

Cytomegalovirus (CMV)

NEW

CE 0483

recomBlot CMV IgG [Avidity] recomBlot CMV IgM

Immunoblot test with antigens produced by recombinant techniques for the detection of IgG or IgM antibodies directed against Cytomegalovirus (CMV).

Human Cytomegalovirus (CMV) belongs to the family of herpes viruses. Infections are common world-wide. The virus persists during the whole life of the infected patient and transmission can result from contact with infected secretions or direct contact with mucous membranes, through sexual contacts, from mother to the unborn child and through blood transfusions and transplantations.

Most acquired CMV infections are often asymptomatic. Clinical pictures vary strong and depend on the age and the immune status. CMV infections of immune competent people occur in most cases asymptomatic or only with minor symptoms. Immunocompromised patients (during transplantations, HIV-infections, chemotherapy) are often (deadly) infected with CMV.

Primary infections during pregnancy can, in 40% of all cases, lead to prenatal infections and infected premature babies who suffer in 10% of all cases under heavy damages. A virus, acquired during pregnancy, can also be transmitted vertically. The clinical consequences on the other hand are more moderate and the prognosis is good.

The *recomBlot* CMV is a western blot assay for the confirmation of uncertain and positive screening results. This assay method allows the proof and identification of IgG and IgM antibodies against different antigen groups. By using recombinant DNA technology highly specific and characteristic proteins can be used. The determination of different antibodies and the possibility of an additional avidity testing is providing additional information for the differentiation between a primary infection and a reactivation.



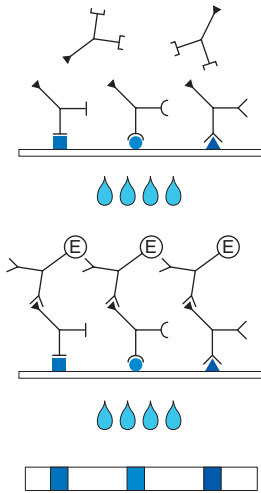
Product Advantages

- **Recombinant antigens**, therefore
 - High sensitivity and specificity
 - Easy and clear interpretation due to easy to read bands
- Easy test procedure; automation possible
- Safe evaluation due to control sera and kit specific control strip
- Separate detection of IgG and IgM antibodies
- Easy and reliable determination of avidity possible
- CE label: The *recomBlot* CMV tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices (approved by notified body no. 0483, EU certificate from November 18th 2002)
- **Excellent determination of infection status by the use of different antigen groups (s. Evaluation)**

Recombinant CMV antigens

Recombinant antigen	Reading frame / protein	Description	Size [kDa]
IE 1	UL123 / IE 1/1	Non structure protein, "immediate-early"-protein	53
p150	UL32 / pp150	Tegument protein	50
CM 2	UL44, UL57 / p52 (DBP)	Non structure protein	45
p65	UL 83 / pp65	Tegument protein	31
gB 1	UL 55 / gB	Membrane glycoprotein gB	25
gB 2	UL 55 / gB	Membrane glycoprotein gB	18

Testprinciple and Procedure



1st Incubation: A test strip loaded with CMV antigens is incubated with diluted serum or plasma in a dish for **60 min.**

wash 3 times

2nd Incubation: Peroxidase conjugated anti-human antibodies (IgG or IgM specific) are added. Incubate for **45 min.**

wash 3 times

3rd Incubation: **5 - 10 minutes** after addition of the coloring solution, insoluble colored bands develop at the sites on the test strips occupied by antibodies.

Evaluation

Three exemplary courses of CMV infections. The sera were kindly donated by Dr. Benedikt Weissbrich, Institute for Virology and Immunology, University of Würzburg.

	Day of sample donation					ELISA		Clinical data
	IE 1 p150	CM 2	p65 gB 1	gB 2		IgG	IgM	
I	1	+	+	+	+	positive	positive	None (immune competent person)
	21	+	+	+	+	positive	positive	
	84	+	+	+	+	positive	positive	
	182	+	+	+	+	positive	positive	
II	1	-	-	-	-	negative	negative	Kidney transplantation, patient was CMV negative prior to transplantation and received positive organ
	34	-	-	-	-	negative	equivocal	
	47	+	+	+	+	positive	positive	
	84	+	+	+	+	positive	positive	
	149	+	+	+	+	positive	positive	
425	+	+	+	+	positive	positive		
III	1	-	-	-	-	negative	negative	None (immune competent person)
	8	+	+	+	+	positive	positive	
	24	+	+	+	+	positive	positive	
	48	+	+	+	+	positive	positive	
	150	+	+	+	+	positive	negative	
332	+	+	+	+	positive	negative		

Remarks

Antibodies against p150 (pp150/UL32) are induced usually during each CMV infection. It was seen in a few cases that no anti-p150 occurred in the IgG response immediately after a primary infection.

Moreover, the following additional antibodies after a primary infection may be detected: anti-IE1, anti-CM2 and anti-p65. If there are no more antibodies detected but these antibodies and anti-p150 (no antibodies against gB1 and gB2), there is evidence for a primary infection. Depending on the moment of the infection an IgM response may be very weak or negative.

A past infection is associated with antibodies against the membrane glycoprotein (gB1, gB2) and the p150 with missing IgM response. Antibodies against the membrane glycoprotein (gB1, gB2) are normally found 6 up to 8 weeks after a primary infection with only very rare exceptions.

Reactivations often show IgG antibodies against p150, the membrane glykoprotein (gB1, gB2) and against CM2, p65 and/or IE1. Besides this, IgM reactivity must be taken into consideration, because in the case of a reactivation, IgM test results are often positive.

Storage and Shelf Life

At 4 °C, 9 months from the time of production

Commercial Product

Article No. 5502 **recomBlot CMV IgG [Avidity]***
Reagents for 20 determinations

Article No. 5503 **recomBlot CMV IgM**
Reagents for 20 determinations

* [] optional available
as additional reagent

Article No. 11010 **Blot, Line - avidity reagent**
Reagent for 25 avidity determinations

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