ESfEQA
European Society for
External Quality Assessment

IFU_SP, Ver_003

Survey for Specific Proteins (SP12, SP4)

EQA Provider: ESfEQA GmbH Heidelberg

Survey Coordinator: Dr. D. Groche

Instructions for Use

Notes:

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 HBsAg, anti-HIV 1/2 and anti-HCV.

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 quantitative control material for External Quality Assessment (EQA) in medical laboratories for the following analytes:

Albumin, α-1-Acid Glycoprotein, α-1-Antitrypsin, α-2-Macroglobulin, Antistreptolysin O (ASO), β-2-Microglobulin, C3, C4, Ceruloplasmin, CRP, Cystatin C, Haptoglobin, IgA, IgE, IgG, IgM, kappa light chain (total and free), lambda light chain (total and free), Prealbumin, RF, soluble Transferrin Receptor (sTfR), Transferrin

2. Product Description

The samples are **liquid or lyophilized** material based on human serum.

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.

After reconstitution, the samples are stable for 7 days in tightly recapped vials when stored at 2-8 °C.

4. Sample Preparation and Analysis

Lyophilized samples: Remove the screw cap from the vial and pipette exactly 1 mL of distilled or deionized water to the lyophilisate. Keep the control sample for about 30 minutes at rest in a light-protected place, then gently agitate the vial occasionally until the lyophilisate is completely dissolved.

Liquid, ready-to-use samples: 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 result 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.

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