ESfEQA
European Society for External Quality Assessment

Survey for HBV Molecular Testing (HBVM)

EQA Provider: ESfEQA GmbH Heidelberg

Survey Coordinator: Dr. H. Depner

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 samples should be handled by trained personnel only.

WARNING: 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 the following parameters:

HBV DNA qualitative

HBV DNA quantitative

It is recommended that participants using devices or methods, which provide quantitative values, **also submit values for** the corresponding **qualitative parameter**. This will enable the participants to compare their results with all laboratories.

2. Product Description

The lyophilized samples are prepared from human material with additives for formulation and stabilization. The samples are based on human serum. Positive samples contain inactivated whole virus.

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. Once the lyophilized survey samples are reconstituted (with sterile, nuclease-free ddH_2O), the analytical components will be stable for 8 hours when stored tightly capped at 2-8°C.

4. Sample Preparation and Analysis

IIn order to ensure that all lyophilized sample material is at the bottom of the tube, briefly spin the tube with the lyophilized control (e.g., 30 seconds at 14.000 rpm) before opening.

Reconstitute each lyophilized survey sample by pipetting **the volume** of Molecular/PCR grade ddH_2O (sterile, nuclease-free) **indicated on the sample labels**. Allow the control to reconstitute for 10-15 minutes, gently swirl and invert the closed tubes to ensure homogeneity.

After reconstitution of the samples, they should be handled/treated like patient samples (serum samples), and nucleic acid extraction and testing should be conducted in accordance with the instructions of the instrument and reagent manufacturers.

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.

For the evaluation of survey results, please indicate the reagent (used for NAT/PCR) and instrument (e.g. thermal cycler, real-time PCR detection system) - indication of the method is optional - and submit your results electronically to ESfEQA at www.esfeqa.eu.

The **unit for reporting** quantitative HBV DNA results in TEQA is '**log10 IU/mL**'.

Contact your local distributor of ESfEQA programs or ESfEQA directly if you need assistance for the registration, configuration and result submission in TEQA. Alternatively, though not preferred, use the result form provided on the ESfEQA website. In both cases indicate the reagent and instrument used for the analysis of the samples - indication of the method is optional.

ESfEQA GmbH
Siemensstr. 38
69123 Heidelberg
Germany

Phone: + 49 6221 4166-700
Fax: + 49 6221 4166-790
info@esfeqa.eu
www.esfeqa.eu

All entries are confirmed by pressing the button "confirm". The successful transmission of the results is indicated by “data saved”.

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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