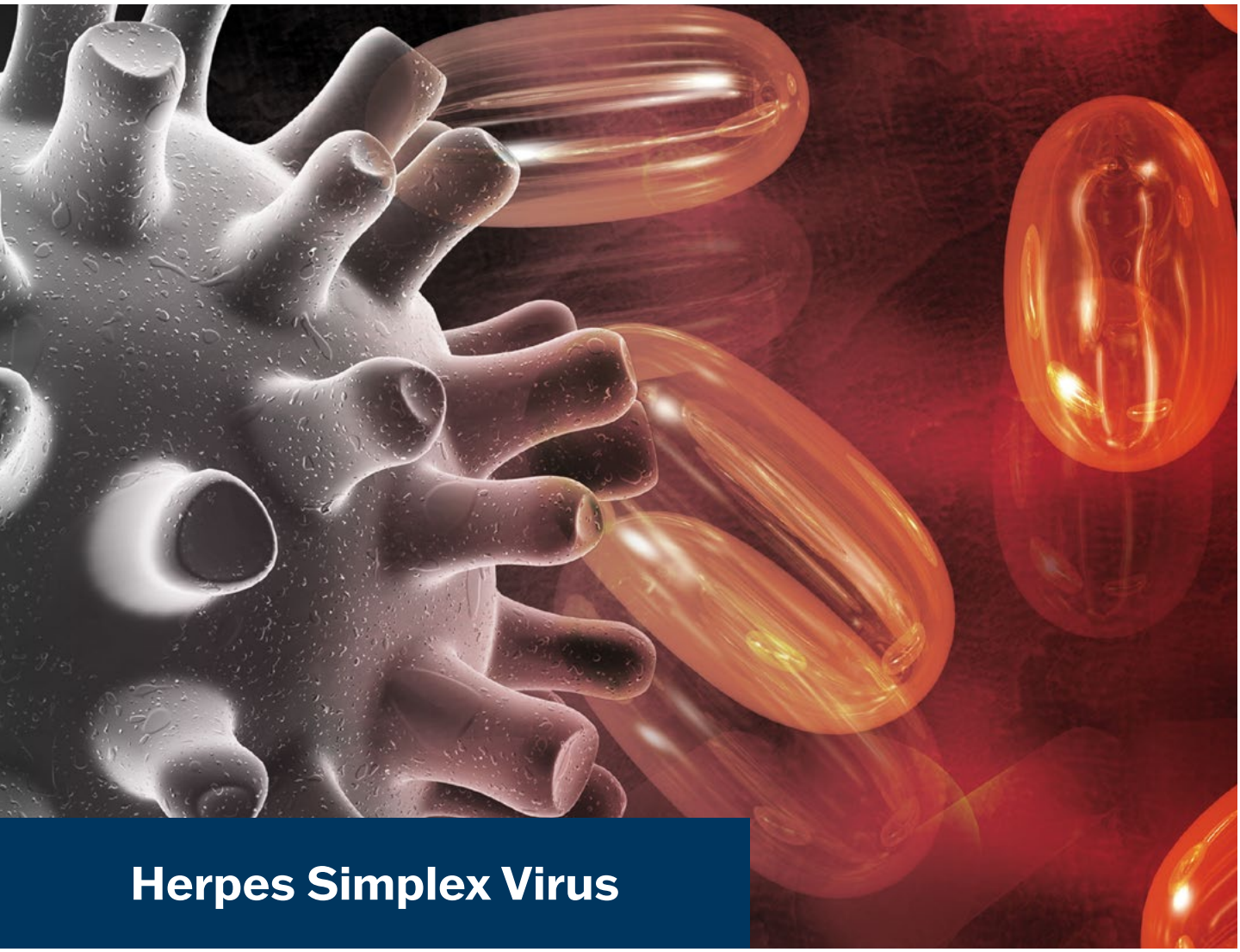


Herpes Simplex Virus

Enzyme immunoassays for the diagnostics of Herpes simplex virus infection

ELISA and **MICROBLOT-ARRAY** kits are optimized and validated for detection of IgG, including their avidity, and IgM antibodies in human serum, plasma or cerebrospinal fluid

CE IVD

Diagnostic kits are intended for professional use in the laboratory.

BG TestLine®

Introduction

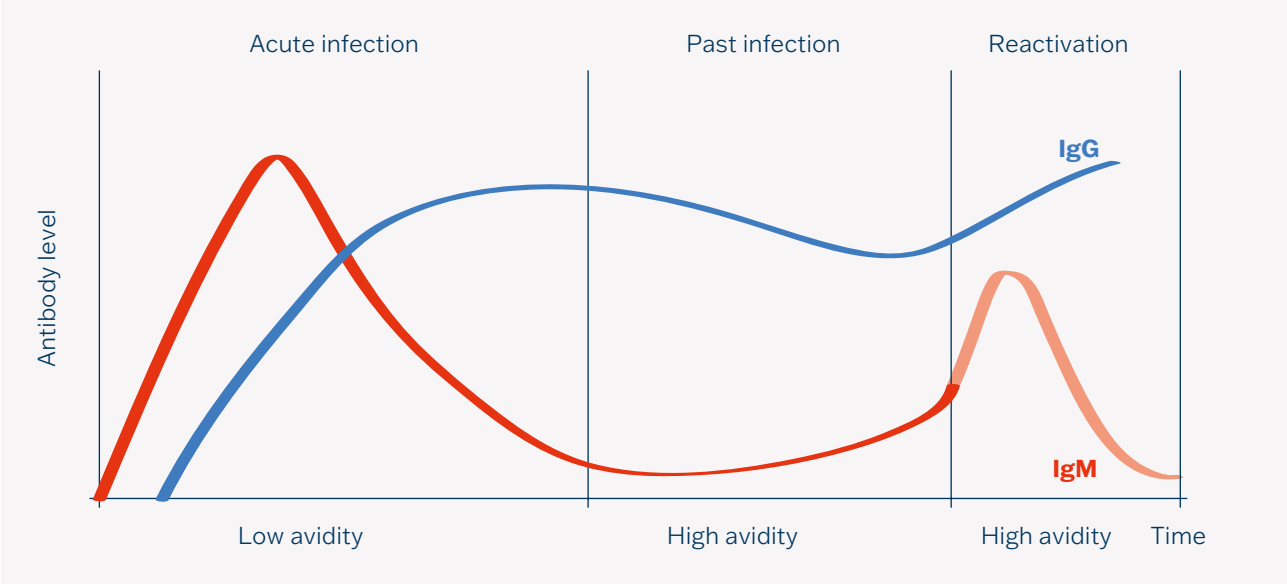
Herpes simplex virus exists in two types (HSV-1 and HSV-2) and belongs to the herpesvirus family. Both varieties have common antigens and cross-react during serological tests. Herpes is transmitted by means of droplet infection or during close contact with an infected person. The only host of the infection is human. 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. Herpetic encephalitis is one of the most serious manifestations of HSV-1 infection. 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.

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

Diagnosis of infection

The primary infection is always accompanied by specific IgM antibodies which are already produced one week after infection and persist for approximately 6 weeks. The specific IgM antibodies may or may not be found during reactivation. Specific IgA antibodies occur shortly after IgM and before an elevation of IgG class. The significant elevation of IgG antibodies level is recorded in paired serum samples examined during primary infections as well as during recurrent one. The specific IgG antibodies occur 2 or 3 weeks after primary infection, however, they may also appear after several months and they mostly remain in reduced levels throughout the entire life of the infected person.

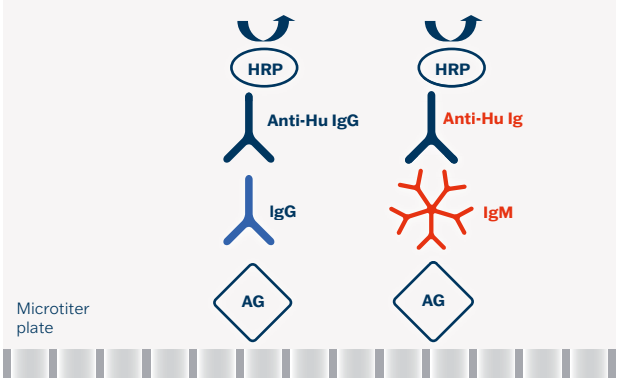
Antibody response



ELISA

Test principle

The assays are based on a sandwich type of ELISA method.



Antigens

EIA HSV 1+2
Mixture of inactivated and purified HSV-1 and HSV-2 strains

EIA HSV 1
Purified and inactivated HSV-1 antigen with a high content of specific immunodominant epitopes

EIA HSV 2
Purified and inactivated HSV-2 antigen with a high content of specific immunodominant epitopes.

Summary protocol

Step		Test steps
	1.	Dilution of samples – serum/plasma 1:101 (10 µl + 1 ml) – cerebrospinal fluid 1:3 (50 µl + 100 µl)
	2.	Pipette Controls and diluted samples 100 µl – Including blank
	3.	Incubate 30 min. at 37 °C
	4.	Aspirate and wash the wells 5 times
	5.	Add Conjugate 100 µl – Including blank
	6.	Incubate 30 min. at 37 °C
	7.	Aspirate and wash the wells 5 times
	8.	Add 100 µl Substrate (TMB-Complete) – Including blank
	9.	Incubate 30 min. at 37°C
	10.	Add 100 µl Stopping solution – Including blank
	11.	Read colour intensity at 450 nm

Clinical application

- Screening test for the detection of specific IgG and IgM antibodies in human serum, plasma or cerebrospinal fluid
- Checking of therapy results using the semiquantitative determination
- Disease stage diagnosis

User comfort

- Ready-to-use components
- Colour-coded components
- Interchangeable components
- Breakable colour-coded microplate strips
- CUT-OFF included
- Semiquantitative evaluation of results (Index of Positivity)

Advantages

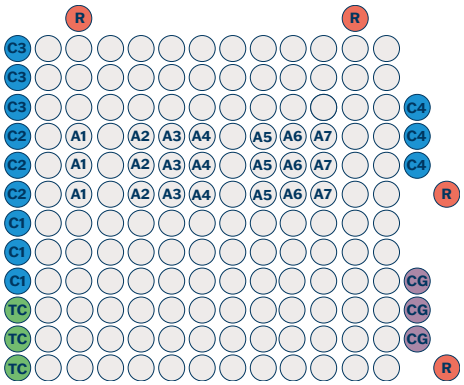
- High diagnostic specificity and sensitivity
- High reproducibility
- High dynamics of antibody response
- Identical assay procedure
- Short total assay time
- Test of avidity (EIA HSV 1+2 IgG)
- Ready for automation
- Determination in cerebrospinal fluid
- Possibility of independent verification (CKS)
- Customer support

Test characteristics

ELISA	Diagnostic sensitivity	Diagnostic specificity
EIA HSV 1+2 IgG	99.9%	95.6%
EIA HSV 1+2 IgM	96.7%	96.7%
EIA HSV 1 IgG	99.9%	96.3%
EIA HSV 1 IgM	94.6%	97.0%
EIA HSV 2 IgG	95.5%	98.2%
EIA HSV 2 IgM	92.3%	98.0%

MICROBLOT-ARRAY

Distribution of antigens and control spots



Description of control spots

- **R** – Reference
- **TC** – Test control
- **CM** – Conjugate control IgM
- **CG** – Conjugate control IgG
- **C1** – Calibration 1
- **C2** – Calibration 2
- **C3** – Calibration 3
- **C4** – Calibration 4

Protocol Summary

Step		Test steps
	1.	Pipette Universal solution 150 µl
	2.	Strips soaking 10 min. at room temperature
	3.	Aspirate
	4.	Dilute samples – serum/plasma 1:51 (10 µl + 500 µl) – cerebrospinal fluid 1:3 (50 µl + 100 µl)
	5.	Pipette Controls and diluted samples 100 µl
	6.	Incubate 30 min. at room temperature
	7.	Quick wash with Universal Solution*
	8.	Aspirate samples and wash strips with 150 µl of Universal solution 3-times for 5 min.
	9.	Pipette Conjugate 100 µl
	10.	Incubate 30 min. at room temperature
	11.	Quick wash with Universal Solution*
	12.	Aspirate samples and wash strips with 150 µl of Universal solution 3-times for 5 min.
	13.	Pipette Substrate solution (BCIP/NBT) 100 µl
	14.	Incubate 15 min. at room temperature
	15.	Quick wash using the distilled water *
	16.	Aspirate Substrate solution and wash strips with 200 µl of distilled water 2-times for 5 min.
	17.	Dry and evaluate strips

* if using a washer, fill the wells to the brim and aspirate immediately after filling the last well

Description of antigens

Antigen	Description
HSV 1+2	Native HSV-1and HSV-2 antigen
gC-1 gC-2	Glycoprotein C-1 specific for *Herpes simplex 1 virus* Glycoprotein C-2 specific for *Herpes simplex 2 virus* Early antibody production
gD-1 gD-2	Glycoprotein D-1 specific for *Herpes simplex 1 virus* Glycoprotein D-2 specific for *Herpes simplex 2 virus* serves to capture and entry of the virus into a potential host cell; stimulates high production of neutralizing antibodies, high similarity between HSV-1 and -2
gG-1 gG-2	Glycoprotein G-1 specific for *Herpes simplex 1 virus* Glycoprotein G-2 specific for *Herpes simplex 2 virus* Appropriate for differentiating between HSV-1 and -2 infection In the IgG class – indications of previous or probably latent infection antibodies are formed only in the convalescent phase, they have been found also in patients with reactivation of infection In the IgM class – antibodies are produced only in the convalescent phase

User Comfort

- Low sample consumption
- Antigens spotted in triplicate – minimizing statistical variation
- Possibility of automatic assay processing and results evaluation
- Parallel testing of multiple markers simultaneously
- High sensitivity and specificity

Test Characteristics

Pathogen	Diagnostic Sensitivity	Diagnostická specificity
Microblot-Array HSV 1+2 IgG	99.9%	97.5%
Microblot-Array HSV 1+2 IgM	95.0%	99.4%

Ordering information

ELISA

Cat. No.	Product	Units
HSVG96	EIA HSV 1+2 IgG	96 wells
HSVM96	EIA HSV 1+2 IgM	96 wells
HS1G96	EIA HSV 1 IgG	96 wells
HS1M96	EIA HSV 1 IgM	96 wells
HS2G96	EIA HSV 2 IgG	96 wells
HS2M96	EIA HSV 2 IgM	96 wells
SK-HSVG96	SmartEIA HSV 1+2 IgG	96 wells
SK-HSVM96	SmartEIA HSV 1+2 IgM	96 wells
SK-HS1G96	SmartEIA HSV 1 IgG	96 wells
SK-HS1M96	SmartEIA HSV 1 IgM	96 wells
SK-HS2G96	SmartEIA HSV 2 IgG	96 wells
SK-HS2M96	SmartEIA HSV 2 IgM	96 wells

SmartEIA kits are designed for automated processing using the Agility® analyser.

MICROBLOT-ARRAY

Cat. No.	Product	Units
HSGMA48	Microblot-Array HSV 1+2 IgG	48
HSMMA48	Microblot-Array HSV 1+2 IgM	48

TestLine®

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CERTIFIED ISO 9001 · ISO 13485

Company is certified to the quality management system standards ISO 9001 and ISO 13485 for in vitro diagnostics.

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