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| /Volumes/dsm/UPH/Creative Services/Graphic Design/Logos/UnityPoint Health/UnityPoint Health/png/1 UP Health 2c H.png  METHODIST | | | Page 1 of 7 | Section: UPM HEMO | Policy #: 43 |
|  | LABORATORY | | Approved by: see signature block at end of document | | Date: 6/4/19  Review by: 6/4/21 |
|  | HEMATOLOGY | | Date Created: 6/20/18  Date Revised: 10/19/18, 6/4/19 | | |
|  | |  | Primary Responsible Parties: Kim Paige  Secondary Responsible Parties: June Bembenek | | |
|  | |  | CAP Standard: | | |
| SUBJECT: | | ERYTHROCYTE SEDIMENTATION RATE | | | |

**Quantitative Capillary Photometry (Aggregation) to Measure Erythrocyte Sedimentation Rate (ESR) - Alcor iSED ESR**

1. **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 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. It is also 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. The ESR provides particularly valuable information in conditions such as temporal arteritis, polymyalgia rheumatica, giant cells arteritis, inflammatory arthropathies etc.

1. **CLINICAL SIGNIFICANCE**

Measurement of the erythrocyte sedimentation rate (ESR) is performed widely as a primary screening test in medicine. Although non-specific it is indicative of the

presence of infectious, inflammatory, degenerative, or neoplastic conditions. The

increased rate of red cell sedimentation in disease is mainly associated with

qualitative and quantitative changes in the plasma proteins.

1. **POLICY SCOPE:**

The scope of this policy applies to all Laboratory staff that prepares or performs testing on laboratory specimens at UnityPoint Methodist.

1. **SPECIMEN**

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| Preferred Specimen | EDTA anticoagulated whole blood from routine venipuncture  2 ml EDTA whole blood with a minimum volume of 1 ml. |
| Storage/Retention | 2-8° C for 7 days |
| Sample Stability | 24 hours at ambient 18-25°C or refrigerated at 2-8 C. Must be at room temperature for 15 minutes before testing. |
| Rejection Criteria | Clotted specimens or those containing fibrin strands. Improper volume collected (less than 1 ml)  Improperly labeled samples.  Grossly hemolyzed.  Samples suspected of intravenous fluid contamination.  Samples exceeding stability requirements, greater than 24 hours old |

1. **REAGENTS**

iWASH cleansing agent (reorder item # 112-12-001)

Seditrol® ESR Quality Controls

6% bleach solution for cleaning

1. **INSTRUMENTATION/EQUIPMENT**

iSED® Automated ESR Analyzer

Waste bottle (reorder item # 112-12-002)

Thermal paper (reorder item # DS-05233)

BD MAP EDTA microtube (reorder #3706)

1. **CALIBRATION**

None required

1. **QUALITY CONTROL**

Two levels run every 24 hours. The order of running controls should alternate daily, control 1 run on odd days and control 2 run on even days. Expiration date is 31 days once pierced. Store at room temperature.

1. To enter Seditrol® ESR Quality Controls for processing:

1. Touch the ‘Add Sample’ icon on the instrument’s touch screen

2. The sample wheel rotates to position the next open slot in the sample entry port

NOTE: 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.

3. Insert the barcoded Seditrol® Level 1 control 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

4. Automatic sample processing then begins

NOTE: The mix cycle for Seditrol® ESR Quality Control is five (6) minutes.

5. Repeat Steps 2-4 to run Seditrol® Level 2

1. **PROCEDURE:**
2. PROCESSING PATIENT SAMPLES

All sample mixing, sample extraction, sample reading and sample disposal is handled automatically by the instrument. Up to 20 sample tubes may be loaded into the sample wheel at any given time. As each sample is processed (19 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 scheduled and placed in the sample wheel.

1. To enter new barcoded samples for processing:

1. Touch the ‘Add Sample’ icon on the instrument’s touch screen

2. The sample wheel rotates to position the next open slot in the sample entry port

NOTE: 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.

3. 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

4. Automatic sample processing then begins

5. Repeat Steps 2-4 until all samples have been loaded and/or all positions in the sample wheel are occupied

1. To enter new samples for processing without barcode:

1. Touch the ‘Add Sample’ icon on the instrument’s touch screen

2. Touch the ‘Add Sample (Manual Sample)’ icon as the sample wheel is rotating to position the next open slot in the sample entry port

3. 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. Alphanumerical ID
2. Patient’s First Name
3. Patient’s Surname

4. Touch the ‘Select’ icon to skip a data field or to confirm entered information

5. The sample wheel rotates to position the next open slot in the sample entry port

6. 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 ‘Select’ icon after each entry. If this step is skipped, the information will not print on the results.

1. **REPORTING RESULTS**

Results are shown on screen after analysis and also printed by the instrument’s internal printer. In the event that the instrument is unable to analyze the sample and report results, the print out will replace the result field with an error message.

AMR: 1-130 mm/hr.

Reportable range: 1-130 mm/hr.

Results <1 or >130 mm/hr will be reported as <1 or >130 mm/hr.

Analyzer will be interfaced with the LIS system and will automatically verify unless the result is less than or greater than the reportable range.

Manual Result Entry:

Enter results in to the LIS in the “Hematology Manual Result Entry” screen. Modify the results, hit the << arrow to put all patients to the left, hit the result button, scan the barcode, hit the tab key, check 2 patient identifiers prior to saving the results.

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| Age | Range |
| Females 0-50 years | <20 mm/hr |
| Females >50 years | <30 mm/hr |
| Males 0-50 years | <15 mm/hr |
| Males >50 years | <20 mm/hr |

1. **PROCEDURAL NOTES/PROBLEM-SOLVING TIPS**
2. If specimens have been refrigerated, specimen must come to room temperature for 15 minutes prior to running.
3. Even small clots in a specimen make the sample unacceptable to for ESR analysis by this method.
4. If instrument is idle for 15 minutes, the analyzer will perform an automatic wash.
5. If for any reason, the iSED® is not available for use, send ESR specimens to Pekin Lab for analysis. The LIS team must be notified that the ESR specimens are being sent to Pekin for testing so that they can change the LIS ESR spot for testing to Pekin. ESR specimen stability for Pekin is 4 hours at RT or 24 hours refrigerated. The last batch for shipment to Pekin must be prepared and in the refrigerator, ready for the courier, by 3:00 PM. All other specimens will be held until 7:00 AM the next morning for shipment to Pekin. Once this change is made, you will have to create a batch list to Pekin in the LIS. To create a batch list follow the hyperlink:[\\Ihs.org\pia\ProjectData\Laboratory Policy and Procedures\Methodist Campus\Hematology 072818\How to create a batch list for UPM-HEMO 43.docx](file:///\\Ihs.org\pia\ProjectData\Laboratory%20Policy%20and%20Procedures\Methodist%20Campus\Hematology%20072818\How%20to%20create%20a%20batch%20list%20for%20UPM-HEMO%2043.docx)
6. All reagents must not be used past expiration date.
7. Product is not intended for use as a standard.
8. Inability to obtain expected values may indicate product deterioration. Discoloration of the product may be caused by excessive heat or cold during shipping or storage.
9. BD Microtainer MAP tubes may be used for pediatric draws or for aliquoting off from a main EDTA tube. If aliquoting off from main EDTA tube, the MAP tube must be rinsed out with DI water to remove the EDTA from the tube and dried before use. Minimum volume is 250 µl.
10. iSed analyzer must have a deep clean performed monthly or every 1000 samples run, whichever comes first. 3.5 ml of 6-7% bleach (no greater than 7%) in a 13x75 tube should be placed into analyzer when prompted. Press continue. The analyzer will run 2 wash cycles, and then perform the deep clean followed by 2 more additional wash cycles. Discard bleach tube. Deep clean can also be activated by pressing the Deep Clean icon on the display.
11. If at any time, there is an issue that necessitates a loaner replacement module iSED, a 20 point comparison verification evaluation must be performed and 2 levels of QC must be tested and within range each day of comparison testing.
12. **REFERENCES**
    1. iSED® Erythrocyte Sedimentation Rate Analyzer Operator Manual, ALCORScientific Inc.(OM112-09-043)
    2. CLSI/NCCLS Clinical Laboratory Technical Procedure Manual; Approved Guideline, GP02.
    3. CAP All Common 50000 (reference range acceptability)

UnityPoint Health Methodist Laboratory is a CAP accredited facility. As of 7/1/11, the responsibility of new and/or substantially revised policies and procedures will be restricted the Laboratory Director whose name appears on the CLIA certificate, whose signature appears below. The biennial review will be completed by the Administrative Director.

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| ***POLICY CREATION :*** |  |
| ***Author: Wendy Quinn and Kim Paige*** | ***May 31, 2018*** |
| ***Medical Director: Elizabeth A. Bauer-Marsh, MD*** | ***May 31, 2018*** |

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| ***MEDICAL DIRECTOR*** | | |
| DATE | NAME | SIGNATURE |
| May 31, 2018 | Elizabeth A. Bauer-Marsh, M.D. |  |
| ***SECTION MEDICAL DIRECTOR*** | | |
| June 20, 2018 | Julia Adams, M.D. |  |
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| **REVISION HISTORY** | | | |
| **Rev** | **Description of Change** | **Author** | **Effective Date** |
| 0 | Initial Release | Wendy Quinn, Kim Paige | 6/20/18 |
| 1 | Per Dr. Racsa added: I. If at any time, there is an issue that necessitates a loaner replacement module iSED, a 20 point comparison verification evaluation must be performed and 2 levels of QC must be tested and within range each day of comparison testing. | June Bembenek | 10/12/18 |
| 2. | Back up testing will now be referred to Pekin Lab for analysis. Added a hyperlink to the procedure on how to create a batch list when sending to Pekin. Inserted Pekin’s specimen stability and shipping information. | Kim Paige | 5-22-19 |

**REVIEWED BY**

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| **Lead** | **Date** | **Coordinator/**  **Manager** | **Date** | Medical Director | **Date** |
| Kim Paige | 6/4/18 |  | 6/4/18  6/4/18 |  | 6/20/18 |
| Kim Paige | 10/22/15 |  | 10/18/18 |  | 10/19/18 |
| Kim Paige | 5/22/19 |  | 5/22/19 |  | 6/4/19 |