

Survey for Erythrocyte Sedimentation Rate

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Instructions for Use

Notes:

The samples should be considered as potentially infectious. Therefore, the usual precautions in the laboratory for handling potentially hazardous samples apply for these controls.



These controls are intended for *in vitro* diagnostic use only by trained personnel.



Potentially Biohazardous Material. This control does contain components from non-human sources and may transmit infectious disease.

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:

The determination of the Erythrocyte sedimentation rate (ESR) may be performed by manual or automated ESR methods.

The samples may not be suitable for testing on Alifax and Alcor iSED instruments.

2. Product Description

Mammalian erythrocytes are suspended in a plasma-like fluid with preservatives.

3. Storage and Stability

The vials should be stored upright at 2-8 °C. Protect the vials from overheating and freezing. The controls are stable at least until the deadline for data submission as indicated below on the sample labels.

After opening, the samples are stable for 30 days, provided they are handled properly.

4. Sample Preparation and Analysis

- (1) Allow the samples to equilibrate to room temperature for 15 minutes prior to testing.
- (2) It is critically important to mix the samples thoroughly at all mixing steps. To mix a sample, hold the vial horizontally between the palms of the hands. Roll the tube back and forth. Occasionally invert the tube. Mix vigorously but do not shake.

Alternatively, resuspend the samples by using a tube-revolver/rotator.

- (3) Continue to mix in this manner until the red cells are completely suspended. Vials stored for a long time may require extra mixing.
- (4) After mixing, the sample should be similar in appearance to fresh whole blood. In unmixed vials, the supernatant may appear cloudy and reddish; this is normal and does not indicate deterioration.
- (5) Gently invert the vial 10 times immediately before sampling. Do not mix the sample on a mechanical analyzer.
- (6) Analyze the samples as instructed by the instrument manufacturer's instructions for your equipment:
 - i) For automated methods, do not remove the diluent from test reservoirs before using this control.
 - ii) For manual methods, if you normally dilute patient samples, also dilute the control.

The Erythrocyte Sedimentation rate should be determined at 20-25°C. No instrumental temperature compensation (if applicable) should be applied.

Sarstedt S-Sedivette (manual method) and **Sarstedt Sediplus** instrument user:

The S-Sedivette is already pre-filled with 0.7 mL citrate solution and has to be filled with the ESfEQA sample material using the aspiration technique (according to Sarstedt technical information). This means that after the ESfEQA sample has been thoroughly mixed and resuspended, please transfer 2.8 mL of the ESfEQA sample into the S-Sedivette, which can be opened using the screw cap. After closing the screw cap, the suspension in the S-Sedivette has to be thoroughly mixed.

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 on <https://tega-labv2.esfeqa.eu>.

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

6. Deadline for Data Submission

Deadlines for data submission 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://tega-labv2.esfeqa.eu>.