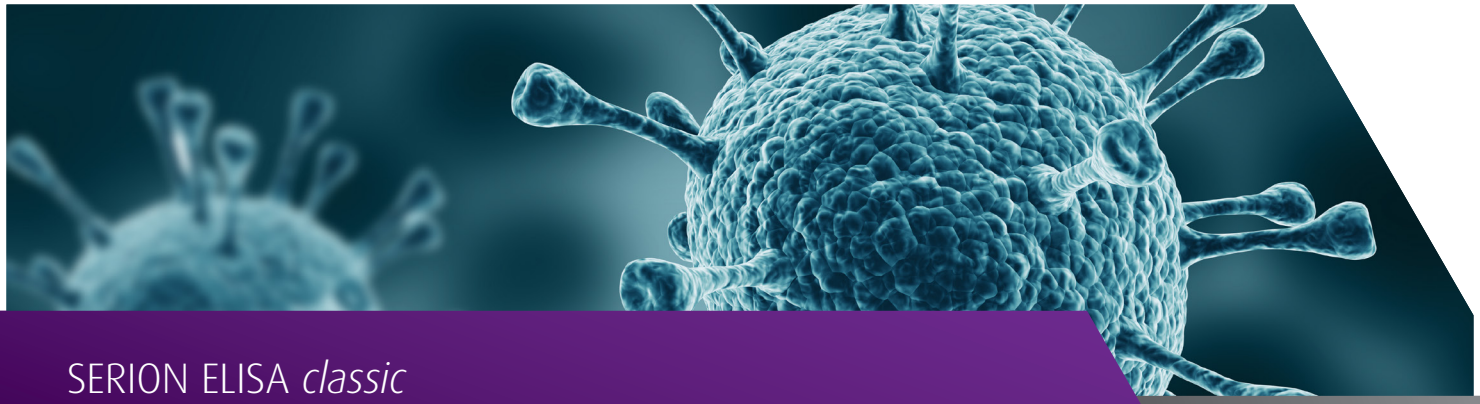

SERION ELISA *classic*

Herpes simplex Virus 1 and 2 IgG/IgM

Intended use

- Qualitative and quantitative detection of human IgG and IgM antibodies in serum or plasma directed against Herpes Simplex Virus (HSV) Type 1 or Type 2
- Detection of HSV 1 or HSV 2 specific IgM antibodies for the diagnosis of acute infections
- Detection of HSV 1 or HSV 2 specific IgG antibodies for the typification of the infection
- Detection of intrathecally synthesized HSV1 and HSV2 IgG antibodies in cerebrospinal fluid

Diagnostic Efficiency

The SERION ELISA *classic* Herpes Simplex Virus 1 and 2 IgG tests were 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. Immunoassays of leading European manufacturers were used as reference tests.

The SERION ELISA *classic* Herpes Simplex Virus 1 and 2 IgM test were evaluated with 153 sera, (for some of which previous test results were available) in comparison with a reference test.

Product	Sensitivity	Specificity
SERION ELISA *classic* Herpes Simplex Virus 1 IgG	97.8 %	95.7 %
SERION ELISA *classic* Herpes Simplex Virus 1 IgM	98.0 %	99.0 %
SERION ELISA *classic* Herpes Simplex Virus 2 IgG	97.6 %	>99 %
SERION ELISA *classic* Herpes Simplex Virus 2 IgM	98.0 %	99.0 %

Precision

SERION ELISA *classic* Herpes Simplex Virus 1 IgG

Sample	Mean Value (OD)	Intraassay CV (%) (n=20)	Mean Value (OD)	Interassay CV (%) (n=10)
Serum 1	0.278	3.4	0.290	4.4
Serum 2	0.561	3.9	0.626	6.2
Serum 3	1.228	2.6	1.391	4.9

SERION ELISA *classic* Herpes Simplex Virus 1 IgM

Sample	Mean Value (OD)	Intraassay CV (%) (n=20)	Mean Value (OD)	Interassay CV (%) (n=10)
Serum 1	0.448	3.9	0.467	9.2
Serum 2	0.940	3.0	0.918	10.5
Serum 3	1.458	2.1	1.487	11.5

SERION ELISA *classic* Herpes Simplex Virus 2 IgG

Probe	Mittlere Extinktion (OD)	Intraassay VK (%) (n=20)	Mittlere Extinktion (OD)	Interassay VK (%) (n=10)
Serum 1	0.472	2.7	0.489	4.7
Serum 2	1.131	2.7	1.082	5.6
Serum 3	1.885	2.8	1.876	3.7

SERION ELISA *classic* Herpes Simplex Virus 2 IgM

Probe	Mittlere Extinktion (OD)	Intraassay VK (%) (n=20)	Mittlere Extinktion (OD)	Interassay VK (%) (n=10)
Serum 1	0.583	6.4	0.679	6.7
Serum 2	1.081	4.8	1.170	6.4
Serum 3	1.492	2.8	1.787	5.4

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 % 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 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 apparent with sudden abortion, vulvovaginitis or penis scrotum efflorescences.

Diagnosis

An important field of application for HSV serology – also during latency – is the detection of serotype-specific HSV IgG antibodies in order to identify potential HSV carriers who could infect susceptible individuals. In particular, the identification of HSV 2 serotype-specific antibodies in pregnant women, who present a high risk of transferring the virus to a newborn child, is recommended. The serological typing of an HSV infection is usually performed by identifying IgG antibodies directed against the viral surface glycoproteins G (gG) of HSV 1 (gG1) and HSV 2 (gG2). Due to the fact that these antibodies are only produced some weeks after a primary infection, the determination of serotype-specific antibodies can also assist in the differentiation between primary infection and reactivation.

Highlights

- Use of inactivated preparations of HSV 1 or HSV 2 for the sensitive demonstration of IgM antibodies
- Use of affinity-purified glycoproteins gG1 of HSV 1 or gG2 of HSV 2 for the specific demonstration of IgG antibodies directed against HSV 1 or HSV 2 for determination of the HSV serotype
- Quantitative determination of all relevant antibody classes for the analysis of serum pairs for disease stage monitoring and therapy control
- Detection of intrathecally synthesized HSV1 and HSV2 IgG antibodies in cerebrospinal fluid

Product	Order-No.
SERION ELISA *classic* Herpes Simplex Virus 1 IgG	ESR1051G
SERION ELISA *classic* Herpes Simplex Virus 1 IgM	ESR1051M
SERION ELISA *classic* Herpes Simplex Virus 2 IgG	ESR1052G
SERION ELISA *classic* Herpes Simplex Virus 2 IgM	ESR1052M

SERION ELISA *control*

Please visit our website for more information.

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