ESfEQA
European Society for External Quality Assessment

Survey for Immunohematology

EQA Provider: ESfEQA GmbH Heidelberg

Study Coordinator: Dr. H. Depner

Instructions for Use

Notes:

Potentially Biohazardous Material. The human blood donations used for manufacturing the controls were found to be non-reactive for HBsAg, anti-HIV 1/2 and anti-HCV. The usual precautions in the laboratory for handling potentially hazardous samples apply for these controls. The controls should be used 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 control material for External Quality Assessment (EQA) in medical laboratories for the following analytes:

ABO-Typing
A-Subtypes
Rh(D)-detection
Rh-typing
Kell-antigen detection
Direct antiglobulin test (direct Coombs test)
Antibody Screening
Antibody Identification (Rh, MNS, Lewis, I, P, Duffy, Kidd, Lutheran)
Cross-Matching

2. Product Description

The samples are of human origin. They are liquid, ready-to-use.

Samples a and **b** represent the erythrocyte suspension and serum sample of one **patient/recipient**, respectively. The erythrocyte suspension contains a red blood cell concentration of 8%:

Sample a: Patient erythrocytes
Sample b: Patient serum

Sample c represents the erythrocyte suspension of one **donor**:

Sample c: Donor erythrocytes

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

Patient erythrocytes - Sample a is intended for use in ABO-Typing, A-Subtypes, Rh(D)-detection, Rh-Typing, Kell-antigen detection, and direct antiglobulin test (direct Coombs test).

Patient Serum - Samples b is intended for use in Antibody Screening, Antibody Identification, and Cross- Matching.

Donor erythrocytes - Samples c is intended for use in Cross-Matching.

For **Cross-Matching, please** perform compatibility testing using the following combination of samples:

Cross-Matching: Sample b (Patient serum) with
Sample c (Donor erythrocytes)

Before using erythrocyte samples, gently agitate the vials until the sedimented blood cells have been completely suspended.

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

5. Dates and Submission of Test Results

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

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Please submit your results, which you have obtained by analyzing the samples for different parameters as described above, for “Patient 1” to ESfEQA electronically at https://teqa.esfeqa.eu while indicating the instrument, method and the reagent used. To enter or change the configuration please refer to the TEQA LAB Instructions at http://www.esfeqa.eu/en/eqa-programs/instructions-for- participants/ .

Contact your local distributor of ESfEQA programs or ESfEQA directly if you need assistance for the registration, configuration and result submission in TEQA.

If you do not want to transfer any result for one of the analytes that have been configured, deactivate the respective analyte for the corresponding survey sample using the cross symbol, which is displayed to the right of the analyte. Please include a brief explanation in the appearing text box, why you have not analyzed that parameter.

By pressing the cross-symbol button again, the result input field is reactivated.

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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