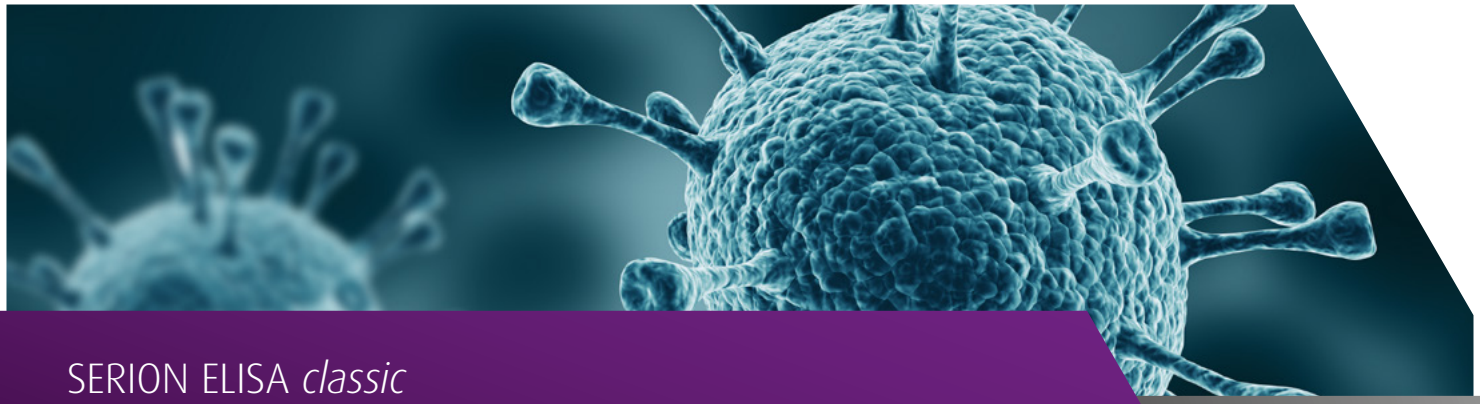

SERION ELISA *classic*

Influenza A and B Virus IgA/IgG/IgM

Intended use

- Qualitative and quantitative detection of human IgA, IgG and IgM antibodies in serum or plasma directed against the conserved nucleo- (NP) and matrix proteins (M) of Influenza A or Influenza B Viruses
- Detection of acute infections
- Detection of intrathecally synthesized IgG antibodies in cerebrospinal fluid

Diagnostic Efficiency

The SERION ELISA *classic* Influenza A (B) Virus IgA and IgG tests were evaluated by the analysis of 68 (76) serum samples from patients and 105 samples from blood donors in comparison to CFT with the presumption that IgA antibody production after an infection and the synthesis of complement binding antibodies takes place simultaneously. SERION ELISA *classic* Influenza A (B) Virus IgA and IgG exclude the often high seroprevalence of the healthy population to detect clinically relevant antibody activities. The SERION ELISA *classic* Influenza A (B) Virus IgM test was validated by the analysis of 105 serum samples from healthy blood donors and 76 (81) samples from patients with suspected Influenza Virus infection. The ELISA of a European manufacturer was used as a reference.

Product	Sensitivity	Specificity
SERION ELISA *classic* Influenza A Virus IgA/IgG	92.3 %	90.1 %
SERION ELISA *classic* Influenza A Virus IgM	95.2 %	98.5 %
SERION ELISA *classic* Influenza B Virus IgA/IgG	> 99 %	92.0 %
SERION ELISA *classic* Influenza B Virus IgM	95.5 %	99.3 %

Precision

SERION ELISA *classic* Influenza A Virus IgA

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.116	4.8	0.120	5.1
Serum 2	1.008	2.9	0.948	3.7
Serum 3	3.088	4.1	3.047	3.9

SERION ELISA *classic* Influenza A Virus IgG

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.160	9.2	0.159	7.2
Serum 2	0.399	4.4	0.435	8.2
Serum 3	1.219	3.9	1.451	4.3

SERION ELISA *classic* Influenza A Virus IgM

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.230	3.1	0.256	8.2
Serum 2	0.732	1.3	0.884	6.2
Serum 3	2.121	1.6	2.146	3.9

SERION ELISA *classic* Influenza B Virus IgA

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.178	4.7	0.185	11.9
Serum 2	0.736	5.4	0.771	3.2
Serum 3	1.919	4.3	1.988	2.4

SERION ELISA *classic* Influenza B Virus IgG

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.800	5.5	0.928	3.0
Serum 2	1.547	4.1	1.765	3.2
Serum 3	1.582	3.7	1.821	2.9

SERION ELISA *classic* Influenza B Virus IgM

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.246	4.3	0.236	7.6
Serum 2	1.114	1.8	1.099	4.0
Serum 3	1.701	1.9	1.519	13.1

Pathogen

The main reservoirs for Influenza Viruses are man and a wide variety of other mammals as well as birds. The pathogens are characterized by a distinct immunogenic variability due to a high mutation frequency and the ability to exchange their genetic material. Point mutations introduce gradual changes in the hemagglutinin and neuraminidase antigens (antigenic drift). Coinfection of a host with two different strains of influenza viruses can result in a reassortment of their segmented RNA genome and produce new subtypes (antigenic shift). It is such an event which may lead to a global pandemic of Influenza.

Disease

Influenza is an acute respiratory disease with highly contagious viruses being transmitted through droplet infection. The spectrum of symptoms, which appear after a short incubation period of one to three days, is variable and ranges from asymptomatic infections to pneumonia, acute respiratory failure and death. A sudden onset of disease is very characteristic for influenza. Fever, cough, headache and muscle aches develop within a few hours of symptoms onset.

Diagnosis

PCR and antigen detection methods are particularly recommended for direct pathogen determination while ELISA is a reliable method for the demonstration of pathogen-specific antibodies, although the relevance of results obtained with antibody detection methods is very dependent upon the antigen utilised in the test. The use of the virus envelope proteins, such as haemagglutinin (HA) and neuraminidase (NA), permits the detection of immunity conferring antibodies, which may persist life-long and may complicate the result interpretation. In contrast, if conserved nucleo- (NP) or matrix proteins (M) are used, then the antibodies detected generally persist only for weeks or months post infection. Consequently, it is possible to better differentiate between past and acute infections.

Highlights

- Use of conserved nucleo- (NP) and matrix proteins (M) for the detection of antibodies directed against Influenza A and B Viruses, independent of the causative virus subtype
- Sensitive demonstration of IgM antibodies for detection of acute / primary infections
- Exclusion of background seroprevalence of IgA and IgG antibodies resulting in the specific detection of clinically relevant antibody activities
- Alternative IgA and IgG borderline ranges for children and adults
- Differentiation of acute from past infections
- Typification of Influenza A and B Virus infections by combined usage of SERION ELISA *classic* Influenza A and B Virus tests
- Detection of intrathecally synthesized Influenza A or B Virus IgG antibodies for CSF diagnostics

Product	Order No. IgA	Order No. IgG	Order No. IgM
SERION ELISA *classic* Influenza A Virus	ESR1231A	ESR1231G	ESR1231M
SERION ELISA *classic* Influenza B Virus	ESR1232A	ESR1232G	ESR1232M

SERION ELISA *control*

Please visit our website for more information.

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