TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	7/23/2014
Department:	Core	**Due Date:**	8/13/2014
		Implementation:	**8/13/2014**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Erythrocyte Sedimentation Rate by ESR STAT PLUS GEC / SGAH / WAH.H02 v2

Sedimentation Rate – Westergren Method SGAH.H12, WAH.H13 v1 (Manual ESR has been discontinued at GEC)

Description of change(s):

ESR STAT PLUS

Section	Reason
6.2	Add detailed handling instructions for controls
8.3, 13	Add comment that specimen must contact self-seal
10.5	Add instruction for resulting outside the AMR

ESR Westergren Method

Section	Reason
3.2	Change room temp. stability to 4 hours
4	Add Reagent information
6.2	Add preparation of unopened vials
8.1	Add testing temperature requirement and note for timing of test
8.3	Add Special Notes section
10.2	Add rounding statement
10.5	Add reporting for results outside of AMR
14.1	Correct upper limit of AMR

These revised SOPs will be implemented on August 13, 2014

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**

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1. TEST INFORMATION

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

Synonyms/Abbreviations
Sed Rate, ESR

Department
Hematology

Form revised 2/02/2007

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	Same as above, 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

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

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

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 at the beginning of every shift.

6.4 Tolerance Limits

Both controls must be within the established ranges. Each lot of control material will arrive with expected ranges.
If one or both controls are out of range, they must be repeated.
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 Review Patient Data

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

6.6 Documentation

- All QC results are documented in the computer.
- 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.

6.7 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, be certain that the printer cable is attached to the ESR STAT PLUS, and 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.**

Form revised 2/02/2007

8.3	Specimen / Reagent Preparation
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, take care to mix the sample be 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 it place in a tube rack on the counter f. With the your 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.

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

8.4	Test Run
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).**
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 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 Priority 3 Limit(s)

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

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

1. Laboratory Safety Manual
2. Material Safety Data Sheets (MSDS)
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

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

Technical SOP

Title	**Sedimentation Rate – Westergren Method**
Prepared by	Ashkan Chini Date: 6/19/2012
Owner	Robert SanLuis Date: 6/11/2014

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

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

Form revised 7/01/01

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1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Sedimentation Rate - Westergren Method	Manual	ESRM

Synonyms/Abbreviations
Sed Rate, ESR

Department
Hematology

2. ANALYTICAL PRINCIPLE

The erythrocytes in well-mixed venous blood tend to settle towards the bottom of a vertical tube. An increase in this tendency of erythrocytes to "sediment" is found in certain pathological conditions, especially in inflammatory disorders. The length of fall of the top of the column of erythrocytes in a given interval of time is the erythrocyte sedimentation rate.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	None defined
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**	2.5 ml, 3.0 ml, 5.0 ml, or 7.0 ml (according to tube used) 2.0 ml (250 µl. if Micro Plugged Dispette is used)
Transport Container and Temperature	Collection Tube at room temperature.
Stability & Storage Requirements	Ambient: (18-25°C) 4 hours Refrigerated: (2-8°C) 12 hours Frozen: Not appropriate
Timing Considerations	N/A
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.
Compromising Physical Characteristics	Clotted or Gross hemolysis: test not performed; Reject sample, cancel test and request redraw.

Criteria	
Other Considerations	Lipemia: Acceptable Icteric: Acceptable

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
Dispette 2 pipets and filling reservoirs	Fisher Healthcare Cat. No. 02 – 065 - 183

4.2 Reagent Preparation and Storage

NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.
Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Reagent	Dispette 2 pipets and filling reservoirs
Container	Plugged Dispette 2 pipets and filling reservoirs containing 0.25 mL normal saline diluent.
Storage	Store at 10 - 24°C
Stability	Until the expiration date printed on the container
Preparation	None

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
ESR-Chex Level 1 and Level 2	Streck Laboratories (Catalog # 214112)

6.2 Control Preparations and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Control	ESR-Chex Level 1 and Level 2
Preparation	1. Remove vials from refrigerator and allow them to equilibrate to room temperature (20-30 minutes). 2. Vortex unopened vials for up to 60 seconds prior to first time use. Unopened vials stored at 2 - 10°C may require extra mixing. Mix previously opened vials through inversion and by vigorously rolling upright between palms until red cells are completely suspended. Continue to mix for 90 seconds. The samples may also be rotated on a rotator prior to use. 3. Draw the sample immediately after thorough mixing is completed. **If mixed vials sit for more than 1 minute before drawing the sample, the vial must be remixed by repeating step 2.** ***Incomplete mixing can invalidate both the sample drawn and the remaining product in the vial.*** 4. Follow the procedure in section 8 for filling the sedimentation rate tube. 5. Wipe threads of vial and cap with clean tissue before closing. Recap the vial tightly.
Storage/Stability	Stable through the expiration date when stored at 2-10°C. After opening, ESR-Chex is stable for 95 days when stored at room temperature (18-30°C) or 2-10°C.

6.3 Frequency

Both levels of control are tested for every 8-hour shift of patient testing.

6.4 Tolerance Limits

6.4.1 Tolerance limits are specific to the lot number. See package insert for specifications.

6.4.2 Rejected runs must be effectively addressed by corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed. Supervisor may override rejection of partial or complete runs only with detailed documentation that follows criteria that is approved by the Medical Director.

6.4.3 Corrective action documentation must include the following: QC rule(s) violated, the root cause of the problem, steps taken to correct the problem, how patient samples were handled, and the date and initials of the person recording the information. See the Laboratory QC Program for more details.

6.5 Review Patient Data

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

6.6 Documentation

- All QC results are documented in the computer.
- 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.

6.7 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

N/A

7.2 Equipment

- Westergren Sedimentation racks
- 60-minute timer
- Tube rocker or rotator

7.3 Supplies

- Disposable Pipette

8. PROCEDURE

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

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

8.1	Specimen Set-Up and Testing
1	Test must be performed at room temperature (18 - 25°C).
2	Hold clear filling reservoir by flared section and shake downwards with a flick of the wrist to force saline to the bottom of the reservoir. Keep upright and remove cap.
3	Add 1mL well mixed EDTA treated whole blood to the filling line level, either from a transfer pipette or directly from the blood tube. Ensure that the blood mixture reaches the filling line.
4	Replace cap securely.
5	Gently mix by inversion. A minimum of 8 inversions is recommended.
6	Ensure that all the blood returns to the bottom section of the reservoir.
7	While holding filling reservoir firmly with one hand, and the Dispette tube with the other hand, penetrate the cap membrane.
8	Gently continue inserting the Dispette tube to the bottom of reservoir. Ensure that the blood level, on rising up the Dispette tube, reaches to or beyond the grommet at the zero level.
9	Place the full Dispette assembly in a leveled plastic or metal stand. Ensure that the Dispette tube is in a vertical position (at a 90 degree angle).
10	Readings are recorded in millimeters at exactly one hour after setting upright. **Note**: It is important to read the test at exactly one hour. It must not be assumed that the reading at 60 minutes will be twice that at 30 minutes because the rate fall is not linear.
11	Use function MEM to enter result. Worksheet: use WHE1 for WAH, GHE for Germantown or SHE1 for SGAH.

8.2	Micro Plugged Dispette - Westergren Sedimentation Rate
1	Transfer by pipette 50µl of 0.85% NaCl, or fill to the first mark at the base of the funnel (the filling reservoir of the dispette).
2	Transfer by pipette 200 µl. of EDTA blood to the funnel or fill to the second mark at the base of the funnel.
3	Gently insert (approximately 1 inch) plastic tube (holding as a pencil so as not to spurt blood) with a twisting motion until the tube is seated. Gently invert the tube to mix at least 3 times. Then continue the twisting motion until the tube is seated at the bottom of the funnel reservoir. Blood will probably be above the 0 mark on the tube.

4	Adjust blood level by gently pressing on the rim of the funnel until the level drops to the 0 level mark. The pipette must remain at the bottom of the filling reservoir.
5	Place the full dispette in a vertical position in the stand.
6	Set a timer for 60 minutes. Read at the end of the 60 minutes. Enter results in LIS as described in 8.1 step 10.

8.3	**Special Notes**
1	Shaking the sample creates bubbles which will affect the result. If bubbles are present in the pipet, repeat the test with a fresh ESR test preparation that has been more carefully mixed.
2	The ESR is affected by vibration; ensure the stand is placed well away from machinery and that the bench is not subjected to knocks.
3	Do not pick up the stand to read the result as this will affect other tests in progress, if any. Bring the eye to the level of the red cells to read accurately from the scale.
4	Occasionally the level of the red cells is not clear cut. In such cases the level where the red cells become fully concentrated should be recorded.
5	In cases of serious infection or leukemia, a heavy layer of white cells may be present on top of the column of red cells. This should be ignored and the reading taken from the level of the red cells only.

9. CALCULATIONS

None required

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

No rounding is necessary. Results are reported as a whole number.

10.3 Units of Measure

mm/hr

10.4 Clinically Reportable Range (CRR)

N/A

10.5 Repeat Criteria and Resulting

IF the result is …	THEN…
0 mm/hr	Report as <1 mm/hr
Above 130 mm/hr	Report as >130 mm/hr

11. EXPECTED VALUES

11.1 Reference Ranges

Female 0 - 30mm/hr

Male 0 - 10mm/hr

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

The sedimentation rate is used in the evaluation of rheumatic diseases (especially rheumatoid arthritis), as well as infections, autoimmune disorders and inflammatory states. Acute phase reactants such as fibrinogen and immunoglobulins increase the sedimentation rate. Increased fibrinogen can be responsible for increased sedimentation rates in tissue injury, acute infections and inflammation. Immunoglobulins are associated more with the increased sedimentation rates of chronic disorders such as immunoproliferative disorders (multiple myeloma), chronic infections, and autoimmune disorders.

13. PROCEDURE NOTES

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

13.1 It is important that the tube be perfectly vertical. Tilting the tube accelerates the sedimentation rate. The red cells aggregate along the lower side while the plasma rises along the upper side. An angle of 3° from the vertical may accelerate the sedimentation rate by as much as 30%.

13.2 Since the dilution is performed in a closed capped pre measured sedivial and auto zeroing, problem of contamination and bubbles are eliminated.

13.3 Sedimentation rate varies little on temperature from 19-27°C. Temperatures below 19°C will lower the ESR value.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

1 – 130 mm/hr

14.2 Precision

N/A

14.3 Interfering Substances

Direct Sun light affects the test.

14.4 Clinical Sensitivity/Specificity/Predictive Values

N/A

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

1. Laboratory Safety Manual
2. Material Safety Data Sheets (MSDS)
3. Laboratory QC Program
4. Repeat Testing Requirements (Laboratory policy)
5. Erythrocyte Sedimentation Rate (automated method), Hematology procedure
6. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
7. Current package insert for ESR-Chex

17. REFERENCES

1. Todd and Sanford Clinical Diagnosis and Management by Laboratory Methods, Davidson and Henry. W.B. Saunders Company, 16th edition, 1979, pgs. 914-915.
2. John B. Miale, Laboratory Medicine, Hematology, C.V. Mosby Company, 6th edition, 1982, pg. 867
3. ERS-Chex package insert, Streck Laboratories, Inc, 07/2012.
4. Jacobs, Demott, Finley, Horvat, Kasten, Jr., Tilzer Laboratory Test Handbook, 3rd edition, 1994.
5. Sedimentation Rate-Modified Westergren Method, SOP ID HE-111 Version 009. Quest Diagnostics Master Control.
6. Guest Scientific distributed by Fisher Healthcare for Dispette 2 pipet and filling reservoirs, revised 08/2011.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SOP H010.002		
000	6/11/14		Update owner	L Barrett	R SanLuis
000	6/11/14	3.2	Change room temp. stability to 4 hours	A Chini	R SanLuis
000	6/11/14	4	Add Reagent information	A Chini	R SanLuis
000	6/11/14	6.2	Add preparation of unopened vials	A Chini	R SanLuis
000	6/11/14	8.1	Add testing temperature requirement and note for timing of test	A Chini	R SanLuis
000	6/11/14	8.3	Add Special Notes section	A Chini	R SanLuis
000	6/11/14	10.2	Add rounding statement	A Chini	R SanLuis
000	6/11/14	10.5	Add reporting for results outside of AMR	A Chini	R SanLuis
000	6/11/14	14.1	Correct upper limit of AMR	A Chini	R SanLuis
000	6/11/14	17	Add Dispette 2 information	A Chini	R SanLuis

19. ADDENDA

None