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| **ESR Erythrocyte Sedimentation Rate of Whole Blood,**  **iSED® Application** | | | | | | | | |
| **Purpose** | This procedure provides instructions for ESR ERYTHROCYTE SEDIMENTATION RATE OF WHOLE BLOOD. | | | | | | | |
| **Principle** | The iSED® analyzer manufactured by Alcor Scientific Inc., uses quantitative capillary photometry (aggregation) to measure erythrocyte sedimentation rate (ESR) faster than traditional methods by capturing the kinetics of Red Blood Cell aggregation in a controlled testing environment during the most critical phase of sedimentation, commonly referred to as the lag or Rouleaux formation phase.  The technical innovation of the iSED® consists of “**directly”** measuring the aggregation of the red blood cells, while the traditional ESR measure **“indirectly”** the aggregation of the red blood cells by recording the length at which the red cells settle in a Westergren tube.  The ESR is helpful in revealing inflammatory activity and in monitoring the progress of conditions associated with acute and chronic inflammation, including infections, cancers, and autoimmune diseases.  The ESR is particularly useful in evaluating patients with unexplained symptoms, when infectious diseases are suspected and when a specific diagnosis is not available effectively using other tests.  Conditions that may increase ESR values:  • Increased levels of fibrinogen and gamma globulins, inflammation, pregnancy, anemia, autoimmune disorders (Rheumatoid Arthritis, Lupus), infections, kidney disease, cancer.  • Technical factors such as mechanical vibrations and elevated room temperature.  Conditions that may decrease ESR values:  • Polycythemia, hyperviscosity, Sickle Cell anemia, low plasma proteins (liver disease).  • Specimen quality such as blood to anticoagulation ratio, age of specimen and fill volume.  • Decreased room temperature. | | | | | | | |
| **Policy Statements** | * This procedure applies to all laboratory technologists performing hematology testing, the section supervisor, and section pathologist. | | | | | | | |
| **Materials** | **Reagents** | | | **Supplies** | | | **Equipment** | |
|  | **iWASH cleansing agent**, item # 112-12-001, chc # 32441. Four bottles per pack.  Type 1 Ultra-Pure Water: exceeds Clinical Lab Reagent Water (CLRW) specifications.  Store at 18°- 30°C.  Unopened shelf life 12 months from the date of manufacture.  **Seditrol® ESR Quality Controls**  6x4.5ml, item # DSC06, chc # 32440.  Store at 18°- 30°C.  Unopened shelf life 18 months from the date of manufacture.  Open vial stability 31 days.  **Concentrated Chlorox Bleach 8.25%**  Grainger item # 41H893  Chc # 9525. | | | **Thermal paper**,  item # DS-05233. Three rolls per pack.  **Waste Bottle**,  item # 112-12-002.  **iSED Test Card,**  item # 112-01000, chc # 32442. 1000 tests per  card. | | | **iSED® analyzer**.  Place the instrument on a stable and level surface free of vibration.  Always keep a distance of at least four (4) inches (10 cm) between the rear of the instrument and the wall to allow for proper ventilation.  It is recommended that the instrument remain on at all times and ready for use. Should the instrument need to be powered off for any reason, run a wash cycle prior powering off the unit.  The instrument is programmed to perform self-cleaning after being idle for fifteen (15) minutes following the last sample tested. The process takes approximately one (1) minute and utilizes approximately 4.5mL of iWASH for each wash cycle. Once completed, testing can resume as normal. | |
| **Sample** | 1. The instrument has been designed to accept most standard 13x75 mm size EDTA blood collection pierceable tubes, including the BD Microtainer® MAP Microtube and Sarstedt S-Monovette® (13x65 mm, 3.4 mL EDTA Tube).  2. K2EDTA anticoagulated venous blood:  a. Minimum required volume for testing is 500ul in standard EDTA tubes, 250ul in BD Microtainer® MAP tubes.  3. Blood at room temperature should be tested within 4 hours of collection. Samples that have been refrigerated can be tested up to for up to 24 hours after collection. All samples should be brought to room temperature before testing.  4. Unacceptable specimens:  a. Clotted or hemolyzed samples  b. Improperly labeled tubes  c. K2EDTA samples kept at room temperature longer than 4 hours  d. Samples kept refrigerated longer than 24 hours  e. Refrigerated samples tested before they are brought to room temperature. | | | | | | | |
| **Quality Control** | 1. Seditrol® ESR Quality Controls are for exclusive use on the iSED. 2. Please make sure the controls are mixed well before loading on the analyzer. 3. One normal control (white top) and one abnormal control (blue top) should be run each day. 4. Alternating which control is loaded first each day will allow for optimum use from each vial. 5. Test time for controls is 3 minutes after a 5 minute mix cycle. 6. Results for controls are entered in Sunquest, function MEM, worksheet H1 ( Mpls. ) or H1S ( St. Paul ), method iSEDM ( Mpls.), iSEDS ( St. Paul ).   All control values must be entered into Sunquest whether in or out of control range. When QC data is entered, it is reviewed using Westgard rules in Sunquest. The computer displays the result's standard deviation from the mean.   1. Patient results cannot be reported when control values are out of range. 2. Notify supervisor of problems encountered with the controls. 3. All control values must be entered into Sunquest, whether they are in or out of range. 4. To enter corrective action in Sunquest; after the standard deviation is displayed, the prompt ENTER QC MODIFIER is displayed, use the QC modifier that best describes the action taken from [Table P – Exclusion Codes.](http://khan.childrensmn.org/Manuals/Lab/SOP/Heme/Res/200727.pdf) 5. Monthly QC data is entered in the Alcor Scientific Quality Assurance Network, Mpls. ID is 835, St. Paul ID is 836. This requires password access.   [Quality Assurance Network](http://www.mylabqc.com/alcor/login.asp) | | | | | | | |
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| **Procedure** | Follow the activities below for ESR ERYTHROCYTE SEDIMENTATION RATE OF WHOLE BLOOD. | | | | | | | |
|  | **Step** | **Action** | | | | | | **Related Document** |
|  | 1 | Touch the icon  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 (5) seconds. As the five (5) second window draws to a close, beeping will become faster. | | | | | |  |
|  |  | The sample wheel rotates to position the next open slot in the sample entry port.  Insert properly mixed samples into the analyzer. | | | | | |  |
|  | 2 | Insert the bar coded 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.  Automatic sample processing then begins.  **NOTE:** If the five (5) second window is missed, simply select the  icon again to restart the sample scheduling process. | | | | | |  |
|  |  | **Manual Patient Data Entry** | | | | | |  |
|  | 1 | Touch the icon as the sample wheel is rotating (indicated by instrument beeping) to position the next open slot in the sample entry port. | | | | | |  |
|  | 2 | 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 Surname | | | | | |  |
|  | 3 | Touch the icon to skip a data field or to confirm entered information.  The sample wheel rotates to position the next open slot in the sample entry port. | | | | | |  |
|  | 4 | 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.  **NOTE:** When manually entering ID, first or last name, always touch the Green Check  icon after each entry. If this step is skipped, the information will not print on the results. | | | | | |  |
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| **Result Reporting** | **Example of Normal Results Print Out**  ===========================  Date: 03/25/2013 Date of analysis  Time: 13:36:24 Time result printed iSED Sn:  01876 Instrument serial number  ID: **812409** Barcoded sample identification ESR (mm/h):  **15** Format of ESR result reported  ===========================  In the event that the instrument is unable to analyze the sample and report results, the print out will replace the ‘**ESR (mm/h):**’ field with an error message.  **For more information on System Status, Error Codes, and Warning Messages please reference to Section 16 in the Operators Manual.**  [**iSED Operators Manual**](https://starnet.childrenshc.org/References/labsop/heme/res/ised-operators-manual.pdf)  In Sunquest:  Function: MEM <CR>  Worksheet: H1(MPLS) H1S (STP) <CR>  Test-1: ESR <CR>  Test-2: <CR>  CAP Method: Modify (M) <CR>  ESR: iSEDM (MIN) <CR>  iSEDS (STP) <CR>  Workload data for - CTLS: <CR>  # Done: <CR>  Workload data for - REPS: <CR>  # Done: <CR>  Accept (A): <CR>  Workload data for - <CR>  Accn. No.: Enter ##### or (C-SED1 or C-SED2 for QC)  ESR: Enter result  Accept (A), Modify (M) or Reject (R): A <CR> | | | | | | | |
| **Calibration** | 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. The instrument range is from 1 to 130mm/hr. During normal operation, parameters affecting calibration are constantly monitored and, if not within expected limits, a warning is given, and further testing prevented. | | | | | | | |
| **Maintenance** | **Smart Cards**  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. | | | | | | | |
|  | **Downloading credits from test card**  1. With the arrow facing upward and forward, insert the test card into the smart card reader located on the front of the instrument  2. Once inserted, the credits will automatically download onto the instrument and the analyzer will indicate with a message on the screen.  3. Total credits available will include the newly downloaded credits and any residual credits prior to download.  4. Once all credits have been downloaded onto the instrument, the test card can be removed and discarded.  **NOTE:** If instrument has negative credits and additional credits have been downloaded from the smart card, the total credits available will be reduced by the total negative credits.  **Low and Zero Credit Indicators and Alarms**  In the case of ‘low’ or ‘zero’ credits, a message will appear on the screen and be accompanied by an alarm alerting the operator of an error or warning message.  **Ignore Request:** If this option is selected, the instrument skips the warning and the operator can continue the sample loading process. Please notify supervisor in these situations.  **Replacing Printer Paper**  A green LED light on the printer will flash to indicate it is out of paper. To replace the printer paper in the instrument, the procedure below should be followed:  1. Pull the lever (A) until the lid is released from its locked position.  2. Open the paper cup lid and remove the remaining paper  3. Insert thermal paper roll into the printer with the paper unwinding from the bottom of the roll  4. Reel off a few inches from a new roll of paper. Hold approximately two (2) inches of paper outside the printer as you place the new roll into the reservoir  5. Close the lid by applying equal amounts of pressure on each side ensuring the lid is in the locked position    **Replacing/Emptying the Waste Bottle**  1. Open the front door to access the bottle compartment(A). | | | | | | | |
|  | **Replacing/Emptying the Waste Bottle**  1. Open the front door to access the bottle compartment (A)  2. Locate the waste bottle in the upper compartment (B).    3. Disconnect the tubing from the waste bottle screw cap.  4. Remove the waste bottle from the instrument and dispose according to your laboratory biologic waste protocol.  5. Replace the waste bottle in the upper compartment (B) and **firmly** reconnect the tubing to the LUER connector on the plastic screw cap with the vent hole positioned at top.  6. Close the front door (A)  7. Press waste bottle emptied icon on Home Screen.    **NOTE:** Be sure to replace the plastic cap with the vent hole at the top.  **NOTE:** Be careful not to kink the line when replacing the bottle.  **NOTE:** It is recommended that the waste bottle be emptied daily.  **NOTE:** This procedure can be done without the waste alarm being triggered.  **Waste Bottle Full Indicators and Alarms**  In the case of a full or nearly full waste bottle, a warning message will appear on the screen and be accompanied by an alarm alerting the operator of an error or warning message.  **WARNING:** This action should be done when this message appear | | | | | | | |
|  | **Replacing iWASH Bottle**  1. Open the front door to access the bottle compartment (A).  2. The iWASH bottle is located in the lower compartment (D).    3. Disconnect the tubing from the iWASH bottle screw cap.  4. Remove the empty iWASH bottle, unscrew the cap and replace it with a new iWASH bottle  5. Place the new iWASH bottle in the lower compartment and **firmly** reconnect the tubing to the LUER connector (E) on the plastic screw cap with the vent hole positioned at top  6. Close the front door (A)  7. Press iWASH changed icon on main page.    **NOTE:** Be sure to replace the plastic cap with the vent hole at the top.  **NOTE:** Be careful not to kink the line when replacing the bottle.  **NOTE:** The instrument is programmed to perform self-cleaning after being idle for fifteen (15) minutes following the last sample tested. The process takes approximately one (1) minute and utilizes 4.5mL of iWASH for each iWASH cycle. Once completed, testing can resume as normal.  **NOTE:** This procedure can be done without the wash alarm being triggered.  **iWASH Bottle Empty Indicators and Alarms**  When the iWASH bottle is empty or nearly empty, a message will appear on the screen and be accompanied by an alarm alerting the operator of the error or warning message.  **WARNING:** This action should be done when this message appears.  **Deep Clean Procedure**  The analyzer will prompt the user when the Deep Clean is needed. The frequency for Deep Cleaning is monthly or every 1000 samples run, whichever comes first. This procedure will clean the aspiration pathway from the needle to the reading cell. | | | | | | | |
|  | Materials needed:  1. Empty, unused 13x75 EDTA tube (Rinse with water before using).  2. 6-7 % hypochlorite (Bleach) Do not dilute unless, greater than 7%.  Three parts (3ml) Concentrated Chlorox Bleach (8.25%) to one part (1ml) water will yield a 6.2% bleach solution.  3. On board iWASH solution.  **Procedure:**  1. Add approximately 4.0 ml of 6-7 % hypochlorite to unused 13 x 75 EDTA tube.  2. Once screen prompts you, insert the Deep Clean tube into the sample loading position and press continue. (Pressing abort will stop the deep clean process)  3. The analyzer will run 2 wash cycles, then automatically perform the Deep Clean (3 minutes), and conclude by automatically running two additional wash cycles.  4. Once the deep clean procedure is completed remove and discard the bleach filled tube.  Note: This procedure can also be activated by pressing the Deep Clean  icon on the home page.  **Pump Tubing Change Required Message**  iSED systems with software version 3.03A or later: After 200 hours of continuous pump use, the iSED will alarm and generate a message that a ‘Tubing Change is Required’. This message only serves as a warning that maintenance should be performed and does not prevent the analyzer from operational use..  iSED systems with software version 3.02 or earlier: The user will not be prompted to change the tubing. The tubing replacement should be done after 30,000 aspirations.  Technical Support should be contacted by phone at (800)495-5270 or +1 (401) 737-3774. Once you have contacted Technical Support, parts and instructions for items that should be replaced will be sent.  **30,000 Test Aspirations Message**  After 30,000 aspirations the iSED will alarm and generate a message to contact Technical Support. Please contact Technical Support @ (800)495-5270 or +1 (401) 737-3774 when this occurs. Once you have contacted Technical Support, parts and instructions for items that should be replaced will be sent.  This message only serves as a warning that maintenance should be performed and does not prevent the analyzer from operational use. | | | | | | | |
| **Reference Intervals** |  | | | | | | | |
| **Limitations** | Reportable range is 1-130 mm/hr  The ESR is a nonspecific reaction. It is highly recommended to perform other tests together with the ESR.  Some interferences which increase ESR:  mechanical vibration, high room temperature.  Some interferences which decrease ESR:  low room temperature, delay in test performance, clotted blood sample, excess anticoagulant, or bubbles in tube. | | | | | | | |
| **Limitations**  **(Sampling Errors)** | **Sampling Error Messages**   |  |  | | --- | --- | | In the event of a sampling error, the following messages will be printed: **Error Message (Printed)** | **Explanation/Solution** | |  |  | | “No Flow Detected” | This error appears when the system is able to withdraw the correct volume from the sample tube but is not able to detect the sample moving in the reading position  Contact Technical Support | | “Abnormal Sample” | Human blood, when stopped into the reading cell, must present a drop in light transmission. This error indicates the detection of an anomalous sample.  New specimen should be drawn | | “Abnormal Reaction” | Usually a hematological sample, after being positioned into the reading cell, starts to form rouleaux (aggregates) with the increase of the detected signal. If the signal detected decreases instead, the error code is provided, indicating a non-standard condition. | | “Insufficient Data Points” | This error appears when the reaction takes too much time to develop, or when the drop of the signal of error 3 takes too much time to end. This is an indication of hyper-viscosity of the sample, or hydraulic malfunctioning.  New specimen should be drawn | | “Sample Too Dark” | Indicates a very high HCT of the sample, with a consequential unreliable result. Instead of providing an inaccurate result, the system provides the error message.  New specimen should be drawn | | “No HCT Detected” | Indicates a very low HCT of the sample, with a consequential unreliable result. Instead of providing an inaccurate result, the system provides the error message.  New specimen should be drawn | | “Sample Too Clear” | Indicates a very low HCT of the sample, with a consequential unreliable result. Instead of providing an inaccurate result, the system provides the error message.  New specimen should be drawn | | “Unable to Withdraw”  ( Short Sample ) | This error appears when the system is not able to aspirate the correct volume from the sample tube  Contact Technical Support | | | | | | | | |
| **References** | 1. iSED Operators Manual, Alcor Scientific, 20 Thurber Boulevard, Smithfield, Rhode Island 02917,   (T) 401.737.3774 (F) 401.737.4519, [www.alcorscientific.com](http://www.alcorscientific.com)    2. Seditrol® ESR Quality Control product insert, 20 Thurber Boulevard, Smithfield, Rhode Island 02917,  315-09-011 Rev H.  3. Caswell, M., et al, Assessment of Diesstosis, extreme leukemic leukocytosis and severe anisocytosis.  and sedimentation rate. Journal of Clinical Pathology, 1991, 44:946-949.  4. Harmening, D.M., Clinical Hematology and Fundamentals of Hemostasis, F. A. Davis, Philadelphia,  PA., 1992, pp. 532-534.  5. Kjeldsberg, et al., Practical Diagnosis of Hematologic Disorders, ASCP Press, 1989, pp. 15-16.  6. Koepke, J.A., et al, The Evolution of the Erythrocyte Sedimentation Rate Methodology, Labmedica  1990, Feb Mar, pp. 22-24.  7. Miale, J.B., Laboratory Medicine, Hematology, 6th edition, C.V. Mosby Company, St. Louis, MO.,  1982, pp. 351-360. | | | | | | | |
| **Historical Record** | **Version** | | **Written/Revised by:** | | **Effective Date:** | **Summary of Revisions** | | |
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