EUROLINE Anti-Hepatitis E Virus (IgA, IgG, IgM)

- **Line blot for the determination of antibodies of classes IgA, IgG or IgM against hepatitis E virus (HEV)**
- **Based on recombinant target antigens of the four human pathogenic genotypes HEV-1 to -4**
- **Fully automated incubation and evaluation using EUROBlotOne / EUROLineScan**

Technical data

Antigen	Recombinant hepatitis E virus antigens GT1–4 (ORF2)
Sample dilution	Serum or plasma, 1:51 in universal buffer (IgA, 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 or 64 membrane strips; kit includes all necessary reagents
Automation	Compatible with all commercial blot processing systems, e.g. EUROBlotOne or EUROBlotMaster from EUROIMMUN; the evaluation is performed using EUROLineScan
Order number	**DY 2525 -1601 A, or M (16 strips)**
	DN 2525-6401 A, G or M (64 strips)
	DN 2525-0510 A, G or M Immunoblot-PreQ (pre-equipped individual channels, 50 strips)

Clinical significance

Hepatitis E is a worldwide distributed infectious disease in mammals and humans which is caused by hepatitis E virus (HEV). Eight HEV genotypes are known: Genotypes 1 and 2 only infect humans and are spread by the faecal-oral route via contaminated potable water; genotypes 3 and 4 are zoonotic pathogens. Pigs, wild boar and deer are reservoir hosts of HEV, as well as crustaceans and mussels. Humans can become infected by consumption of insufficiently cooked meat or by direct contact with pigs. HEV can also be transmitted by blood transfusions. Genotypes 5 and 6 were detected in wild boar and the genotypes 7 and 8 in camels.

Independent of the genotype, acute HEV infections are mostly asymptomatic and self-limiting. The incubation time of clinically manifest acute HEV infection ranges from two to eight weeks. Like other viral hepatitides, it manifests after a short prodromal stage with flu-like symptoms, myalgia and malaise, followed by jaundice, pruritus and darkened urine. HEV-1 and HEV-2 infections are associated with a more aggressive clinical course: 16% of infected persons develop acute hepatitis, compared to 2% of the persons with HEV-3 or HEV-4 infections. HEV-1 and HEV-2 infections during pregnancy, especially in the third trimester, can lead to acute liver failure. In these cases, the mortality amounts to 25%. Chronic courses may occur in immunosuppressed persons, but have so far only been reported for HEV-3 and HEV-4. Infections with genotypes 1 or 3 is associated with different neurological as well as haematological and renal diseases, acute pancreatitis, myocarditis, arthritis and autoimmune thyropathy. HEV-1 epidemics regularly occur in Asia, especially in India and northwestern China and in parts of Africa. HEV-2 outbreaks were reported in Latin America, Namibia, Nigeria and Sudan. Both genotypes were detected in individual cases in western industrial countries, namely in returning travellers. Zoonotic HEV-3 and HEV-4 infections are rare. According to estimations, there are more than 20 million HEV infections worldwide per year, with over three million clinical cases of acute hepatitis and 70,000 deaths.

Hepatitis E diagnostics are based on the determination of viral RNA and virus-specific antibodies of classes IgA, IgG and IgM. The detection of HEV RNA in blood or stool indicates an acute or chronic HEV infection. The viremia in the acute phase usually lasts six to eight weeks. With clinical symptoms and an increase in transaminases, a positive IgA and/or IgM test and a significant IgG titer increase in a serum pair (taken with an interval of 8 to 14 days) indicate an acute infection. Anti-HEV IgA and IgM are detected one to four weeks after infection, up to three months after start of the disease. Specific IgG usually occurs after IgA/IgM and can be detected months to years after infection. Reinfection causes another seroconversion.

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Test principle

The EUROLINE is a qualitative in vitro immunoassay in which membrane strips printed with lines of purified, biochemically characterised antigens are used as solid phase. Each antigen is coated onto a separate membrane fragment, allowing the production process and thereby the efficiency of antibody detection to be optimised for each protein. Correct performance of all test steps is confirmed by staining of several control bands.

Automatic processing

EUROBlotOne is a fully automatic device for the standardised processing of EUROIMMUN line blot 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 the EUROBlotScanner. Also in this case, the evaluation is carried out automatically by EUROLineScan. The bidirectional communication with a laboratory information system for import of work lists and export of results is enabled by EUROLineScan or, optionally, the laboratory management software EUROLabOffice.

Specificity and sensitivity

The analytical sensitivity and specificity were determined by investigating precharacterised quality assessment samples (INSTAND e.V., NEQAS) using the EUROLINE Anti-Hepatitis E Virus (IgG, IgM and IgA) from EUROIMMUN.

The sensitivity and specificity of the EUROLINE Anti-Hepatitis E Virus (IgG and IgM) amounted to 100 % with respect to the target values specified by the quality assessment institutes.

Since there are no target values by the quality assessment institutes for determination of IgA, the correlation with the CE-marked EUROIMMUN Anti-Hepatitis E Virus (HEV) ELISA (IgA) was determined for the EUROLINE Anti-Hepatitis E Virus (HEV) (IgA). The agreement with the reference test was 100 % (borderline results excluded).

IgG (n = 20)		Quality assessment target	
		positive	negative
EUROLINE Anti-Hepatitis E Virus (IgG)	positive	13	0
	negative	0	7

Quality assessment samples: INSTAND e.V. (n = 14), NEQAS (n = 6)

IgM (n = 19)		Quality assessment target	
		positive	negative
EUROLINE Anti-Hepatitis E Virus (IgM)	positive	6	0
	negative	0	13

Quality assessment samples: INSTAND e.V. (n = 13), NEQAS (n = 6)

IgA (n = 16)		EUROIMMUN Anti-Hepatitis E Virus (HEV) ELISA (IgA)	
		positive	negative
EUROLINE Anti-Hepatitis E Virus (IgA)	positive	5	0
	borderline	1	0
	negative	0	10

Quality assessment samples: INSTAND e.V. (n = 14), NEQAS (n = 2)

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