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Erythrocyte Sedimentation Rate iSED™ Analyzer-RO

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This procedure provides instructions on performing an erythrocyte sedimentation rate (ESR) using the *i*SED™. It also provides instructions for instrument operation, including quality control, maintenance, and running samples.

II. PRINCIPLE:

A. The erythrocyte sedimentation rate (ESR) is the rate in millimeters per hour that erythrocytes settle out of the plasma in a column of anticoagulated whole blood. The rate of red blood cell settling is affected by three factors: (1) red blood cell number and shape; (2) mechanical and technical factors (e.g. temperature, tube diameter, bubbles, etc.); and (3) plasma factors. When the first two factors are constant, the plasma composition of the blood becomes the single most important factor. The presence of fibrinogen, alpha-2-globulin, beta and gamma globulins decrease the red blood cell zeta potential promoting rouleaux which results in a faster sedimentation rate. The erythrocyte sedimentation rate thus reflects changes in plasma proteins which accompanies acute and chronic infections, inflammation, malignancy, multiple myeloma, macroglobulinemia and hyperfibrinoginemia. The major disadvantage of this procedure is that the sedimentation rate is dependent on red blood cell (RBC) number and is prolonged by anemia. The erythrocyte sedimentation rate is used primarily to follow the progress of inflammatory diseases such as rheumatoid arthritis during treatment.

B. The *i*SED™ analyzer utilizes photometric rheoscope as its methodology. The *i*SED™ analyzer's speed, accuracy and 100 µL sample size are built around a micro flow cell which captures the most robust early phase – aggregation – of rouleaux formation in RBC sedimentation. The sample is mixed for thirty seconds. This is followed by a patented ultrasonic blast which disaggregates the red cells. Aggregation kinetics is proven to have greater than 95% correlation with the Westergren method. *i*SED™ advanced automation assures repeatability by removing external variables such as mixing, vibration, temperature, timing and other factors that introduce imprecision in manual and semi-automated Westergren methods. The *i*SED™ produces results in 20 seconds. The results correspond to the traditional Westergren method results of mm/hr.

III. ACRONYMS:

A. College of American Pathologists (CAP)

B. Laboratory Information System (LIS)

IV. SPECIMEN COLLECTION AND HANDLING:

Type	A. Whole blood collected in a 4 mL Hemogard vacutainer. B. **Microtainer specimens are NOT acceptable!**
Anticoagulant	K_2EDTA
Amount	A. Whole blood 1. Minimum sample size is 2.0 mL. 2. Optimum sample size is 4.0 mL.
Special Handling	A. Specimen must be at **room temperature**. No pre-mixing is necessary as the *i*SED™ delivers a patented ultrasonic blast to disperse specimen aggregation. B. Samples containing sickle cells, lipemia or cold agglutinins may give false results.
Timing	Specimen is stable for 48h at refrigerated (2-8^{o}C) temperature.
Criteria for Unacceptable Specimens	Specimens containing clots or inappropriate volume are unacceptable and must be redrawn.

V. REAGENTS:

A. **iWash:**

1. 500mL plastic tank with screw cap. Ready to use.
2. **Storage**: Store at room temperature. Stable indefinitely unless visible signs of deterioration. Supplied by Alcor Scientific.

B. **Clorox (Germicidal):**

1. Sodium Hypochlorite 8.25%
2. **Storage:** Stable under normal use and storage conditions.

   WARNING: Clorox Germicidal. Avoid acidification or contact with ammonia containing products, which can generate hazardous chlorine gas.
3. **Clorox Germicidal Ultra Health Risk:** Respiratory irritant if mist or vapor is inhaled, nausea and vomiting if ingested. May irritate skin. Contact with eyes can cause severe, but temporary injury to the eye.

   WARNING: Clorox Germicidal contains a strong oxidizing agent. Causes substantial but temporary eye injury. May irritate skin. May cause nausea and vomiting if

ingested. Exposure to vapor or mist may irritate nose, throat and lungs. Recommended: Wear gloves, a lab coat and safety glasses or equivalent for protection.

VI. SUPPLIES:

A. **Smart Card Reader:** Conform to ISO 7816-1 T0 protocol. Supplied by Alcor Scientific.

B. **Printer Paper:** Thermal roll 57mm x 25m. Supplied by designated hospital office supply vendor.

VII. MAINTENANCE:

A. Refer to Attachments A and B for maintenance information.

B. Refer to *i*SED™ Operator Manual for specific instructions for programming date, time, sample mixing and control mixing times.

VIII. QUALITY CONTROL (QC):

A. Quality control consists of two levels of barcoded Seditrol® (P/N DSC 06). They are supplied ready to use. No reconstitution is necessary. The QC is composed of stabilized human red cells suspended in a buffered fluid and preservative.

B. Once pierced, a Seditrol® tube has a 60-day onboard expiration. Each Seditrol® QC tube is individually barcoded for automatic identification by the instrument. An unlimited number of on-demand QC samples can be performed at any time.

C. **QC Product Limitations:**

1. Seditrol® QC should not be used past the expiration date on the product label.
2. Seditrol® QC is not intended for use as a standard.
3. Inability to obtain expected values may indicate inconsistencies in overall process control, product deterioration, or other process variation. Discoloration of Seditrol® QC may be caused by excessive heat or cold during shipping or storage which may or may not affect performance.

D. **QC Storage and Stability:**

1. Seditrol® QC will remain stable to expiration date when stored unopened at 18° to 30° C. Once pierced, the Seditrol® tube is stable for 60 days at room temp (18° to 30° C). **DO NOT FREEZE OR EXPOSE TO EXCESSIVE HEAT.**

E. An ESR correlation check between the both iSED™ analyzers is performed twice per year as follows:

1. Set up a blood on iSED™A.
2. Set up the same blood on the iSED™B.
3. Record results on the iSED™ QC and Maintenance Log.
4. Results should be within ± 10 mm/hr.

F. Proficiency (i.e. accuracy and reliability) testing is accomplished at least twice per year by participation in a College of American Pathologists (CAP) proficiency program or equivalent.

IX. PROCEDURE:

A. Turn the instrument ON using the ON/OFF switch located on the back of the instrument.

B. Verify that communication is established with the host computer.

C. Insert controls first by selecting  on the touch screen. Place first control in the open slot. Listen for the beep. The sample will mix one cycle.

D. Repeat with the second control tube.

E. To start running a patient sample, select  on the touch screen. 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.will mix one cycle.

NOTE: Gently load the specimens into the iSED; do not try to shove the tube in. If excess labels are present, remove as many as you can rather than trying to shove the tube in.

F. To run multiple tests, insert a second tube into open slot. Listen for beep. Sample will mix one cycle again. Continue loading samples.

G. After 20 seconds, results will be displayed on the screen, printed and sent to the LIS automatically.

H. The test tube will eject into the tray once the test is complete.

I. To end or stop, select  .

NOTE: If a tube gets “stuck” in the *i*SED™, press the big red “X” on the main screen to allow the iSED to expel the tube itself. Do not rotate the wheel manually to extract the tube.

NOTE: If a Tail Sensor Error appears, perform the Bleach Cleaning Procedure (Attachment B).

J. Results are shown on screen after analysis and also printer by the instrument’s inteRnal printer. The printout results present the following information:

Printed Result Example:

Date format: Month/Day/Year
Time format: Hour/Minute/Second
Result format: mm/hour
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Date: 03/25/2013	Date of analysis
Time: 13:36:24	Sample insertion time
*i*SED Sn.: 00001	Instrument serial number
ID: 812409	Barcoded sample identification
Time: 13:39:44	Time result printed

X. EXPECTED VALUES:

A. **NORMAL RANGE:** For current normal values, refer to Hematology Normal Values-RO procedure.

B. **REPORTABLE RANGE:** The reportable range of the iSED™ analyzer is 0-130 mm/hr.

C. **REPORTING OF RESULTS:**

1. If a negative result is obtained, check sample for a clot and repeat (on alternate *i*SED™ if available).

2. For extremely elevated values (130), check sample for a clot and repeat (on alternate *i*SED™ if available).
3. *i*SED™ instrument errors do not go across into the LIS. Instrument tapes should be reviewed periodically to see if there are any instrument errors that need to be addressed. Otherwise, they will show up on the pending log.

XI. LIMITATIONS:

A. The erythrocyte sedimentation rate is a phenomenon confined to fresh blood and transient, not a hematic matrix component (at corpuscular/ molecular level). The procedures used to determine the ESR cannot be calibrated as they are susceptible to a variety of errors (temperature, hematocrit, erythrocyte mean corpuscular volume, plasma viscosity, etc.) *i*SED™ results are affected by these variables to a limited degree. For this reason, it is possible to observe instrument performances deviations compared to other procedures if the above variables are not taken into account.

B. Erythrocyte sedimentation remains an only partly understood phenomenon. It is a nonspecific reaction (from a clinical point of view) that is affected by several technical aspects. The ESR is often normal in patients with cancer. International guidelines for diagnosis and management of multiple myeloma do not mention the Erythrocyte Sedimentation Rate. However there are national guidelines that include ESR together with other clinical tests. It is then highly recommended to perform other tests together with ESR in the diagnosis of cancer since a normal ESR value is not enough to exclude that the patient is not affected by this pathology.

C. Sample mixing is programmed at the beginning of the analysis with the purpose of homogenizing the sample. An inefficient homogenization can affect the results given by the instrument that in fact measures erythrocyte aggregation kinetics.

D. Anemia does not appear to affect the *i*SED™ methodology.

E. Refer to *i*SED™ Operator Manual for information on System Status Messages, System Warning Messages and System Error Codes.

XII. NOTES:

A. The test should be set up within 48h if sample consistently kept at 4^{o}C; otherwise, some samples with elevated ESRs will be falsely low. On standing, erythrocytes tend to become spherical and less readily form rouleaux.

B. Removal of fibrinogen by defibrination (e.g. clot formation) lowers the ESR.

C. Gross hemolysis means fewer RBCs (simulates anemia) and zeta potential change, resulting in an increased ESR.

D. RBCs with abnormal or irregular shapes (e.g. sickle cells, spherocytes) hinder rouleaux and lower the ESR.

E. Heparin alters the membrane zeta potential and thus cannot be used as an anticoagulant.

XIII. REFERENCES:

A. Brown, B. Hematology: Principles and Procedures. 4th Ed., Philadelphia: Lea & Febinger, 1984: 52-54.

B. Henry, JB. Clinical Diagnosis and Management. 18th Ed., Philadelphia: WB Saunders, 1991: 589-590, 599-601.

C. Koepke, JA., et.al. "The Evolution of Erythrocyte Sedimentation Rate Methodology", Labmedica. February/March 1990.

D. National Committee for Clinical Laboratory Standards. Standardized Method for the Human Erythrocyte Sedimentation Rate (ESR) Test. Willanova, PA: 1977. International Council for Standardization in Haematology, Medical Laboratory Observer, November, 1992.

E. iSED™ Operator Manual, OM 112-09-043 rev A, October 22, 2013.

F. Alcor Product Notification re: Seditrol® stability, October 2020.

G. iSED™ Operator Manual, OM 112-09-043 rev L, July 1, 2021.

Attachments

Attachment A - Instrument Maintenance and Parts Replacement.pdf
Attachment B – iSED™ BLEACH CLEANING PROCEDURE (As Needed).pdf

Approval Signatures

Step Description	Approver	Date
	Ann Marie Blenc: System Med Dir, Hematopath	12/9/2021
Hematology Medical Director Designee	Ann Marie Blenc: System Med Dir, Hematopath	12/9/2021
Policy and Forms Steering Committee Approval (if needed)	Michele Sedlak: Medical Technologist Lead	12/8/2021
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	12/1/2021
System Manager	Rebecca Bacarella: Mgr Laboratory	12/1/2021
	Michele Sedlak: Medical Technologist Lead	11/30/2021

Applicability

Royal Oak