BioVendor Group CLIA

Hepatitis E

Hepatitis E

Diagnostic panel
Gastrointestinal diseases

CE
IVD
TUV NB 0483
The kits are CE-IVD certified and intended for professional use.

Designed for the platform
Kleeya®

Introduction

Hepatitis E is an acute viral disease of the liver that occurs worldwide. It is caused by the hepatitis E virus (HEV), which belongs to the *Hepeviridae* family. Several genotypes have been identified, differing in their epidemiology and modes of transmission. Genotypes 1 and 2 occur predominantly in developing countries and are responsible for large-scale outbreaks; they are transmitted mainly via the fecal–oral route, most commonly through contaminated drinking water. In contrast, genotypes 3 and 4 circulate primarily in animals (particularly pigs and deer) and are zoonotic, with the ability to infect humans. These genotypes are transmitted through the consumption of contaminated food, as well as via blood products and organ transplants.

Prevalence

Globally, more than 20 million HEV infections are estimated to occur each year, of which approximately 3 million are symptomatic. HEV is a leading cause of acute viral hepatitis in many Asian and African countries. In recent years, the number of diagnosed cases has also been increasing in Europe, where infection is often associated with the consumption of insufficiently cooked meat.

Clinical manifestations

The incubation period is typically 15–64 days.

Asymptomatic course
In genotype 3, more than 95% of infection cases are asymptomatic.

Symptomatic infection
Usually acute, presenting with symptoms such as fatigue, low-grade fever, gastrointestinal disturbances, and hepatitis with jaundice.

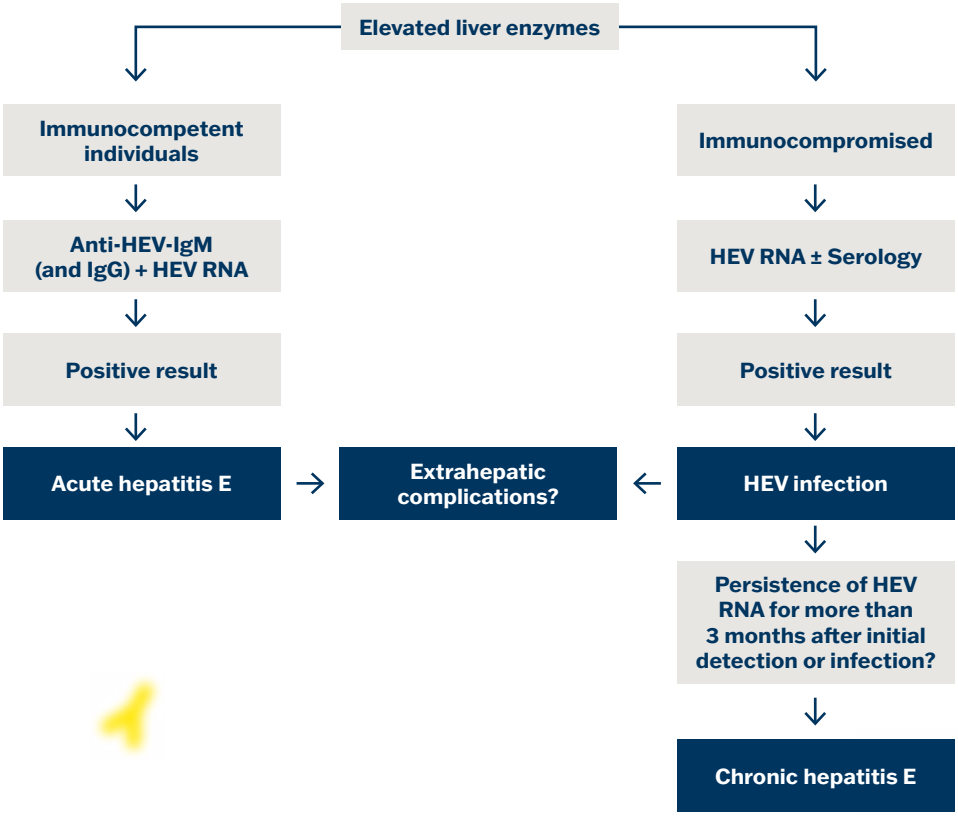
Fulminant hepatitis
Occurs in selected high-risk groups and is particularly dangerous for pregnant women, in whom, according to WHO data, the case fatality rate in the third trimester may reach up to 20–25 %, especially in infections caused by hepatitis E virus genotype 1.

Chronic hepatitis
Chronic hepatitis develops especially in infections caused by genotype 3 in immunocompromised patients (e.g., after organ transplantation, in HIV infection, or in hematological malignancies), in whom it may lead to progressive fibrosis and cirrhosis over months to several years.

Diagnostics and testing

The primary diagnostic approach is serology, specifically the detection of anti-HEV IgM and IgG antibodies. The presence of IgM indicates an acute infection, while IgG reflects a past infection or immune status. Molecular methods (PCR) enable direct detection of viral RNA and are particularly suitable for immunocompromised patients, in whom serological testing may be less reliable. In addition, biochemical liver function tests are performed, typically showing elevated levels of ALT, AST, and bilirubin. Serological testing is rapid, widely accessible, and easily integrated into routine laboratory workflows, making it the most appropriate method for initial diagnosis, screening, and monitoring the prevalence of hepatitis E in the population.

Test scheme

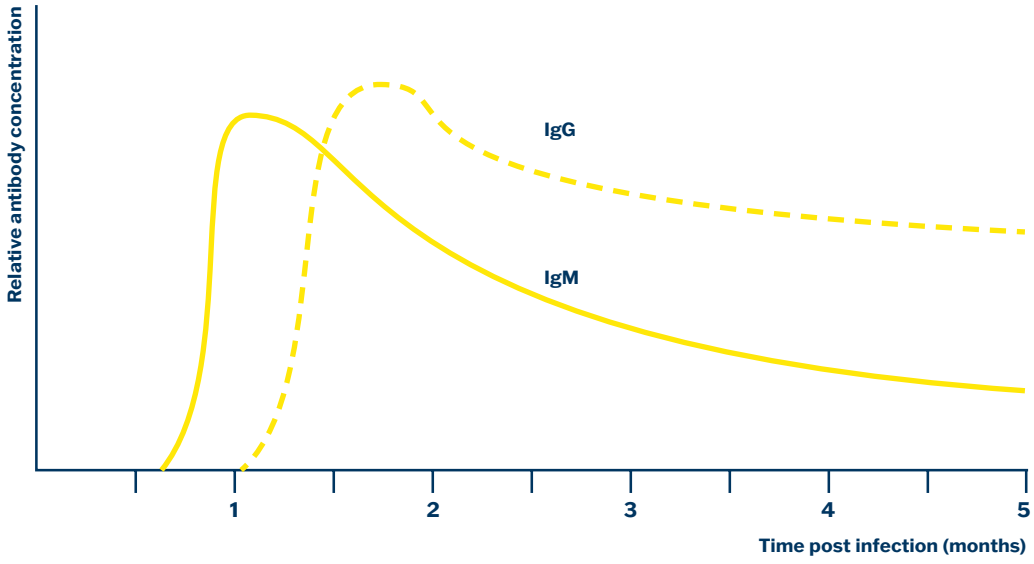


Source: J Hepatol. 2018 Jun;68(6):1256- 1271. doi: 10.1016/j.jhep.2018.03.005. Epub 2018 Mar 31.

Interpretation of results

IgG	IgM	
–	–	No evidence of HEV infection. If clinical suspicion persists, repeat testing should be performed after approximately 1 to 2 weeks.
–	+	Anti-HEV IgM antibodies are present, suggesting a possible early stage of HEV infection. Direct pathogen detection or repeat testing after approximately 1 to 2 weeks is recommended.
+	+	Evidence of acute HEV infection.
+	–	Anti-HEV IgG antibodies are present, indicating a past or possibly recent HEV infection.

Antibody response in hepatitis E



Treatment and prevention

Most hepatitis E infections do not require specific treatment; therefore, management is primarily symptomatic. In immunocompromised patients, in whom the infection often progresses to a chronic form, ribavirin is used as part of the treatment.
An important component of care is the prevention of complications, particularly avoidance of hepatotoxic substances and regular monitoring of liver function.
A vaccine against hepatitis E is currently available only in certain countries, such as China.

Prevention of infection relies mainly on adherence to hygiene measures and ensuring access to safe drinking water. Thorough cooking of meat at temperatures above 71 °C is essential, as well as caution when consuming liver products or raw meat from pigs and wild boar, which represent the most common source of zoonotic transmission.

Clinical applications

- Detection of specific antibodies
- Disease stage determination
- Infection identification

Antigens

Hepatitis E

Highly purified recombinant HEV ORF2C antigen.

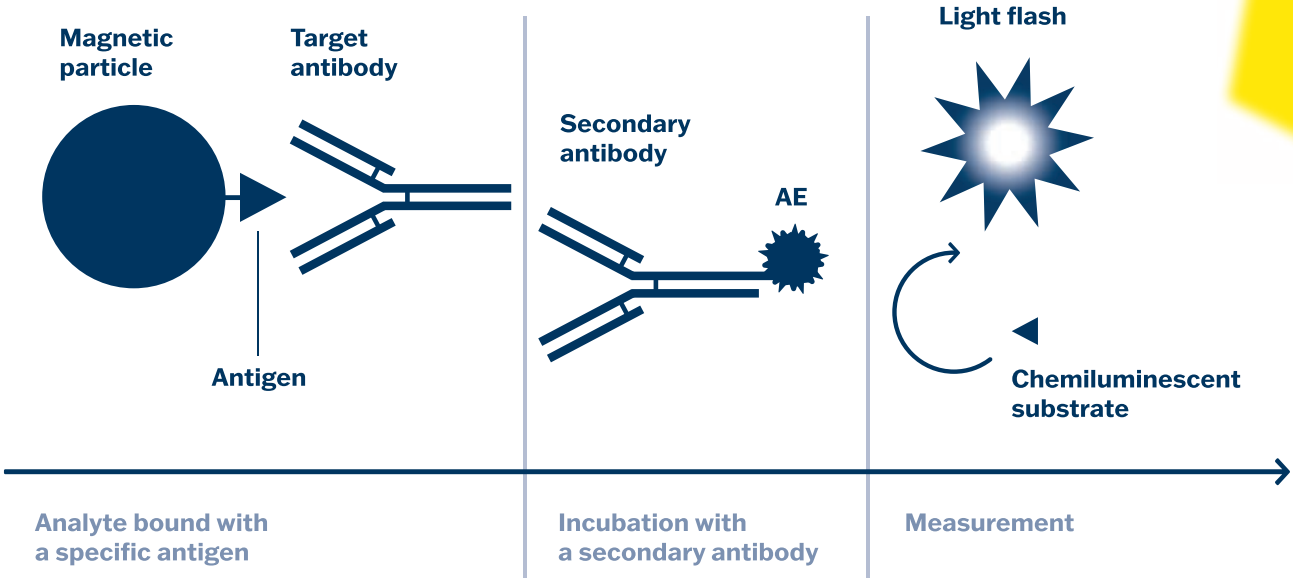
Test characteristics

Kit	Interpretation	Diagnostic sensitivity	Diagnostic specificity
***recom*CLIA HEV IgG ***	IU/ml	97.4%	97.6%
***recom*CLIA HEV IgM**	COI (cut-off Index)	97.5%	100%

* The CLIA assays are calibrated using the WHO International Standard (NIBSC 95/584) for the detection of antibodies against hepatitis viruses.

How does CLIA method work?

CLIA is a fully automated, fast, specific and sensitive method. It combines the use of magnetic particles for immunocomplex separation of the antigen and flash chemiluminescence for sensitive detection. The use of magnetic particle suspension facilitates automation, significantly shortens reaction times and improves the specificity of the determination. Flash chemiluminescence of acridinium ester provides an intense light signal even at very low concentrations and its intensity is measured in relative units of light (RLU). CLIA kits are designed for use on the KleeYa® automated platform.



CLIA kits

The diagnostic CLIA kits are intended for the detection of IgG and IgM antibodies against the hepatitis E virus (HEV) in human serum and plasma. The IgG assay is quantitative and the IgM assay is semi-quantitative. These fully automated kits are intended for professional laboratory use on the KleeYa® analyzer.

Control set CLIA

Control sera are used to verify the accuracy of results obtained with the CLIA kits.

Ease of use

- Fully automated method
- Kits include all necessary reagents, incl. calibrators
- Control materials are available as independent sets

Advantages

- High diagnostic sensitivity and specificity
- Low sample and reagent consumption
- Short test time
- Full traceability of reagent consumption and number of tests available using RFID tags
- LIS connectivity available
- Superior customer service

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Ordering information

CLIA kits

The diagnostic CLIA kits are intended for the detection of IgG and IgM antibodies against the hepatitis E virus (HEV) in human serum and plasma.

Kit	Catalogue number	Number of tests
*recom*CLIA HEV IgG	75004	100
*recom*CLIA HEV IgM	75005	100

Control sets

Control sera are used to verify the accuracy of results obtained with the CLIA kits.

Kit	Catalogue number	Number of tests
*recom*CLIA Control Set HEV IgG	75002	2 × 50
*recom*CLIA Control Set HEV IgM	75003	2 × 50

Complementary products

These products are developed and manufactured by Mikrogen GmbH

Kit	Catalogue number	Number of tests
*recom*CLIA Sample Diluent A*	10120	2 × 200

* An essential item required for use with the recomCLIA HEV IgM product.

Contact us at

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or visit our website

clia.biovendor.group

DISTRIBUTOR

BioVendor Group®

MANUFACTURER

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