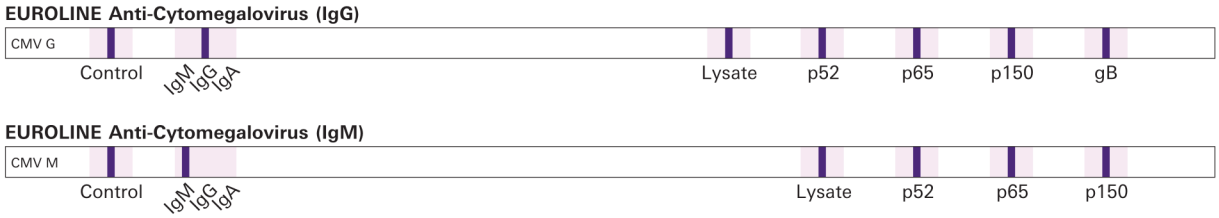
EUROLINE Anti-Cytomegalovirus (IgG, IgM)



- **Line blot for the detection of IgG or IgM antibodies against cytomegalovirus (CMV)***
- **Virus lysate from CMV-infected cells and target antigens which are relevant over the course of CMV infection allow antibody detection in all infection phases**
- **Fully automated incubation and evaluation using EUROBlotOne/EUROLineScan**

Technical data

Antigen	Virus lysate from CMV-infected cells, recombinant CMV antigens
Sample dilution	Serum or plasma, 1:51 in universal buffer (IgG) or IgM sample buffer (IgM)
Test procedure	30 min / 30 min / 10 min (sample/conjugate/substrate incubation), room temperature, fully automatable
Test kit format	16, 50 or 64 membrane strips; kit includes all necessary reagents
Automation	Compatible with the EUROBlotOne or EUROBlotMaster from EUROIMMUN; the evaluation is performed using the EUROLineScan software.
Order number	**DN 2570-1601 G or M (16 strips)** **DN 2570-6401 G or M (64 strips)** **DN 2570-5001 G or M Immunoblot-PreQ (pre-equipped individual channels, 50 strips)****

Clinical significance

The human cytomegalovirus (CMV, also human herpes virus 5; *Herpesviridae* family) is present worldwide. The virus is transmitted diaplacentally or during birth, by mucous membrane contact with nasal secretion, saliva, lacrimal fluid, urine, blood or genital fluids as well as via breast milk, blood products or organ transplants. After the viraemic phase CMV persists lifelong and can be reactivated under immunosuppressive treatment or during pregnancy. The prevalence of CMV infections is 40 to 70% in western industrialised countries and 80 to 100% in resource-poor rural areas and developing countries.

A CMV infection can result from primary infection, reinfection with a different virus strain or reactivation of the virus. In immunocompetent persons, primary infections with CMV and reactivations usually proceed asymptomatically, in 5 to 20% of cases they manifest with general flu-like symptoms, and sometime the symptoms resemble mononucleosis. Severe courses of primary infection with pneumonia, myo- and pericarditis, encephalitis or meningitis are very rarely observed. Periconceptional primary infections and infections during the first trimester of pregnancy involve the risk of severe damage to the unborn child. Infections in the third trimester, reactivations and reinfections are significantly less dangerous. Approximately 5 to 10% of infected neonates show microcephaly, intracranial calcification or chorioretinitis at birth; up to 4% do not survive. The majority of CMV-infected newborns are asymptomatic at birth, with 5 to 20% of cases developing long-term effects such as hearing disorders, hearing loss, mental retardation and behavioural disorders. CMV has an immunosuppressive effect, promoting opportunistic bacterial or fungal infections as well as rejection reactions.

Anti-CMV IgM is found in primary and secondary infections as well as reactivations. It can persist for several months, sometimes for up to a year following primary infection. IgM and IgG against CMV-p52 and -p65 already occur at an early stage of primary infection, followed by antibodies against CMV-p150. The latter persist for a long time and are often detected isolated in reactive and secondary infections or, compared to antibodies against other CMV antigens, in higher concentrations. High-avidity anti-CMV IgG and/or IgG against CMV glycoprotein B (gB) can indicate a past infection. Reactivation of CMV is confirmed by detection of the pathogen, for instance, in the blood, genital secretions, urine or saliva, and of high-avidity IgG. Primary infection in pregnant women with positive anti-CMV IgM results is confirmed by IgG seroconversion and low-avidity anti-CMV IgG. Immunoblots with recombinant CMV-specific antigens have a higher specificity than ELISA based on virus extract as the antigen. They also enable differentiation of latent infections from active virus replication and can provide information on the time point of primary infection by means of phase-specific antibodies. Differential diagnosis should primarily include EBV and acute HIV infection as well as other prenatal infections in newborns.

* The test is not intended to be used for the determination of suitability of sample material for transfusion, transplantation or cell administration in accordance with EU regulation 2017/746.
** compatible only with the EUROBlotOne

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Test principle

The test kit contains test strips coated with parallel lines of highly purified antigens. In the first reaction step, diluted patient samples are incubated with the immunoblot strips. In the case of positive samples, specific IgG and IgM antibodies (also IgA) will bind to the antigens. To detect the bound antibodies, a second incubation is carried out using enzyme-labelled antibodies of class IgG or IgM (enzyme conjugate), which promote a colour reaction upon addition of the substrate solution. Correct performance of all test steps is confirmed by staining of several control bands.

Automated processing

EUROBlotOne is a fully automatic device for the standardised processing of EUROIMMUN line assays (EUROLINE, EUROLINE-WB, Westernblot) – from sample recognition to the final test result. Samples are pipetted by the device and all incubation and washing steps are carried out automatically. Finally the data of the pictures taken by the integrated camera are automatically evaluated and digitally archived by the EUROLineScan software. Alternatively, the immunoblot strips can be incubated by the EUROBlotMaster and scanned using a flatbed scanner. Also in this case, the automatic evaluation is carried out by the EUROLineScan software. The bidirectional communication with a laboratory information management system for import of work lists and export of results is enabled by EUROLineScan or, optionally, the laboratory management software EUROLabOffice 4.0. A separate results sheet can be produced for each sample.

Specificity and sensitivity

To investigate the analytical sensitivity and specificity, 189 and 101 quality assessment samples, respectively, were analysed using the EUROLINE Anti-Cytomegalovirus (IgG) and (IgM). Compared to the quality assessment target values, the sensitivity amounted to 98.7 % (IgG) and 95.5 % (IgM) and the specificity to 100 % (IgG) and 97.5 % (IgM).

IgG (n = 189)		Quality assessment target values	
		positive	negative
EUROLINE Anti-Cytomegalovirus (IgG)	positive	154	0
	negative	2	33

Quality assessment samples: INSTAND e. V. (n = 77), Labquality (n = 69), RfB (n = 43)

IgM (n = 101)		Quality assessment target values	
		positive	negative
EUROLINE Anti-Cytomegalovirus (IgM)	positive	21	2
	negative	1	77

Quality assessment samples: INSTAND e. V. (n = 40), Labquality (n = 18), RfB (n = 43)

A study investigated IgG antibodies against gB in pregnant women with primary (n = 20) or secondary (n = 19) CMV infection with the EUROLINE Anti-Cytomegalovirus (IgG). The specificity (no detection of anti-gB antibodies in primary infection) amounted to 75 % and the sensitivity (detection of anti-gB antibodies in secondary infection) to 100 %. Moreover, this panel was investigated with the EUROLINE Anti-Cytomegalovirus (IgM). The specificity (no detection of anti-CMV IgM in secondary infection) amounted to 94.7 % and the sensitivity (detection of anti-CMV IgM in primary infection) to 100 %.

Anti-gB IgG (n = 39)		Stage of CMV infection	
		primary (n = 20)	secondary (n = 19)
EUROLINE Anti-Cytomegalovirus (IgG)	positive	4	19
	borderline	1	0
	negative	15	0

IgM (n = 39)		Stage of CMV infection	
		primary (n = 20)	secondary (n = 19)
EUROLINE Anti-Cytomegalovirus (IgM)	positive	20	1
	borderline	0	0
	negative	0	18

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DN_2570_D_UK_A03, 08/2022