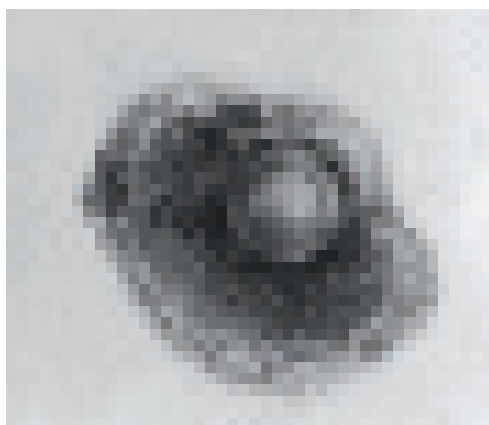


SERION ELISA *classic*

Varicella-Zoster Virus IgA / IgG / IgM

SERION ELISA *classic* Varicella-Zoster Virus IgA, IgG and IgM tests are quantitative and qualitative immunoassays for detection of human antibodies in serum, plasma or cerebrospinal fluid directed against Varicella-Zoster Virus. The SERION ELISA *classic* Varicella-Zoster Virus products are recommended for differentiation of acute infections from reactivations and for the determination of the immune status. The SERION ELISA *classic* Varicella-Zoster Virus IgG is validated for the detection of antibodies in cerebrospinal fluid.



Electron micrograph of a Varicella-Zoster Virus (Source: Centers for Disease Control and Prevention, United States Department of Health and Human Services)

Pathogen

The ubiquitous Varicella-Zoster Virus (VZV), as well as HSV, CMV and EBV, belong to the group of human Herpes viruses. The highly contagious viruses are transmitted by droplet-(contaminated aerosols) or smear-infection (vesicles with contaminated contents, or eschar).

Disease

A seasonal increase in infection rates during winter and spring is observed in temperate climate zones. Most pre-school children experience a primary infection, 95 % of adults are seropositive. Individuals are infectious 1 to 2 days before the onset of exanthema and for 7 days after the last efflorescence occurred. Following infection pathogens persist in spinal ganglia and may reactivate leading to Zoster. The incubation period is two to three weeks. After a short prodromal period with unspecific symptoms, the primary manifestation of a VZV infection, the clinical picture of varicella (chickenpox) appears. Polymorphic exanthemas with a strong itch leading to papulation, vesicles and eschar (so-called "starry sky") during the different development stages are typical for this children's disease. In general, the course of disease is

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benign. Complications during primary infections are limited to individuals at-risk, e.g. immunocompromized patients, children younger than one year and elderly persons and pregnant women. Bacterial super infections, varicella pneumonia and various CNS manifestations such as encephalitis, may present. Reactivation of persisting viruses can lead to the clinical picture of herpes zoster (shingles).

Diagnosis

Serological diagnosis of VZV infections is possible by the detection of specific IgA, IgG or IgM antibodies. Therefore, the ELISA is the method of choice in routine diagnostics, although FAMA is still the gold standard. The SERION ELISA *classic* Varicella-Zoster Virus IgG is based on glycoprotein antigens for detection of neutralizing antibodies. A good correlation with the FAMA was demonstrated. The antibody activity is measured in International Units based on the WHO standard "International Standard for Varicella Zoster Immunoglobulin". Therefore comparison of results from different laboratories is possible.

Validation of SERION ELISA *classic* Varicella-Zoster Virus

The diagnostic efficiency of the SERION ELISA *classic* VZV IgG test was evaluated at the University of Jena, Germany, by the analysis of 180 clinically defined serum samples in comparison to FAMA and to an ELISA of a leading European manufacturer. The performance characteristics of the SERION ELISA *classic* VZV IgA test were assessed in an external study in a laboratory at the University of Freiburg, Germany, with 135 pretested serum samples. For evaluation of the SERION ELISA *classic* VZV IgM test 95 serum samples from blood donors and 31 serum samples from patients with

suspected VZV primary infection or reactivation were analyzed and compared with the results of an ELISA of a leading European manufacturer.

SERION ELISA <i>classic</i>	Sensitivity	Specificity
Varicella-Zoster Virus IgA	53 %*	> 99 %
Varicella-Zoster Virus IgG	> 99 %	97,8 %
Varicella-Zoster Virus IgM	> 99 %	99 %

* The threshold was calibrated in order to exclude clinically inapparent virus reactivations.

Precision

SERION ELISA *classic* Varicella-Zoster Virus IgA

Sample	Mean value OD	Intraassay CV (%) (n=20)	Mean value OD	Interassay CV (%) (n=10)
weak positive	0,600	4,4	0,597	3,6
positive	1,721	3,2	1,723	2,5

SERION ELISA *classic* Varicella-Zoster Virus IgG

Sample	Mean value OD	Intraassay CV (%) (n=20)	Mean value OD	Interassay CV (%) (n=10)
positive	0,870	2,8	0,950	3,8
positive	2,472	2,5	2,556	2,7

SERION ELISA *classic* Varicella-Zoster Virus IgM

Sample	Mean value OD	Intraassay CV (%) (n=20)	Mean value OD	Interassay CV (%) (n=10)
positive	1,022	2,0	1,090	5,3
positive	2,937	1,7	3,113	2,4

Order Information

SERION ELISA *classic* Varicella-Zoster Virus IgA

Order Nr.: ESR 104 A

SERION ELISA *classic* Varicella-Zoster Virus IgG

Order Nr.: ESR 104 G

SERION ELISA *classic* Varicella-Zoster Virus IgM

Order Nr.: ESR 104 M

SERION ELISA *control* Varicella-Zoster Virus IgA

Order Nr.: BR 104 A

SERION ELISA *control* Varicella-Zoster Virus IgG

Order Nr.: BR 104 G

SERION ELISA *control* Varicella-Zoster Virus IgM

Order Nr.: BR 104 M

The SERION ELISA *classic* Varicella-Zoster Virus IgG is evaluated for the analysis of cerebrospinal fluid.

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

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