Survey for antibodies against Hepatitis B

EQA Provider:	ESfEQA GmbH Heidelberg
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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 Hepatits B 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

Sample 1: HBV_2019_01_a
Sample 2: HBV_2019_01_b
Sample 3: HBV_2019_02_a
Sample 4: HBV_2019_02_b

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

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.

Quantitative analysis: For measurement results below/ above the measuring range of the instrument, the lower/ upper measuring limit should be reported as a quantitative value.

5. Dates and Submission of Test Results

Testing Period for Sample 1 and 2: 18/02/19 – 11/03/19
Testing Period for Sample 3 and 4: 15/04/19 – 06/05/19

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.

6. Deadline for Data Submission

Deadline for data submission (time zone GMT +1):

Sample 1 and 2:	11/03/19
Sample 3 and 4:	06/05/19

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. The reports and certificates will be available within 3 weeks after the deadline of data submission.

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