

## Survey for antibodies against Hepatitis E Virus

EQA Provider: ESfEQA GmbH  
 Heidelberg

Survey Coordinator: Dr. D. Groche

### Instructions for Use

#### Notes:

The samples should be considered as potentially infectious. The usual precautions in the laboratory for potential hazardous samples apply for these samples. The blood donations used for production were found to be non-reactive for anti-HIV 1/2 and anti-HCV. The samples should be applied by trained personnel only



**WARNING:** Contains methylisothiazolones.  
 H317 May cause allergic skin reaction.



This product contains human source material and should be considered as potentially infectious.

Various tasks of the proficiency testing scheme may occasionally be given over to qualified subcontractors. However, ESfEQA is responsible to the participants for the subcontractor's work.

Results from sample analysis may only be disclosed to colleagues from other laboratories after the testing period has been concluded.

By registering for and participating in this EQA participants agree to accept the general terms and conditions of ESfEQA GmbH. These can be retrieved online at [www.esfeqa.eu](http://www.esfeqa.eu).

### 1. Intended Use

The samples are intended for use as qualitative and quantitative control material for External Quality Assessment (EQA) in medical laboratories antibodies against Hepatitis E Virus:

anti-HEV IgG (qualitative and quantitative)  
 anti HEV IgM (qualitative and quantitative)

Please note that, in general, we will not issue a certificate of successful participation for the quantitative determination of anti-HEV antibodies since the target values are reagent-specific and a bias to the calculated consensus value does not necessarily represent a poor laboratory performance. The statistical evaluation is for information purposes only.

### 2. Product Description

The liquid samples derive from defibrinated human plasma and are ready-to-use.

### 3. Storage and Stability

The samples should be stored upright at 2-8 °C. They are stable at least until the deadline for data submission as indicated on the sample labels.

### 4. Sample Preparation and Analysis

Allow the sample to equilibrate to room temperature for 15 minutes prior to testing. Directly before use, agitate the sample by gently inverting the vial several times.

All samples should be treated the same way as patient samples and analyzed in accordance with the instructions of the instrument and reagent manufacturer.

### 5. Dates and Submission of Test Results

Testing Periods: Please refer to the sample labels. Results can be submitted anytime within the testing period indicated on the sample labels.

Please submit your results electronically to ESfEQA at <https://teqa.esfeqa.eu>.

Contact your local distributor of ESfEQA programs or ESfEQA directly if you need assistance with registration in TEQA. Alternatively, though not preferred, use the fax form provided on the ESfEQA website. In both cases indicate the instrument and method used for the analysis of the samples.

Quantitative results are generally reported with a value and a unit. The participant determines the number of digits for reporting. Results specified as e.g. '< below measuring range' or '< 0.02' are not valid. If the analyzer system displays such results, they shall be interpreted as following: For results within the measuring range and below the Limit of Quantification (LoQ) the obtained value should be reported. For results below the Limit of Detection (LoD), this limit should be reported. For samples that have analyte concentrations above the test range, the sample can be diluted (if recommended for particular applications) or the upper test range limit can be reported as result.

### 6. Deadline for Data Submission

The deadlines for submitting results are indicated on the sample labels (time zone GMT +1).

### 7. Reports and Certificates

The data will be evaluated by ESfEQA. The individual laboratory reports and certificates can be retrieved online at <https://teqa.esfeqa.eu>.