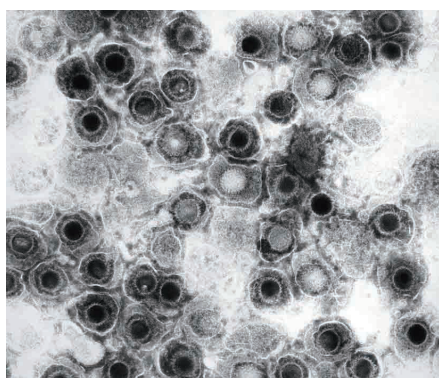


SERION ELISA *classic*

Herpes Simplex Virus 1 IgG / IgM

Herpes Simplex Virus 2 IgG / IgM

SERION ELISA *classic* Herpes Simplex Virus Type 1, respectively Type 2 IgG and IgM tests are quantitative and qualitative immunoassays for the detection of human antibodies in serum or plasma directed against Herpes Simplex Virus (HSV). SERION ELISA *classic* Herpes Simplex Virus IgM tests are recommended for the diagnosis of acute infections. SERION ELISA *classic* Herpes Simplex Virus IgG tests are used for the typification of the infection.



Electron micrograph of Herpes Simplex Viruses (Source: Centers for Disease Control and Prevention, United States Department of Health and Human Services).

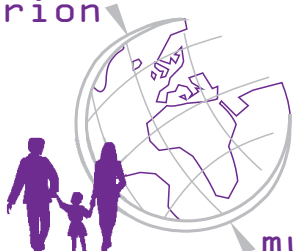
Pathogen

Herpes Simplex Virus 1 and Herpes Simplex Virus 2 are human pathogen DNA viruses belonging to the family of *Herpesviridae*. Herpes viruses are globally spread. In industrialized countries seroprevalence for Herpes virus infections amounts to 50 % in the second decade of life, in adults even up to 90 % for HSV Serotype 1 (HSV 1) and 10 to 15 % for HSV Serotype 2 (HSV 2).

Disease

Primary infection may result from direct contact with infected persons (saliva or urogenital secretion), transplacental transmission or iatrogenic through transfusions or transplantations. The incubation period is 2 to 12 days. Contagiousness can persist as long as there are skin and mucosa efflorescences (about 3 weeks). Primary HSV 1 infections process inapparently in 90 % of cases. The remainder show characteristic herpes vesiculation in areas of the lips, mouth or cornea and conjunctiva. These pustular eruptions can spread on eczematous skin with life-threatening effects. Further complications are encephalitis (70 % lethality) or meningo-encephalitis. 12 % of primary HSV 2 infections are apparent with sudden abortion, vulvovaginitis or penis scrotum efflorescences.

serion



multianalyt™

Diagnosis

Although most Herpes genitalis infections are caused by HSV 2, up to 20 % can be due to HSV 1. Symptoms of primary infection are identical, the reactivation rate of HSV 1 genitalis is lower. The SERION ELISA *classic* HSV 1 and HSV 2 IgM provide a comprehensive and sensitive detection of primary infections, the assays being based on inactivated HSV 1 and HSV 2. In contrast, IgG antibodies directed against the virus specific glycoproteins gG1 and gG2 are generated two to three months after primary infection in most cases. The detection by use of SERION ELISA *classic* HSV 1 and HSV 2 IgG based upon specific glycoproteins allows the differentiation of the virus type specific immune response.

Validation of SERION ELISA *classic* HSV 1 and HSV 2 IgG

The SERION ELISA *classic* HSV 1 IgG was evaluated by the analysis of 127 positive and 37 negative serum samples from blood donors. The ELISA of a leading European manufacturer was used as reference test. The evaluation of the SERION ELISA *classic* HSV 2 IgG was performed by the analysis of 193 serum samples in comparison to a FDA-approved reference test of a leading north American manufacturer. Sera classified as borderline were not included in the calculation.

SERION ELISA <i>classic</i>	Sensitivity	Specificity
Herpes Simplex Virus 1 IgG	> 99 %	> 99 %
Herpes Simplex Virus 2 IgG	> 99 %	> 99 %

Precision

SERION ELISA *classic* Herpes Simplex Virus 1 IgG

Sample	Mean Value OD	Intraassay CV (%) (n=20)	Mean Value OD	Interassay CV (%) (n=10)
weak positive	0,278	3,4	0,290	4,4
positive	0,561	3,9	0,626	6,2
strong positive	1,228	2,6	1,391	4,9

SERION ELISA *classic* Herpes Simplex Virus 1 IgM

Sample	Mean Value OD	Intraassay VCV (%) (n=20)	Mean Value OD	Interassay CV (%) (n=10)
weak positive	0,448	3,9	0,467	9,2
positive	0,940	3,0	0,918	10,5
strong positive	1,458	2,1	1,487	11,5

SERION ELISA *classic* Herpes Simplex Virus 2 IgG

Sample	Mean Value OD	Intraassay CV (%) (n=20)	Mean Value OD	Interassay CV (%) (n=10)
weak positive	0,472	2,7	0,489	4,7
positive	1,131	2,7	1,082	5,6
strong positive	1,885	2,8	1,876	3,7

SERION ELISA *classic* Herpes Simplex Virus 2 IgM

Sample	Mean Value OD	Intraassay CV (%) (n=20)	Mean Value OD	Interassay CV (%) (n=10)
weak positive	0,583	6,4	0,679	6,7
positive	1,081	4,8	1,170	6,4
strong positive	1,492	2,8	1,787	5,4

Order Information

SERION ELISA *classic* Herpes Simplex Virus 1 IgG

SERION ELISA *classic* Herpes Simplex Virus 1 IgM

SERION ELISA *classic* Herpes Simplex Virus 2 IgG

SERION ELISA *classic* Herpes Simplex Virus 2 IgM

Reference serum Herpes Simplex Virus 1 IgG

Reference serum Herpes Simplex Virus 1 IgM

Reference serum Herpes Simplex Virus 2 IgG

Reference serum Herpes Simplex Virus 2 IgM

Order Nr.: ESR 1051 G

Order Nr.: ESR 1051 M

Order Nr.: ESR 1052 G

Order Nr.: ESR 1052 M

Order Nr.: BR 1051 G

Order Nr.: BR 1051 M

Order Nr.: BR 1052 G

Order Nr.: BR 1052 M

Please visit our website www.virion-serion.com for more information on our SERION ELISA *classic* products.

Institut Virion\Serion GmbH
Serion Immundiagnostica GmbH
Friedrich-Bergius-Ring 19
97076 Würzburg, Germany

Tel.: +49 (0)931 3045-222
Fax: +49 (0)931 3045-100
dialog@virion-serion.de
www.virion-serion.com

Institut Virion\Serion GmbH
Beijing 100005, China
www.virion-serion.cn