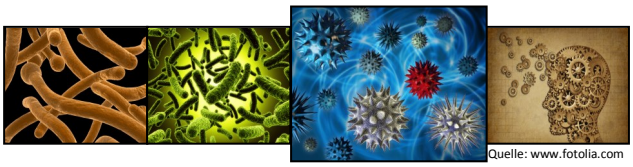


Cytomegalo Virus (CMV) ELISA

CMV is a ubiquitously common virus. Infection with CMV can occur in three different stages: primary infection, latency or reactivation. In healthy people, infection with CMV is usually subclinical. The most serious consequences are for newborns infected with utero. Such a congenital infection can lead to significant effects for the newborn child, such as severe mental impairment, numbness or death. The congenital CMV infection is the world's most frequent congenital viral infection with 0.3-2.5% of all live births. In transplant recipients, a CMV infection can be a trigger of rejection reactions. In addition, the immune system is too weak in patients with a deficient immune system to prevent an outbreak of CMV-related disease.

Serology

CMV IgG

- Life-long ab-persistence after infection
- Appearing IgG-antibody demonstrates a primary infection
- Increasing titer may express an acute infection or reactivation

CMV IgM

- Develops prior to IgG
- Persists several weeks up to 6 months

Characteristics

- High sensitivity and specificity data
- Mixture of native and recombinant antigens
- Early detection of immune response due to the use of recombinant antigen
- CSF Diagnostic tool available
- High specificity with potentially cross-reactive sera

Order No.:

CMV IgG/IgM Testkit	**EC 113.00**
CMV IgG CSF Standards	**EC 113L60**

Cytomegalo Virus

Clinical Picture

- Viral Syndrom:
  - Fever
  - Lassitude
  - Sore throat etc.
- Direct Damage of Organs:
  - Pneumonia
  - Retinitis
  - Colitis
  - Hepatitis
  - Mononucleosis
  - Meningoencephalitis
- Infection:
  - Mostly subclinical

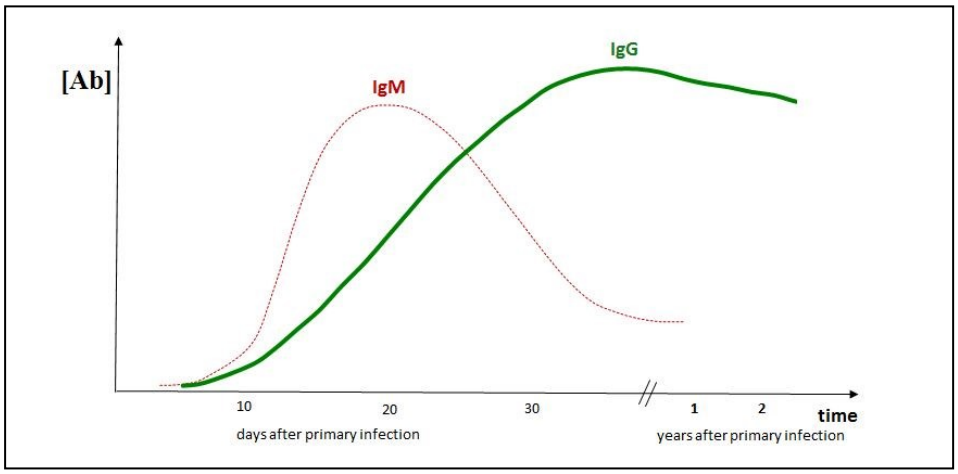
Epidemiology

- Prevalence Rate:
  - Industrial Countries: 50%
  - Others: 100%
- Vaccination not available

Course of Infection

- Infection: asymptomatisch
- Change to latency
- Often occuring reactivation
- Insufficient Immune System as a risk factor
- Severe etiopathology for at-risk patients

Antibody-Titer– Course CMV



Infection during Pregnancy

- Most common infection in new borns (0,3-2,5% world-wide)
- Transmission from mother to fetus
- Consequences for the infected child:
  - Mental damage
  - Anacousia
  - Death
- Late damage possible
- Infections during birth are mostly asymptomatic

Performance Data

Sensitivity and specificity were determined by testing 569 sera in CMV IgG ELISA and 672 sera in CMV IgM ELISA in comparison with a reference ELISA.

IgG Sensitivity and Specificity

Serum collection (n=569)

CMV IgG ELISA	Referenz ELISA		
	negative	borderline	positive
negative	186	0	4
borderline	0	0	6
positive	1	1	371

This yields a **sensitivity of 98.9%** and a **specificity of 99.5%** for IgG. The **diagnostic sensitivity** was determined by testing 81 clinically characterized sera. This yields a sensitivity of **97.5%**.

IgM Sensitivity and Specificity

Serum collection (n=672)

CMV IgM ELISA	Referenz ELISA		
	negative	Borderline	Positive
negative	327	10	11
borderline	4	4	5
positive	5	5	301

This yields a **sensitivity of 96.5%** and a **specificity of 98.5%** for IgM.
Borderline sera were not included in the calculation.
The **diagnostic sensitivity** was determined by testing 83 clinically characterized sera. This yields a sensitivity of **93.9%**.

CSF diagnostic

Sensitivity and Specificity

To determine the sensitivity/specificity of the CMV CSF IgG ELISA, 25 resp.26 CSF/serum pairs were compared with a reference ELISA. Liquor-Serenkollektiv (n=25)

CSF-serum collective (n=25)

CMV CSF IgG ELISA	Reference ELISA	
	normal	pathological
normal	0	0
pathological	1	24

CSF-serum collective (n=25)

CMV CSF IgG ELISA	Reference ELISA	
	normal	pathological
normal	24	1
pathological	0	1

This gives a **sensitivity** and **specificity** of **>99.9%**.

All Virotech ELISAs have the following characteristics

- Uniform, user-friendly test protocol
- Uniform evaluation by ready-to-use cut-off controls
- Ready-to-use controls, conjugates, substrates
- Conjugates and controls well-defined by coloured vial caps
- Colour coded microtiter plates
- Microtiter plates with breakable wells
- Identical incubation times (30’ – 30’ – 30’)
- Identical calculation with same borderline range: 9 VE – 11 VE*
- User-friendly software

Package contents quantitative ELISA test kits (Diphtherie, Tetanus)

- 12 microtiter strips with breakable wells
- 6 standards for making a standard curve for quantitative tests or 4 PL
- Highly positive and weakly positive test control
- Dilution buffer, wash solution
- Anti-human-conjugates (IgG, IgM, IgA) to be used on any of the VT ELISAs
- Substrate, stopping solution
- Test protocol sheet

Package contents semiquantitative ELISA test kits

- 12 microtiter strips with breakable wells
- Dilution buffer, wash solution
- Negative, cut-off, positive control (Ig-class and lot specific)
- Anti-human-conjugates (IgG, IgM, IgA) to be used on any of the VT ELISAs
- Substrate, stopping solution
- Test protocol sheet

The controls are packed as set including negative, cut-off and positive control, exempt our IgA sets that include IgA conjugate in addition to the controls!

*Exception B. burgdorferi Veterinär ELISA

VIROTECH Diagnostics GmbH Löwenplatz 5 D-65428 Rüsselsheim
+49 (0)6142 69090 +49 (0)6142 690919
info@virotechdiagnostics.com www.virotechdiagnostics.com