TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	8/28/2012
Department:	Core	**Due Date:**	9/30/2012

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Sedimentation Rate – Westergren Method GEC.H10, SGAH.H12, WAH.H13 v000

Description of change(s):

SOP standardized to current format, given new numbers
Changes to content listed below

Section	Reason
1	Modified Local Code
6.6 & 6.7	Added standard information
7.3	Updated Supply list
8.1	Modified Procedure
8.2	Added Micro-Plugged Dispette
11.1	Corrected Reference Values
13	Edited Procedure notes
14	Added AMR

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

Approved draft for training all sites (version 000)

Technical SOP

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

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

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

Form revised 3/31/00

TABLE OF CONTENTS

1. TEST INFORMATION

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

Synonyms/Abbreviations
Sed Rate, ESR

Department
Hematology

Form revised 3/31/00

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) 12 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.
Other Considerations	Lipemia: Acceptable Icteric: Acceptable

4. REAGENTS

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. Mix 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.

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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 Lead Technologist 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
- Fisherbrand Dispette Cat# 02-675-179

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	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.
2	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.
3	Replace cap securely.
4	Gently mix by inversion. A minimum of 8 inversions is recommended.
5	Ensure that all the blood returns to the bottom section of the reservoir.
6	While holding filling reservoir firmly with one hand, and the Dispette tube with the other hand, penetrate the cap membrane.
7	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.
8	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).
9	Readings are recorded in millimeters at exactly one hour after setting upright.
10	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.

9. CALCULATIONS

None required

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…**
0 mm/hr	Report as 0 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 – 145 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, 11/2009.
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

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SOP H010.002		

19. ADDENDA

None