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Erythrocyte Sedimentation Rate using the Alcor iSED ESR Analyzer

Purpose

This procedure provides instructions for performing an automated erythrocyte sedimentation rate using the iSED ESR analyzer. The rate at which red blood cells aggregate in whole blood has a direct effect on the resulting sedimentation rate. Sedimentation rate is therefore an indirect representation of the rate of aggregation. The iSED erythrocyte sedimentation analyzer uses photometrical rheology to directly measure the aggregation of red blood cells. Once the sample is automatically processed and in position a sensitive optical detector in the iSED follows the progress of aggregation over time. This produces a signal that is a direct representation of the aggregation. The magnitude of time-dependent change is correlated to the Westergren method.

Scope

This procedure is intended to be used by all personnel trained and competent to perform and implement any of the activities described in this procedure.

Specimen

- Whole blood collected in K3-EDTA or K2-EDTA anticoagulant tube (13 X 75 tube with pierceable cap or BD Microtainer® MAP Microtube)
- Sample volume for testing: 400uL
- Minimum dead volume: 100uL
- Sample must be neither clotted nor hemolyzed
- Sample stability: room temperature (18-25°C) up to **28 hours** and refrigerated (4-8°C) up to **48 hours**

Specimen rejection

Specimens received:
- Frozen
- Clotted
- >28 hours, room temperature or >48 hours refrigerated

Equipment

- iSED PRO Series S, iSED (serial numbers >5000), iSED ELITE, and miniiSED

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Reagents and/or Media

The following contains the list of reagents and/or media required.

Description	Reorder #
iWASH cleansing agent	112-12-001
Waste bottle	112-12-002
Seditrol® ESR Quality Control	DSO5233
Test Card 10,000 qty	112-10000
Thermal Paper	DS-05233

Safety Precautions

Refer to the safety manual for general safety requirements.

Quality Control

- Seditrol® is human based whole blood quality control.
- Seditrol® QC is kept at room temperature (18 – 30°C).
- Seditrol® QC open vial stability is 60 days.
- The unopened shelf life of Seditrol® QC is 18 months from the date of manufacture.
- Test time for QC is 20 seconds after at least 25 minutes of mixing on a mechanical rocker or rotator prior to initial use, and at least 5 minutes for succeeding use.
- The Seditrol® QC tubes can be pierced up to 40 times without degrading the performance.
- Two different levels of Seditrol® QC are analyzed at least once in 24 hours.

Step	Action
1	Touch the "Add Sample" icon on the instrument's touch screen: 
2	The sample wheel rotates to position the next open slot in the sample entry port.
3	The onscreen information bar will report "iSED is Waiting" and the instrument will beep quietly for five (5) seconds. As the five (5) second window draws to a close, beeping will become faster.
4	Insert the barcoded Seditrol® Level 1 control tube with the oriented to the right. A red light will illuminate, and a distinctive beep will sound when the barcode is successfully recognized.

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Erythrocyte Sedimentation Rate using the Alcor iSED ESR Analyzer, Continued

Quality Control, Continued

Step	Action
5	Automatic sample processing then begins. **NOTE**: The mix cycle for Seditrol® ESR Quality Control is five (5) minutes.
6	Repeat steps 2 – 4 to run Seditrol® Level 2.
7	Log QC results in one of the following: • iSED QC manual log • iSED QC excel file in OneDrive • Alcor QAP website: iQAP - ALCOR Scientific (iqaponline.com). Use assigned Username and Password • **NOTE**: Corrective action must be taken when controls are out. Record action taken in the comment section of manual log.
8	QC results should be reviewed by a CLS before reporting patient results.

Quality Control Limitations

- The quality control product should not be used past expiration date.
- The quality control product is not intended for use as standard.
- Inability to obtain expected values may indicate product deterioration. Discoloration of the product may be caused by excessive heat or cold during shipping or storage.
- QC results should be reviewed and accepted/approved by CLS before reporting patient results.

Before you begin

- Place the sample at room temperature for at least (15) minutes if previously refrigerated (4C)

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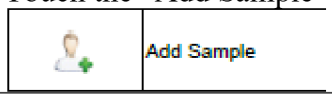
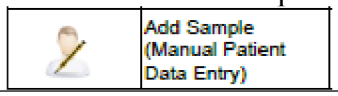
Procedure

Follow the steps below to run a barcoded patient sample:

Step	Action
1	Touch the "Add Sample" icon on the instrument's touch screen: 
2	The sample wheel rotates to position the next open slot in the sample entry port.
3	The onscreen information bar will report "iSED is Waiting" and the instrument will beep quietly for five (5) seconds. As the five (5) second window draws to a close, beeping will become faster.
4	Insert the barcoded tube with the barcode oriented to the right. A red light will illuminate and a distinctive beep will sound when the barcode is successfully recognized
5	Automatic sample processing then begins.
6	Repeat steps 2 – 4 until all samples have been loaded and/or all positions in the sample wheel are occupied. • **NOTE:** If the five (5) second window is missed, simply select the  icon again to restart the sample scheduling process.
	Follow the steps below to run a manual data entry patient sample:
Step	**Action**
1	Touch the "Add Sample" icon on the instrument's touch screen: 
2	The sample wheel rotates to position the next open slot in the sample entry port.
3	The onscreen information bar will report "iSED is Waiting" and the instrument will beep quietly for five (5) seconds. As the five (5) second window draws to a close, beeping will become faster.
4	Insert the tube. The instrument will try and read the barcode. If unable, the operator will be prompted to enter patient identification data manually using the alphanumeric keyboard.
5	Remove tube from the sample wheel to allow for a visual tube identification to input patient data

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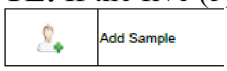
Erythrocyte Sedimentation Rate using the Alcor iSED ESR Analyzer, Continued

Procedure, Continued

Step	Action
6	Patient information must be recorded in one or more of the following data fields: • Alphanumerical ID • Patient's First Name • Patient's Surname
7	Touch the  icon to skip a data field or to confirm entered information.
8	Sample processing will begin once patient data has been entered
9	Repeat steps 2 – 4 until all samples have been loaded and/or all positions in the sample wheel are occupied. • **NOTE:** If the five (5) second window is missed, simply select the  icon again to restart the sample scheduling process.

Releasing Results

Results are shown on screen after analysis and also printed by the instruments internal printer.

Results will be AUTOVERIFIED. If autoverification is OFF, then follow workflow below.

If the instrument is …	Then you can ...
Interfaced	Release the results in Cerner through ARE, instrument queue.
Not interfaced	Release results in Cerner through ARE manually.

Reportable Range

1 – 130 mm/hr

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Reference Ranges

	Age	Sedimentation Rate
Male	<50 Years	<15 mm/hr
Male	>50 Years	<20 mm/hr
Female	<50 Years	<20 mm/hr
Female	>50 Years	<30 mm/hr
Children	≤14 Years	<14 mm/hr

Limitations

- Blood that is hemolyzed, clotted or grossly lipemic should not be tested and should be redrawn.
- iSED results are NOT affected by Hematocrit or MCV.
- Some interferences which will increase ESR:
  - Increased level of fibrinogen, gamma globulins
  - Technical factor: mechanical vibration, high room temperature
- Some interferences which will decrease ESR:
  - Abnormally shaped RBCs (sickle cells, spherocytosis)
  - Technical factors: low room temperature, delay in test performance (> 2hr), clotted blood sample, excess anticoagulant, bubbles in tube.
- ESR is a nonspecific reaction. It is highly recommended to perform other tests together with ESR, since an ESR value is not enough to exclude that the patient is not affected by a pathology or to diagnose a clinical condition.

Alcor iSED Preventive Maintenance

Maintenance

The instrument does not require any scheduled maintenance; however, it is recommended that the instrument be always kept free from dusty and particulate environments.

Refer to the iSED Operator's Manual for detailed information on AS NEEDED maintenance and troubleshooting help.

Non-Controlled Documents

The following non-controlled documents support this policy.

Operator's Manual. iSED Erythrocyte Sedimentation Rate Analyzer Cat.112-00101. Alcor Scientific. 112-09-03 Rev. H
Alcor Seditrol ESR Control Kit Package insert #315-09-011 Rev.3
CLSI/NCCLS Clinical Laboratory Technical Procedure Manual; Approved Guideline, GP02
Alcor Technical Bulletin 1013 Rev.0. Extended Stability or iSED Family of Analyzers. Sept 9, 2025.

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- Hematology-Urinalysis Working Group

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Hematology Regional Docs

Operations Director Approval

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Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
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