

# Herpes Simplex Virus 2 (HSV-2)

## Overview

### Clinical

Herpes simplex virus (HSV) is a common human pathogen, causing infections of orofacial mucosal surfaces (HSV-1) and genital mucosal surfaces (HSV-2)<sup>1</sup>.

Symptoms can include painful, recurring blisters or ulcers. New infections may cause fever, body aches and swollen lymph nodes.

HSV-2 mostly spreads by spreads by sexual contact and causes genital herpes.<sup>2</sup>

Neonatal herpes can occur when an infant is exposed to HSV during delivery. However, it is a serious condition that can lead to lasting neurologic disability or death. The risk for neonatal herpes is greatest when a mother acquires HSV for the first time in late pregnancy<sup>2</sup>.

### Epidemiology

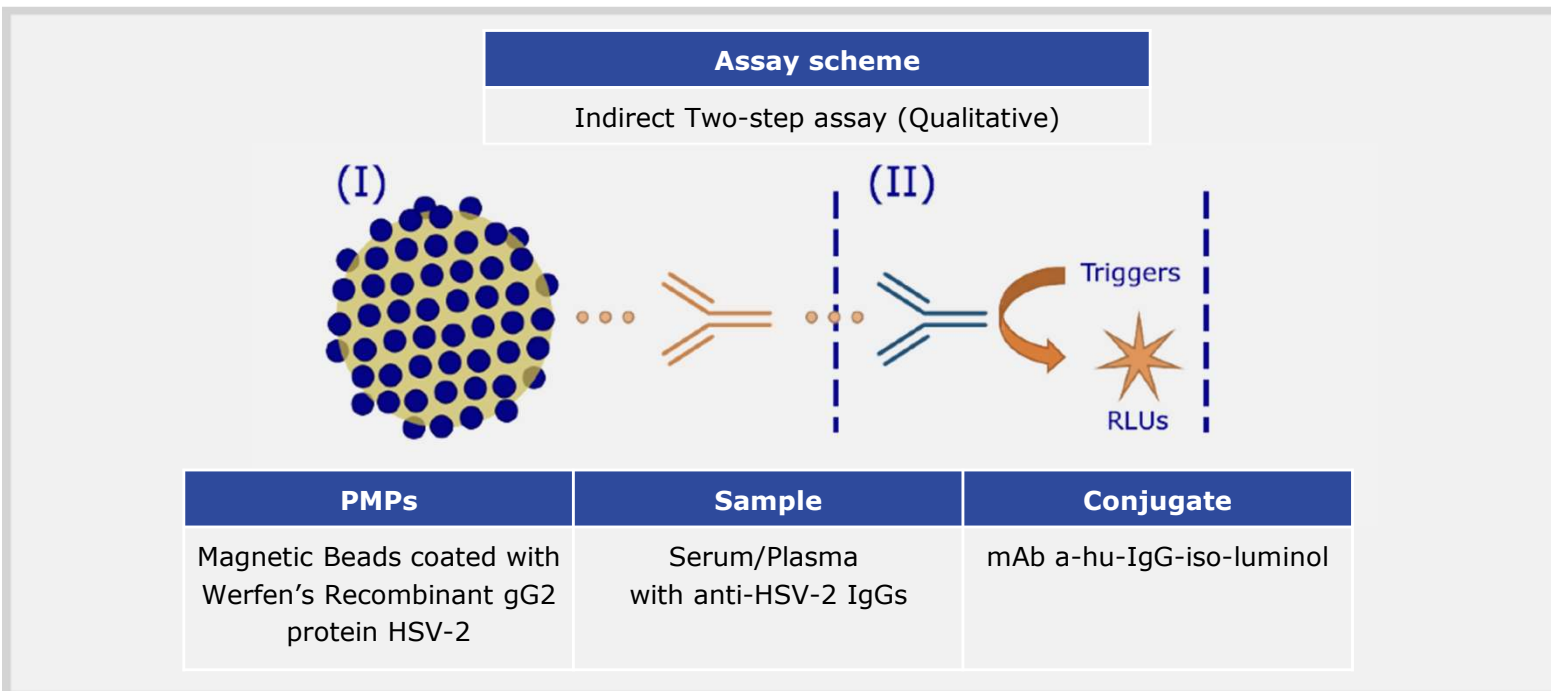
It is estimated that 491 million (13%) people aged 15–49 has been infected with HSV-2<sup>2</sup>.

The US CDC estimated that there were 572,000 new genital herpes infections in the United States in a single year between 2015 and 2016<sup>3</sup>.

## HSV-2 IgG CLIA

### Assay Scheme

Qualitative detection of antibodies (IgG) to HSV-2 in human serum or plasma



1 Taylor et al. Herpes Simplex Virus. Fontiers in Bioscience March 2002

2. Herpes Simplex Virus WHO Key Facts. April 2023. Accessed March 2024. <https://www.who.int/news-room/fact-sheets/detail/herpes-simplex-virus>

3.-Genital Herpes Detailed CDC Fact sheet. July 2021. Accessed March 2024. <https://www.cdc.gov/std/herpes/stdfact-herpes-detailed.htm#ref1>

# Evaluation of HSV-2 IgG CLIA vs reference assay

HSV-2 IgG CLIA Assay	Reference Method			Total
	IND	NEG	POS	
NEG	5	275	3	283
POS	0	1	174	175
Total	5	276	177	458

**Table 2:** External evaluations were performed in a clinical laboratory. Samples were characterized by another commercially available ELISA HSV-2 IgG method and was tested with HSV-2 IgG CLIA assay. IND results were not used in calculations

N	Relative Sensitivity		Relative Specificity		Overall Agreement	
	Value	95% CI	Value	95% CI	Value	95% CI
453	98.3%	95.1% to 99.7%	99.6%	98.0% to 100.0%	99.1%	97.8% to 99.8%

**Table 3:** Results on table 3 were obtained for relative sensitivity, specificity and overall agreement

## Cross-reactivity Test with HSV-2 IgG CLIA

Cross-reactivity	
Cross-reactant type	Agreement
Anti-Toxo IgG ( <i>Toxoplasma gondii</i> )	8/8
Anti-Rubella IgG	10/10
Anti-HIV (Human Immunodeficiency Virus)	10/10
Anti-HSV-1	10/10
Anti-HHSV6 IgG (Human Herpesvirus 6)	10/10
Anti-HHSV8 IgG (Human Herpesvirus 8)	10/10
Anti-EBV (Epstein-Barr Virus)	10/10
Anti-PV B19 (Parvovirus B19)	7/7
Syphilis	10/10
Anti-VZV (Varicella Zoster Virus)	9/9

**Table 4. Cross-reactant sample testing.** 94 specimens with potential cross-reactivity with the HSV-2 IgG CLIA assay were tested against commercially available HSV-2 IgG assay. Table above is showing the agreement between methods

## Werfen's Biomaterial offering

### Recombinant gG2 protein HSV-2 (ref 3000-5282 / 3000-5283)

**Storage:** -70°C

**Source:** *Trichoplusia ni*

**Storage buffer:** HEPES, NaCl, pH 8.2

**Protein concentration:** 0.8 – 1.5 mg/mL

**Preservative:** None

This product is manufactured using CrisBio™ technology from ALGENEX S.L

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Contact [oem@werfen.com](mailto:oem@werfen.com) for further technical information and product availability