ALCOR SCIENTIFIC

SEDITROL® QUALITY CONTROL

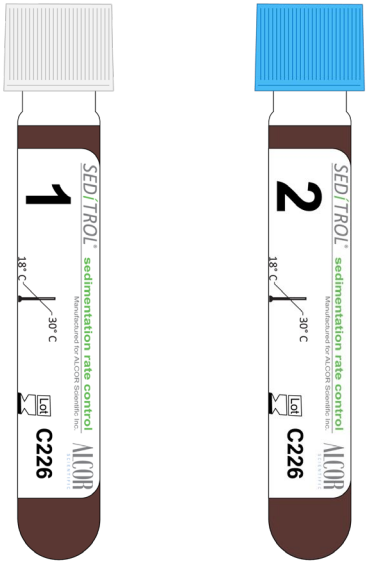
Erythrocyte Sedimentation Rate Analyzer

WHY USE QUALITY CONTROLS?

The use of quality control material is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Two levels of control are available to allow performance monitoring within the clinical range.

SEDITROL QC STORAGE & STABILITY

- Do not refrigerate, freeze, or expose controls to excessive heat
- Store at room temperature only (18° C to 30° C)
- Avoid prolonged exposure to light
- 18-month shelf life from the date of manufacture
- 60-day open vial stability
- Store upright
- Mix well* before analysis



* It is important to follow the instructions in this training module, in the Seditrol Instructions for Use, and in the Operator's Manual for proper mixing and storage of QC material.

SEDITROL® ESR QUALITY CONTROL

Seditrol Quality Control for ESR is a bi-level, quality control material composed of stabilized human red blood cells suspended in a buffered fluid and preservative.

Seditrol requires more mixing than patient samples because the control material matrix is very viscous compared to fresh, whole blood samples and additional mixing and processing time is required. Each tube of Seditrol is conveniently barcoded to signal to the analyzer that a control sample has been loaded.

Note: To ensure consistent results, Quality Control (QC) samples must be well mixed for at least 25 minutes on a mechanical rocker or rotator prior to their first use. Ensure that the cells have been thoroughly resuspended before placing the control tubes onto the ALCOR ESR analyzer. For each subsequent QC event after a thorough initial mixing, QC samples should be placed on a mechanical rocker or rotator for at least 5 minutes before placing the control tubes onto the ALCOR ESR analyzer.

PROCEDURE

Product should be used in accordance with the Seditrol Instructions for Use and the analyzer Operator's Manual.

Ensure that the cells have been thoroughly resuspended before placing the control tubes onto the analyzer.

To run QC on the ALCOR analyzer:

1. Quality Control (QC) samples must be well mixed before placing the control tubes onto the ALCOR ESR analyzer as follows
    a. For first use, place QC samples on a mechanical rocker or rotator for at least 25 minutes.
    b. For each subsequent use, after a thorough initial mixing, QC samples should be placed on a mechanical rocker or rotator for at least 5 minutes.
2. Insert one (1) tube of Seditrol Level 1 ensuring that the barcode is read and recognized by the analyzer
3. Repeat step 2 using one (1) tube of Seditrol Level 2
4. After each use, wipe any residual material from the exterior of the cap
5. Store as described in the Storage and Stability Section

For complete quality control procedure instructions, please refer to

Seditrol Instructions for Use #315-09-011

miniiSED Operator's Manual #1017-09-001

iSED Operator's Manual #112-09-043

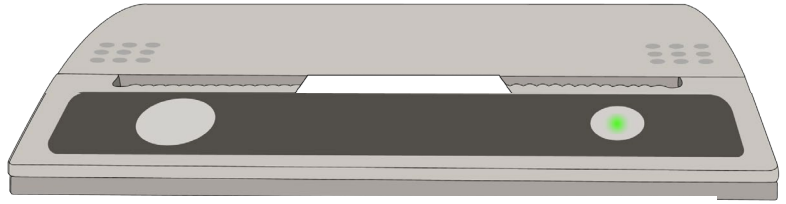
QC RESULTS

ALCOR analyzers utilize a single reading cell for analysis and therefore 100% quality control of the analyzer is performed every time a quality control is run.

Like patient testing, quality control results will be shown on the analyzer touch screen and printed (when applicable). Results should be compared with the product insert.

QC Result Format

Date format:	Month/Day/Year
Time format:	Hour/Minute/Second
Serial number	Instrument serial number
ID:	QC Lot (read from barcode)
Result format:	ESR value in mm/hour



RECOMMENDATIONS

Some helpful tips:

- ALCOR recommends running quality controls at least once per day, however it is up to each individual lab to determine the quantity and frequency of controls per an Individualized Quality Control Plan (IQCP), as recently established by CMS, CAP, and COLA
- Each new set of controls must be placed on a rocker for 25 minutes prior to first use; then mix for 5 minutes each day of use until depleted or expired.
- Store controls upright at room temperature
- Remember an additional 20µL of sample is withdrawn from the first test run following a wash cycle. To ensure the volumes for Level 1 and Level 2 remain as consistent as possible it is recommended to alternate the order controls are run each day. We suggest to start with Level 1 controls on all odd days and Level 2 on all even days in the month.
- Enroll in ALCOR's Quality Assurance Program for online, unlimited access to Levy Jennings reports and to see how your laboratory's QC results compare to the peer group

THANK YOU!

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