Anti-CMV p52 ELISA (IgM)

- **Based on CMV p52, a highly specific target antigen of IgM antibodies in acute CMV infections**
- **Reduced cross reactivity compared to lysate-based test systems**
- **Fully automated processing and evaluation**

Technical data

Antigen	Recombinant highly purified CMV p52 antigen (ppUL44)
Calibration	Semiquantitative; calculation of a ratio from the extinction of the sample and the extinction of the calibrator
Result interpretation	Ratio < 0.8: negative Ratio ≥ 0.8 to < 1.1: borderline Ratio ≥ 1.1: positive
Sample dilution	Serum or plasma, 1 : 101 in sample buffer
Reagents	Ready for use, with the exception of the wash buffer (10x); colour-coded solutions, in most cases exchangeable with those in other EUROIMMUN ELISA kits
Test procedure	30 min / 30 min / 15 min, room temperature, fully automatable
Measurement	450 nm, reference wavelength between 620 nm and 650 nm
Test kit format	96 break-off wells; kit includes all necessary reagents
Order no.	**EI 2570-9601-2 M**
Related products	Anti-CMV ELISA (IgG, IgM) (EI 2570-9601 G, M) Anti-CMV ELISA for avidity determination (EI 2570-9601-1 G) Anti-CMV gB ELISA (IgG) (EI 2570-9601-3 G) Anti-CMV ELISA for CSF diagnostics (EI 2570-9601-L G)

Clinical significance

Cytomegalovirus (CMV) belongs to the group of human pathogenic herpes viruses. These viruses characteristically remain in the organism latently after a primary infection. Therefore, a reactivation of the disease can occur, usually with mild symptoms. In Germany around 50 % of adults are infected with CMV. The level of infection increases with age. The disease course of a CMV infection is strongly influenced by the immune status of the patient. Persons with an intact immune system show mostly no or only mild flu-like symptoms. In individuals with a weakened immune system (e.g. transplant patients, HIV-infected persons) severe complications can occur affecting one or more organs, such as the lungs, liver, CNS and retina of the eye. CMV infections play a decisive role in pregnancy. A foetus is particularly at risk if the mother comes into contact with the virus for the first time during pregnancy. Around 1 % of newborns are infected with the virus, 10 % of these show severe symptoms which, in the long term, can lead to mental and physical damage. A CMV infection in pregnancy is notifiable. Persons with a high risk of disease can be passively immunised with specific hyperimmunoglobulins. Freshly infected persons are treated with virostatics.

Diagnostic application

Infections with CMV can be diagnosed by detection of specific antibodies of classes IgG and IgM. Antibodies of class IgM reliably indicate a fresh infection. Their detection cannot, however, be used to distinguish between a primary infection or a reactivation, since they can occur in both. With the antigen p52 used in this ELISA, IgM antibodies against CMV can be detected with a higher specificity than with lysate-based test systems. With a positive IgM result, the determination of the avidity of pathogen-specific IgG antibodies or the determination of IgG antibodies against the glycoprotein B (gB) are suitable methods for differentiating between a primary infection and a reactivation.

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Reference range

Levels of anti-CMV p52 antibodies were analysed in a panel of healthy blood donors (n = 500) using the EUROIMMUN ELISA. With a cut-off of ratio of 1.0, 1.0 % of the blood donors were anti-CMV p52 virus positive (IgM). The prevalences for CMV-specific IgM antibodies in healthy blood donors and pregnant women given in literature are 0.5 to 0.8 %.

Reproducibility

The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation using six samples. The intra-assay CVs are based on 20 determinations and the inter-assay CVs on two determinations performed in ten different test runs.

	Intra-assay variation, n = 20		Inter-assay variation, n = 2 x 10	
Sample	Mean value (ratio)	CV (%)	Mean value (ratio)	CV (%)
1	0.1	10.1	0.1	7.3
2	0.4	6.1	0.5	5.3
3	0.6	8.0	0.7	6.5
4	1.0	6.5	1.3	8.1
5	2.5	4.1	2.5	7.5
6	5.7	4.4	7.1	6.2

Sensitivity and specificity

257 clinically precharacterised patient samples from external quality assessment schemes were investigated using the EUROIMMUN Anti-CMV p52 ELISA (IgM). The sensitivity was 100 %, at a specificity of 100 %. Borderline results were not included in the calculation.

n = 257		Quality assessment target		
		positive	borderline	negative
EUROIMMUN Anti-CMV p52 ELISA (IgM)	positive	73	0	0
	borderline	3	0	1
	negative	0	0	180

For evaluation of the specificity of the Anti-CMV p52 ELISA (IgM) a study was performed on 70 patient sera that had been tested as seropositive for rheumatoid factors and a variety of autoantibodies (ANA). Furthermore, 250 sera from pregnant women and 88 sera from children of 1 to 10 years old were analysed. Compared to a CMV lysate-based IgM ELISA, the Anti-CMV p52 ELISA (IgM) showed in total a higher specificity.

Panel	**n**	**Positive results (%)**	
		Anti-CMV p52 ELISA (IgM)	**Lysate-based Anti-CMV ELISA (IgM)**
Rheumatoid factors	35	2.9 %	2.9 %
Various autoantibodies (ANA)	35	0.0 %	11.4 %
Pregnant women	250	0.8 %	0.8 %
Children (1 to 10 years old)	88	1.1 %	2.3 %

Cross reactivity

Sera from patients with different herpes virus infections were analysed using the Anti-CMV p52 ELISA (IgM) and a CMV lysate-based ELISA (IgM). 8 of 22 samples from patients with acute EBV infection were positive with the anti-CMV p52 ELISA (IgM). It is known that EBV infections can lead to polyclonal stimulation of B cells, which may result in the production of IgM antibodies against different infectious agents with which the patient already had contact. Furthermore, cross reactions with antibodies against other herpes viruses cannot be ruled out entirely. The Anti-CMV p52 ELISA (IgM) shows less cross reactivity than the lysate-based ELISA.

IgM antibodies against	**n**	**Positive results (%)**	
		Anti-CMV p52 ELISA (IgM)	**Lysate-based Anti-CMV ELISA (IgM)**
EBV-CA	22	36.4 %	40.9 %
HSV	10	10.0 %	40.0 %
VZV	10	0.0 %	0.0 %

Literature

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