Erythrocyte Sedimentation Rate (iSED)

Principle

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.

Safety

All specimens, reagents and controls should be handled as though capable of transmitting infectious diseases. Wear appropriate personal protective equipment when running patient samples or performing scheduled maintenance. Refer to: Policy and Procedures Safety Manual Infection Control and Procedures 11-085-01.

Specimen Requirements

1. Sample volume required for testing/Minimum dead volume:
   100uL/ 500uL whole blood.

2. Specimen Considerations:
   - Sample must be whole blood collected in K3-EDTA or K2-EDTA anticoagulant tube (13 X 75 tube with pierceable cap or BD Microtainer® MAP Microtube)
   - Sample must be neither clotted nor hemolyzed. Do Not Mix Vigorously.
   - Sample should be tested within 24 hours at room temperature or refrigerated (2-8°C).
   - Sample must be at room temperature for at least (15) minutes if previously refrigerated.

Reagents

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

Erythrocyte Sedimentation Rate (iSED)

Quality Control

- Seditrol® Quality Controls are used for iSED.
- Two different levels of Seditrol® QC are analyzed at least once every 24 hours.
- Seditrol® QC open vial stability is 31 days.
- Seditrol® QC is kept at room temperature (18 – 30°C).

Procedure for running controls:

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.
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 results in the QC log and **Enter QC results DAILY in the Alcor website: http://www.mylabqc.com/alcor/login.asp.** **Refer to attachment A: Alcor QC program instructions** **NOTE**: Corrective action must be taken when controls are out. Indicate the corrective action in the daily quality control audit sheet.
8	Print Levey-Jennings Report for the QC program monthly.

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.

Erythrocyte Sedimentation Rate (iSED)

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. **NOTE**: *The mix cycle for all samples is five (5) minutes.*
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.

The following procedure should be followed if the internal barcode reader is unable to read the barcode information on the inserted tube:

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	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.
4	Remove tube from the sample wheel to allow for a visual tube identification to input patient data.
5	Patient information must be recorded in one or more of the following data fields: • Alphanumerical ID • Patient's First Name • Patient's Last Name
6	Touch the  icon to skip a data field or to confirm entered information.
7	Sample processing will begin once patient data has been entered. **NOTE:** (*For tubes removed from sample wheel)* If patient information data is not entered within ten (10) seconds from the last pressed key, the loading process will abort and the operator will restart the loading process for that tube.

Erythrocyte Sedimentation Rate (iSED)

Procedure, continued

Follow the steps below to run a non-barcoded patient sample:

Step	Action
1	Touch the "Add Sample"  icon on the instrument's touch screen.
2	Touch the "Add Sample"  (Manual Patient Data Entry) icon as the sample wheel is rotating (indicated by instrument beeping) 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: • Alphanumerical ID • Patient's First Name • Patient's Last Name **NOTE:** When manually entering ID, first or last name, always touch the  icon after each entry. If this step is skipped, the information will not print on the results.
4	Touch the  icon to skip a data field or to confirm entered information.
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. **NOTE:** 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.

Erythrocyte Sedimentation Rate (iSED)

Result Reporting

Results are printed by the instrument's internal printer.

Releasing the results:

If the instrument is …	Then you can ...
Interfaced	Auto-verification "**ON**" • Result are released automatically. • Check Instrument Activity Monitor to monitor result that are held. Auto-verification "**OFF**" • Release the results in Cerner through ARE, instrument queue.
Not interfaced	• Release results in Cerner through ARE manually.

- **Reporting Notes:**
  - iSED Results will only be auto-verified and/or interfaced with Cerner if the results are within linearity and/or there were no error codes posted during sample run.
  - If the instrument is unable to analyze the sample and report results, the print out will replace the result field with an error code.
  - For results with error codes, refer to operator's troubleshooting section of the manual to determine if follow up steps must be taken prior to accepting and reporting results.
  - Always check the printout, before accepting the run and releasing results.
  - For any result outside of the linearity (<1 or >130), you need to verify it by re-running the sample.

IMPORTANT NOTE:

The results for outside linearity will not post to Cerner. The CLS would need to check the print-out for the result. When resulting manually in Cerner ARE, CLS would need to type in '0' for the less than 1 result or 131 for the greater than 130 result. Cerner would automatically convert the result to <1 or >130 with the flag.

Reportable Range

1 – 130 mm/hr

Reference Range

Male	≥50 Years	0-20 mm/hr
Female	<50 Years	0-20 mm/hr
Female	≥50 Years	0-30 mm/hr
Children	≤14 Years	0-10 mm/hr

Erythrocyte Sedimentation Rate (iSED)

Limitations of the Procedure

- 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.

NOTE: 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.

Maintenance

The instrument does not require any special daily maintenance, however it is recommended that the instrument be kept free from dusty and particulate environments at all times.

For Daily, Weekly and Monthly AS NEEDED maintenance, refer to the maintenance log.

Please refer to Sections 15 & 16 of the iSED Operator's Manual for detailed information on AS NEEDED maintenance and troubleshooting help.

Controlled Documents

The following controlled documents support this procedure.

Reference
1. iSED® Erythrocyte Sedimentation Rate Analyzer Operator Manual, ALCOR Scientific Inc. (OM112-09-043)
2. CLSI/NCCLS Clinical Laboratory Technical Procedure Manual; Approved Guideline, GP02
Attachments
A: Alcor QC Program Instructions

Erythrocyte Sedimentation Rate (iSED)

Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Name of responsible person/date	Med. Dir. Reviewed/ Date	Director of Lab Ops. reviewed/ date	Date change Implemented
Major	1. Regional Template Update 2. Revised index no. 3. Added auto-verification under Result reporting and added Auto-verification criteria under reporting notes 4. Added Alcor QC program result entry	Yvette Lingat 4/20/2020		Mary Lou Beaumont	4/28/2020