



SERION ELISA *classic*

Enterovirus IgA/IgG/IgM

Intended use

- Qualitative and quantitative detection of human antibodies in serum or plasma directed against Enteroviruses
- Confirmation of contact with the pathogen
- Support in the categorization of the disease stage
- Detection of intrathecally synthesized IgG antibodies for CSF Diagnostics

Diagnostic Efficiency

The performance characteristics of the SERION ELISA *classic* Enterovirus IgA, IgG and IgM tests were calculated using the results from an in-house study utilising more than 40 sera from patients with suspected current infection and over 80 sera from blood donors and pregnant women. The assays were validated using the SERION ELISA *classic* Enterovirus tests based on inactivated virus particles as a reference.

Product	Sensitivity	Specificity
SERION ELISA <i>classic</i> Enterovirus IgA	93.8 %	97.7 %
SERION ELISA <i>classic</i> Enterovirus IgG	92.0 %	95.4 %
SERION ELISA <i>classic</i> Enterovirus IgM	93.3 %	96.7 %

Precision

SERION ELISA *classic* Enterovirus IgA

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.103	4.0	0.118	10.4
Serum 2	0.358	3.9	0.414	6.2
Serum 3	1.140	2.4	1.347	5.1

SERION ELISA *classic* Enterovirus IgG

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.326	2.0	0.321	10.9
Serum 2	0.837	2.1	0.876	9.6
Serum 3	1.550	2.2	1.629	8.2

Pathogen

The pathogenic Enteroviruses consist of some 60 serotypes of which the Cosackieviruses, ECHO viruses and Enteroviruses serotypes 70 and 71 are of particular significance for humans. The surface of the icosahedral virus capsid consists of the structural proteins VP1, VP2 and VP3, which are responsible for the antigenic properties and the division into the various serotypes.

Disease

Transmission of the virus between hosts occurs primarily by direct contact or droplet infection. In addition, the virus may be transmitted via the placenta. The incubation period is generally 3 to 5 days. Some 90 to 95% of all Enterovirus infections are asymptomatic or manifest with unspecific febrile symptoms and are therefore frequently not identified. The illnesses which may result from Enterovirus infection are numerous and

SERION ELISA *classic* Enterovirus IgM

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.140	4.2	0.153	6.1
Serum 2	0.413	3.6	0.445	3.6
Serum 3	1.233	2.0	1.333	3.5

include upper respiratory tract infection (summer flu), pneumonia, pleurodynia, herpangina, hand, foot and mouth disease, febrile generalised exanthems, conjunctivitis, gastroenteritis, Bornholm disease, hepatitis, myocarditis, pericarditis, meningitis, encephalitis, paralysis, and fetal damage with possible perinatal disease including pneumonia, myocarditis and meningoencephalitis. Infections with Enteroviruses occur throughout the year but do show a seasonal increase during the summer and autumn months in temperate regions.

Diagnosis

The demonstration of infection by the detection of specific antibodies generally requires the analysis of serum pairs. A positive result for IgM or IgA combined with rising IgG activity serves as clear evidence of an acute or recent infection. Persisting IgM and IgA antibody levels are frequently observed in chronic infections.

Highlights

- Use of a mixture of recombinant antigens derived from conserved and subtype-specific epitopes of the VP1 proteins of ECHO virus E6 and E9 as well as Coxsackievirus B1, B3 and B5
- Demonstration of all Serotypes because of the chosen antigen
- Sensitive demonstration of IgM antibodies for detection of primary infections, particularly in children
- IgA and IgG detection for confirmation of acute, chronic and previous infections
- Exclusion of background seroprevalence of IgG antibodies resulting in the specific detection of clinically relevant antibody activities
- Quantification of IgA, IgG and IgM antibodies for disease stage monitoring and therapy control
- Detection of intrathecally synthesized IgG antibodies for CSF Diagnostics

Product	Order No.
SERION ELISA <i>classic</i> Enterovirus IgA	ESR133A
SERION ELISA <i>classic</i> Enterovirus IgG	ESR133G
SERION ELISA <i>classic</i> Enterovirus IgM	ESR133M

SERION ELISA *control*

Please visit our website for more information.

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