ESfEQA
European Society for External Quality Assessment

Survey for Erythrocyte Sedimentation Rate on ALCOR iSED® analyzers

EQA Provider: ESfEQA GmbH Heidelberg

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Instructions for Use

Notes:

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

Potentially Biohazardous Material. This control contains components from human source material and should be considered potentially infectious. The human whole 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.

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) on ALCOR iSED® analyzers. The samples are not suitable for testing with other ESR analytical devices.

2. Product Description

The control material is composed of stabilized human red cells suspended in a buffered fluid and preservative.

Sample 1: ESRAL_2023_02_a
Sample 2: ESRAL_2023_02_b

3. Storage and Stability

The vials should be stored at 18-30 °C. Protect the vials from overheating and freezing. The controls are stable at least until the deadline for data submission as indicated below. After opening, the samples are stable for 31 days when tightly capped.

4. Sample Preparation and Analysis

Product should be treated the same as patient specimens and analyzed in accordance with the instructions from the operator's manual. It is critically important that the blood cells at the bottom of the tube are completely resuspended. Therefore, gently invert the closed tubes either manually or on a rotator until the blood cells are completely suspended. This may require up to 25 minutes of gentle mixing. Vials stored for a long time may require extra mixing.

(1) Touch the 'Add Sample' icon,  , on menu screen.

(2) Insert the first sample in the empty sample position presented by the instrument, making sure to orient the barcode label facing right, toward the internal barcode reader. If the barcode is not immediately recognized, rotate the tube slightly until a beep is heard. The beep indicates the instrument has successfully read the barcode.

(3) The instrument will present the next open position.

(4) Repeat step 2 using the second sample.

(5) Read the control results printed by iSED®.

5. Dates and Submission of Test Results

Testing Period for Sample 1 and 2: 30/10/23 - 20/11/23

Please submit your results electronically to ESfEQA on https://teqa.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

Deadlines for data submission are (time zone GMT +1):

Sample 1 and 2: 20/11/23

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. The reports and certificates will be available within 3 weeks after the deadline of data submission.

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