ESfEQA
European Society for External Quality Assessment

Survey for antibodies against Hepatitis B Virus (HBV, HBV12)

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.

1. Intended Use

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

anti-HBc IgG, anti-HBc IgM, anti-HBe,
anti-HBs (qualitative and quantitative), HBeAg,
HBsAg (qualitative and quantitative)

2. Product Description

The samples are liquid, 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 below.

4. Sample Preparation and Analysis

For handling precautions, refer to the “Technical Rules for Biological Agents - Protective measures for activities involving biological agents in laboratories - TRBA 100” (available at https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRBA/TRBA-100.html), or to "Biosafety in Microbiological and Biomedical Laboratories - CDC/NIH - Latest edition", or to the regulations currently in use in your country.

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.

Attention: Despite careful selection and preparation of EQA samples from native human material, individual lots may occasionally contain fibrin particles and clots may be observed in these samples. In such a case, we recommend that participants centrifuge the sample for 10 minutes at high speed (e.g. 10,000 rcf) to sediment the fibrin particles/clot. The supernatant can then be transferred to a new container/cup for subsequent analysis on the test system.

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

For determining anti-HBs with Beckman Coulter instruments we recommend the following workflow:

1. Analyze the sample under routine conditions (undiluted).
   a. If you receive any positive anti-HBs result in the undiluted sample confirm it with analysis of the sample with a 1:3 dilution. If this result is negative (after multiplication of the result with the dilution factor of 3), a negative result should be reported.
   b. If you receive any negative anti-HBs result in the undiluted sample a negative result should be reported.

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 result form provided on the ESfEQA website. In both cases indicate the instrument and method used for the analysis of the samples.

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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.

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