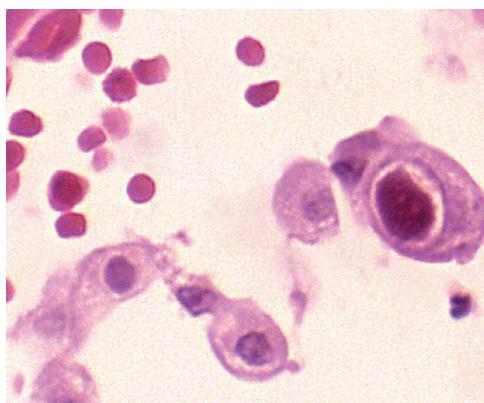


SERION ELISA *classic* Cytomegalovirus IgG / IgM

SERION ELISA *classic* Cytomegalovirus IgG and IgM tests are quantitative and qualitative immunoassays for the detection of human antibodies in serum, plasma or cerebrospinal fluid directed against Cytomegalovirus. The SERION ELISA *classic* Cytomegalovirus IgM is recommended for the detection of acute infections and suitable for newborn screening on dried blood spots (DBS). Positive results should be further tested with conformational assays, e. g. avidity tests. The SERION ELISA *classic* Cytomegalovirus IgG is recommended for determining immune status.



Micrograph of a pneumocyte infected with Cytomegalovirus (Source: CDC, Centers for Disease Control and Prevention, United States Department of Health and Human Services).

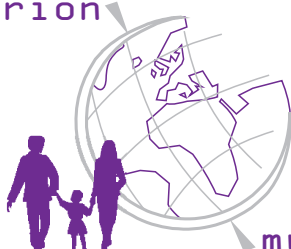
Pathogen

Cytomegalovirus (CMV) is a DNA virus and a member of the Human Herpesvirus group. Primary infection may result from contact with saliva, genital secretions, urine and breast milk of infected persons, as well as transplacentally or iatrogenically (transfusions, transplantations). After primary infection a lifelong latent infection status ensues. The virus resides in lymphocytes where it may be reactivated under certain circumstances. The frequencies of infection in the developed and underdeveloped countries vary between 45 % and 50 % or over 90%, respectively.

Disease

Primary infections are usually asymptomatic. Clinical manifestations vary considerably depending on age and immunocompetence ranging from localised infections to generalised disease. Significant clinical disease or death may follow infection of immunocompromised individuals. Reactivation in immunocompetent adults and concomitant secretion of the virus is usually asymptomatic. In immunocompromised patients reactivation of CMV infection may result in clinically severe disease. CMV infection is

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the major cause of complications in iatrogenic immunosuppression after organ transplantation and in HIV-infected persons.

Primary as well as reactivated infections of pregnant women may result in foetopathy. The risk of fetal damage is higher in case of primary infections than during reactivations. If seroconversion occurs during pregnancy, virus transmission to the fetus occurs in 40 % of the cases. Up to 15 % of the affected infants suffering damage at birth. Late manifestations of disease can be observed in 10 to 15 % of infected children. CMV-infection is the most frequent congenital and postnatal infection.

Diagnosis

The diagnosis of a CMV infection is ocured by clinical symptoms and medical examination. For serological diagnosis immunoglobulin specific ELISA are recommended.

Validation of SERION ELISA *classic* Cytomegalovirus

For the validation of SERION ELISA *classic* Cytomegalovirus IgG and IgM 331 serum samples from patients (pregnant women, patients undergoing transplantation, patients with HSV-, VZV-, HHV 6-, EBV, Rubella- and Toxoplasmosis infections) were analysed in comparison to commercially available ELISA. Sera classified as borderline were not included in the calculation. Samples with slight to moderate haemolysis (n=25), lipaemic (n=15) and icteric sera (n=60) do not influence the test result.

Sensitivity and Specificity

SERION ELISA <i>classic</i>	Sensitivity	Specificity
Cytomegalovirus IgG	99,0 %	> 99 %
Cytomegalovirus IgM	> 99 %	92,0 %

Precision

The intra- and interserial precisions were determined by the analysis of serum samples of different reactivities.

SERION ELISA *classic* Cytomegalovirus IgG

sample	Mean value OD	Intraassay CV (%) (n=20)	Mean value OD	Interassay CV (%) (n=10)
weak pos.	0,548	5,70	0,477	10,30
positive	1,166	7,00	1,041	8,60
strong positiv	2,644	4,80	2,276	6,70

SERION ELISA *classic* Cytomegalovirus IgM

sample	Mean value OD	Intraassay CV (%) (n=20)	Mean value OD	Interassay CV (%) (n=10)
weak pos.	0,473	3,1	0,416	6,6
strong positiv	1,346	2,3	1,098	14,2

Order Information

SERION ELISA *classic* Cytomegalovirus IgG

SERION ELISA *classic* Cytomegalovirus IgM

Avidity reagent Cytomegalovirus

Reference serum Cytomegalovirus IgG

Reference serum Cytomegalovirus IgM

Reference serum Cytomegalovirus avidity

Order Nr.: ESR 109 G

Order Nr.: ESR 109 M

Order Nr.: B 109 AVID

Order Nr.: BR 109 G

Order Nr.: BR 109 M

Order Nr.: BR 109 AVID

The SERION ELISA *classic* Cytomegalovirus IgG is evaluated for the analysis of cerebrospinal fluid.

The SERION ELISA *classic* Cytomegalovirus IgM is evaluated for neonatal screening on Dried Blood Spots (DBS).

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

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