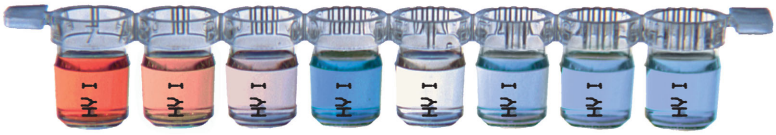
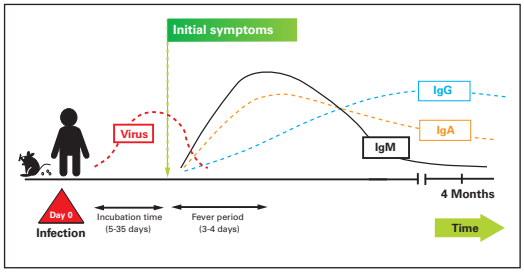
Anti-Hanta Virus Pool ELISA (IgM)



Indication: Test system for the in vitro determination of antibodies against Hantavirus (strains Hantaan, Dobrava and Puumala) in human serum or plasma for the diagnosis of the following diseases: haemorrhagic fever with renal syndrome (HFRS), kidney failure, acute respiratory syndrome, Hantavirus pulmonary syndrome (HPS), Hantavirus cardiopulmonary syndrome (HCPS).

Clinical Significance:

Hantavirus serotype	Occurrence	Main vector	Symptoms / Disease		Lethality
Puumala	Central, northern and western Europe, Asia (1,000 cases/year in Finland)	Bank vole	high fever, 3-5 days influenza-like symptoms	HFRS (nephropathia epidemica)	< 1 %
Dobrava	Balkan countries	Yellow-necked mouse		HFRS	< 1 %
Seoul	Russia, South East Europe, China, Japan, Korea (several 100,000 cases/year in China and Korea alone)	Norway rat		HFRS	up to 5 %
Hantaan	Korea and South East Asian regions, eastern Russia, southern Europe	Striped field mouse		HFRS	~10 %
Saaremaa	Central Europe, Nordic and Baltic countries	Striped field mouse		HFRS	unknown
Sin Nombre	American continent	Deer mouse		HPS/HCPS	~40 %
Andes	American continent	Deer mouse, cotton rat, rice rat, white-footed mouse		HPS/HCPS	up to 36 %



Hantaviruses belong to the Bunyaviridiae family (other members are Sandfly fever virus, Crimean Congo fever virus) and they are transmitted by rat and mouse species. They cause persisting infections in their hosts and are excreted via saliva, faeces and urine. Transmission to humans occurs through the respiratory tract by inhalation of dust and aerosols containing virus-contaminated excrements of inapparently infected rodents. Hantaviruses are found worldwide. The Hanta species Hantaan, Seoul, Puumala and Dobrava are the causative agents of the haemorrhagic, nephropatic syndrome (HFRS), whose degree of manifestation depends on the virus type involved. HFRS can be treated with chemotherapy.

The incubation period is 5 to 35 days. The disease generally starts with abrupt high fever, which lasts for 3 to 4 days, and unspecific flu-like symptoms, e.g. headache, myalgia, shivering and conjunctivitis. This phase continues for 4 to 10 days. In approximately 30% of cases this is followed by haemorrhagic symptoms, which manifest themselves as petechiae of the eye and the mucous membranes and which are often accompanied by thrombocytopenia, haematuria and proteinuria. Kidney function may be impaired to the extent that dialysis is required. The lethality rate of nephropathia epidemica is approximately 1%. In approx. 16% of cases, acute kidney failure is associated with an involvement of the lungs showing peribronchial infiltrates and pleural effusion. The first week of infection is characterised by a decrease in blood pressure which leads to a state of shock in 1 to 15% of patients and is fatal in one in three cases. In reconvalescent patients the remission of symptoms and the return to normal electrolyte levels take up to 3 months.

Anti-Hanta Virus Pool ELISA (IgM): Diagnosis of Hantavirus infections is generally based on the clinical picture and serological test results. Cultivation of the virus is difficult and hardly ever succeeds. Detection of viral RNA in the blood using PCR can only be carried out during the first few weeks after infection since the viraemic phase is very brief and ends shortly after the occurrence of the first symptoms. IgM antibodies against Hantavirus can be found at an early stage and often occur with the onset of first symptoms. IgG antibodies can be detected shortly after. Whereas IgM antibodies generally disappear within 2 to 3 months (in individual cases weak IgM results can still be found 1 to 3 years after infection), IgG antibodies persist for many years, sometimes even lifelong. The Anti-Hanta Virus Pool ELISA contains a mixture of recombinant nucleocapsid antigens from the Hantavirus strains Hantaan, Dobrava and Puumala, which are found in Asia and Europe. With this mixture, it provides a sensitive and specific test system for the detection of Hantavirus infections in these regions.

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)
ß2-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 (TBII; 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)

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

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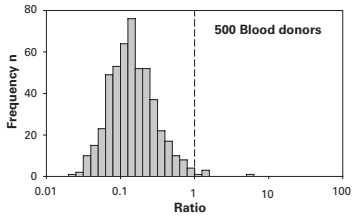
Test Characteristics
Anti-Hanta Virus Pool ELISA (IgM)

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.

Serum	*Intra-assay variation, n=20*		*Inter-assay variation, n=4 x 6*	
	Mean value (Ratio)	CV (%)	Mean value (Ratio)	CV (%)
1	1	2.5	4	9.0
2	2	3.5	4	6.2
3	4	7.5	2	10.4

Reference range: The levels of anti-Hantavirus antibodies (IgM) were analysed with the EUROIMMUN Anti-Hanta Virus Pool ELISA (IgM) in a panel of 500 healthy blood donors. With a cut-off of ratio 1.0 RU/ml, 1% of the blood donors were anti-Hantavirus positive (IgM).



Correlation with the PROGEN ELISA: A panel of 40 patient samples was investigated using the EUROIMMUN Anti-Hanta-Virus Pool ELISA (IgM) and the PROGEN Hantavirus ELISA (IgM). The agreement between the qualitative results of the two ELISAs was 78% (excluding borderline sera). Six of the seven discrepant samples achieved a negative result in the EUROIMMUN Anti-Hantavirus IIFT (IgM).

n = 40		PROGEN Hantavirus ELISA (IgM)		
		pos.	borderl.	neg.
EUROIMMUN Anti-Hanta Virus Pool ELISA (IgM)	pos.	10	0	0
	borderl.	3	0	0
	neg.	7*	5	15

* 7 discrepant samples: 6 negative and 1 positive in the EUROIMMUN Anti-Hantavirus IIFT (IgM)

Sensitivity and specificity (IgM): 8 clinically characterised patient samples (INSTAND quality assessment, Germany) were tested using the EUROIMMUN Anti-Hanta Virus Pool ELISA (IgM). Both the specificity and sensitivity were 100%.

n = 8		Target values INSTAND		
		pos.	borderl.	neg.
EUROIMMUN Anti-Hanta Virus Pool ELISA (IgM)	pos.	5	0	0
	borderl.	0	0	0
	neg.	0	0	3

Cross reactions: 77 sera from patients with different infectious diseases (positive IgM results) were investigated with the EUROIMMUN Anti-Hanta Virus Pool ELISA (IgM). No cross reactions (CR) were found.

Parameter	n	CR	Parameter	n	CR
B. burgdorferi	9	0%	Parvovirus B19	8	0%
CMV	9	0%	Rubella virus	10	0%
EBV-CA	9	0%	HSV-1 + HSV-2	2	0%
Measles virus	8	0%	VZV	4	0%
Mumps virus	9	0%	Toxopl. gondii	9	0%

Technical data:

Antigen	A mixture of recombinant antigens from the Hantavirus strains Hantaan, Dobrava and Puumala.
Calibration	Semiquantitative, calculation of a ratio from 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, with the exception of the wash buffer (10x). Color-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	EI 278h-9601-1 M

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

ANA Profile 5: nRNP/Sm, Sm, RNP70, RNPA, RNPC, SS-A, Ro-52, SS-B, Scl-70, PM-Scl, Jo-1, CENP B, PCNA, dsDNS, nucleosomes, histones, ribosomal P-proteins, AMA M2

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

Systemic Sclerosis Profile: Scl-70, CENP A, CENP B, RP11, RP155, Fibrillarin, NOR90, Th/To, PM-Scl100, PM-Scl75, Ku, PDGFR, Ro-52

Myositis Profile 3: Mi-2, Ku, PM-Scl100, PM-Scl75, SRP, Jo-1, PL-7, PL-12, OJ, EJ, Ro-52

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

Neuronal Antigens Profile 2: amphiphysin, CV2.1** PNMA2 (Ma-2/Ta), 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:

neuronal antigens (+ recomb. Hu, Yo, Ri)
HEp-2 cell antigens (+ SS-A and Ro-52, CENP B)

Infectious serology:

EUROLINE:

Bordetella pertussis (IgA, IgG)
Borrelia-RN-AT (p18, p19, p20, p21, p58, OspC, p39, p83, LBb, LBa, VlsE Bg, VlsE Bb, VlsE Ba)
EBV Profile (IgG, IgM, VCA gp125, VCA p19 and EBNA-1, p22, EA-D)
Hanta virus (IgG, IgM)
TORCH Profile* (T. gond., rubella, CMV, HSV-1, -2)

Westernblot:

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

EUROLINE-WB:

Anti-Borrelia (B. afzelii + rec. VlsE)
Anti-HSV (HSV-1 + HSV-2 gG2)
Helicobacter pylori (IgA, IgG)
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 triiodothyronine (FT3)
free thyroxine (FT4)
thyrotropin (TSH)
calcitonin

* Currently not available as IVD in the EU.
** CV2 partial protein, which only contains the N-terminally localised epitopes of the antigen.

Made in Germany

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