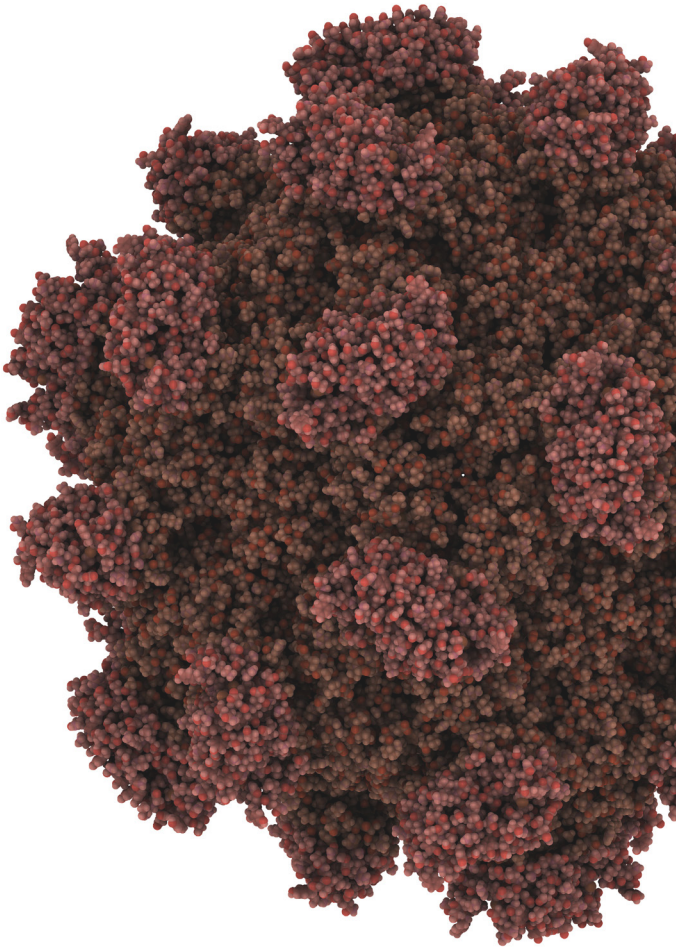
Anti-Hepatitis E Virus

Sensitive and specific IgG and IgM antibody determination



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The new language of life

Infections with Hepatitis E Virus
A global threat

Pathogen

Hepatitis E virus (HEV) is a non-enveloped virus of the *hepeviridae* family with a diameter of 32 – 34 nm.

Epidemiology

Hepatitis E virus is considered the most common cause of acute viral hepatitis worldwide. The (+)ssRNA virus occurs worldwide in several human pathogenic subtypes, which differ significantly in distribution.

Transmission

Transmission of HEV genotypes 3 and 4 occurs mainly through consumption of infected meat (pig, wild boar). The HEV genotypes 1 and 2 are transmitted through smear infection, contaminated water or food. Transmission through infected blood products, blood transfusions or transplants is also possible.

Clinical Symptoms

In immunocompetent individuals, most HEV infections remain clinically inapparent. After an incubation time of 15 to 60 days, hepatitis E may manifest with fever, arthralgia, myalgia, and jaundice. The disease is usually self-limiting. Complications occur with neurological symptoms such as neuralgic amyotrophy, Guillain-Barré syndrome, encephalitis and myelitis.
In patients with immune deficiencies or under immune suppression, e. g. after organ transplantation, an HEV infection can lead to glomerulonephritis or take a chronic course that may induce acute liver failure and liver cirrhosis. In pregnant women, infection with HEV genotypes 1 and 2 can lead to severe courses with high mortality.

Diagnosis

The diagnosis is based on the clinical symptoms and confirmed by laboratory methods incl. determination of liver function parameters (AST, ALT, AP, gGT). Various direct (RT-PCR) and indirect methods for the determination of antibodies (e.g. ELISA, CLIA, Immunoblot) are available for laboratory diagnostic confirmation.
IgM und IgG antibodies are generated during primary infection. Whereas IgM antibodies are usually no longer detectable a few months after primary infection, IgG antibodies remain much longer and confirm a contact with the pathogen.

Anti-Hepatitis E Virus IgG/IgM Abs.

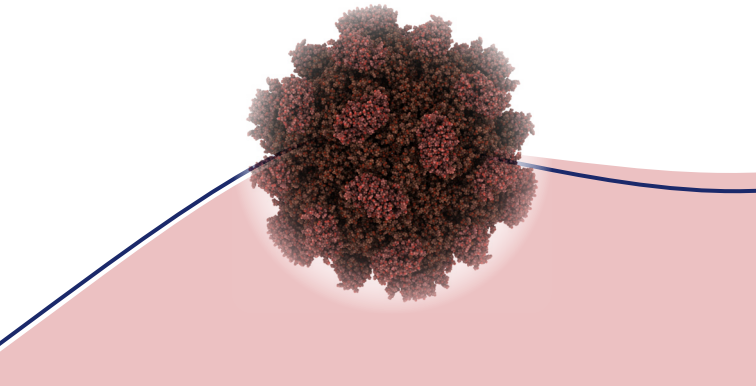
Reliable antibody determination

Antigen

The Alegria Anti-Hepatitis E Virus IgG and IgM Abs. Monotests are based on recombinant ORF2 Antigens (capsid protein) of the HEV genotypes 1 and 3 for a sensitive and specific determination of IgG and IgM antibodies.

Calibration

The Alegria Anti-Hepatitis E Virus IgG and IgM Abs. Monotests are calibrated using internal reference samples. Results are expressed in U/mL.



Sensitivity and Specificity

	Sensitivity	Specificity	Diagnostic Efficiency
Anti-Hepatitis E Virus IgG	92.0 %	> 99 %	98.8 %
Anti-Hepatitis E Virus IgM Abs.	76.9 %	> 99 %	98.9 %

Precision Anti-Hepatitis E Virus IgG

	Intraassay Repeatability		Interassay Reproducibility	
	Antibody Activity (U/mL)	Coeffcient of Variation (CV)	Antibody Activity (U/mL)	Coeffcient of Variation (CV)
Sample 1	22.4 U/mL	2.6 %	16.8 U/mL	8.4 %
Sample 2	77.5 U/mL	4.2 %	38.6 U/mL	6.6 %
Sample 3	113.4 U/mL	2.4 %	134.5 U/mL	4.2 %

Precision Anti-Hepatitis E Virus IgM Abs.

	Intraassay Repeatability		Interassay Reproducibility	
	Antibody Activity (U/mL)	Coeffcient of Variation (CV)	Antibody Activity (U/mL)	Coeffcient of Variation (CV)
Sample 1	21.4 U/mL	2.0 %	14.9 U/mL	4.4 %
Sample 2	22.5 U/mL	2.0 %	21.3 U/mL	2.7 %
Sample 3	194.5 U/mL	3.9 %	166.1 U/mL	12.0 %

Product Highlights

- ELISA-based random access determination of IgG and IgM antibodies against Hepatitis E Virus
- Full automation and complete traceability with Alegria 2
- Lab-on-a-Strip: ready-to-use test-specific reagents in individually sealed and barcoded Alegria Monotest strips
- Sensitive and specific detection of antibodies against recombinant ORF2 antigens of the HEV genotypes 1 and 3
- Integrated Rf-absorption prior to IgM detection
- Excellent diagnostic efficiency
- High reproducibility for reliable results
- Economical all-in-one Alegria Monotests, particularly suited for small series
- Flexible combination of Alegria Monotests for optimal workflow efficiency

Ordering *information*

- Anti-Hepatitis E Virus IgG ..... **ORG 921G**
- Anti-Hepatitis E Virus IgM Abs. ..... **ORG 921MX**

Scan here **for more information** about Alegria Anti-Hepatitis E Virus Monotests

Literature

Aslan, A.T. and Balaban, H.Y. (2023) Hepatitis E virus: Epidemiology, diagnosis, clinical manifestations, and treatment. World J. Gastroenterol. *26*, 5543 - 60.

European Association for the Study of the Liver (2018) EASL Clinical Practice Guidelines on hepatitis E virus infection. J. Hepatol. *68*, 1256 – 71.

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