



Anti-Parvovirus B19 ELISA (IgG)



Indication: Test system for the in vitro determination of antibodies against parvovirus B19 in human serum or plasma for the diagnosis of the following disease: parvovirus B19 infection (fifth disease, erythema infectiosum, megalocerythema, Sticker's disease).

Clinical significance: Parvovirus B19 is the smallest ("parvo") known virus, with a genome length of 5000 to 5500 base pairs. It is a single-stranded DNA virus from the family of Parvoviridae and has a diameter of 21 to 23 nm. Its replication takes place predominantly in haematopoietic cells. Parvovirus was discovered in blood donors in 1974 by the Australian virologist Yvonne Cossart. It obtained its name from sample B19 in which it was found by coincidence. The virus has a low sequence variability. Up until now three different genotypes have been identified. Parvovirus B19 is characterised by a very high stability with regards to environmental factors and detergents.

Parvovirus B19 infections occur worldwide, mainly in spring. They occur in local epidemics, especially in child day care centres, schools and hospitals. In central Europe they can be described as endemic. Parvovirus B19 is transmitted by droplets, via blood or blood products or diaplacentally. The incubation period is 4 to 14 days. The virus can be detected in the serum of the infected person between the 3rd and 16th day after infection. When the exanthema appears the patient is no longer infectious.

Typically headaches, itching, myalgia and fever occur in the prodrome phase. Fresh parvovirus B19 infections (anti-Parvovirus B19 IgM) can occur in all age groups. Acute infections are found most frequently in 6 to 15 year olds. The prevalence of antibodies against parvovirus B19 (anti-parvovirus B19 IgG) increases with age. In Germany this amounts to around 35% for 4-6 year olds, 58% for 10-15 year olds, 70% for 25-29 year olds and 79% for 65-69 year olds.

In children parvovirus B19 causes fifth disease. The exanthema generally begins with an intense redness and swelling on the cheeks (butterfly form; "slapped cheek"). Individual large areas of bright red colour are found on the forehead and around the ears. The exanthema extends to the extensor side of the arms, as well as the buttocks and legs. The extremities are most severely affected; surfaces of the hands and feet can also be afflicted. The exanthema is characteristically garland-shaped or net-like. It lasts for 6 to 21 days and subsides with an undulating form. As well as exanthema, lymph node swelling and flu-like symptoms are frequently observed. Accompanying symptoms are occasionally pruritus, subfebrile temperature and arthralgia. Symmetrical arthritis of the small joints can occur as a complication in children. In adults the infection can trigger acral erythema and arthritis (acute symmetrical polyarthropathy), which is difficult to differentiate clinically from chronic polyarthrititis. 17 to 33% of all heart muscle inflammation cases can be attributed to parvovirus B19. Parvovirus B19 multiplies in erythroblastocytes, causing temporary anaemia. The infection can lead to complications and even death in immunocompromised patients. Diaplacental parvovirus B19 infections during pregnancy can lead, via inhibition of foetal erythropoiesis, to anaemia, hypoxia and in extreme cases to hydrops fetalis (in around 12% of cases) and foetal death.

Application of the Anti-Parvovirus B19 ELISA (IgG): Fifth disease may be difficult to distinguish from other diseases such as chickenpox, rubella, measles, scarlet fever or drug-induced exanthema. Moreover, most parvovirus B19 infections proceed asymptotically. Determination of anti-parvovirus B19 antibodies using ELISA is the standard method for the diagnosis of parvovirus B19 infections. With the Anti-Parvovirus B19 ELISA (IgG) even large patient panels can be investigated rapidly and reliably.

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-NC16A-4X (IgG)
BP230-CF (IgG)
C1q (IgG)
cardiolipin (IgA, IgG, IgM, IgAGM)
circulating immune complexes (CIC)
cyclic citrullinated peptide (CCP; IgG)
centromere protein B (IgG)
desmoglein 1 (IgG)
desmoglein 3 (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)
Sa (IgG)
Scl-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:

gliadin (GAF-3X; IgA, IgG)
Saccharomyces cerevisiae (IgA, IgG)

Infectious serology:

Adenovirus (IgA, IgG, IgM)
Borrelia (IgG, IgM)
Borrelia VlsE (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)
Parvovirus B19 (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)

Allergyology:

total IgE
Allercoast™ 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



Immunblots der EUROIMMUN AG

Autoantikörper-Diagnostik:

EUROASSAY:

Profile bestehend aus bis zu 7 Antigenen von: ENA und verwandte Antigene: nRNP/Sm, Sm, SS-A, Ro-52, SS-B, Scl-70, Jo-1, dsDNS, Histone, Nukleosomen, CENP B, PM-Scl, ribosomale P-Proteine, AMA M2

Leber-Antigene: LKM-1, LC-1, SLA/LP, AMA M2, M4, M9

ANCA-Antigene: MPO, PR3

Schilddrüsen-Antigene: TG, TPO

EUROLINE:

ANA-Profil 1: nRNP/Sm, Sm, SS-A, Ro-52, SS-B, Scl-70, Jo-1, CENP B, dsDNS, Nukleosomen, Histone, ribosomale P-Proteine

ANA-Profil 3: nRNP/Sm, Sm, SS-A, Ro-52, SS-B, Scl-70, PM-Scl, Jo-1, CENP B, PCNA, dsDNS, Nukleosomen, Histone, ribosomale P-Proteine, AMA M2

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

Myositis-Profil: Mi-2, Ku, PM-Scl, Jo-1, PL7, PL12, Ro-52

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

Neuronale-Antigene-Profil 2: Amphiphysin, CV2.1** PNMA2 (Ma-2/ta), Ri, Yo, Hu

Anti-Ganglioside-Profil 1: GM1, GD1b, GQ1b

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

ANCA Profile: MPO, PR3, GBM

EUROLINE-WB:

neuronale Antigene (+ rekomb. Hu, Yo, Ri)
Hep-2-Zell-Antigene (+ SS-A und Ro-52, CENP B)

Infektions-Serologie:

EUROLINE:

Bordetella pertussis (IgA, IgG)
Borrelia-RN-AT (p18, p19, p20, p21, p58, OspC, p39, p83, LpB, LpA, VlsE Bg, VlsE Bb, VlsE Ba)
EBV-Profil (IgG, IgM, VCA gp125, VCA p19 und EBNA-1, p22, EA-D)
Hantaviren (IgG, IgM)
Rötelnviren (IgG)
TORCH-Profil* (T. gond., Röteln, CMV, HSV-1, -2)

Westernblot:

Borrelia burgdorferi (IgG, IgM)
Borrelia afzelii (IgG, IgM)
Borrelia garinii (IgG, IgM)
Echinococcus granulosus (IgG)
Epstein-Barr-Viren (IgG, IgM)
Helicobacter pylori (IgA, IgG)
Treponema pallidum (IgG, IgM)
Virulenzfakt. von Yers. enterocol. (IgA, IgG)

EUROLINE-WB:

Anti-Borrelia (B. afzelii + rekomb. VlsE)
Anti-HSV (HSV-1 + HSV-2 gG2)
Treponema pallidum + Cardiolipin

Allergologie:

EUROASSAY:

Profil Haustiere (IgE)
Profil Nahrungsmittel (IgE)
Profil Inhalation (IgE)
Profil Insektengifte (IgE)
Profil Latex (IgE)
Profil Latex plus (mit Ficus u. Früchten; IgE)

EUROLINE:

Profil Atopie (IgE)
Profil Nahrungsmittel (IgE)
Profil Inhalation (IgE)
Profil Inhalation (Pädiatrie; IgE)
Profil Pollen-Nahrungsmittel-Kreuzreakt. (IgE)

Software/Automaten:

EUROLineScan
Kamerasystem EUROBlotCamera
Scannersystem EUROBlotScanner
Inkubationsautomat EUROBlotMaster

Radioimmunoassays der EUROIMMUN AG

Autoantikörper-Diagnostik:

Thyreoperoxidase (TPO; IgG)
Thyreoglobulin (TG; IgG)
TSH-Rezeptor (TRAb; IgG)
Acetylcholin-Rezeptor (AChR; IgG)
Glutamatdecarboxylase (GAD; IgG)
Insulin (IAA; IgG)
P/Q-Calciumkanäle* (VGCC; IgG)
Tyrosinphosphatase (IA-2; IgG)
dsDNS (IgA/IgG/IgM)

Antigen-Bestimmung:

Thyreoglobulin (TG)

Hormon-Bestimmung:

freies Trijodthyronin (FT3)
freies Thyroxin (FT4)
Thyreotropin (TSH)
Calcitonin

* In der EU zur Zeit nicht als IVD im Vertrieb.
** CV2-Teilprotein, welches ausschließlich die N-terminal lokalisierten Epitope enthält.

Hergestellt in Deutschland

Version: 02/10
EL_2580_D_UK_A04

Test characteristics Anti-Parvovirus B19 ELISA (IgG)

Linearity: The linearity of the test was investigated using serial dilutions of patient sera with high antibody concentrations. The Anti-Parvovirus B19 ELISA (IgG) is linear in the measurement range of 2-184 RU/ml.

Reproducibility: The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation using 3 sera. The intra-assay CVs are based on 20 determinations and the inter-assay CVs on 4 determinations performed in 6 different test runs.

Reference range: The levels of anti-parvovirus antibodies (IgG) were analysed with the EUROIMMUN Anti-Parvovirus B19 ELISA in a panel of 500 healthy blood donors. With a cut-off value of 5 IU/ml, 67.8% of blood donors were anti-parvovirus positive (IgG), in agreement with the known infection level in adults.

Correlation with the Biotrin ELISA: Antibody concentrations were determined in 279 sera of a mixed panel using the Anti-Parvovirus B19 ELISAs from EUROIMMUN and Biotrin. The qualitative results of the ELISAs were 99% in agreement (excluding borderline sera).

Titer course: A panel of 10 sera from patients with suspected acute parvovirus B19 infection was analysed using the EUROIMMUN Anti-Parvovirus B19 ELISA (IgG and IgM). At the first blood withdrawal anti-IgM antibodies against parvovirus B19 could already be detected in all 10 samples (not shown), whereas anti-IgG antibodies either occurred in low concentrations or not at all. Ten days later a second serological examination was performed. IgG seroconversion was found in three samples and a significant increase in IgG was detected in seven sera.

Technical data:

Antigen

Recombinant virus structural protein.

Calibration

Quantitative, in international units per millilitre (IU/ml). Based on the international standard preparation for anti-parvovirus B19 plasma (NIBSC code 01/602) of the World Health Organization (WHO).

Calibration serum 1: 200 IU/ml
Calibration serum 2: 25 IU/ml
Calibration serum 3: 5 IU/ml; cut-off
Calibration serum 4: 1 IU/ml

Interpretation of results

<4 IU/ml: negative
≥4 to <6 IU/ml: borderline
≥6 IU/ml: 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

60 min (37 °C) / 30 min / 15 min. Room temperature. Fully automatable.

Measurement

450 nm. Reference wavelength between 620 nm and 650 nm.

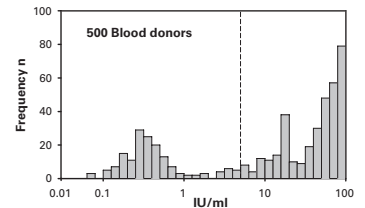
Test kit format

96 break-off wells. Kit includes all necessary reagents.

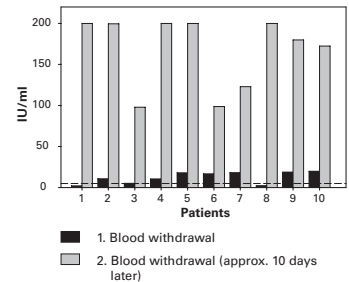
Order number

EL 2580-9601 G

Serum	Intra-assay variation, n=20		Inter-assay variation, n=4 x 6	
	Mean value (IU/ml)	CV (%)	Mean value (IU/ml)	CV (%)
1	21	7.7	23	6.0
2	18	2.5	18	1.6
3	10	2.7	10	2.1



n = 279		Biotrin Anti-Parvovirus B19 ELISA (IgG)		
		pos.	borderl.	neg.
EUROIMMUN Anti-Parvovirus B19 ELISA (IgG)	pos.	171	4	1
	borderl.	0	0	4
	neg.	2	1	96





95-100% agreement between the results of the EUROIMMUN Anti-Parvovirus B19 ELISA (IgG, IgM) and the ELISAs from MIKROGEN, Biotrin and Siemens Healthcare Diagnostics

n = 75 (mixed panel)		MIKROGEN recomWell Parvovirus B19 ELISA (IgG)		
		pos.	borderl.	neg.
EUROIMMUN Anti- Parvovirus B19 ELISA (IgG)	pos.	57	0	0
	borderl.	1	0	0
	neg.	0	1	16

There was a 100% agreement between the results of the EUROIMMUN Anti-Parvovirus B19 ELISA (IgG) and the MIKROGEN recomWell Parvovirus B19 ELISA (IgG). Borderline sera were not included.

n = 279 (mixed panel)		Biotrin Parvovirus B19 ELISA (IgG)			n = 252 (mixed panel)		Biotrin Parvovirus B19 ELISA (IgM)		
		pos.	borderl.	neg.			pos.	borderl.	neg.
EUROIMMUN Anti- Parvovirus B19 ELISA (IgG)	pos.	171	4	1	EUROIMMUN Anti- Parvovirus B19 ELISA (IgM)	pos.	40	0	6
	borderl.	0	0	4		borderl.	6	2	8
	neg.	2	1	96		neg.	1	2	187

There was a 99% (IgG) and 97% (IgM) agreement between the results of the EUROIMMUN Anti-Parvovirus B19 ELISA and the Biotrin Parvovirus B19 ELISA. Borderline sera were not included.

n = 60 (mixed panel)		Siemens Healthcare Diagnostics Novagnost Parvovirus B19 ELISA (IgG)			n = 40 (mixed panel)		Siemens Healthcare Diagnostics Novagnost Parvovirus B19 ELISA (IgM)		
		pos.	borderl.	neg.			pos.	borderl.	neg.
EUROIMMUN Anti- Parvovirus B19 ELISA (IgG)	pos.	40	0	0	EUROIMMUN Anti- Parvovirus B19 ELISA (IgM)	pos.	6	0	2
	borderl.	0	0	1		borderl.	0	0	2
	neg.	0	4	15		neg.	0	1	29

There was a 100% (IgG) and 95% (IgM) agreement between the results of the EUROIMMUN Anti-Parvovirus B19 ELISA and the Siemens Novagnost Parvovirus B19 ELISA. Borderline sera were not included.



Excellent agreement between the results of the EUROIMMUN Anti-Parvovirus B19 ELISA (IgG, IgM) with target values from INSTAND, Labquality and NEQAS quality assurance schemes

Investigated sera	49 clinically and serologically precharacterised sera (IgG) 58 clinically and serologically precharacterised sera (IgM)
Origin of sera	INSTAND e. V., Duesseldorf, Germany Labquality, Helsinki, Finland NEQAS, UK (only IgM)
Test systems used	Anti-Parvovirus B19 ELISA (IgG) (order no. EI 2580-9601 G) Anti-Parvovirus B19 ELISA (IgM) (order no EI 2580-9601 M)
Manufacturer	EUROIMMUN AG
Date	January 2006 to September 2009

n = 49		Target results from INSTAND, Labquality (IgG)*		
		positive	borderline	negative
EUROIMMUN Anti-Parvovirus B19 ELISA (IgG)	positive	40	0	0
	borderline	0	0	0
	negative	0	0	9

*NEQAS only offers a quality assurance scheme (QAS) for anti-Parvovirus B19 IgM.

There was a 100 % agreement between the results of the EUROIMMUN Anti-Parvovirus B19 ELISA (IgG) and the target values from INSTAND and Labquality quality assessment schemes.

n = 58		Target results from INSTAND, Labquality, NEQAS (IgM)		
		positive	borderline	negative
EUROIMMUN Anti-Parvovirus B19 ELISA (IgM)	positive	10	0	0
	borderline	0	0	0
	negative	4**	0	44

**The four discrepant sera derived from Labquality QAS and were tested as IgM negative for parvovirus by up to one third of participants using ELISAs from Biotrin, Focus, Novatec, Novagnost or individual in-house ELISAs.

**There was a 93 % agreement between the results of the EUROIMMUN Anti-Parvovirus B19 ELISA (IgM) and the target values from INSTAND, Labquality and NEQAS quality assessment schemes.
All discrepant sera were derived from the Labquality QAS and showed highly variable results in a variety of different test systems.**