



## Anti-VZV Glycoprotein ELISA (IgM)



**Indications:** Test system for the in vitro determination of antibodies against varicella zoster virus in human serum or plasma for the diagnosis of the following diseases: varicella and herpes zoster infections.

**Clinical significance:** Varicella zoster virus (VZV), synonym: human herpes virus 3 (HHV3), is the causative agent of chickenpox (varicella). After first manifestation the virus establishes latency in sensory nerve cells and can subsequently reactivate to cause herpes zoster (shingles) as second manifestation. The virus is strictly human. Chickenpox, a very contagious disease, has traditionally been regarded as a benign, inevitable disease among children with typical blister-like rash of the entire skin. Now we know that varicella can also be a serious infection, even in childhood, but especially in young and older adults and during pregnancy.

Zoster is the endogenous recurrence of an earlier varicella infection or the result of a reinfection with existing residual immunity. VZV is latent in multiple ganglia along the entire human neuraxis. In zoster, the rash affects the spreading area of one or several sensitive nerve roots, especially T3-L3 and N. trigeminus. Central nervous system (CNS) complications can follow both primary infection and reactivation of VZV. The more serious manifestations arise when VZV invades the spinal cord (myelitis), brain (encephalitis) or the cerebral arteries (cerebral vasculitis).

Antibodies against VZV can be found in the serum of almost all patients during and after a varicella infection. They can be determined using ELISA and IFA. IgG and IgM antibodies against VZV are markers to confirm suspected VZV infections. IgA titers are typical for re-infections (zoster), but they may also occur in acute infections. In addition to the classical serodiagnosis of VZV, especially IgG and IgM antibodies suggestive of acute infection, measurement of VZV IgG avidity provides information allowing to distinguish exactly between acute and chronic infection.

**Application of the Anti-VZV Glycoprotein ELISA:** Since direct identification of the virus is difficult and therefore unsuitable for routine diagnostics, detection of specific antibodies of class IgM and IgG (varicella) or IgA and IgG (zoster) in serum is used to confirm a clinical diagnosis. In contrast to conventional Anti-VZV IgM ELISA, which are generally based on lysates from VZV infected cells, the new EUROIMMUN Anti-VZV Glycoprotein ELISA (IgM) uses highly purified glycoproteins from Varicella Zoster viruses, which represent the main target antigen. Thus cross-reactions with other herpes viruses and false-positive reactions in general are minimised, at the same sensitivity.

In cases where symptoms are ambiguous, acute and reactivated infections can also be clearly differentiated by additionally determining the antibody avidity using the EUROIMMUN Anti-VZV ELISA (IgG) (order no. EI 2650-9601-1 G) (low-avidity antibodies = acute infection).

Panel	n	Positive results Anti-VZV (IgM) in %	
		Commercial ELISA based on lysate antigens	EUROIMMUN ELISA based on purified glycoproteins
Healthy children	56	1.8	0
Healthy pregn. women	100	3.0	0
Healthy blood donors	500	0.6	0.4

Suspected cases of VZV myelitis or encephalitis should be verified by the determination of an intrathecal synthesis of antibodies against VZV in cerebrospinal fluid (CSF). For this EUROIMMUN offers an Anti-VZV ELISA which was developed specifically for CSF diagnostics (order no. EI 2650-9601-L G).

### EUROIMMUN Microplate ELISA

- Autoantibody determination:**
- AMA M2-3E (IgG)
  - ANCA Profile (IgG)
  - ANA Screen (IgG)
  - ANA Screen 9\* or 11\* (IgG)
  - ANA VarioProfile (IgG)
  - BP180-4X (IgG)
  - C1q (IgG)
  - cardiolipin (IgA, IgG, IgM, IgAGM)
  - circulating immune complexes (CIC)
  - cyclic citrullinated peptide (CCP; IgG)
  - centromere protein B (IgG)
  - double-stranded DNA (dsDNA, nDNA; IgG)
  - dsDNA-NcX (IgG)
  - ENA Pool\* (IgG)
  - ENA PoolPlus (IgG)
  - ENA ProfilePlus 1 or 2 (IgG)
  - ENA SLE Profile 1 or 2 (IgG)
  - GAD
  - GAD/IA-2 Pool
  - glomerular basement membrane (GBM; IgG)
  - β2-glycoprotein 1 (IgA, IgG, IgM, IgAGM)
  - histones (IgG)
  - IA-2
  - intrinsic factor (IgG)
  - Jo-1 (IgG)
  - liver cytosolic antigen type 1 (LC-1; IgG)
  - liver-kidney microsomes (LKM-1; IgG)
  - myeloperoxidase (MPO; IgG)
  - nRNP/Sm (IgG)
  - nucleosomes (IgG)
  - p53 (IgG)
  - parietal cells (PCA; IgG)
  - PM-Scl (PM-1; IgG)
  - phosphatidylserine (IgA, IgG, IgM, IgAGM)
  - proteinase 3 (IgG)
  - PR3 hn-hr (IgG)
  - PR3 capture (IgG)
  - rheumatoid factor (IgA, IgG, IgM)
  - ribosomal P-proteins (IgG)
  - Sci-70 (IgG)
  - single-stranded DNA (ssDNA; IgG)
  - SLA/LP (IgG)
  - Sm (IgG)
  - SS-A (Ro; IgG)
  - SS-B (La; IgG)
  - thyroglobulin (TG; IgG)
  - thyroid peroxidase (TPO; IgG)
  - tissue transglutaminase (endomy.; IgA, IgG)
  - TSH receptor (TBI; IgG)
  - TRAK Fast (IgG)
- Further autoimmune diagnostics:**
- GAF-3X (IgA, IgG)
  - gliadin (IgA, IgG)
  - Saccharomyces cerevisiae (IgA, IgG)

- Infectious serology:**
- Adenovirus (IgA, IgG, IgM)
  - Borrelia (IgG, IgM)
  - Borrelia VisE (IgG)
  - Chlamydia pneumoniae (IgA, IgG, IgM)
  - Chlamydia trachomatis (IgA, IgG, IgM)
  - Cytomegalovirus (IgG, IgM)
  - Diphtheria toxoid (IgG)
  - Epstein-Barr virus capsid ag (IgA, IgG, IgM)
  - Epstein-Barr virus early ag (IgA, IgG, IgM)
  - Epstein-Barr virus nuclear ag, EBNA-1 (IgG)
  - Helicobacter pylori (IgA, IgG)
  - Helicobacter pylori CagA (IgA, IgG)
  - HSV-1 glycoprotein C1; IgA, IgG, IgM)
  - HSV-2 glycoprotein G2; IgA, IgG, IgM)
  - HSV-1/2 Pool (IgA, IgG, IgM)
  - Influenza virus type A (IgA, IgG, IgM)
  - Influenza virus type B (IgA, IgG, IgM)
  - Legionella pneumophila (IgA, IgG, IgM)
  - Measles virus (IgG, IgM)
  - Mumps virus (IgG, IgM)
  - Mycoplasma pneumoniae (IgA, IgG, IgM)
  - Parainfluenza virus Pool (IgA, IgG, IgM)
  - RSV (IgA, IgG, IgM)
  - Rubella virus (IgG, IgM)
  - SARS-CoV (IgG)
  - TBE virus (IgG, IgM)
  - Tetanus toxoid (IgG)
  - Toxoplasma gondii (IgG, IgM)
  - Treponema pallidum (IgG, IgM)
  - Varicella zoster virus (IgG, IgM)
  - Yersinia enterocol. virulence fact. (IgA, IgG)

- Allergology:**
- total IgE
  - Allercoat™ 6-ELISA (600 different allergens and allergen mixtures)

**Serum proteins and tumour markers:**  
anti-p53

\* Currently not available as IVD in the EU.

Made in Germany



## EUROIMMUN Immunoblots

### Autoantibody determination:

#### EUROASSAY:

flexible profiles of up to 7 antigens from:

ENA and related antigens: nRNP/Sm, Sm, SS-A, Ro-52, SS-B, Scl-70, Jo-1, dsDNA, histones, nucleosomes, CENP B, PM-Scl, ribosomal P-proteins, AMA M2

liver antigens: LKM-1, LC-1, SLA/LP, AMA M2, M4, M9

ANCA antigens: MPO, PR3

thyroid antigens: TG, TPO

#### EUROLINE:

ANA Profile 1: nRNP/Sm, Sm, SS-A, Ro-52, SS-B, Scl-70, Jo-1, CENP B, dsDNA, nucleosomes, histones, ribosomal P-proteins  
ANA Profile 3: nRNP/Sm, Sm, SS-A, Ro-52, SS-B, Scl-70, PM-Scl, Jo-1, CENP B, PCNA, dsDNA, nucleosomes, histones, ribosomal P-proteins, AMA M2

Anti-ENA Profile 1: nRNP/Sm, Sm, SS-A, Ro-52, SS-B, Scl-70, Jo-1

Myositis Profile: Mi-2, Ku, PM-Scl, Jo-1, PL-7, PL-12, Ro-52

Liver Profiles: AMA M2, 3E (BPO), Sp100, PML, gp210, LKM-1, LC-1, SLA/LP, Ro-52

Neuronal Antigens Profile: amphiphysin, CV2/CRMP5, PNMA2 (Ma-2), Ri, Yo, Hu

Anti-Ganglioside Profile 1: GM1, GD1b, GQ1b

Anti-Ganglioside Profile 2: GM1, GM2, GM3, GD1a, GD1b, GT1b, GQ1b

ANCA Profiles: MPO, PR3, GBM

#### EUROLINE-WB:

liver-specific antigens (+ recomb. SLA/LP)  
neuronal antigens (+ recomb. Hu, Yo, Ri)  
HEp-2 cell antigens (+ SS-A and Ro-52, CENP B)  
Myositis ag (Mi-2, Ku, PM-Scl, Jo-1, PL-7, PL-12)

### Infectious serology:

#### EUROLINE:

EBV Profile (IgG, IgM, VCA gp125, VCA p19 and EBNA-1, p22, EA-D)

TORCH Profile\* (T, gond., rubella, CMV, HSV-1, -2)

Malaria Profile 1: Plasmodium falciparum HRP-2 and MSP-2, Plasmodium vivax MSP and CSP

#### Westemblo:

Borrelia burgdorferi (IgG, IgM)  
Borrelia afzelii (IgG, IgM)  
Borrelia garinii (IgG, IgM)  
Epstein-Barr virus (IgG, IgM)  
Helicobacter pylori (IgA, IgG)  
Treponema pallidum (IgG, IgM)  
Yersinia enterocol. virulence fact. (IgA, IgG)

#### EUROLINE-WB:

Anti-Borrelia (B. afzelii + rec. VisE)  
Anti-HSV (HSV-1 + HSV-2 gG2)  
Treponema pallidum + cardiolipin

### Allergology:

#### EUROASSAY:

Domestic Animal Profile (IgE)  
Food Profile (IgE)  
Inhalation Profile (IgE)  
Insect/Venom Profile (IgE)  
Latex Profile (IgE)  
Latex plus Profile (with ficus and fruit; IgE)

#### EUROLINE:

Atopy Profile (IgE)  
Food Profile (IgE)  
Inhalation Profile (IgE)  
Paediatric Inhalation Profile  
Pollen-Food Cross Reaction Profile (IgE)

### Software/Automation:

EUROLINEScan  
camera system EUROBlotCamera  
scanner system EUROBlotScanner  
incubation processor EUROBlotMaster

## EUROIMMUN Radioimmunoassays

### Autoantibody determination:

thyroid peroxidase (TPO; IgG)  
thyroglobulin (TG; IgG)  
TSH receptor (IgG)  
acetylcholine receptor (AChR; IgG)  
glutamic acid decarboxylase (GAD; IgG)  
insulin (IAA; IgG)  
P/Q calcium channel\* (VGCC; IgG)  
tyrosine phosphatase (IA2; IgG)  
dsDNA (IgA/IgG/IgM)

### Antigen determination:

thyroglobulin (TG)

### Hormone determination:

free triiodothyronin (FT3)  
free thyroxin (FT4)  
thyrotropin (TSH)  
calcitonin

\* Currently not available as IVD in the EU.

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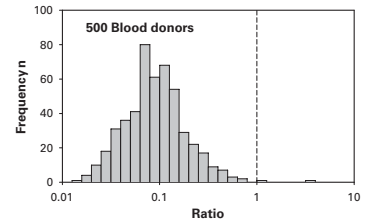
Version: 01/08  
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# Test characteristics Anti-VZV Glycoprotein ELISA (IgM)

**Reproducibility:** Coefficients of variation (CVs) were determined using data from three sera with values at different points on the standard curve. The intra-assay CVs are based on 20 measurements for each serum and the inter-assay CVs on four measurements repeated on six different days.

Serum	Intra-assay variation, n = 20		Inter-assay variation, n = 4 x 6	
	Mean value (ratio)	CV (%)	Mean value (ratio)	CV (%)
1	1.9	7.7	2.3	8.5
2	3.1	4.9	3.0	8.5
3	4.6	5.6	3.9	7.9

**Reference range:** Levels of anti-VZV antibodies (IgM) were analyzed in a panel of 500 healthy blood donors using the EUROIMMUN ELISA. With a cut-off of ratio 1.0 RU/ml, 0.4% of the blood donors were anti-VZV positive.



**Sensitivity and Specificity:** A panel of 21 clinically characterised patient samples (INSTAND e.V., Germany, Labquality, Finland) was investigated using the EUROIMMUN ELISA. The sensitivity and specificity amounted to 100% each.

n = 21	INSTAND/Labquality		
	pos.	bdl.	neg.
EUROIMMUN Anti-VZV Glycoprotein ELISA (IgM)	7	0	0
	bdl.	0	0
	neg.	0	14

**Cross-reactions:** 72 sera of patients with different other serologically characterised, acute infections (positive IgM results) were tested using the EUROIMMUN Anti-VZV Glycoprotein ELISA (IgM). No cross-reactions (CR) could be found. One patient diagnosed for CMV infection also exhibited anti-VZV glycoprotein antibodies, which probably resulted from a polyclonal B-cell activation.

Parameter	n	CR	Parameter	n	CR
HSV Pool	3	0%	Mumps virus	5	0%
EBV-CA	8	0%	Rubella virus	8	0%
CMV	16	6%	Borrelia burgd.	10	0%
Measles virus	11	0%	Toxoplasma g.	12	0%

### Technical data:

Antigen	Highly purified VZV glycoproteins from Varizella Zoster viruses (strain „Elle“, cultivated in NMDF cells).
Calibration	Semiquantitative, ratio calculation based on 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. Exception: 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 ≥ 620 nm.
Kit format	96 break-off wells, including all necessary reagents.
Order no.	EI 2650-9601-2 M