

with HEV genotype 3

recomWell HEV IgG recomWell HEV IgM

Enzyme immunoassay with antigens produced by recombinant techniques for the detection of IgG and 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 head-ache 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%.

For the *recom*Well HEV IgG, IgM purified recombinant antigens of the HEV genotypes 1 and 3 are used, thus guaranteeing reproducibly high sensitivity and specificity. The other HEV-genotypes 2 and 4 can be diagnosed by cross-reactivity. The *recom*Well HEV IgG, IgM is highly suitable as a screening assay, especially in case of negative resulting hepatitis A-C-screening assay findings.



Product Advantages

- Recombinant antigens
 - High sensitivity and specificity
 - > Excellent discrimination between negative and positive results
- Very good linearity using HEV IgG WHO international standard
- Sensitive detection of all four HEV genotypes occurring worldwide, including autochthonous HEV infections caused by HEV genotype 3
- Separate detection of IgG and IgM antibodies
- Identical procedure for IgG and IgM determination
- Test procedure and reagents identical in all MIKROGEN recomWell ELISA reagents exchangeable
- Easy test procedure; quantification; automation possible
- Break-a-part: single sample examination possible
- CE label: The *recom*Well HEV tests meet the high standards of the European directive 98/79/EC on *in vitro* diagnostic medical devices

Test Principle and Procedure



Indirect sandwich test. Recombinant antigens are bound to the solid phase.

1 st Incubation	Add patient samples diluted 1:101 (sample: 10 µl of serum or plasma), incubate for 1 h at 37 °C.
	wash 4 times
2 nd Incubation	Add peroxidase conjugated anti-human IgG or IgM antibodies (conjugate), incubate for 30 min at 37 °C.
	wash 4 times
Color reaction	Add ready-to-use TMB solution and incubate for 30 min at room temperature. Stop the substrate reaction with H_3PO_4 and measure the extinction at 450 nm.

Evaluation

Sensitivity

RT-PCR positive samples ¹	<i>recom</i> Well HEV	
(n = 6)	lgG	lgM
negative	0	0
borderline	0	1
positive	6	5
Sensitivity	100 %	100 %

¹ 3 samples examined by in-house-PCR-test Mikrobiologie Universitätsklinikum Regensburg, 3 samples examined by Mikrogen HEV PCR *ampli*Cube HEV.

Specificity

	recomWell HEV	
	lgG (n = 134) ¹	lgM (n = 359)²
negative	132	354
borderline	1	0
positive	1	5
Specificity	98.5 %	98.6 %

¹ Blood donor sera that have been concordantly evaluated as negatives in another HEV ELISA IgG and in *recom*Line HEV IgG. ² 159 sera from patients with clinical suspicion of non-E hepatitis; serologically defined by a *recom*Well ELISA, and by another ELISA, and/or by a *recom*Line assay; positive for either HBs-IgM-, HAV-IgM-, CMV-IgM- Parvo-IgM antibodies, HCV-IgG antibodies; and 200 negative blood donors.

Article No.

- 5004 *recomWell HEV IgG* Reagents for 96 determinations
- 5005 *recom*Well HEV IgM Reagents for 96 determinations

recomWell HEV	
lgG	lgM
1	1
0	1
88	87
98.9 %	98.9 %
	recomW IgG 1 0 88 98.9 %

¹Samples from patients with suspicion of an acute hepatitis and IgG and IgM antibodies against HEV

Seroprevalence

Bavarian red cross blood donor sera	recomWell HEV	
(n = 200)	lgG	lgM
negative	134	198
borderline	6	0
positive	60	2
Seroprevalence	33 %	1 %

Storage At +2°C - +8°C