Hepatitis E Virus (HEV)

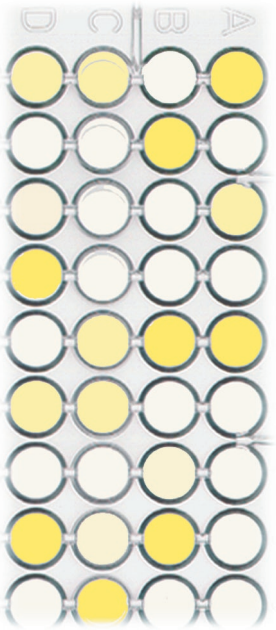
MIKROGEN
molekularbiologische Entwicklungs-GmbH

NEW

ELISA

*recom*Well HEV IgG
*recom*Well 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



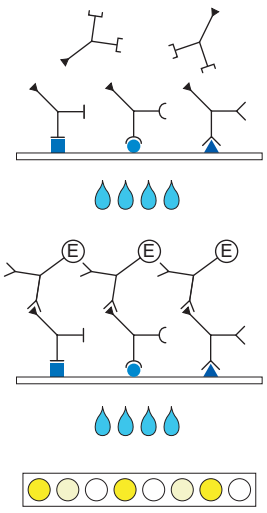
Hepatitis E virus (HEV) is one of the most common causes of faecal-orally acquired hepatitis world-wide. Infections usually result from contaminated drinking water. Concerning the distribution of the virus, a distinction is made between regions in which HEV is endemic and those in which infections occur sporadically. In recent years reports of sporadic HEV infections in non-endemic regions without travel-association have been more frequent. Besides the routes of transmission from person-to-person and through contaminated foods or blood products, a zoonotic infection from pigs or other animals to humans is under discussion. Investigations of the distribution of HEV in non-endemic regions suggest that HEV infections can sometimes follow an asymptomatic or subclinical course, especially in industrialised countries.

Acute hepatitis E is a severe illness with a comparable clinical presentation 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 and chronic persistent infections are unknown. HEV infections during pregnancy follow a fulminant course in a high percentage of cases, 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*Well HEV IgG, IgM uses purified recombinant antigens, thus guaranteeing reproducibly high sensitivity and specificity. It is highly suitable as a screening test.

Test Principle and Procedure

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



1st Incubation: Add patient samples diluted 1:101 (sample: 10 µl of serum or plasma), incubate for **1 h** at **37 °C**.

Wash 4 times

2nd 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.

Product Advantages

- **Recombinant antigens**, therefore
  - ➢ High sensitivity and specificity
  - ➢ Excellent discrimination between negative and positive results
- Separate detection of IgG and IgM antibodies
- Identical procedure for IgG and IgM determination
- Test procedure and reagents identical in all MIKROGEN ELISA - reagents exchangeable
- Easy test procedure; automation possible
- Easy to quantify
- Break-a-part: single sample examination possible
- CE label: The *recom*Well HEV tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices

Evaluation

Sensitivity

RT-PCR positive samples[1] (n = 14)	***recom*Well HEV**	
	IgG	**IgM**
negative	0	0
borderline	1	0
positive	13	14
Sensitivity	100 %	100 %

[1] Universitätsklinikum Charité, Berlin

IgM ELISA[2] **positive** (n = 16)	***recom*Well HEV**	
	IgG	**IgM**
negative	0	0
borderline	0	0
positive	16	16
Accordance	100 %	100 %

[2] In-house-test, Max von Pettenkofer-Institut, Munich

Specificity

A diagnostic specificity can not be calculated at present, as no serological „gold standard“ is defined for HEV. Alternatively, the reactivity rate of hepatitis A-B-C positive sera was compared to the seroprevalence in blood donors.

BRK sera (bavarian red cross, n = 200)	***recom*Well HEV**	
	IgG	**IgM**
negative	176	198
borderline	5	1
positive	19	1
Sero-prevalence	12,0 %	1,0 %

Hepatitis A, B, C positive samples[3] (n = 66)	***recom*Well HEV**	
	IgG	**IgM**
negative	58	65
borderline	0	0
positive	8	1
Reactivity rate	12,1 %	1,5 %

[3] positive for (each and/or) HBs, HBe antigen, anti HBs IgM, anti HBs, anti HBc, anti HCV, anti HAV IgM, anti HAV IgG antibodies (Universitätsklinikum Charité, Berlin).

Storage and Shelf Life

At 4 °C 12 months from the date of production

Commercial Product

Article No. 5004 ***recom*Well HEV IgG**
Reagents for 96 determinations
(Mikrotiter plates: 12 x 8 wells)

Article No. 5005 ***recom*Well HEV IgM**
Reagents for 96 determinations
(Mikrotiter plates: 12 x 8 wells)

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