HEM.SEDIMAT.1.0 SEDIMENTATION RATE OF ERYTHROCYTES USING SEDIMAT

PRINCIPLE

Sedimat 15 is an automated reader to be used in conjunction with the Sediplast Erythrocyte Sedimentation Rate system. After properly preparing Sediplast with patient sample, the pipette can be inserted in any available channel. Sedimat 15 has 8 pipette channels with an independent timer and can be started at random. The reader is provided with an LC display and 3 push pads to interact with. Automatically, Sedimat 15 detects the presence of Sediplast pipettes inserted into any channel, checks for proper preparation, initiates a timer, reads the sedimentation rate after 15 minutes and emits a signal when the test is complete. Results can be printed or transmitted to an LIS.

Sedimat is based upon the ability of red blood cells to block the transmission of infra-red light. Located on either side of each channel are 8 infra-red emitting diodes and detectors. When a properly prepared Sediplast pipette is inserted, the transmittance of all infra-red light is blocked due to the presence of blood inside the pipette. At the conclusion of the test the head scans the plasma (which permits infra-red light transmission) and the settled red blood cells (which block infra-red light transmission). The level at which the infra-red light transmission is blocked indicates the meniscus and equates to the Sedimentation rate.

DOCUMEN OWNER

Supervisor, Hematology and Special Coag

SPECIMEN

A. EDTA (lavender) vacutainer tube

B. Minimum volume needed to fill Sediplast tube is 0.8 ml blood.

C. Specimen is acceptable for analysis up to 12 hours at room temperature, and up to 24 hours at 2-8°C.

D. Specimens that cannot be read (due to lipemia) must be performed by visually reading pipette sedimentation in mm. See Procedure Notes.

E. Clotted specimens are unacceptable.

REAGENTS

Sediplast vial with 0.2 mL of 3.8% sodium citrate used as diluent. Store in a cool, dry location at room temperature.

EQUIPMENT

A. Sedimat 15 Plus automated reader
B. SED CHEK 2 (ESR-5CT) controls
C. Sediplast vial with 0.2 ml of 3.8% sodium citrate used as diluent
D. Sediplast pipettes and Sediplast vials with diluent

E. Base for Sedimat
F. Power adapter (120 VAC 60 Hz)
G. Printer (optional)
H. Printer paper (optional)
I. Plastic transfer pipettes
J. Leveling plate

CALIBRATION

A. Before turning on power, remove pipettes from all channels.

B. Plug unit into an outlet. Sedimat 15 will automatically perform a self-check. There is no ON/OFF switch.

C. Sedimat 15 will begin the self-check, indicated on the LC display by "AUTOTEST" which checks mechanical and electronic operation. In the final phase, it operates a self-calibration of each channel.

D. If nothing happens, check the fuse by removing it from the back of the Sedimat 15 and, in case of failure, replace it with a new fast 630 mA fuse.

E. At the conclusion of "AUTOTEST" the LC display will display "CHANNEL STATUS".
   1. The Sedimat 15 has 3 touchpad keys: The left touchpad is the Scroll key; the middle touchpad is the Shift key; and the right touchpad is the Enter key.
   2. Any channel with unsuccessful self-calibration will display "REMOVE PIPETTES". Remove pipettes if present, or press the ENTER key. Sedimat 15 performs its self-calibration while displaying "WAIT."
   3. When AUTOTEST is completed successfully, the display shows "CHANNEL STATUS".

F. In case of unsuccessful AUTOTEST, one error message is displayed: ERR 1 - ERR 2 - ERR 3 - ERR 4: call for Technical Service ERR - 5 C- # (where # stands for channel's number out of service). The Sedimat 15 reader can still work with other channels not appearing as failed. Press the ENTER key.

G. Sedimat 15 displays "CHANNEL STATUS" and is ready to work. By pressing the ENTER key once more, the LC display changes to "C # READY".

H. Scrolling by using the scroll pad to "C # FAILURE" shows which channel will not accept pipettes.

QUALITY CONTROL

A. Storage and Stability:
   1. Polymedco Sed-Chek 2 Normal and Abnormal control. Store vials at room temperature..
   2. Stable unopened until expiration on the vial label.
   3. Stable opened for 31 days at room temperature.
   4. Avoid prolonged exposure of opened vials and tubes to light.
   5. Vials should be kept tightly closed after use to avoid evaporation.

6. Do not freeze. Do not expose to excessive heat.
7. Normal and Abnormal controls are analyzed and results recorded during each 24 hours of analyzer use.
   NOTE – QC should be run directly after AUTOTEST since the instrument is turned off/on during this calibration step.

B. Handling instructions:
   1. Invert the vial until packed cells have been resuspended. Continue mixing for 30 seconds. Avoid foaming. DO NOT VORTEX.
   2. Follow procedure below for filling sediplast tubes. Do NOT void diluent from tube.
   3. After each use, recap immediately.

C. If recovered values do not fall within expected range, evaluate all mechanical and physical factors that could affect the outcome, such as temperature, vibration, tube position and product expiration. First, set up a new QC tube and rerun. If values are still out, then set up a new QC tube with a fresh vial of Sed-Chek 2. If the values are still outside the expected range, contact supervisor.

D. When a new lot number of controls is received, each lab must run the new lot number and ensure that the values meet the manufacturer's range before the new lot number is put into use. When control values are within the expected range, patient values can be reported with assurance. The expected range is lot specific and is documented on the package insert.

E. Enter control results in computer.

PROCEDURE

A. Perform AUTOTEST once every 24 hours. See Calibration section. (NOTE – Run QC after performing AUTOTEST)

B. Filling instructions for Sediplast system:
   1. Remove the pink stopper on the prefilled vial (0.2 ml of 3.8% sodium citrate is used as diluent.)
   2. Using a transfer pipette, fill the vial to the bottom of the indicated fill line with 0.8 ml of well-mixed EDTA blood to make required 4:1 dilution. (Note: Mix EDTA tube a minimum of 5 minutes if within 15 minutes of collection. For longer elapsed time from collection, 10 – 15 minutes of mixing are necessary.)
   3. Replace pierceable stopper and gently invert several times to mix.
   4. Place vial in its rack on a level surface. Carefully insert the pipette through the pierceable stopper until the pipette comes in contact with the bottom of the vial. The diaphragm of the pink stopper is calibrated to break under the light pressure made by inserting the pipette. The pipette will autozero the blood and any excess will flow into the reservoir compartment.
   5. To ensure proper results, it is essential that the pipette makes FIRM contact with the bottom of the vial.

C. Level plate by turning the black adjustable legs so that the air bubble moves into the small centering circle on the level. When the bubble is located exactly within the circle, the plate is level. This ensures accurate ESR results will be obtained.

D. Place Sedimat onto the plate.

E. Sedimat 15 Operating Instructions:

1. Upon conclusion of the autotest phase, Sedimat 15 will check the operating status of each channel. LCD will read “WAIT” and then change to “CHANNEL STATUS”.
2. Once the Sediplast pipette has been properly inserted into the vial, place an identifier tag on the Sediplast vial, place a barcode label on the identifier tag or handwrite the name on the identifier tag and place the filled vial in a Sediplast rack.
3. Using the hand held barcode reader, scan each bar-coded sample and immediately place into an available channel. Samples must be scanned and inserted one at a time.
4. If not using barcodes, insert Sediplast pipette(s) into any available channel. Make sure marks and numbers of pipette face outward to avoid possible interference when scanning. Sedimat will confirm the inserted pipette(s) for each channel. LCD will read: “CONF” and indicate the channel number(s).

   Example: CONF. C-1 (confirming channel 1)

5. Press the [ENTER] (right) key. Sedimat 15 will scan the pipette(s) and start the internal timer for each channel. LCD will read “SCAN” and indicate the channel number(s).

   Example: SCAN. C-1 (confirming channel 1)

   After scanning of pipette(s) is completed, “CHANNEL STATUS” will appear on LCD.

   NOTE: Throughout the test cycle, Sedimat 15 will perform multiple reading scans. At the end of the 15 minute cycle, Sedimat 15 will perform a final scan to provide the result.

6. At the conclusion of the test, Sedimat 15 will automatically scan the Sediplast pipette(s). LCD will read “SCAN” and indicate the channel number(s).

   Example: SCAN C-1

   After scanning is complete, a signal (beeping) will be emitted indicating end of test. LCD will read “END” and indicate the channel number(s).

   Example: END C-1

7. For results press [ENTER] (right) key and return to CHANNEL STATUS IF NOT ALREADY. Press ENTER key and then press the [SCROLL] (left) key for the results of each channel.

NOTE: If using thermal printer, results will automatically be printed.

NOTE: Removal of pipette(s) resets the channel to READY STATUS and transfers results to FILED READINGS. Results remain in memory (filed readings) for each channel until the next completed test. And again, the removal of pipette from the channel.

F. Dispose of Sediplast tubes and pipettes after use in proper container.

CALCULATIONS

None

REPORTING RESULTS

A. Entering results in Misys:

FUNCTION:	MEM
WORKSHEET:	Site specific
METHOD:	Site specific
ACC.NO.:	

Toplab:

a. Pathway:	3 Technical Processing
	3 Result Processing
	1 Accession Entry
b. Allow release:	<Y> : Y
c. Worklist:	(site specific)

Enter result from display, then at A (Accept), M (Modify), R (Reject). Enter A to accept results and press [ENTER]/

B. Results of 140 mm or greater are to be reported as > 140.

C. Reference range:

MALE	
Age 0 – 50	0 - 20 mm/hr
Age > 50	0 - 25 mm/hr
FEMALE	
Age 0 – 50	0 – 20 mm/hr
Age > 50	0 – 30 mm/hr

PROCEDURE NOTES

A. Backup method:
1. Call SVIN and ask for the backup Sedimat (QC instrument before testing); or
2. Ship specimens to another site for testing. As always, notify the receiving lab of intent to send specimens

B. To print data if not automatically printed:
1. Press [ENTER] (right) key to display a main menu.
2. Press [SCROLL] (left key) until PRINT OF DATA is displayed.
3. Press [ENTER] key. “FILE” is shown on the LC display.

4. Press the [ENTER] key. “PRINT C1-8" is displayed.
5. Press the [ENTER] key to print the results of the removed pipettes of 8 channels.

C. To set date and time:
1. Press [ENTER] to display a main menu.
2. Press [SCROLL] key until “DATE-TIME” is displayed, the press [ENTER] key.
3. Press the [SHIFT] (middle) key to have each date and time digit blinking, alternatively.
4. Press the [SCROLL] (left) key to modify.
5. Press the [ENTER] key to confirm the choice and exit back to the “DATE-TIME” main menu.

D. Do not allow any liquid to come in contact with electronic components located inside the unit.

E. Do not rotate, move, or remove any confirmed pipette during its working time (from CONF to END).

F. Error message during a test:

ERR 6: Removal of one or more pipettes whose time is not elapsed. Pipette must be discarded and test set up again.

G. The erythrocyte sedimentation rate (ESR) is a nonspecific measurement used to detect and monitor an inflammatory response to tissue injury (an acute phase response) in which there is a change in the plasma concentration of several proteins (termed acute phase proteins). This procedure, very simply, consists of allowing a specific amount of blood to sit in a vertical position for a period of time (usually 1 hour). The distance, in millimeters, that the red cells fall during this time period is the erythrocyte sedimentation rate and is reported in mm/hour. The ESR is affected by three factors:
1. Erythrocytes:
Macrocytes tend to settle more rapidly than microcytes. Red blood cells which show an alteration in shape, such as sickle cells and spherocytes, are unable to aggregate or form rouleaux and the sedimentation rate is decreased. Anisocytosis and poikilocytosis reduce the ability of the red blood cell to form large aggregates and thereby tend to falsely lower an ESR. In severe anemia, the ESR is markedly elevated.
2. Plasma composition:
The plasma composition is the single most important factor determining the ESR. Rouleaux and aggregation of the red blood cells are controlled primarily by the levels of acute phase proteins (most notable, fibrinogen, α-1 globulin, and α-2 globulin), increasing as these three plasma protein levels are increased in the plasma. As the concentration of protein increases so does the viscosity of the plasma. Although an increased plasma viscosity will tend to inhibit the fall of the red blood cells, the increase in plasma proteins are generally those which cause rouleaux and aggregation of the red cells, which affects the ESR more greatly than does the increased plasma viscosity. Increased concentrations of albumin will tend to lower the ESR.
3. Mechanical / Technical Factors:

The rack holding the tubes should not be subject to any movement or vibration. Minor, everyday variations in room temperature do not significantly affect the ESR. With large changes in temperature, however, the sedimentation rate increases as the temperature increases.

REFERENCES

A. Sedimat 15 User Manual, Version 3.1, Polymedco, Cortlandt Manor, NY, June, 2001
B. Sediplast on Sedimat 15 Plus, Polymedco, Inc. v:52515-00, May 2013.
C. Sediplast Westergren ESR System product insert, LP Italiana Spa, Milano, Italy.
D. Brown, B., Hematology: Principles and Procedures, 6th Ed., 1993, pp. 107-108.

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IMPLEMENTATION DATE (Pre-SharePoint): December 2001