TEST ID: HEVQU

HEPATITIS E VIRUS RNA DETECTION AND QUANTIFICATION BY REAL-TIME RT-PCR, SERUM

USEFUL FOR

- Virologic detection and confirmation of hepatitis E virus (HEV) infection in immunosuppressed individuals at risk for or suspected to have acute or chronic hepatitis E
- Monitoring HEV RNA levels and determining eradication of chronic HEV infection in immunosuppressed individuals

CLINICAL INFORMATION

Hepatitis E virus (HEV) is a causative agent of acute self-limited or fulminant hepatitis. HEV has been responsible for large outbreaks of disease in developing countries, primarily through waterborne transmission. Hepatitis E also can occur in industrialized countries, usually as sporadic cases due to zoonotic infection transmitted by the fecal-oral route. A major natural reservoir of HEV is pigs.

In immunocompetent individuals, hepatitis E is mainly a self-limited infection, frequently nonsymptomatic, and does not result in chronic infection. However, in otherwise healthy pregnant patients, hepatitis E can be severe, resulting in significant morbidity and mortality. In immunocompromised individuals, such as organ transplant recipients, hepatitis E can be chronic with detectable HEV RNA levels in serum and plasma beyond 3 months after infection. HEV-specific IgM antibody is detectable by serologic testing by 4 weeks after infection in immunocompetent individuals, but it may not be detectable until 6 months after infection in immunosuppressed patients.

HEV RNA levels in serum or plasma are usually detectable in all infected individuals by 3 weeks after infection and become undetectable by 7 weeks in immunocompetent individuals. Due to the limitations of HEV serologic testing in immunosuppressed patients, molecular testing (eg, RT-PCR assay) for HEV RNA in serum or plasma is an increasingly important tool in the diagnosis of acute or chronic HEV infection in these patients.

Currently, ribavirin is used as the antiviral agent of choice for organ transplant recipients with chronic HEV, and monitoring of HEV RNA levels in serum or plasma is used to assess response to such antiviral therapy. Significant decreases in HEV viral load or clearance of HEV RNA may be important predictors of virologic response during antiviral therapy.

REFERENCE VALUES

Undetected

ANALYTIC TIME

1 day

CONTENT AND VALUES SUBJECT TO CHANGE. SEE THE MAYO MEDICAL LABORATORIES TEST CATALOG FOR CURRENT INFORMATION.
INTERPRETATION

The quantification range of this assay is 100 IU/mL to 5,000,000 IU/mL (2.00 log to 6.70 log IU/mL), with a limit of detection (based on a 95% detection rate) of 25 IU/mL (1.40 log IU/mL).

An "Undetected" result indicates that hepatitis E virus (HEV) RNA is not detected in the serum specimen (see Cautions). Repeat testing in 1 to 2 months is recommended for those at risk of HEV infection. The limit of detection (based on a 95% detection rate) for this assay is 25 IU/mL.

A result of "<100 IU/mL" indicates that the HEV RNA level present in the serum specimen is below 100 IU/mL (2.00 log IU/mL), and the assay cannot accurately quantify the HEV RNA present below this level.

A quantitative value (reported in IU/mL and log IU/mL) indicates the HEV RNA level (ie, viral load) present in the serum specimen.

A result of ">5,000,000 IU/mL" indicates that the HEV RNA level present in the serum specimen is above 5,000,000 IU/mL (6.70 log IU/mL), and this assay cannot accurately quantify the HEV RNA present above this level.

An "Indeterminate" result suggests the presence of an atypical HEV target sequence. Since the HEV RNA sequence is atypical, repeat testing is unlikely to change this result and, therefore, is not recommended.

An "Equivocal" result indicates that the presence or absence of HEV RNA in the serum specimen could not be determined with certainty due to atypical RT-PCR probe reactivity. Submission of a new specimen for testing is recommended.

An "Inconclusive" result indicates that the presence or absence of HEV RNA in the serum specimen could not be determined with certainty after repeat testing in the laboratory, possibly due to RT-PCR inhibition. Submission of a new specimen for testing is recommended.

CLINICAL REFERENCE