

Survey for Erythrocyte Sedimentation Rate on ALIFAX ESR analyzers

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Instructions for Use

Notes:

The samples are suitable on ALIFAX ESR line analyzers only.



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

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:

Determination of the Erythrocyte sedimentation rate (ESR) on ALIFAX ESR line analyzers. The samples are not suitable for testing with other ESR analytical devices.

Suitable only with Alifax ESR line analyzers if upgraded with the software version 6.01A or upper for TEST1 (REF: SI 195.210/THL; SI 195.220/BCL; SI 195.230/SDL; SI 195.240/YDL; SI 195.250/MDL; SI 195.260/XDL); ROLLER 20 (REF: SI R20-LC), software version 1.0.0 and upper for TEST1 2.0: (REF: SI 195.210/THL), software version 1.00A or upper for ROLLER 20 (REF: SI R20-PN), software version 4.01A or upper for ROLLER 20 (REF: SI R20-MC), software version 4.03A or upper ROLLER 10 PLUS NEEDLE (REF: SI R10-PN), and software version 1.00.08 or upper for JO-PLUS (REF: SI 804.100).

2. Product Description

The samples have certain turbidity values, on which the ALIFAX analyzer performs transmittance measurements related to ESR values in human samples.

Three samples (a, b, c) are provided.

3. Storage and Stability

The vials should be stored in a dark place at 4-25 °C. Protect the vials from overheating and freezing. The controls are stable at least until the deadline for data submission as indicated on the sample labels. After opening, the samples are stable for 6 weeks at 2-8 °C.

4. Sample Preparation and Analysis

- (1) For analyzers upgraded with the following software versions, ensure that the 'Latex priming' is activated: 6.51D or upper for TEST 1, 6.51C or upper for ROLLER 20, 3.00A or upper for ROLLER 10, 1.01.00 or upper for JO-PLUS.
- (2) Perform the washing procedure according to the instrument operator manual.
- (3) For TEST1 an ROLLER 20-LC analyzers: from MAIN MENU press key 6 and then key 1 to start the procedure.
- (4) For ROLLER 20-PN analyzers: from MAIN MENU press 'Main', a scroll down menu will be displayed, then press 'Standard' to start the procedure.
- (5) For all ALIFAX analyzer types: prepare three washing tubes containing 3 ml of distilled water.
- (6) For TEST1 analyzers: load the sample tubes 1-3 and the washing tubes on the rack or on the rotor for ROLLER 10/20 and MicroTEST1 analyzers.
- (7) Verify the loading position indicated on the sample tubes, according to the following scheme:
 1. Washing tube – position no. 1
 2. tube ESRAF "a" – position no. 2
 3. tube ESRAF "b" – position no. 3
 4. tube ESRAF "c" – position no. 4
 5. Washing tube - position no. 5
 6. Washing tube - position no. 6
- (8) On TEST1 analyzer with the internal barcode reader (IBCR) the tubes must be placed with the labels on the right way for the barcode reading. Note: it is highly recommended to respect strictly the samples loading sequence as described above in order to avoid a wrong instrument check.

- (9) Following the TEST1 analyzer menu driven instructions, open the loading door and insert the rack with the test-tubes prepared for the check. After closing the front door, the analysis of controls will be started automatically.
- (10) In case of use in analyzer MicroTEST1 and ROLLER 10/20 with external barcode reader (EBCR), execute the reading of the barcode of each single test tubes while loading the test-tubes on the mixing rotor.
- (11) If the analyzer is without any bar-code reader or the reader is not able to read the barcodes in the test tubes, the barcode indicated on each single sample tube needs to be entered manually. Note: it is necessary to enter the whole barcode carried on each single sample tube. The content of the barcode is displayed in the menu 'Rack insertion'. If the displayed number does not correspond with the number of the sample tube, the displayed number can be deleted, corrected and saved by pressing 'enter'. Note that the last three digits of the barcode for all three sample tubes have to be identical. Otherwise an error message will be displayed, and the analysis will not be performed.
- (12) Upon completion of the mixing phase the analyzer will perform the dispensing and the analysis of the control standards.
- (13) After the analysis of the control standards, the results obtained will be printed as ESR values (mm/h).

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.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 fax 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

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://tega.esfeqa.eu>.