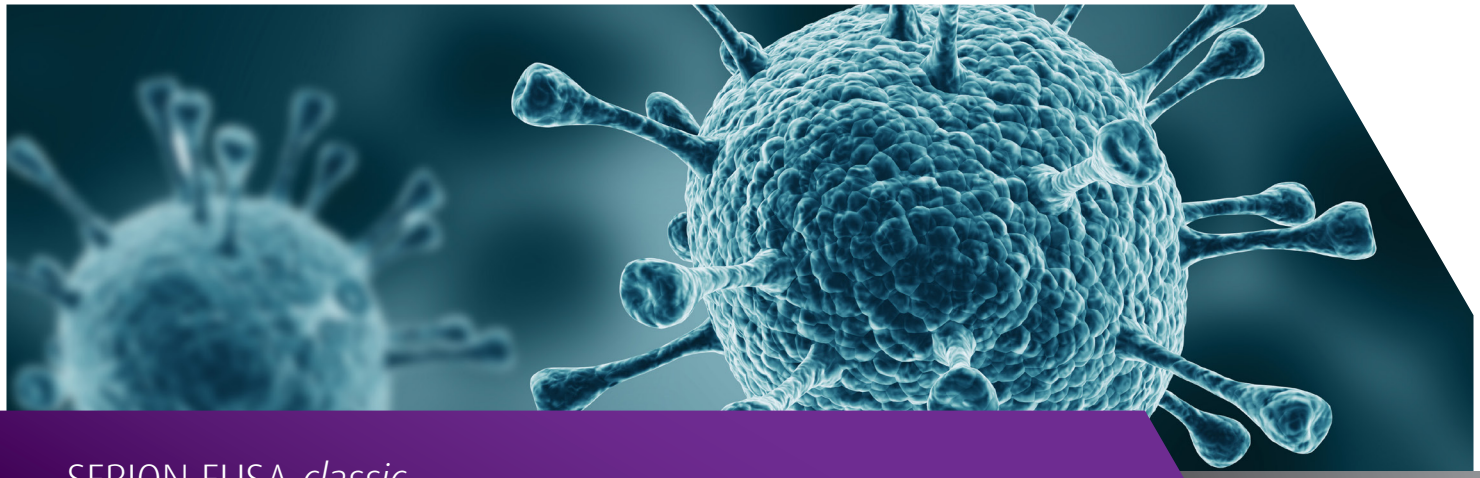

SERION ELISA *classic*

Cytomegalovirus IgG/IgM

Intended use

- Qualitative and quantitative detection of human IgG and IgM antibodies in serum or plasma directed against Cytomegalovirus
- Detection of IgM antibodies supports in the diagnosis of acute infections
- Detection of IgG antibodies allows for the determination of immune status
- Detection of intrathecally produced IgG antibodies in cerebrospinal fluid
- Determination of IgG antibody avidity, by using the corresponding avidity reagent, in order to differentiate between acute and past infections

Diagnostic Efficiency

To calculate the performance characteristics of the SERION ELISA *classic* Cytomegalovirus IgG and IgM tests, 91 serum samples from healthy blood donors and 91 serum samples from patients with suspected infection were examined in comparison to Cytomegalovirus IgG and IgM ELISA test systems from another manufacturer. Analyses have been performed according to the corresponding instructions for use.

Product	Sensitivity	Specificity
SERION ELISA *classic* Cytomegalovirus IgG	>99 %	>99 %
SERION ELISA *classic* Cytomegalovirus IgM	97.1 %	99.0 %

Precision

SERION ELISA *classic* Cytomegalovirus IgG

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.440	3.1	0.436	4.5
Serum 2	1.187	2.3	1.272	2.4
Serum 3	1.606	2.4	1.708	2.0

SERION ELISA *classic* Cytomegalovirus IgM

Probe	Mittlere Extinktion (OD)	Intraassay VK (%) (n=20)	Mittlere Extinktion (OD)	Interassay VK (%) (n=10)
Serum 1	0.718	3.1	0.824	3.1
Serum 2	1.136	1.8	1.270	2.4
Serum 3	1.709	1.9	1.793	2.3

Pathogen

Cytomegalovirus (CMV) is a human pathogenic DNA virus belonging to the herpes virus group. Primary infection may result from contact with saliva, genital secretions, urine and breast milk of infected persons, as well as from transfusions or transplantations.

Disease

Primary infections usually remain asymptomatic. Clinical manifestations vary considerably depending on age and immunocompetence ranging from localized infections to generalized diseases. Significant clinical diseases or death may follow infection of immunocompromized individuals. Reactivation in immunocompetent adults is usually asymptomatic but accompanied by virus secretion. In immunocompromized patients reactivation of CMV infections may result in clinically severe diseases. CMV infection is a major cause of complications in iatrogenic immunsuppression after organ transplantation and in HIV infected persons. CMV is the most important causative agent of congenital and postnatal infections. Primary infections as well as reactivations during pregnancy may result in fetopathy. The risk of fetal damage is higher in cases of primary infections than during reactivations.

Diagnosis

The diagnosis of CMV infections is performed on the basis of clinical symptoms and medical examinations. For serological diagnosis immunoglobulin specific IgM and IgG ELISA and, when necessary, tests for avidity determination are recommended.

Highlights

- Sensitive IgM detection as an initial test for the diagnosis of acute infections, particularly during pregnancy
- Demonstration of IgG antibody activity for determination of immune status expressed in PEI-U/ml referenced to the national CMV IgG reference serum of the Paul-Ehrlich-Institute (Germany)
- No significant cross-reactivity with antibodies against other Herpes Viruses, Rubella Virus or *Toxoplasma gondii*
- Detection of intrathecally synthesized IgG antibodies for CSF diagnostics
- Differentiation of acute from past infections by determination of IgG antibody avidity using the corresponding avidity reagent
- Sensitive IgM detection in Dried Blood Spots (DBS) for demonstration of infections in neonates

Product	Order No.
SERION ELISA *classic* Cytomegalovirus IgG	ESR109G
SERION ELISA *classic* Cytomegalovirus IgM	ESR109M
SERION ELISA *avidity reagent* Cytomegalovirus	B109AVID

SERION ELISA *control*

Please visit our website for more information.

Flyer Cytomegalovirus V10.19/01

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