TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	4/19/2017
Department:	Core Lab	**Due Date:**	5/9/2017
		Implementation:	**5/9/2017**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Erythrocyte Sedimentation Rate by ESR STAT PLUS SGAH.H02 v5

Description of change(s):

Section	Reason
6.3	Delete requirement to perform QC at start of every shift – *Changed to match practice / be less restrictive*

This revised SOP will be implemented on May 9, 2017

Document your compliance with this training update by taking the quiz in the MTS system.

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Technical SOP

Title	**Erythrocyte Sedimentation Rate by ESR STAT PLUS**
Prepared by	Wendell McMillan Date: 7/20/2009
Owner	Robert SanLuis Date: 9/14/2012

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Erythrocyte Sedimentation Rate	ESR STAT PLUS	ESR

Synonyms/Abbreviations
Sed Rate, ESR

Department
Hematology

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2. ANALYTICAL PRINCIPLE

The ESR STAT PLUS analyzer uses centrifugation and laser optic principles to measure the ESR in anticoagulated whole blood. The ESR STAT PLUS obtains the result in approximately 4 minutes and uses a small volume of blood. A filled calibrated hematocrit tube is spun at 1500-2000 rpm for 3 minutes. An interface forms between the cells and the plasma at the start of the analysis. It is tracked by the laser for the duration of the 3 minutes. Up to 100 measurements are taken during the cycle.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Collection tube must be filled properly and mixed thoroughly.
Special Collection Procedures	None defined
Other	N/A

3.2 Specimen Type & Handling

Criteria		
Type -Preferred **-Other Acceptable**	Whole Blood (K_3EDTA or K_2EDTA) None	
Collection Container	2.5 mL, 3.0 mL, 5.0 mL, or 7.0 mL Lavender top tube (K_3EDTA or K_2EDTA)	
Volume - Optimum **- Minimum**	1 mL 100 µL	
Transport Container and Temperature	Collection container at room temperature	
Stability & Storage Requirements	Room Temperature:	(18-30°C) 6 hours
	Refrigerated:	(2-8°C) samples should be analyzed within 12 hours of collection, bring specimen to room temperature before analysis.
	Frozen:	Not appropriate
Timing Considerations	N/A	

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Criteria	
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS. Notify a caregiver
Compromising Physical Characteristics	Gross hemolysis or clotted. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code explanation. Notify a caregiver
Other Considerations	N/A

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

None

5. CALIBRATORS/STANDARDS

Not applicable

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
SEDRite™ PLUS (2 levels)	R & D Systems, Inc, # ESRC 20002

6.2 Control Preparation and Storage

Control	SEDRite™ PLUS (2 levels)
Preparation	• Allow to warm to room temperature, 20-25ºC, for 25 minutes before use. • To mix, hold a vial horizontally between the palms of the hands and roll the vial back and forth for 30-60 seconds; occasionally invert the vial. Mix **vigorously** but do not shake. Continue to mix in this manner until the red cells are completely suspended. • **Do NOT mix on a mechanical mixer.** • Vials stored for a long time may require extra mixing. • Gently invert the vial 10 times immediately before sampling.

Storage/Stability	Unopened: 2 - 8°C, until expiration date Opened: 2 - 8°C, 30 days

6.3 Frequency

Level 1 and level 2 of the SEDRite Plus are run once per shift ~~at the beginning of every shift~~.

To enter QC results in Unity Real Time:

1. Log into Unity Real Time
2. Select the appropriate Lab site
   a. GEC: "544235 GEC X-pand 1"
   b. WAH: "216442 WAH Centaur"
   c. SGMC: "137244 SGAH Centaur"
3. Select "ESR"
4. Control 1 results are entered as Level 1
5. Control 2 results are entered as Level 2
6. SAVE

6.4 Tolerance Limits and Criteria for Acceptable QC

A. Both controls must be within the established ranges. Each lot of control material will arrive with expected ranges.

B. Corrective Action

IF …	THEN…
one or both controls are out of range	Repeat QC. If the control is still out of range on repeat, run a fresh vial of control material. If there continues to be a problem, notify the supervisor immediately.

- No patient samples are to be reported if the controls are not in range.
- All corrective action must be documented as specified in the Laboratory QC Program.

6.5 Documentation

- QC tolerance limits are programmed into the Unity Real Time; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.

- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.6 Quality Assurance Program

- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials and previously analyzed samples. Performance of the new lot must be equivalent to the previous lot; utilize published TEA for acceptability criteria.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

ESR STAT PLUS instrument

7.2 Equipment

Scanner
Printer

7.3 Supplies

Alcohol preps
Printer Paper
Lithium Heparin Coated Calibrated Analysis Tubes
(Kit includes: 500 analysis tubes and wipes)

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Instrument Maintenance
1.	Clean the interior of the instrument with alcohol preps
2.	Document on the ESR Stat Plus Maintenance Log

8.2	Instrument Set-up Protocol
1.	Insert an empty analysis tube into the "0" slot under the lip on the outside edge of the rotor. The blank should be run in the "0" slot every time the instrument is used. This blank acts as a balance. Results may be deemed to be correct even if results are determined without the index tube in place.
2.	If a printer is used, verify the printer cable is attached to the ESR STAT PLUS, the thermal paper roll is properly installed and the printer is turned on.
3.	Turn on the ESR STAT PLUS.
4.	The instrument will, upon being turned on, run through an equilibration process which will take 5 minutes. Proceed with running controls and patient samples after the instrument presents the ready screen.

8.3	Specimen / Reagent Preparation
1.	The patient samples and control samples must be at room temperature.
2.	See section 6.2 for proper handling of control material. **Do not place control materials on mechanical rockers.**
3.	To prepare patient samples, mix the whole blood samples thoroughly. • If the samples are being rocked, you may pick up the EDTA blood collection tube and draw a sample immediately into the calibrated analysis tube. • If the samples have not been rocked, carefully mix the sample by gentle inversion 8-10 times before drawing sample into the calibrated analysis tube.
4.	When the instrument asks for the sample, either patient or QC, to be placed in the first slot, it is time to fill the calibrated analysis tube with the sample. a. remove a wipe from the wipe container b. remove a calibrated analysis tube from the tube container
5.	Hold the calibrated analysis tube at the end with the self seal. a. Remove the cap from the EDTA blood collection tube **Note**: face protection must be worn during this process b. Tilt the blood collection tube enough to present the sample c. Place the end of the calibrated analysis tube into the blood sample and draw the sample up to the fill mark d. Remove the calibrated analysis tube from the blood sample when filled e. Cap the EDTA sample and place in a tube rack on the counter f. With your other hand, pick up the wipe, wrap it around the calibrated analysis tube up to the fill mark and draw the tube through the wipe to remove any excess blood. g. **Invert the calibrated analysis tube to cause the fluid to contact the self-seal**. Hold the tube vertically for 5 seconds.
6.	The sample is ready for insertion into the instrument.

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8.4	Test Run
1.	Open lid by pressing lid release on left side of the lid
2.	Remove the rotor lock by pulling up on the lock at center of the rotor
3.	**PRECAUTION: Whenever you remove the plastic rotor lock, always put it on the shelf near the lid hinge. This will prevent running the analyzer without the rotor lock in place.**
4.	Press 1 for ESR Test
5.	Insert the prepared capillary tube into slot 1 of the rotor and press 0
6.	Input the accession numbers into the identification number area
7.	Press E to start
8.	Fit rotor lock onto samples and close the lid, making sure lid "click" is heard
9.	Press E to confirm and to begin analysis
	To process more than 1 sample in a cycle:
1.	After the first sample accession number is entered, press E, then press 0
2.	Input the accession number into the identification number area
3.	Press E
4.	Fit rotor lock onto samples and close the lid, making sure lid "click" is heard
5.	Press E to confirm and to begin analysis

At the completion of the analysis, the ESR STAT will show the following:

```
 ESR    31     mm/hr                    press 1 to print results

 ID:  79462222                          Tube: 1
(E=next, C=standby)
```

* If you have run only one sample, the screen will present results and the bottom of screen will read (C=standby)

To view the second sample result, press E=Next to view result

8.5	Special Handling
1.	**If you are distracted and the blood sample in the blood collection tube is allowed to sit for more than one minute, be sure to re-mix the sample by gentle inversion at least eight (8) times.**
2.	**When not in use – The lid must be closed and locked (an audible click confirms locking of lid).**

8.5	Special Handling
3.	To retrieve prior results: Go to the Standby screen. Select C=prior results, enter the accession number for the sample result to be retrieved. The results will be presented on the screen. The ESR STAT will remember results for the last four cycles (up to 12 prior results). If the instrument is turned off, all prior results will be lost.

Note:
If the instrument is not used within 15 minutes since the last sample is run, the instrument will automatically equilibrate for 1 minute. For the auto equilibration to start, the instrument lid must be closed and locked.

The user may interrupt the auto equilibration by pressing STOP. Interrupting the auto equilibration will have no adverse impact on results.

To operate the ESR STAT PLUS after the analyzer has completed the equilibration sequence; the standby screen will automatically appear as follows:

```
1  ESR Test
2  Date-Time Settings

 (C=previous results)
```

9. CALCULATIONS

None

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

N/A

10.3 Units of Measure

mm/hr

10.4 Clinically Reportable Range (CRR)

N/A

10.5 Review Patient Data

Review patient results for unusual patterns, trends or distributions in patient results, such as an unusually high percentage of abnormal results.

10.6 Repeat Criteria and Resulting

IF the result is …	THEN…
Outside of the AMR	Repeat testing, ensuring that the sample is mixed well. If results still exceed the AMR, report as <1 or >145 mm/hr

11. EXPECTED VALUES

11.1 Reference Ranges

Female 0 – 30 mm/hr
Male 0 – 10 mm/hr

11.2 Critical Values

None established

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

The Erythrocyte Sedimentation Rate is a widely used, non-specific screening test. It is indicative of the presence of infectious, inflammatory, degenerative or neoplastic conditions. The increased rate of red cell determination is mainly associated with qualitative and quantitative changes in the plasma proteins.

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved/cleared
- **Validated Test Modifications:** None

1. The patient sample must be filled to the fill line properly, not more than +/- 1 mm.
2. The patient/control sample must be at room temperature

3. The capillary tube should not lay down in a horizontal position for more than 5 minutes
4. The analysis tube must be wiped clean of any blood before starting analysis
5. When filling the calibrated tube the sample must come in contact with the white seal at the end by holding the tube vertically for 5 seconds.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

1 - 145 mm/hr

14.2 Precision

N/A

14.3 Interfering Substances

N/A

14.4 Clinical Sensitivity/Specificity/Predictive Values

N/A

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

1. Laboratory Safety Manual
2. Safety Data Sheets (SDS)
3. Laboratory Quality Control Program
4. Repeat Testing Requirements (Lab policy)
5. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
6. ESR Stat Plus Maintenance Log (AG.F212)
7. Package insert for SEDRite Plus Hematology Controls

17. REFERENCES

1. HemaTechnologies, Inc. User Manual ver. 3.5
2. May 2012-ESR STAT PLUS Instructions for Use, ver 3.6-3.7
3. ERYTHROCYTE SEDIMENTATION RATE (ESR-W) WESTERGREN PROCEDURE 1998

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	9/14/12		Update owner		R SanLuis
000	9/14/12	3.2	Revise unacceptable specimens, add action for hemolyzed or clotted sample	L Barrett	R SanLuis
000	9/14/12	6.3	Change frequency to every shift	L Barrett	R SanLuis
000	9/14/12	6.7	Add use of TEA for lot to lot runs	L Barrett	R SanLuis
000	9/14/12	7.2	Add printer and scanner	A Chini	R SanLuis
000	9/14/12	7.3	Add alcohol prep and paper	A Chini	R SanLuis
000	9/14/12	8	Remove kit package insert since N/A Add section 8.1, renumber subsequent	L Barrett	R SanLuis
000	9/14/12	11.2	Title change to local terminology	L Barrett	R SanLuis
000	9/14/12	15	Update to standard wording	L Barrett	R SanLuis
000	9/14/12	16	Update titles, add TEa	L Barrett	R SanLuis
000	9/14/12	19	Remove package insert, add Weekly PM and log	L Barrett, A Chini	R SanLuis
001	5/20/14	6.2	Add detailed handling instructions for controls	C Reidenauer	R SanLuis
001	5/20/14	8.3, 13	Add comment that specimen must contact self-seal	C Reidenauer	R SanLuis
001	5/20/14	10.5	Add instruction for resulting outside the AMR	C Reidenauer	R SanLuis
001	5/20/14	16	Move log from section 19, Add package insert for Controls	C Reidenauer	R SanLuis
001	5/20/14	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	R SanLuis
2	10/14/14	6.3	Add QC entry instruction for Unity Real Time	A Chini	R SanLuis
2	10/14/14	6.6	Replace LIS with Unity Real Time	A Chini	R SanLuis
3	1/25/17	Header	Add other sites	L Barrett	R SanLuis
3	1/25/17	6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
3	1/25/17	10.5	Move patient review from section 6	L Barrett	R SanLuis
3	1/25/17	15	Update to new standard wording	L Barrett	R SanLuis
4	4/13/17	6.3	Delete requirement to perform QC at start of every shift	L Barrett	R SanLuis

19. ADDENDA

A. Weekly Preventive Maintenance

Appendix A

Weekly Preventive Maintenance

1. Turn instrument off.

2. Remove Rotor; remove any analysis tubes that may have fallen out.

3. Examine rotor edge at end of each slot to determine if hairline cracks are present. If cracks are present you may continue to use instrument. Contact HemaTechnologies for a replacement rotor.

4. Return rotor to analyzer being careful to place the notched "0" position in the "V" groove on the instrument drive spindle.

5. Once rotor is in place, check alignment by spinning by hand. If Rotor spins level:
    a. replace hold down screw, **hand tighten only**
    b. replace blank index tube in "0" slot