VirClia® monotest

# HEPATITIS E

## Complete daily serological testing

### HEPATITIS E VIRCLIA® IgG MONOTEST
### HEPATITIS E VIRCLIA® IgM MONOTEST
### HEPATITIS E VIRCLIA® IgG AVIDITY MONOTEST

Chemiluminescent immunoassays (CLIA) to detect antibodies against hepatitis E virus in human serum or plasma samples.




- **Complete solution** as an aid in the diagnosis of hepatitis E: HEV IgM, HEV IgG and HEV IgG avidity.
- **Recombinant antigens**.
- **Highly specific IgM immunocapture method**.
- **Quantification of IgG antibodies concentration** using international units per milliliter (IU/ml) in accordance with the WHO standard.
- **First and only commercial avidity test** as an aid in the diagnosis of acute hepatitis E infection.
- **Monotest format with ready-to-use reagents**.
- **Simple and automated protocol that provides results within 1 hour**.
- **Compatible tests with VirClia® panel**, a broad solution for infectious diseases in CLIA monotest format (>90 parameters).

vircell MICROBIOLOGISTS

# Hepatitis E

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## Fundamentals

Hepatitis E virus (HEV) is one of the main causes of acute hepatitis in the world and its incidence has increased dramatically in recent years. Its greatest clinical impact is in immunosuppressed patients, pregnant women, and patients with underlying liver disease.

According to the WHO, it is one of the leading causes of death from acute viral hepatitis worldwide.

## Diagnostic tools

Detection of viral RNA is the gold standard although, due to the short duration of viremia, an undetectable result in the symptomatic phase is not conclusive.

The initial screening diagnosis is usually made indirectly, due to the fastness and availability of serological techniques. The presence of **Anti-HEV IgM antibodies** is an indicator of acute infection with an important implication in the clinical diagnosis, but when its reactivity is isolated, a new determination is recommended to show seroconversion to Anti-HEV-IgG.

**Anti-HEV-IgG antibodies** can last for more than 10 years and are indicators of past infection. However, a greater than fourfold increase in baseline antibody level can also be used as a diagnostic criterion for recent HEV infection. **IgG avidity assays** determine the affinity of these antibodies and can distinguish recent infections with low avidity from past infections with high avidity.

## Main recomendations for screening

- In all patients with acute hepatitis or acute liver failure.
- In patients with known or recently diagnosed chronic liver disease with decompensation and / or data suggestive of acute liver inflammation.
- In the evaluation of all patients with chronic hepatitis as well as in patients with liver disease of uncertain origin.
- In all organ donors.

## The True Monotest

- On-demand testing: **One monotest= one reportable test**. Nothing else is required.
- **Individual Quality Control per monotest,** no need for extra controls or calibrations.
- **Random Access automated protocol** with results in 1 h.
- **Same day results**, no batching, no sample cumulation.




## Performance

The sensitivity and specificity were determined against a commercial kit.

| | No. of samples | Sensitivity | Specificity |
|---|---|---|---|
| **HEV VIRCLIA IgM** | **256** | **95%** | **99%** |
| **HEV VIRCLIA IgG** | **254** | **92%** | **99%** |
| **HEV VIRCLIA IgG AVIDITY** | **153** | **93%** | **91%** |


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- Dichtl, K. *et al.* 2021. Evaluation of a Novel CLIA Monotest Assay for the Detection of Anti-Hepatitis E Virus-IgG and IgM: A Retrospective Comparison with a Line Blot and an ELISA. Pathogens 2021, 10, 689.
- Lier, C. *et al.* 2019. Evaluation of the performance of semi-automated serological tests VirClia® for the detection of IgM and IgG anti-Hepatitis E Virus (HEV). XXIes Journées Francophones de Virologie, Lyon, France.
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NEW
INNOVATIVE TECHNOLOGY

1
MONOTEST FORMAT

1h
AUTOMATED RESULTS WITH IN 1 HOUR

COMPLETE SOLUTION

BETTER PATIENT CARE

## Ordering information and related products

| Reference | Description | Class | Content |
|---|---|---|---|
| VCM066 | HEPATITIS E VIRCLIA® IgG MONOTEST (quantitative) | $CE_{0123}$ IVDR | 24 tests |
| VCM067 | HEPATITIS E VIRCLIA® IgM MONOTEST (capture) | $CE_{0123}$ IVDR | 24 tests |
| VCM093 | HEPATITIS E VIRCLIA® IgG AVIDITY MONOTEST | $CE_{0123}$ IVDR | 12 tests |


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