

# Intended use

- Qualitative and quantitative detection of human IgA, IgG and IgM antibodies in serum or plasma directed against Herpes Simplex Viruses
- Demonstration of HSV 1/2 specific IgM antibodies for the detection of acute infections.
- Detection of HSV 1/2 specific IgG antibodies for the determination of the immune status
- Detection of intrathecally synthesized IgG antibodies in cerebrospinal fluid
- Detection of HSV 1/2 specific IgA antibodies for the diagnosis of reactivations

# Diagnostic Efficiency

SERION ELISA *classic* Herpes Simplex Virus 1/2 IgA was evaluated with 104 sera from healthy blood donors in comparison to a test from another manufacturer. The SERION ELISA *classic* Herpes Simplex Virus 1/2 IgG test was validated in a comprehensive external study at the German Reference Laboratory for Herpes Simplex Virus and Varicella- Zoster Virus located at the University in Jena by the

analysis of 241 serum samples in comparison to immunoassays of European manufacturers. The evaluation of the SERION ELISA *classic* Herpes Simplex Virus 1/2 IgM test was performed by the analysis of 176 serum samples in comparison to the test results of European manufacturers.

Produkt	Sensitivität	Spezifität
SERION ELISA <i>classic</i> Herpes Simplex Virus 1/2 IgA	90.9 %	95.8%
SERION ELISA <i>classic</i> Herpes Simplex Virus 1/2 IgG	95.5%	>99 %
SERION ELISA <i>classic</i> Herpes Simplex Virus 1/2 IgM	95.7 %	94.3%

## Precision

#### SERION ELISA classic Herpes Simplex Virus 1/2 IgA

Sample	Mean Value (OD)	Intraassay CV (%) (n=20)	Mean Value (OD)	Interassay CV (%) (n=10)
Serum 1	0.537	6.2	0.542	9.0
Serum 2	0.966	7.1	0.920	5.8
Serum 3	2.453	3.2	1.684	9.7

#### SERION ELISA classic Herpes Simplex Virus IgG

Sample	Mean Value (OD)	Intraassay CV (%) (n=20)	Mean Value (OD)	Interassay CV (%) (n=10)
Serum 1	0.391	2.7	0.435	6.7
Serum 2	1.138	2.2	1.179	3.5
Serum 3	1.773	2.2	1.841	2.3

### serion\diagnostics

Your Partner in Infectious Serology

#### SERION ELISA classic Herpes Simplex Virus IgM

Sample	Mean Value (OD)	Intraassay CV (%) (n=20)	Mean Value (OD)	Interassay CV (%) (n=10)
Serum 1	0.924	3.7	0.970	5.9
Serum 2	1.178	2.8	1.146	6.0
Serum 3	2.272	1.9	2.077	5.8

#### Pathogen

Herpes Simplex Virus 1 (HSV 1) and Herpes Simplex Virus 2 (HSV 2) are DNA viruses belonging to the family of Herpesviridae. They occur globally. In industrialized countries the seroprevalence amounts to 50 % for HSV 1 and 5 % for HSV 2 in the second decade of life, in adults even up to 90 % for HSV 1 and 10 to 15 % for HSV 2.

#### Disease

The transmission of Herpes Simplex Virus 1 occurs by contact with contaminated salivary or smear infection. Herpes Simplex Virus 2 is transmitted via contact with infected of mucosal skin. Primary HSV 1 infections process inapparently in 90% of cases. 10% of infected persons suffer from inflammations of cornea and conjunctiva or show the characteristic herpes vesiculation at the lips. These pustular eruptions can spread on eczematous skin with life-threatening effects. Other complications are encephalitis or meningoencephalitis. 12% of primary HSV 2 infections are

## Highlights

- Use of inactivated preparations of HSV 1 or HSV 2
- · Sensitive demonstration of IgM antibodies for the detection of acute infections
- · Detection of IgA antibodies in particular for the diagnosis of reactivations
- · Detection of IgG antibodies for the confirmation of contact with the pathogen
- Quantitative determination of all relevant antibody classes for the analysis of serum pairs for disease stage monitoring and therapy control
- $\cdot$  Detection of intrathecally synthesized HSV 1/2 specific IgA and IgG antibodies for CSF diagnostics

Product	Order-No.
SERION ELISA <i>classic</i> Herpes Simplex Virus 1/2 IgA	ESR105A
SERION ELISA <i>classic</i> Herpes Simplex Virus 1/2 IgG	ESR105G
SERION ELISA classic Herpes Simplex Virus 1/2 IgM	ESR105M

apparent with sudden abortion, vulvovaginitis or penis scrotum efflorescences. After primary infection local ganglions show life-long virus persistence, enabling the reactivation of latent infections.

#### Diagnosis

Diagnosis of Herpes Simplex Virus infections during the symptomatic phase of disease is based, primarily, on expensive direct demonstration of the pathogen by virus isolation methods or polymerase chain reaction (PCR). During the course of a primary infection, the humoral response is characterized by the initial manufacture of IgM, followed, somewhat delayed, by IgG antibodies. Primary infections can consequently be identified serologically by demonstration of seroconversion. IgM antibodies to Herpes Simplex Viruses may persist for months or even years, and may complicate the interpretation of serological test results. Determination of HSV specific IgA antibodies may be useful in supporting the diagnosis of a reactivation.

**SERION ELISA control** *Please visit our website for more information.* 

virion\serion