

# Hepatitis E Virus (HEV)

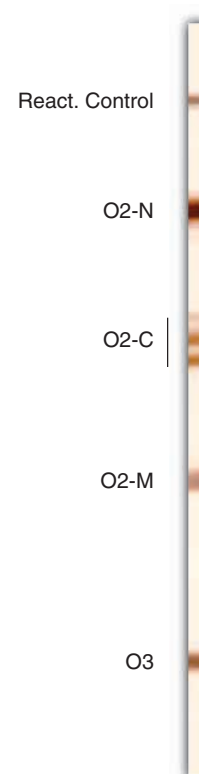
## recomBlot HEV IgG/IgM

Immunoblot test 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 the causative agent of the enteritically transmitted non-A, non-B hepatitis. Infections are transmitted primarily by the fecal-oral route, often through contaminated drinking water. Person-to-person transmission of HEV appears to be uncommon.

HEV causes gastroenteritis together with nausea and diarrhea. Symptoms following an average infection period of seven weeks are vomiting, fever, arthralgia and headache. Typically they decline after six weeks. Illness severity increases with age. The overall case-fatality rate is 0.5-3 %. Fulminant hepatitis is more commonly associated HEV infection than with other known types of viral hepatitis, particularly among pregnant women, in whom maternal hepatitis E case-fatality rates of 15-25 % have been reported. No evidence for chronic infection has been detected in long-term follow-up of patients with hepatitis E.

recomBlot HEV IgG/IgM uses recombinant antigens, which are separated by gel electrophoresis and transferred to nitrocellulose membrane (Western blot). Screening results can be easily and safely confirmed with this test.



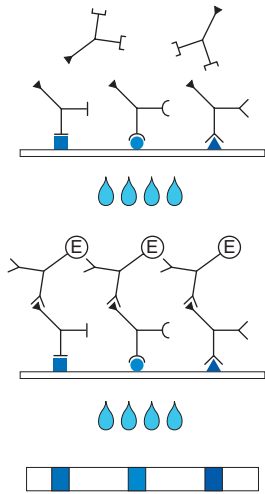
### Product advantages

- **Recombinant antigens**, therefore
  - Highest sensitivity and specificity
  - Simple and clear interpretation due to easy to read bands
- Easy test procedure; automation possible
- Safe evaluation due to kit specific control strip as well as cut-off control
- Separate detection of IgG and IgM antibodies possible
- CE label: The recomBlot HEV IgG/IgM meets the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices

### Recombinant Antigens used in the Test

HEV Antigen	Recomb. Antigen	~ Size [kDa]
N-terminal part of the capsid antigen (GST fusion protein)	O2-N	50
C-terminal part of the capsid antigen (triple band)	O2-C	38 - 41
middle part of the capsid antigens	O2-M	28
open reading frame 3	O3	15

## ■ Test Principle and Procedure



**1<sup>st</sup> Incubation:** A test strip loaded with HEV antigens is incubated with diluted serum or plasma in a dish for **2 h**.

*wash 4 times*

**2<sup>nd</sup> Incubation:** Peroxidase conjugated anti-human antibodies (IgG- or IgM-specific) are added. Incubate for **1 h**.

*wash 4 times*

**3<sup>rd</sup> Incubation:** **5 - 10 minutes** after addition of the coloring solution (TMB), insoluble colored bands develop at the sites on the test strips occupied by antibodies.

## ■ Evaluation

### Acute HEV infections

		positive	equivocal	negative
Madras (n = 40)	IgG	97,5 %	2,5 %	0,0 %
	IgM	85,6 %	0,0 %	14,3 %

### Blood donor sera

		positive	equivocal	negative
Bavaria (n = 197)	IgG	5,0 %	9,6 %	85,3 %
	IgM	0,0 %	0,5 %	99,5 %
Madras (n = 200)	IgG	44,0 %	17,0 %	39,0 %
	IgM	1,5 %	4,5 %	94,5 %

## ■ Storage and Shelf life

At 4 °C, 18 months from the time of production

## ■ Commercial Product

Article No. 5002 **recomBlot HEV IgG/IgM**  
Reagents for 20 determinations