Hepatitis E Virus (HEV)

MIKROGEN DIAGNOSTIK

NEW

Automated Strip Interpretation recomScan

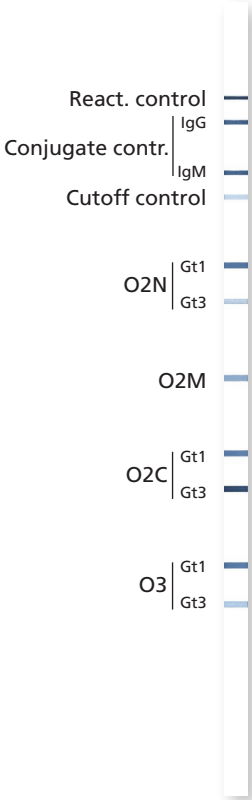
*recom*Line HEV IgG/IgM

Strip immunoassay with recombinant antigens for the detection of IgG or IgM antibodies against Hepatitis E virus (HEV) in human serum or plasma

Hepatitis E virus (HEV) is one of the leading causes of faecal-orally acquired hepatitis worldwide, usually resulting from contaminated drinking water. In developed countries, hepatitis E is usually transmitted through infected pork, which was not sufficiently cooked. HEV can be transmitted through blood products, blood transfusions and organ donation. In Europe most cases of hepatitis E are caused by the HEV genotype 3.

The HEV infection usually remains asymptomatic. Acute hepatitis E is an illness with a clinical presentation comparable to hepatitis A. Typical signs of hepatitis E include flu-like symptoms, vomiting, diarrhoea, fever, arthralgia and headache usually associated with a rise in liver enzyme values. Cholestatic jaundice that develops during the course of disease can persist for several weeks. HEV infection is usually self-limiting. In endemic regions in a high percentage of cases HEV infections during pregnancy follow a fulminant course, accompanied by a high mortality rate of approx. 20%. In males and non-pregnant females the mortality rate is 0.5% - 4.0%.

The *recom*Line HEV IgG/IgM uses purified recombinant antigens, thus reproducibly ensuring high sensitivity and specificity. The selection of homologous proteins from two different genotypes (genotype 1 and genotype 3) facilitates a high sensitivity also in non-endemic areas with a high percentage of autochthonous cases of hepatitis E.



Product advantages

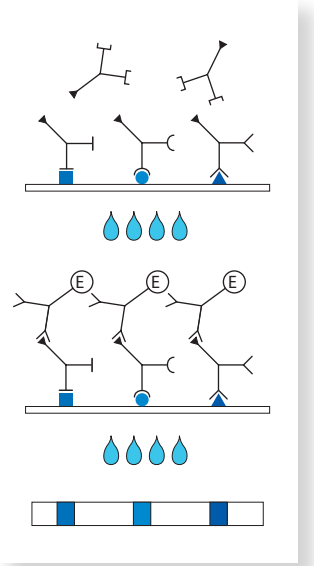
- Recombinant antigens
  - ➢ High sensitivity and specifity
  - ➢ Easy and clear interpretation due to easy to read bands
  - ➢ Homologous antigens of two different genotypes: genotype 1 and genotype 3
  - ➢ Detection of all four HEV-genotypes
- Easy test procedure; automation possible
- Easy and objective evaluation and documentation by *recom*Scan software
- Test procedure and reagents identical in all MIKROGEN strip tests - reagents exchangeable
- Separate detection of IgG- and IgM-antibodies - conjugate control on each strip
- Safe evaluation due to test strip specific cutoff control
- CE label: The *recom*Line HEV test meet the high standard of EC directive 98/79/EC on in vitro diagnostic medical devices
- Application for confirmation as well as for screening

Recombinant HEV antigens

Antigen	Location	Origin
O2N	N-terminal part of ORF* 2 protein (HEV capsid-protein)	Genotype 1, Genotype 3
O2M	Middle part of ORF* 2 protein (HEV capsid-protein)	Genotype 1
O2C	C-terminal part of ORF* 2 protein (HEV capsid-protein)	Genotype 1, Genotype 3
O3	ORF* 3 protein of HEV	Genotype 1, Genotype 3

*ORF = open reading frame

Test Principle and Procedure



1st Incubation A test strip loaded with HEV antigens is incubated with diluted serum or plasma in a dish for **1 hour**.

wash 3 times

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

wash 3 times

Color reaction **8 minutes** after addition of the coloring solution, insoluble colored bands develop at the sites on the test strips adhered by antibodies.

Evaluation

Sensitivity

	HEV acute sera[1] (n = 89)	
	IgG	IgM
negative	3	6
borderline	1	0
positive	85	83
Sensitivity	96.6 %	93.3 %

[1] Charité, University Hospital, Berlin, Germany

Specificity

	HEV seronegative	
	IgG[1] (n = 69)	IgM[2] (n = 256)
negative	67	248
borderline	0	1
positive	2	7
Specificity	97.1 %	96.9 %

[1] Blood donor sera have been concordantly evaluated as negatives in *recom*Well HEV IgG and another HEV ELISA IgG.
[2] 156 sera from patients with clinical suspicion of non-E hepatitis; Serologically defined by *recom*Well HEV IgM ELISA, by another ELISA, and a confirmatory assay; positive for either HBs-IgM-, HAV-IgM-, CMV-IgM- Parvo-IgM antibodies, HCV-IgG antibodies; and 100 negative blood donors.

Seroprevalence

	Blood donors (Bavarian Red Cross) (n= 100)		Hepatitis A, B, C positive samples[1] (n = 49)	
	IgG	IgM	IgG	IgM
negative	69	99	44	49
borderline	0	0	1	0
positive	31	1	4	0
	31 %	1 %	10.6 %	0 %
	Seroprevalence		Reacitivity rate	

[1] Positive for (and/ or in each case) HBs-, HBe-antigen, HBs-IgM-, anti-HBs-, anti-HBc-, anti-HCV, HAV-IgM-, HAV-IgG-antibodies

Article-No

5072 ***recom*Line HEV IgG/IgM**
Reagents for 20 determinations

5070 ***recom*Line HEV IgG/IgM**
Reagents for 100 determinations

Storage

+2°C - +8°C

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