BioVendor Group CLIA

HSV 1+2

Antibody determination

***Herpes simplex virus* IgG, IgM**

Diagnostic panels:
TORCH
Herpes viruses

IVD CE 2265

The kits are CE-IVD certified and intended for professional use.

Designed for the platform

Kleeya®


diatron

Introduction

Herpes simplex virus exists in two types (HSV-1 and HSV-2) and belongs to the *Herpetoviridae* family. Both types of virus also share common antigens that can cross-react in serological tests. The only host of the infection is human. Herpes is transmitted by means of droplet infection or during close contact with an infected person. The virus replicates primarily in the mucous membranes of the eye, mouth, nose, and genitals. Primary infection of HSV-1 generally occurs already during childhood. HSV-1 usually infects the bulbar conjunctiva or oral mucosa. The infection is frequently asymptomatic or may lead to the appearance of herpetic lesions.

HSV-2 infection is one of the most common venereal diseases which result in the formation of lesions in the genital mucosa. There are also rare cases of transplacental transmission of this disease. The infection of a child through cervical secretions during childbirth occurs more commonly. One of the most serious forms of HSV infection is herpetic encephalitis.

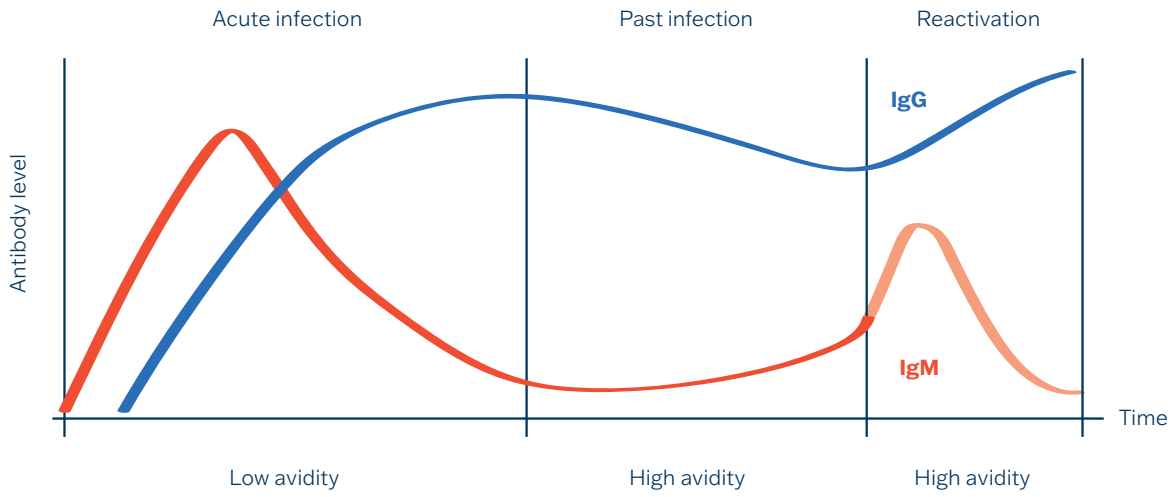
The infection tendency to persist in the organism is characteristic for HSV disease. It may also be reactivated under certain conditions (stress, reduced immunity).

Antibody determination

Diagnostic importance of antibody classes

The diagnosis of the disease is based on the clinical picture, epidemiological history, and laboratory tests. Primary infection is associated with the production of specific IgM class antibodies. These are detectable as early as 1 week after infection and persist for about 6 weeks. Specific IgG antibodies usually appear 2 to 3 weeks after IgM antibodies but may appear several months later.

Viral reactivation may or may not be associated with the production of IgM antibodies. Significant increases in IgG levels are seen in paired sera in both primary and recurrent infections. Specific IgG antibodies usually remain at low levels throughout life.



Clinical application

– The diagnosis and screening of HSV infection using IgG and IgM antibodies in human serum or plasma in the general population.

Antigens

***Herpes simplex virus* IgG, IgM**
Mixture of inactivated and purified HSV-1 and HSV-2 strains

Test characteristics

Kit	Calibration scale	Diagnostic sensitivity	Diagnostic specificity
CLIA HSV 1+2 IgG	0.5–160 U/ml	89.22%	97.50%
CLIA HSV 1+2 IgM	3–160 U/ml	94.59%	87.37%

Correlation of methods

CLIA kits were compared to established ELISA kits from TestLine of the BioVendor Group. 96–99% agreement was found among the compared methods.

Accuracy and analytical sensitivity

High precision ensures consistent and reliable results of each measurement:

		IgG	IgM
Repeatability	Intra assay (within run)	12.62%	7.63%
	Reproducibility	12.88%	12.19%

Clinical function

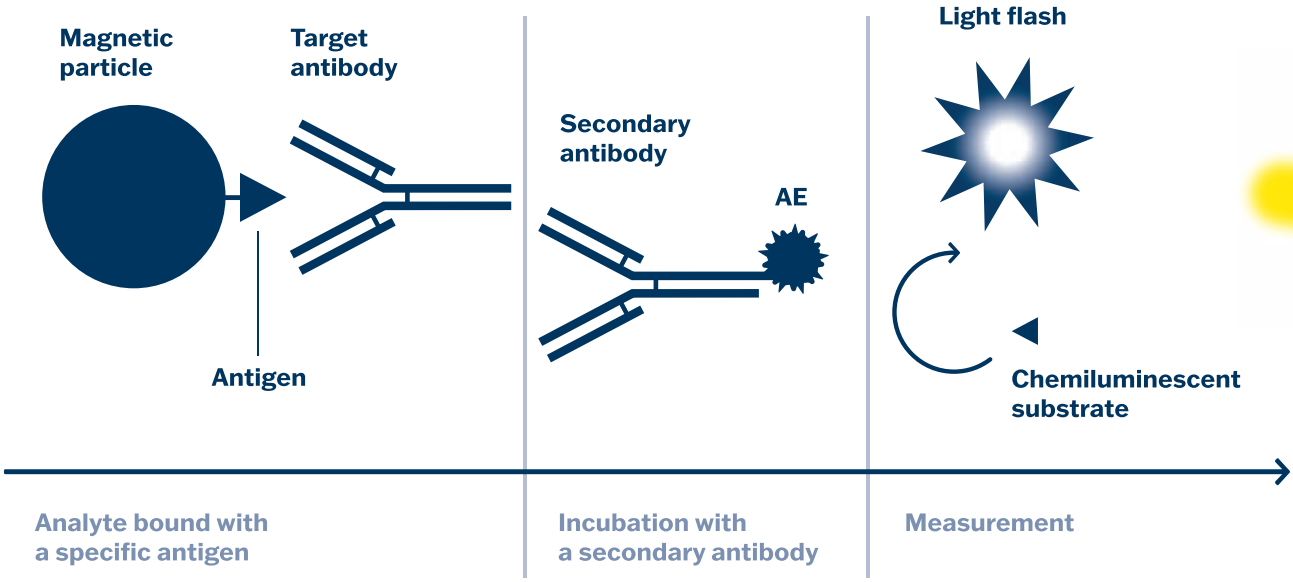
The quality of the CLIA HSV 1+2 IgG and IgM kits were verified within an external clinical performance study at a specialized laboratory according to the strict requirements of the European IVDR directive.

The obtained comparison of clinical samples with the reference commercial kits demonstrated high level of agreement:

	IgG	IgM
Comparison with the reference method	91.55%	89.39%

How does CLIA method work?

CLIA is a fully automated, fast, specific and sensitive method. It combines the use of magnetic particles for immunocomplex separation of the antigen and flash chemiluminescence for sensitive detection. The use of magnetic particle suspension facilitates automation, significantly shortens reaction times and improves the specificity of the determination. Flash chemiluminescence of acridinium ester provides an intense light signal even at very low concentrations and its intensity is measured in relative units of light (RLU). CLIA kits are designed for use on the KleeYa® automated platform.



CLIA kits

Diagnostic CLIA kits are intended for the diagnosis and screening of HSV infection using IgG and IgM antibodies in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory on a KleeYa® analyzer. Results are reported in U/ml.

Control set CLIA

Control sera verify the accuracy of results obtained by the CLIA kits.

Ease of use

- Fully automated method
- Kits include all necessary reagents, incl. calibrators
- Working strength reagent solution
- Control sera available as independent sets
- Results in U/ml

Advantages

- High diagnostic sensitivity and specificity
- Low sample (10 µl) and reagent consumption
- Short test time (30–40 min)
- Full traceability of reagent consumption and number of tests available using RFID tags
- LIS connectivity available
- Superior customer service

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Ordering information

CLIA kits

Diagnostic CLIA kits are intended for the diagnosis and screening of HSV infection using IgG and IgM antibodies in human serum or plasma on a KleeYa® analyser.

Kit	Catalogue number	Number of tests
CLIA HSV 1+2 IgG	CL-HSVG100	100
CLIA HSV 1+2 IgM	CL-HSVM100	100

Control set

Each set contains two vials of positive and two vials of negative control serum with the predetermined level of specific antibodies. They are designed to verify the accuracy of results obtained with CLIA kits.

Kit	Catalogue number	Number of tests
Control set CLIA HSV 1+2 IgG	CL-HSVGCON	2 x 20
Control set CLIA HSV 1+2 IgM	CL-HSVMCON	2 x 20

Contact us at

clia@biovendor.group

or visit our website

clia.biovendor.group

BIOVENDOR.GROUP

PRODUCER:

TestLine®

TestLine Clinical Diagnostics s.r.o.
Křižíkova 68
612 00 Brno
Czech Republic

ENIP1201