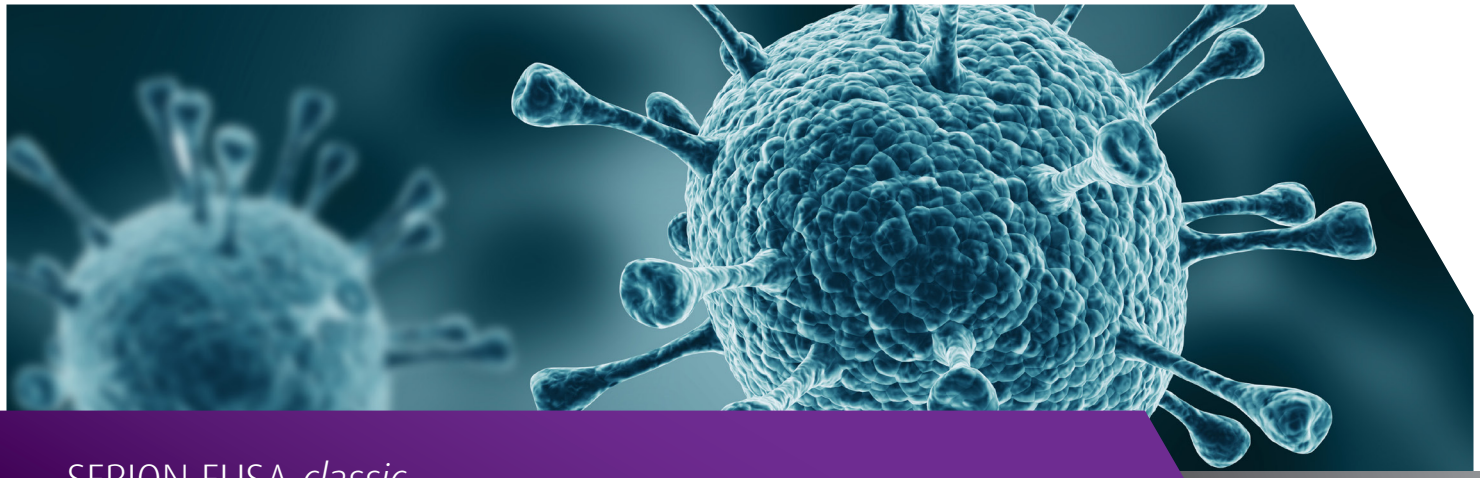

SERION ELISA *classic*

Varicella-Zoster Virus IgA/IgG/IgM

Intended Use

- Qualitative and quantitative detection of human IgA, IgG and IgM antibodies in serum or plasma directed against Varicella-Zoster Virus
- Determination of IgM antibodies for confirmation of acute infections
- Demonstration of IgG antibodies directed against the VZV glycoprotein allows for the determination of the immune status
- Detection of IgA and IgG antibodies in cerebrospinal fluid
- Demonstration of IgA antibodies is particularly recommended for confirmation of reactivations

Diagnostic Efficiency

The diagnostic efficiency of the SERION ELISA *classic* Varicella-Zoster Virus IgG test was evaluated at the University of Jena, Germany, by the analysis of 180 clinically defined serum samples in comparison to FAMA (Fluorescense-Antibody-Membrane-Antigen-Test) and to an ELISA of a leading European manufacturer.

The performance characteristics of the SERION ELISA *classic* Varicella-Zoster Virus IgA test were assessed in an external study in a laboratory at the University of Freiburg, Germany, with 135 pretested serum samples.

To evaluate the SERION ELISA *classic* Varicella Zoster Virus IgM test, 82 serum samples were examined in comparison to test systems from other manufacturers. The serum panel also includes sera from patients with suspected infections, sera from pregnant women and routine laboratories.

Product	Sensitivity	Specificity
SERION ELISA *classic* Varicella-Zoster Virus IgA	51.0 % (98%)*	>99 %
SERION ELISA *classic* Varicella-Zoster Virus IgG	98.1 %	>99 %
SERION ELISA *classic* Varicella-Zoster Virus IgM	>99 %	>99 %

* The sensitivity of the test would be 98% if the borderline values were set to 10-15 U/ml. For better differentiation between clinically relevant IgA and clinically irrelevant IgA-titers, the borderline value was set to 35 and 50 U/ml.

Precision

SERION ELISA *classic* Varicella-Zoster Virus IgA

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.600	4.4	0.597	3.5
Serum 2	1.206	3.0	1.236	2.7
Serum 3	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)
Serum 1	0.870	2.8	0.950	3.8
Serum 2	1.190	9.2	1.302	3.7
Serum 3	2.472	2.5	2.556	2.7

SERION ELISA *classic* Varicella-Zoster Virus IgM

Probe	Mittlere Extinktion (OD)	Intraassay VK (%) (n=20)	Mittlere Extinktion (OD)	Interassay VK (%) (n=10)
Serum 1	1.022	2.0	1.090	5.3
Serum 2	1.752	2.4	1.838	4.6
Serum 3	2.937	1.7	3.113	2.4

Pathogen

The ubiquitous Varicella-Zoster Virus belongs to the group of human Herpes viruses. Transmission occurs generally via droplets and aerosols or contact with virus containing vesicles or scabs.

Disease

The incubation time ranges from two to three weeks. After a primary prodromal period with unspecific symptoms, the clinical picture of chickenpox appears. Polymorphic exanthemas with a strong itch leading to papulation, vesicles and eschar during the different development stages are typical for this children's disease. In healthy children, chickenpox is usually a harmless and self-limiting infection which results in the establishment of life-long immunity to the virus. Most pre-school children experience a primary infection. About 95 % of adults react serologically positive. Primary infection during pregnancy can cause transmission of the virus to the fetus which may lead to congenital varicella syndrome. Currently some 5 to 7 % of women of child-bearing age in Germany have no immunity to VZV. After primary infection the pathogen persists in the spinal ganglia. Following a latent phase, which may last over decades, declining immunity with advancing age allows the virus to replicate. This reactivation can lead to the clinical picture of *Herpes zoster* (shingles).

Diagnosis

IgG as well as IgM and, in most cases, also IgA antibodies are produced within a few days following the regular course of a primary infection with VZV. In cases of *Herpes zoster*, IgG and IgA concentrations rise rapidly within a few days of disease onset. In most cases, IgM antibody activity is also detectable once more.

Highlights

- Use of the VZV glycoprotein for the demonstration of IgG antibodies for immune status determination with quantitative presentation of the IgG antibody activity in mIU/ml referenced to the WHO Standard
- Borderline range of 50-100 mIU/ml according to the recommendations of the Robert-Koch Institute, Berlin, Germany
- Exclusion of background seroprevalence of IgA antibodies resulting in the specific detection of clinically relevant antibody activities
- Detection of intrathecally synthesized IgA and IgG antibodies for CSF diagnostics

Product	Order No.
SERION ELISA *classic* Varicella-Zoster Virus IgA	ESR104A
SERION ELISA *classic* Varicella-Zoster Virus IgG	ESR104G
SERION ELISA *classic* Varicella-Zoster Virus IgM	ESR104M

SERION ELISA *control*

Please visit our website for more information.

Institut Virion\Serion GmbH
Friedrich-Bergius-Ring 19, 97076 Würzburg, Germany
Tel. +49 931 3045 0 Fax +49 931 3045 100
Mail info@serion-diagnostics.de Web www.serion-diagnostics.de

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