Herpes Simplex Virus 1 (HSV-1)

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)[1].

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

HSV-1 mostly spreads by oral contact and causes infections in or around the mouth (oral herpes or cold sores). It can also cause genital herpes.[2]

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[2].

Epidemiology

It is estimated that 3.7 billion people under the age of 50, or 67% of the global population, had HSV-1 infection (oral or genital). Most HSV-1 infections are acquired during childhood[2].

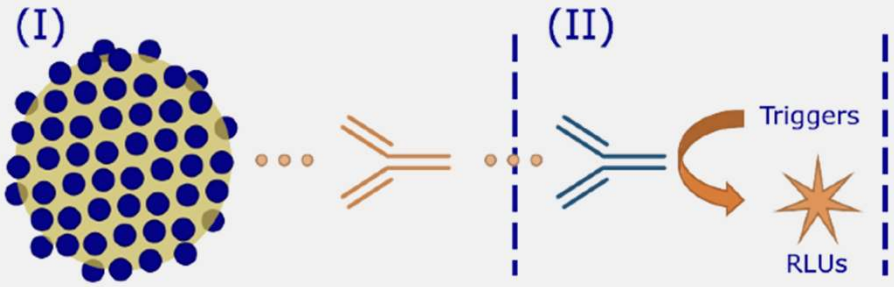
Neonatal herpes is rare, occurring in an estimated 10 out of every 100 000 births globally[2].

HSV-1 IgG CLIA

Assay Scheme

Qualitative detection of antibodies (IgG) to HSV-1 in human serum or plasma

Assay scheme
Indirect Two-step assay (Qualitative)



PMPs	Sample	Conjugate
Magnetic Beads coated with Werfen's Recombinant gG1 protein HSV-1	Serum/Plasma with anti-HSV-1 IgGs	mAb a-hu-IgG-iso-luminol

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

Evaluation of HSV-1 IgG CLIA vs reference assay

	Reference Method			
HSV-1 IgG CLIA Assay	IND	NEG	POS	Total
NEG	7	112	2	121
POS	3	2	312	317
Total	10	114	314	438

Table 2: External evaluations were performed in a clinical laboratory. Samples were characterized by another commercially available ELISA HSV-1 IgG method and was tested with HSV-1 IgG CLIA assay. IND results were not used in calculations

	Relative Sensitivity		Relative Specificity		Overall Agreement	
N	Value	95% CI	Value	95% CI	Value	95% CI
438	99.4%	97.7% to 99.9%	98.2%	93.8% to 99.8%	99.1%	97.6% to 99.7%

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

Cross-reactivity Test with HSV-1 IgG CLIA

Cross-reactivity	
Cross-reactant type	Agreement
Anti-Toxo IgG (*Toxoplasma gondii*)	8/8
Anti-Rubella IgG	10/10
Anti-HIV (Human Immunodeficiency Virus)	10/10
Anti-HSV-2	7/7
Anti-HHSV6 IgG (Human Herpesvirus 6)	10/10
Anti-HHSV8 IgG (Human Herpesvirus 8)	9/9
Anti-EBV (Epstein-Barr Virus)	10/10
Anti-PV B19 (Parvovirus B19)	10/10
Syphilis	10/10
Anti-VZV (Varicella Zoster Virus)	10/10

Table 4. Cross-reactant sample testing. 94 specimens with potential cross-reactivity with the HSV-1 IgG CLIA assay were tested against commercially available HSV-1 IgG assay. Table above is showing the agreement between methods

Werfen's Biomaterial offering

Recombinant gG1 protein HSV-1 (ref 3000-5288 / 3000-5279)
Storage: -70ºC
Source: *Trichoplusia ni*
Storage buffer: HEPES, NaCl, pH 7.5
Protein concentration: 0.5 – 2 mg/mL
Preservative: None

This product is manufactured using CrisBioTM technology from ALGENEX S.L
The content within this brochure is provided for informational purposes.
Contact immunoassay@werfen.com for further technical information and product availability

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