as 300 copies/mL, minimizing the risk of missed diagnoses.	 Controllable Specific primers and probes are used as internal controls to monitor the sample collection and testing process, ensuring the accuracy of the test results.	 Preventable Uracil-DNA glycosylase (UDG) is included as an anti-contamination component to reduce the risk of nucleic acid amplification product contamination.	 Excellent Clinical trial results show a 100% concordance rate for Herpes Simplex Virus Type I (HSV-1) and Type II (HSV-2).
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Product specifications

Intended Use	This product is intended for the in vitro qualitative detection of nucleic acids from <i>Treponema pallidum</i> (syphilis), Herpes Simplex Virus Type I (HSV-1), and Type II (HSV-2) in swab or tissue exudate samples from genital ulcer lesions.
Target Population	Individuals with genital (including perianal) ulcers or vesicles who are highly suspected of being infected with syphilis or herpes viruses.
Limit of Detection	The limit of detection for <i>Treponema pallidum</i> , Herpes Simplex Virus Type I (HSV-1), and Type II (HSV-2) is 300 copies/mL.
Package size	24 tests/kit, 48 tests/kit, 96 tests/kit
Compatible Instruments	ABI 7500, QuantStudio™ 5, SLAN-96P/SLAN-96S

Reference:

1. Who-guidelines-management-symptomatic-sti-2021
2. Global health sector strategy on Sexually Transmitted Infections, 2016-2021
3. Syphilis Diagnosis WS 273-2018 (China)
4. Genital Herpes Diagnosis WS/T 236-2017 (China)
5. Chinese Guidelines for the Diagnosis and Treatment of Sexually Transmitted Diseases

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