ESR Auto Plus Procedure
Erythrocyte Sedimentation Rate Automated Instrument

Principle: The instrument is designed to accurately and precisely measure the sedimentation rate of erythrocytes in vacuum tubes using infrared light and a measuring arm. The results are recorded as mm per hour (Westergren method) by converting to the QuickMode Method, a scientifically developed method for measuring ESR in 30 minutes. The instrument also makes a partial compensation for temperatures above 26 degrees C (77 degrees F).
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.

Specimen Collection: The ESR-Vacuum Tubes, 1.2 ml, contain 3.2% Sodium Citrate as an anticoagulant. Mix the blood with the sodium citrate solution immediately after drawing the patient sample by inverting the tube at least 6 to 8 times. The air bubble in the tube must reach the opposite end of the tube between every inversion. Hold the tube at an angle of about 35 degrees to enhance mixing. The mixing procedure is very important! If the sodium citrate is not properly mixed with the blood, microscopic clots/aggregates may form and cause results to appear higher than they actually are.

Specimen Type: Patient samples may be drawn directly into an ESR-Vacuum Tube or into an EDTA vacuum tube. When using an EDTA vacuum tube, transfer the well-mixed patient sample into the ESR-Vacuum Tube. Fill the ESR-Vacuum Tube to the whole fill line. Do not remove the sodium citrate in the ESR-Vacuum Tube.

Specimen Stability: ESR analysis can be performed over a 72-hour period following collection and storage at 2-10°C in an ESR-Vacuum Tube. Specimens are stable 4 hours at room temperature.

Reagents: ESR-Vacuum Tube, 1.2 ml, 3.2% Sodium Citrate

Labeling: Place identification labels on Control & Patient ESR tubes such that the identification label is over the Streck label and close to the cap. There MUST be an open space from the label at the back of the tube AND the label MUST be at least 3-5 mm from the top of the meniscus of the specimen. When placed in the instrument, the label must be facing to the front. Inaccurate results may be obtained if the tube is labeled or placed in the instrument incorrectly.

Calibration: Although no calibration is required, it is recommended to run a system check using the test rack every day the ESR-Plus is in use.
To run a test rack:

1. From Standby (time is shown on the display), press and hold NOT OK. The Main menu will be shown.
2. Enter 5, RUN TEST RACK, from the Main menu. You will be prompted:

RUN TEST RACK
Insert Rack. (OK)

3. Insert the test rack and press OK to start the verification procedure.
4. After the test rack has been read, the results will be reported on the printout.
5. If the printout indicates TEST OK, continue to the QC procedure.
6. If the printout indicates FAILED TEST, the instrument will ask if you want to retry.
7. Press OK to retry. Press NOT OK to exit. Retry the test rack run once. If the printout still indicates FAILED TEST, clean the failing tube. Retry again and if still fails, ask the Hematology ESR technical expert to review / possibly calibrate. If she is not available or unable to correct problem, notify Technical Services at Streck Laboratories, Inc. at 800-843-0912 @ extension 7510.

Quality Control: Run two levels of quality control for each 8 hours of use. Results of quality control and test rack must be in acceptable range or no patient results shall be reported. ESR-Chex is stable through the expiration date when stored at 2 degrees to 10 degrees C. After opening, ESR-Chex is stable throughout the open-vial dating, as indicated on the assay sheet, when stored at room temperature (18 – 30 degrees C) or 2 – 10 degrees C. Discoloration of the product may be caused by overheating or freezing during shipping or storage. Gross hemolysis may be indicative of product deterioration. Moderately colored supernatant is normal and should not be confused with deterioration of the product.
Upon receipt of a new control lot, the laboratory must establish its own mean and limits and perform parallel testing with current lot. The control means established should fall within the expected range specified for the control. If recovered values do not fall within the Expected Range, evaluate all mechanical and physical factors that could affect the outcome, such as temperature, vibration, tube position and product expiration. Inadequate mixing of the product will affect the outcome of the test. Call Technical Services, Streck Laboratories, Inc., (800-843-0912 ext. 7510) or consult Technical Services at www.streck.com if further assistance is required.

Handling instructions:

1. Remove vials from the refrigerator and allow them to equilibrate to room temperature (20 –30 minutes).
2. If the Control Vial is being opened for the first time, vortex for 60 seconds prior to first use. This is vital as the Control Cells may form micro-clumps after long periods of storage. The micro-clumps must be broken up for the cells to settle properly.
3. Mix vials through inversion and by vigorously rolling upright between palms until red cells are completely suspended. Continue to mix for 90 seconds.
4. Allow bubbles to disperse and re-mix by inversion prior to sampling.
5. Draw the sample immediately after thorough mixing is completed. If the mixed vials sit for more than 1 minute before drawing the sample, the vial must be remixed. **Incomplete mixing can invalidate both the sample drawn and the remaining product in the vial.** Follow the following directions for filling the sedimentation rate tube. Wipe threads of vial and cap with clean tissue before closing. Recap the vial tightly. Store the open vials at room temperature (18 – 30 degrees C) or 2 – 10 degrees C.

To run controls:

1. From Standby (time is shown on the display), press and hold NOT OK. The Main menu will be shown.
2. Enter 4, CONTROL SAMPLES, from the Main menu.
3. Enter 1, RUN A CONTROL SAMPLE, from the Control menu.
4. Indicate Level 1 or Level 2. Press OK. (The program will automatically name this sample by its lot number followed by a sequence number. Example: The lot number is 1234A. This is the first sample analyzed for this lot. The automatic ID number will be 1234A/00. The next sample of this level will be named 1234A/01, etc.
5. Transfer 1.2 ml of the well mixed control material into an ESR-Auto plus 1.2 ml vacuum tube per above Handling instructions.
6. When prompted, insert the well mixed sample (3-5 minutes on the ESR mixer) into any free position in the ESR-Auto Plus. The position light will turn red and the ESR-Auto Plus will initiate testing.
7. Control results will automatically print when the test is complete. If the result is outside the expected range, an alarm message will be presented along with the ticket.

NOTE: If controls are run as patient samples, instead of from the Control menu, the data will not be stored in the QC data files.

To enter a new control lot number in the QC database:

1. From Standby (time is shown on the display), press and hold NOT OK. The Main menu will be shown.
2. Enter 4, CONTROL SAMPLES, from the Main menu
3. Enter 3, REGISTER A NEW CONTROL, from the Control menu
4. Indicate Level 1 or Level 2. Press OK. (This will delete the previous control values for that level.)

5. You will be asked if you are sure you want to proceed. Press OK to clear old statistics and register a new control lot. Press NOT OK to exit.
6. Enter the lot number of the control. Press and hold any key to enter digits instead of numbers. Press OK when finished.
7. Enter the expiration date of the control. Press OK.
8. Enter the minimum value of the control. Press Ok.

9. Enter the maximum value of the control. Press OK.
10. A report of the assay values will be generated on the printer. Verify the data and press OK to accept.

Note: Registering a new control lot will delete the previous control values for that level.
Note: Each control level can hold up to 100 samples. When capacity is filled, the oldest value will be deleted and the new value will be stored.
Note: Parallel test each new lot number to confirm manufacturer recommendations. See instructions above.
To show sample data:

1. From Standby (time is shown on the display), press and hold NOT OK. The Main menu will be shown.
2. Enter 4, CONTROL SAMPLES, from the Main menu.
3. Enter 2, SHOW Control Samples from the Control Menu
    a. Enter 1, SHORT REPORT
    b. Enter 2, LONG REPORT
    c. Enter 3, SHOW ON LCD

NOTE: Control samples are stored in their own log files and hold up to 100 samples per level. Statistical reports can be generated from these log files. There are three options for reviewing QC data: the SHORT REPORT generates a statistical report of a control sample level; the LONG REPORT generates a statistical report and log file print of a control sample level, and the SHOW ON LCD is used to manually view data and to delete individual data points.

Running Patient Samples: Always check the label to be sure there is an open space in the back of the tube and between the specimen meniscus and the label.

To Run Samples with a bar code:

1. From Standby (time is shown on the display), scan the patient sample with the barcode wand to enter the patient ID number. Press OK.
2. When prompted, insert the well-mixed patient sample (minimum of 3-5 minutes on the ESR-Mixer) into any free position in the ESR-Auto Plus with the patient label facing the front of the instrument. The position light will turn red and the ESR-Auto Plus will initiate testing.

To Run Samples without a bar code:

1. From Standby (time is shown on the display), enter the patient ID number. Use the NOT OK key to delete any digits entered incorrectly. An ID code may contain a maximum of 10 digits. Press OK.
2. When prompted, insert the well-mixed patient sample (a minimum of 3-5 minutes on the ESR-Mixer) into any free position in the ESR-Auto Plus with the patient label facing the front of the instrument. The position light will turn red and the ESR-Auto Plus will initiate testing.

Results Reporting
The ESR-Auto Plus will automatically scan the sample and print the result when the sedimentation test is finished. Any error codes will be printed on the ticket with the result when TICKET PRINT STYLE printout is selected. If there are errors, re-mix and re-run the specimen. DO NOT REPORT if errors present. **** The exception to this is the "Alarms: High temperature compensated" error. This is just an indication that the room temperature is > 26C and thus the instrument software has compensated the result for high temperature. This result is valid, report.

Note: See the ESR-Auto Plus Operator and Technical Manual for additional software options such as searching for a stored patient result or accessing the result predict mode.
If interfaced, the Auto Plus will transmit directly to the host computer. If not interfaced, patient test results will be manually entered under EM (Enter Manually) in the host computer. Results must be scrutinized for accuracy and consistency with the patient's condition. Any problems must be resolved prior to reporting results.

Limitations of the Procedure:

1. Improper mixing will cause inaccurate result in both controls and patients.
2. Improper labeling may lead to inaccurate results.
3. Cannot read specimen accurately if Hemoglobin is <3.0 g/dl.
4. Cannot read specimen accurately if severely lipemic.
5. Room temperature must be between 5C – 40C for proper operation.
6. Relative humidity should be < 80% for temperatures up to 31C, decreasing linearly to 50% relative humidity at 40C.
7. _____
8. _____

Reportable range: 0 – 120 mm/hr.

Preventive Maintenance

Daily:

1. Run Test Rack every 24 hours.
2. Run Controls every 8 hours (once per shift).

Weekly:

1. Verify that the printer head on the internal printer is free from dust.
2. Clean the instrument using a soft, damp cloth or paper. The covers may be carefully cleaned with 5% bleach solution. Always remove the power cord from the ESR-Auto Plus before cleaning with any liquid.

As Needed: Clean the tubes if appear dirty.

1. Turn off the instrument / remove the power cord.
2. Dampen a swab with 5% bleach solution and swab the tubes in a swirling motion from mid-tube up.
3. Swab tubes with a dry swab using a swirling motion from mid-tube up.

DO NOT BLOW CANNED AIR OR VACUUM THE TUBES.

References

1. ESR-Auto Plus Operator and Technical Manual, Streck Laboratories, Inc. (Part number 320578).
2. NCCLS Clinical Laboratory Technical Procedure Manual – Third Edition; Approved Guideline: Vol. 16, No. 15.