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Owner:	<i>Alex Alba: Spvr, Laboratory</i>
Policy Area:	<i>Lab - Hematology</i>
References:	
Applicability:	<i>Sutter Roseville Medical Center</i>

## Erythrocyte Sedimentation Rate Using the iSED Analyzer

### Purpose

This procedure describes how to perform testing for erythrocyte sedimentation rate using the automated iSED analyzer.

### Policy

- This policy is to be followed when an erythrocyte sedimentation rate test is requested.
- In the event the primary iSED analyzer is out-of-service, samples will be performed on the secondary iSED analyzer as a backup plan for ESR testing.
- Test code: **ESR**

### Principle

The iSED® analyzer, manufactured by Alcor Scientific Inc., uses quantitative capillary photometry (aggregation) to measure erythrocyte sedimentation rate (ESR) faster than traditional methods by capturing the kinetics of Red Blood Cell aggregation in a controlled testing environment during the most critical phase of sedimentation, commonly referred to as the lag or rouleaux formation phase.

The ESR is helpful in revealing inflammatory activity and in monitoring the progress of conditions associated with acute and chronic inflammation, including infections, cancers, and autoimmune diseases. The ESR is particularly useful in evaluating patients with unexplained symptoms, when infectious diseases are suspected and when a specific diagnosis is not available effectively using other tests

### Supplies

- iSED® Automated ESR Analyzer
- iWASH cleansing agent
- Waste bottle
- Thermal paper
- Seditrol® ESR Quality Controls
  - Controls are stable to expiration date when stored unopened at 18° to 30° C. Once opened product is stable for 60 days at room temp (18° to 30° C) when tightly capped.

# Specimen Requirements

Whole blood specimen collected in EDTA anti-coagulant tube

- Specimen cannot be clotted or hemolyzed
- Minimum sample volume: 500uL (0.5mL) whole blood
- Minimum sample volume for pediatric testing: 400 uL (0.4ml) whole blood
- Sample must be tested within 6 hours of collection, if stored at room temperature
- Sample must be tested within 24 hours of collection, if stored refrigerated
- **NOTE:** Sample must sit out at room temperature for 15 minutes before testing if it was refrigerated

# Blood Collection Tube Requirements

- Standard 13 X 75 mm EDTA anticoagulant tube with pierceable cap
- BD microtainer MAP Microtube

# Calibration Requirements

There are no calibration requirements for this analyzer

# Quality Control

2 levels of quality control are performed once daily on each analyzer at the start of the shift, prior to patient testing.

Due to priming of analyzer with sample when performing QC, a larger sample volume of the first control loaded and run is aspirated. To maintain equal usage of controls, on odd days, Level 1 control will be run first on the analyzer and on even days, Level 2 control will be run first on the analyzer.

- Seditrol ESR Control 1 = ESR Normal Control
  - Sunquest QC code: **C-ESRN**
- Seditrol ESR Control 2 = ESR Abnormal Control
  - Sunquest QC code: **C-ESRA**
- Seditrol ESR Quality Controls are intended for exclusive use on iSED.
- When opening a new vial of control, it must be pre mixed on a rocker for 25 minutes prior to running on the analyzer to ensure uniform mixing of QC material. After the initial opening, the control can be premixed for 10 minutes
- Store control vials in an upright position

# Procedure A

Follow steps below to perform ESR quality control on the iSED analyzer

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. <b>NOTE:</b> The on screen information bar will report "waiting sample" and the instrument will beep quietly for five (5) seconds. As the five (5) second window draws to a close, beeping will become faster.

3	Insert the barcoded Seditrol® Level 1 control 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 <b>NOTE:</b> Rotate the loading on the control vials on the iSED analyzer. Load normal control first on odd dates and abnormal control vial on even dates
4	Automatic sample processing then begins. • <b>NOTE:</b> The mix cycle for Seditrol® ESR Quality Control is five (5) minutes.
5	Repeat Steps 2-4 to run the next vial of Seditrol® control.
6	QC results are reviewed and released in the Sunquest LARS application using QC codes C-ESRN (Level 1) and C-ESRA (Level 2)
7	If controls are within acceptable limits, proceed with patient testing.
8	If one or more controls are not within acceptable limits, proceed with taking corrective action to resolve out-of-control failures prior to proceeding with patient testing. • <b>NOTE:</b> 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. ◦ First step is to repeat QC with the same vial of control. ◦ If QC fails again, proceed with opening a new vial of control. ◦ If QC still is out of control, proceed with calling technical support for further troubleshooting.

## Procedure B

All sample mixing, sample extraction, sample reading and sample disposal is handled automatically by the instrument. Up to 20 sample tubes may be loaded into the sample wheel at any given time. As each sample is processed (19 seconds), the sample tube is ejected from the sample wheel and retained in the external sample collection tray. As soon as a sample is ejected, another tube may be scheduled and placed in the sample wheel.

**Follow the steps below to process patient BARCODED samples on the iSED analyzer**

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. <b>NOTE:</b> The on screen information bar will report "waiting sample" and the instrument will beep quietly for five (5) seconds. As the five (5) second window draws to a close, beeping will become faster
3	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.
4	Automatic sample processing then begins
5	Repeat Steps 2-4 until all samples have been loaded and/or all positions in the sample wheel are occupied. <b>NOTE:</b> If the 5 second window is missed, select the "Add sample" icon again to restart the sample loading process

**Follow the steps below to process patient NON BARCODED samples on the iSED analyzer**

Step	Action
1	Touch the 'Add Sample' icon on the instrument's touch screen
2	Touch the 'Add Sample (Manual Sample)' icon as the sample wheel is rotating to position the next open slot in the sample entry port
3	The instrument will prompt the operator to enter patient identification data manually using the alphanumeric keyboard. Patient information must be recorded in one (1) or more of the following data fields: <ul style="list-style-type: none"> <li>• Alpha numerical ID (i.e. Accession Number or MRN)</li> <li>• Patient's First Name</li> <li>• Patient's Last Name</li> </ul>
4	Touch the 'Select' icon to skip a data field or to confirm entered information. <ul style="list-style-type: none"> <li>• <b>NOTE:</b> When manually entering ID, first or last name, always touch the 'Select' icon after each entry. If this step is skipped, the information will not print on the results.</li> </ul>
5	The sample wheel rotates to position the next open slot in the sample entry port.
6	Insert the tube and sample processing will begin. <ul style="list-style-type: none"> <li>• <b>NOTE:</b> If all of the patient identification fields are skipped, and no tube is inserted, the instrument will automatically abort the loading procedure for that sample and resume sample processing for tubes already in sample wheel. If a tube has been inserted, the sample will be automatically assigned an ID number and processed.</li> </ul>

## Reporting Results

Results are shown on screen after analysis and also printed by the instrument's internal printer. In the event that the instrument is unable to analyze the sample and report results, the print out will replace the result field with an error message.

Step	Action						
1	Results are reported in the Sunquest LIS using automated or manual entry <table border="1" data-bbox="251 1312 1274 1879"> <thead> <tr> <th>If</th> <th>Then</th> </tr> </thead> <tbody> <tr> <td>Automated</td> <td> <ul style="list-style-type: none"> <li>• Results within the technical range will autofile</li> <li>• If outside the technical range then review and release results in LARS</li> <li>• Method code RVESR1 or RVESR2</li> </ul> </td> </tr> <tr> <td>Manual</td> <td> <ul style="list-style-type: none"> <li>• Obtain instrument printout and document result on ESR worksheet for corresponding patient</li> <li>• Enter result in Sunquest Roll and Scroll</li> <li>• Function MEM</li> <li>• Worksheet RVHESR</li> <li>• Enter ACC number</li> <li>• Enter ESR result in whole number</li> <li>• Accept results and verify correct manual entry of results and document "RVS" next to tech code/initials on worksheet when complete</li> </ul> <p><b>NOTE:</b> If result is outside the technical limit (1-130 mm/hr), result must be</p> </td> </tr> </tbody> </table>	If	Then	Automated	<ul style="list-style-type: none"> <li>• Results within the technical range will autofile</li> <li>• If outside the technical range then review and release results in LARS</li> <li>• Method code RVESR1 or RVESR2</li> </ul>	Manual	<ul style="list-style-type: none"> <li>• Obtain instrument printout and document result on ESR worksheet for corresponding patient</li> <li>• Enter result in Sunquest Roll and Scroll</li> <li>• Function MEM</li> <li>• Worksheet RVHESR</li> <li>• Enter ACC number</li> <li>• Enter ESR result in whole number</li> <li>• Accept results and verify correct manual entry of results and document "RVS" next to tech code/initials on worksheet when complete</li> </ul> <p><b>NOTE:</b> If result is outside the technical limit (1-130 mm/hr), result must be</p>
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reported as <1 or >130

## Reference Range and Technical Range

- Female (<50 years): 0 - 25 mm/hr
- Female (≥ 50 years): 0 - 30 mm/hr
- Male (<50 years): 0 - 15 mm/hr
- Male (≥ 50years): 0 - 20 mm/hr
- Critical Value: None
- Technical Limit: 1-130 mm/hr

## Preventative Maintenance

All maintenance is to be documented on *Form A: iSED Preventative Maintenance Log*

Frequency	Action
Weekly	<b>Empty Waste Bottle</b> <ul style="list-style-type: none"><li>• Pour down dirty sink and flush sink with water for 60 seconds</li><li>• Press the waste bottle emptied icon on screen when complete</li></ul>
Monthly	<b>Perform Deep Clean Cycle (blue scrubber icon)</b> <ul style="list-style-type: none"><li>• Add 3.5mL of 6-7% bleach to an empty 13 X 75 mm non additive blood collection tube.</li><li>• Once prompted on screen, insert the deep clean tube into the sample loading position and press continue. <b>NOTE:</b> Verify lid is secure on tube before loading.</li><li>• The analyzer will run 2 wash cycles and then automatically perform the deep clean (3 minutes) and conclude by running 2 additional wash cycles.</li><li>• Once the deep clean is complete, remove and discard bleach filled tube</li></ul>
As needed	<ul style="list-style-type: none"><li>• Inspect interior surfaces and rear fan assembly for heavy dust accumulation and clean as needed</li><li>• Replace iWASH bottle<ul style="list-style-type: none"><li>◦ Press iWASH changed icon on screen when complete to reset count</li></ul></li><li>• Change printer paper (indicated by blinking green light)</li><li>• Power down instrument<ul style="list-style-type: none"><li>◦ <b>IMPORTANT:</b> Must perform wash cycle <u>first</u> (yellow scrubber icon)</li></ul></li><li>• Replace sample needle (after 30,000 piercings)<ul style="list-style-type: none"><li>◦ Please contact Technical Support for instructions on replacing the needle</li></ul></li></ul>

## Smart Card: Downloading Credits

In order to process and analyze samples, test known as 'credits' must be downloaded onto the instrument from a smart card preloaded with tests of various quantities

Step	Action
1	With the arrow facing upward and forward, insert the test card into the smart card reader located in the front of the instrument

2	Once inserted, the credits will automatically download onto the instrument and the analyzer will indicate with a message on the screen
3	Total credits available will include the newly downloaded credits and any residual credits prior to download
4	Once all credits have been downloaded onto the instrument, the test card can be removed and discarded

## References

- iSED Erythrocyte Sedimentation Rate Operator's Manual, 112-09-073 Rev E.
- iSED Icon Quick Reference Guide, 112-09-072 Rev C.

All revision dates:

11/5/2021, 1/4/2021

## Attachments

[iSED Analyzer Preventative Maintenance Log.FormA SN 02589.xls](#)

[iSED Analyzer Preventative Maintenance Log.FormA SN 02445.xls](#)

## Approval Signatures

Step Description	Approver	Date
Medical Director	Lindsey Westerbeck: Dir, Lab	11/5/2021
Laboratory Director	Lindsey Westerbeck: Dir, Lab	11/5/2021