

Document Title:	ERYTHROCYTE SEDIMENTATION RATE USING THE ALCOR SCIENTIFIC iSED ANALYZER
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Author:	Effective Date:	Supersedes Procedure #
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REVISION HISTORY

Procedure #	Version #	Revision Date	Reason for Revision
SH.CP.AU.hem.0001	.0004	9/26/2017	Update for new SW version 03.02A; update maintenance
SH.CP.AU.hem.0001	.0005	2/2/2018	Add open expiration date to control vials per CAP inspection

TITLE: ERYTHROCYTE SEDIMENTATION RATE USING THE ALCOR SCIENTIFIC iSED ANALYZER

I. PURPOSE

A. INTRODUCTION AND CLINICAL SIGNIFICANCE:

The erythrocyte sedimentation rate (ESR/Sed Rate) can be used as a simple screening test to help decide if a patient with only vague abnormal physical findings requires further testing for disease. The ESR reflects the speed erythrocyte sedimentation and can be used to represent the degree of a patient's inflammatory status. The age and sex of the patient influence the normal ranges.

Red cell sedimentation is accelerated by an increase in the plasma concentration of "acute phase proteins", which are increased in acute tissue damage, chronic inflammation, chronic infection, and pregnancy. The ESR reflects both the increase in certain accelerating proteins, such as fibrinogen and gamma globulins, and the decrease in retarding proteins, such as albumin.

High values are found in cancers, multiple myeloma, leukemias, lymphomas, breast cancer, lung cancer, rheumatoid arthritis, lung failure, some types of infections, liver metastasis, and acute/chronic inflammatory diseases.

B. PRINCIPLE:

The instrument is designed to accurately and precisely measure the sedimentation rate of erythrocytes by sampling directly from the primary 13 x 75mm EDTA blood collection tube (lavender top). The iSED uses advanced Rheology Technology to measure the "earliest and most critical phase" of the Erythrocyte Sedimentation, which is called Rouleaux Formation. It is well known, in fact, that the rouleaux formation is the critical phase of ESR and the one that it is ultimately determine the length at which the red cells will sediment in the Westergren tube. The iSED 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.

II. SCOPE

To be used by UR Medicine Labs Hematology and Chemistry Lab staff at 601 Elmwood Avenue, Rochester, NY for Erythrocyte Sedimentation Rate analysis.

III. RESPONSIBILITIES

Department and functional responsibilities are defined below:

Group/Person	Responsibility
Quality Assurance	<ul style="list-style-type: none"> Supports the development of this document
Medical Director	<ul style="list-style-type: none"> Ensures that the procedure is followed Review and approval of this document
Supervisor	<ul style="list-style-type: none"> Ensures that the procedure is followed Review and approval of this document
End User	<ul style="list-style-type: none"> Follows the procedure

IV. SPECIMENS

A. Specimen Collection:

- 13 x 75mm EDTA anticoagulant tube (lavender top) with pierceable cap
- Minimum volume - Sample volume for testing is 100µL whole blood
- (600µL dead volume)
- TO AVOID HEMOLYSIS, DO NOT MIX VIGOROUSLY. DO NOT VORTEX.

B. Stability/Storage


- Preferably the sample should be tested within 4 hours of venipuncture. However, EDTA tubes preserve integrity of patient samples for up to 24 hours from the time of collection whether stored at room temperature (20-25°C) or at 2°-10°C.
- Specimens >24 hours from collection time should be resulted as follows:
“.ND- Specimen beyond stability limit for assay.”
- Sample Storage:
 - Post analysis: samples are stored for the remainder of the day at room temperature and for two additional days at 4°C.
 - Refrigerated samples must be at room temperature for at least fifteen (15) minutes before testing.

Note: *The instrument requires no additional or special sample preparation. As with all anti-coagulant collection tubes, the tubes should be well mixed after filling to help avoid clotting or other aggregates that may alter ESR test results. Specimens with bubbles may need to be rerun.*

V. QUALITY CONTROL/CALIBRATION

- Two levels of quality control are used to monitor the accuracy and precision of the Alcor iSED ESR Analyzer.

- B. Quality control is accomplished by processing the control fluids when the instrument is in an operational state or according to laboratory policies. Quality control will be performed once a day or additionally as needed.
- C. Quality control results are entered into the laboratory information system. Refer to the LIS procedure for entering QC results and determining acceptability.
- D. Quality Control Testing and Review
 - 1. Manual Quality Control Records:
 - a. Daily review of the manual QC is performed by the staff running the controls and should be performed prior to release of any patient results. Supervisor/Designee will also review QC results on a regular basis.
 - 2. Limitations
 - a. Controls should not be used past expiration date. Once opened product is stable for 30 days at room temperature (18 to 30 degrees °C when tightly capped).
 - b. Inability to obtain expected values may indicate deterioration of the control material. Discoloration of the control may be caused by excessive heat or cold during shipping or storage.
 - 3. Quality Control Testing
 - a. Two QC levels will be run daily and filed electronically in the LIS.
 - b. Two levels of QC must also be run:
 - 1) After any maintenance is performed.
 - 2) Whenever there is a software update, usually done by vendor.
 - c. Preparing the QC fluid for analysis
 - 1) If a new vial of QC is used, vortex vials until all RBC are in suspension. Label the control vial with the expiration date 30 days after opening.
 - 2) Store opened and unopened vials at room temperature in a vertical position (it will be easier to resuspend cells in vials at room temperature).

NOTE: IF CONTROL MATERIAL DOES NOT MIX PROPERLY, IT MAY BE DUE TO EXPOSURE TO EXTREME HEAT OR COLD. DO NOT USE CONTROL MATERIAL AND NOTIFY A SUPERVISOR FOR FURTHER INSTRUCTION.
 - d. Running Quality Control on Analyzer
 - 1) Mix QC samples for a minimum of 15 minutes before placing on the analyzer
NOTE: New vials should be vortexed before use.
 - 2) Touch the “Add Sample” icon  on menu screen.

- 3) Insert one tube of Seditrol Level 1, in the empty sample position presented by the instrument, making sure to orient the barcode label facing right, toward the internal barcode reader. If the barcode is not immediately recognized, rotate the tube slightly until a beep is heard. The beep indicates the instrument has successfully read the barcode.
- 4) The instrument will present the next open position.
- 5) Repeat step 2 using one tube of Seditrol Level 2.
- 6) Control results will automatically print when the test is complete.
- 7) Results are entered into the LIS via the corresponding instrument interface.
- 8) See Auto Lab QC procedure SH.CP.AU.gen.0001.

4. Troubleshooting Quality Control

- a. The technologist must perform the necessary steps to correct the problems when QC is not within the acceptable range.

Note: Patient samples should not be run until QC is within acceptable ranges.

- b. Record all steps on the Hematology Daily Log form (HH.CP.HE.frm.0001).
- c. If QC is out of the acceptable range, mix and retest control(s) to see if control(s) will come back into the acceptable range.
- d. If QC is still out of range, open a new vial and mix according to lab protocol and rerun control(s).
- e. If QC is still out of range, check to see:
 - (1) If a new lot of QC is being used and the ranges need to be updated.
 - (2) That all the maintenance was done according to protocol.
 - (3) That all parameters are properly set within the instrument.
- f. If QC is still out of range, switch to the back-up analyzer and notify supervisor.

E. CALIBRATION

Alcor iSED instruments are factory calibrated utilizing samples which are compared with results from a unique Reference Instrument. The Reference Instrument is correlated with the reference Westergren method. During normal operation parameters affecting calibration are constantly monitored and, if not within expected limits, a warning is given and further testing prevented.

VI. SPECIAL SAFETY PRECAUTIONS

- A. All specimens should be considered potentially infectious and must be handled with precautions used for human blood, in accordance with UR Medicine Labs Hematology-Chemistry Laboratory safety policy (SH.CP.AU.gen.0005).

- B. Wherever there are moving parts use caution with correcting malfunctions and when operating system.
- C. For in vitro diagnostic use only.
- D. Disposal of all waste material should be in accordance with local guidelines.
- E. Safety data sheet available on request.

VII. MATERIALS AND EQUIPMENT

A. Equipment

Alcor Scientific iSED analyzer

Product# 112-0010



B. Supplies


- | | |
|-----------------------------------|-----------------------|
| 1. iWash Fluid (4 pack) | Product# 112-12-001 |
| 2. Printer paper (3 pack) | Product# DS-05233 |
| 3. Test Card (5000 tests) | Product# DS-112-05000 |
| 4. Waste Replacement Bottles (24) | Product# 112-12-002 |

C. Reagents/Controls

- | | |
|-----------------------------|----------------|
| 1. Seditrol Quality Control | Product #DSC06 |
|-----------------------------|----------------|

VIII. MAINTENANCE

A. Daily Maintenance: (see also SH.CP.AU.frm.0225)

- 1. A wash cycle  should be run at the beginning of each day, PRIOR to replacing the waste bottle and/or if the instrument is powered off for any reason.
- 2. Check printer paper supply.

3. Inspect wash and waste bottle levels

- a. Wash/waste level: View current wash/waste volumes on the Home screen



- b. Emptying/Replacing Waste Bottle: The waste bottle will be emptied and cleaned daily along with the cap to the waste bottle and the waste port.

- (1) Run a wash cycle prior to emptying the Waste bottle.
- (2) Open the front door, the waste bottle is located in the upper compartment.
- (3) Disconnect the Luer connector from the screw cap BEFORE taking the bottle out.
- (4) Remove the waste bottle from the compartment, unscrew the cap, and dispose of the waste according to lab protocol.
- (5) Replace the bottle into the upper compartment and firmly reconnect the Luer connector on the plastic screw cap with the vent hole positioned at the top.

NOTE: Be sure to replace the plastic cap with the vent hole at the top and be careful not to kink the line when replacing the bottle.

- (6) Close the front access door and press the “waste bottle emptied” icon



on the Home screen.

NOTE: This procedure can be done without the waste alarm being triggered. It is recommended to perform this task daily.

- c. Run controls and verify they have passed. If controls fail, follow process in Section V.D.4.

B. Weekly Maintenance


1. Perform Deep Clean/Wash procedure:

Materials needed:

- Empty and unused 13x75 tube (Do not use SST tube)

- 6-7 % hypochlorite (bleach) Do not dilute unless, greater than 7%.
- On board iWASH solution

Procedure:

- a. Add approximately 3.5 ml of 6-7 % hypochlorite to unused 13 x 75 tube.
- b. Press the Deep Clean icon  on the Home screen.
- c. Once the screen prompts, insert the Deep Clean tube into the sample loading position and press continue. (Pressing abort will stop the deep clean process)
- d. The analyzer will run 2 wash cycles, then automatically perform the Deep Clean (3 minutes), and conclude by automatically running two additional wash cycles.
- e. Once the deep clean procedure is completed, remove and discard the bleach filled tube.

C. Biweekly/As needed maintenance

1. Replace iWASH bottle: A warning message will pop up on the screen when the wash bottle is low or empty.
 - a. Open the front door to access the bottle compartment.
 - b. The iWASH bottle is located in the lower compartment.
 - c. Disconnect the LUER connector from the iWASH bottle screw cap.
 - d. Remove the empty iWASH bottle, unscrew the cap and replace it with a new iWASH bottle.
 - e. Place the new iWASH bottle in the lower compartment and firmly reconnect the LUER connector (E) on the plastic screw cap with the vent hole positioned at top.
 - f. Close the front door.

- g. Press iWASH changed icon  on main page.


2. Switch iSED interface (biweekly)

- a. Stop the iSED SMH interface by the following process:
 - 1) In Soft, access the Interfaces Menu on the top menu bar.
 - 2) Open "Instruments Lab" menu and locate the iSED SMH – SSED1 interface.

- 3) Stop the interface by clicking the "Stop Interface" button. 

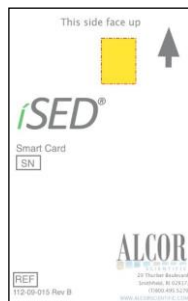
- b. Unplug the blue interface cable from the back of the analyzer that is currently in use.

- c. Plug the cable into the other analyzer that will be used.
- d. Notify CLSS that the interface should be switched from #1 to #2 or #2 to #1.
- e. When CLSS has finished, restart the iSED SMH interface by the following process:
 - 1) In Soft, access the Interfaces Menu on the top menu bar.
 - 2) Click on the “Interface Setup” button to open the interfaces menu.
 - 3) Open “Instruments Lab” menu and locate the iSED SMH – SSED1 interface.

- 4) Start the interface by clicking the ”Start Interface” button .
- 5) Restart the Autodownloading and Autoposting by clicking on the “Autodownload2” line and then click “Start Interface”.

Autodownloading (2)	
Autodownload2	AUTD2
Inst AutoDownload	AUTOD
Autoposting (1)	
Inst AutoPosting	AUTOP

- 6) Repeat the process with “Inst AutoDownload” and “Inst AutoPosting” lines (in that order), clicking Start Interface after each line is chosen.
- f. Run controls to verify that interface switch is working.
3. Downloading credits from a test card (SMART cards):
 - a. In order to process and analyze samples, tests, known as ‘credits’, must be downloaded onto the instrument from a smart card preloaded with tests of various quantities.
 - b. With the arrow facing upward and forward, insert the test card into the smart card reader located on the front of the instrument. Credits will download automatically. Once all the credits have been downloaded, the test card can be removed and discarded.



4. Inspect and clean instrument exterior and interior surfaces with a damp cloth as needed.
5. Inspect rear fan assembly for dust and clean with damp cloth as necessary.
6. Regularly clean the instrument using only water and mild detergents to wipe the surface of the instrument and sample tray.


IX. PROCEDURE

All sample mixing, sample extraction, sample reading and sample disposal are handled automatically by the instrument. Up to 20 sample tubes may be loaded into the sample well at any given time. As each sample is processed (20 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 placed in the sample wheel.

NOTE: DO NOT VORTEX SAMPLE.

NOTE: When loading patient samples, DO NOT place the tube in the sensor field in front of the rotating wheel. Doing so will cause the wheel to stop rotating and may abort any samples that are already running or cause an error code to occur!

A. To run patient samples with a bar code:



1. Touch the add sample icon. 
2. The sample wheel rotates to position the next open slot in the sample entry port. *The onscreen information bar will report "waiting sample" and the instrument will beep quietly for five seconds. As the five 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 sound when the barcode is successfully recognized.

NOTE: If the five second window is missed, simply select the add sample icon again to restart the sample scheduling process.


4. Repeat Steps 2-4 until all samples have been loaded and/or all positions in the sample wheel are occupied (maximum of 20).
 5. Automatic sample processing then begins.
- B. Running Patient Samples without a barcode or with a bad barcode (two options)

NOTE: When loading patient samples, DO NOT place the tube in the sensor field in front of the rotating wheel. Doing so will cause the wheel to stop rotating and may abort any samples that are already running or cause an error code to occur!



1. Samples without a barcode

- a. Touch the  icon as the sample wheel is rotating (indicated by instrument beeping) to position the next open slot in the sample entry port.
- b. 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:
 - 1) Alphanumeric ID
 - 2) Patient's First Name
 - 3) Patient's Surname
- c. Touch the  icon to skip a data field or to confirm entered information.
- d. The sample wheel rotates to position the next open slot in the sample entry port.

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.

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.


2. Samples with a bad barcode


- a. Touch the  icon as the sample wheel is rotating (indicated by instrument beeping) to position the next open slot in the sample entry port.
- b. Insert the tube, the instrument will try and read the barcode. If unable to read the barcode, the operator will be prompted to enter patient identification data manually using the alphanumeric keyboard.
- c. Remove tube from sample wheel to allow for a visual tube identification to input patient data (*Optional*).
- d. Patient information must be recorded in one (1) or more of the following data fields:
 - 1) Alphanumeric ID
 - 2) Patient's First Name
 - 3) Patient's Surname
- e. Touch the  icon to skip a data field or to confirm entered information.
- f. The sample wheel rotates to position the next open slot in the sample entry port.

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 have to restart the loading process for that tube.

NOTE: (*For tubes not removed from the sample wheel*) If patient information is not entered within ten (10) seconds from the last pressed key, the instrument will automatically assign an identification number.

C. Cancelling a sample

1. During the mixing cycle of five minutes, press the  icon.

NOTE: Pressing the  button during the mixing cycle will abort all samples on that test run.

NOTE: For details on error messages and troubleshooting, see the Operator's Manual pg.39 for the *Error message table* and pg. 42 for the *Troubleshooting table*.

*****Technical Support Phone Number: 401-737-3774*****

X. LIMITATIONS

- A. The erythrocyte sedimentation rate is a transient phenomenon confined to fresh blood. It is not a hematic matrix component at the corpuscular or molecular level. The procedures used to determine the ESR cannot be calibrated since they are susceptible to a variety of factors, e.g. temperature, hematocrit, erythrocyte mean corpuscular volume, plasma viscosity, etc. For this reason, it is possible to observe instrument performance deviations, compared to other procedures, when the above variables are not taken into account.
- B. Erythrocyte sedimentation remains a confusing, partly understood phenomenon and, clinically, 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 pathology.
- C. Note that the ESR denotes merely the presence of tissue damage or disease, but not its severity; it may be used to follow the progress of the diseased state, or monitor the effectiveness of treatment.
- D. Some interferences which increase ESR:
 1. increased level of fibrinogen, gamma globulins
 2. technical factor: mechanical vibration, high room temperature
- E. Some interferences which decrease ESR:
 1. abnormally shaped RBC (sickle cells, spherocytosis)
 2. technical factors: low room temperature, delay in testing
- F. Specimen Integrity and Unacceptable Specimens:
 1. The following samples have questionable sample integrity and must be recollected: Partially clotted (fibrin strands) and clotted specimens, contaminated specimens, specimen not received in correct container, improperly labeled (wrong patient) specimens.

2. Grossly hemolyzed or lipemic specimen: specimen may need to be recollected, if the iSED is unable to read them.
3. Sample mixing is performed at the beginning of the analysis with the purpose of homogenizing the sample. An inefficient homogenization can affect the results given by the instrument.
4. Refrigerated specimens must be brought to room temperature before testing.
5. Excessive delay in transport to laboratory: samples that are >24 hours old will not be tested.

XI. CALCULATIONS N/A

XII. INTERPRETATION

Red cell sedimentation is accelerated by an increase in the plasma concentration of “acute phase proteins”, which are increased in acute tissue damage, chronic inflammation, chronic infection, and pregnancy. The ESR reflects both the increase in certain accelerating proteins, such as fibrinogen and gamma globulins, and the decrease in retarding proteins, such as albumin.

High values are found in cancers, multiple myeloma, leukemias, lymphomas, breast cancer, lung cancer, rheumatoid arthritis, lung failure, some types of infections, liver metastasis, and acute/chronic inflammatory diseases.

XIII. PROFICIENCY TESTING

CAP Proficiency Testing is performed on three samples twice per year and results are filed in the Hematology proficiency testing binder and in the Hematology supervisor office.

XIV. RESULT REPORTING

- A. Results are transmitted to the LIS instrument specific interface and autorelease in the absence of any error codes.
- B. If a sampling error occurs, the instrument will try to resolve it automatically up to a maximum of three attempts. After the third attempt, if the instrument is unable to resolve the sampling error, an error message will be printed on the tape.
- C. Reportable range: 1-130 mm/hr
- D. Samples with a result less than 1 mm/hr and greater than 130 mm/hr will print out as “<1 mm/hr” and “>130 mm/hr”, respectively, and should be reported as “<1 mm/hr” and “>130 mm/hr”.
- E. Normal Reference Range:

Age	Sex	Mm/hr.
-----	-----	--------

0-49 Yr.	M	0-15
0-49 Yr.	F	0-20
> 50 Yr.	M	0-20
> 50 Yr.	F	0-30

- F. Specimens >24 hours from collection time should be resulted as follows:
“.ND - Specimen beyond stability limit for assay.”

XIV. TRAINING

Personnel	Training Required
Management	Read
End User	Read Perform Skills Assessment Knowledge check

XV. REFERENCES

- A. iSED Operator’s Manual, Alcor Scientific, 112-09-043, Rev. H.
- B. NCCLS Clinical Laboratory Technical Procedure Manual – Third Edition; Approved Guideline: Vol.16.No.15.
- C. CLSI. Procedures for the Erythrocyte Sedimentation Rate Test; Approved Standard-Fifth Edition. CLSI document H02-A5. Wayne, PA: Clinical and Laboratory Standards Institute; 2012.
- D. Clinical Laboratory Medicine, K.D. McClatchey, 1994: 34:847-848
- E. Clinical Diagnosis by Laboratory Methods, Todd and Sanford, 15th edition, p.133-135.

ALCOR SCIENTIFIC iSED Analyzer - Knowledge Check

SH.CP.AU.hem.0001.0004

In the event of a question answered incorrectly: Single-line through the incorrect answer, initial & date, then select the correct answer.

ALWAYS HAVE CHANGES INITIALED BY YOUR TRAINER.

Circle the correct letter of the answer for each of the following statements.

1. The iSED analyzer testing is done using:
 - a. Wintrobe tubes
 - b. Streck ESR Pediatric tubes
 - c. EDTA/whole blood samples
 - d. iSED specific tubes.

2. The sample volume that the iSED analyzer withdraws for testing is:
 - a. 50 ul
 - b. 100 ul
 - c. 200 ul
 - d. 500 ul

3. After proper sample mixing, the iSED instrument can produce ESR results in a minimum time of:
 - a. 20 seconds
 - b. 1 minute
 - c. 2 minutes
 - d. 10 minutes

4. The number of sample tubes that may be loaded into the sample wheel at any given time is:
 - a. 5
 - b. 10
 - c. 15
 - d. 20

5. When placing the specimen tube into the instrument's sample entry port, the barcode is oriented:
 - a. to the left
 - b. to the right
 - c. upward
 - d. downward

6. Which of the following are required in order to process and analyze samples on the iSED instrument?
 - a. Smart Card Test Credits
 - b. iWASH Fluid
 - c. Waste Bottle
 - d. All of the above

7. The icon on the iSED instrument's touch screen that activates the "run wash cycle" is represented by a:
a. Plus sign b. Sponge c. Buoy d. Wrench and screwdriver
8. Which of the following tasks should be performed prior to powering off the iSED instrument?
a. Run both levels of QC b. Run a wash cycle c. Both a and b d. None of the above
9. The iSED instrument range for reporting erythrocyte sedimentation rates is:
a. 0 – 120 mm/hr. b. 0 – 100 mm/hr. c. 0 – 150 mm/hr. d. 1 – 130 mm/hr.
10. Which of the following are NOT acceptable to run on the iSED analyzer?
a. Clotted samples
b. Samples with fibrin strands
c. Sickle cell patient samples
d. Both a and b
e. All of the above

Any incorrect answers I may have initially written have been discussed and corrected. I now understand the answers I may have gotten wrong.

PASSING GRADE IS 75% OR GREATER

Employee name (print)

Employee signature

(Date)

Supervisor/Manager name (print)

Supervisor/Manager signature

(Date)