TRAINING UPDATE

Lab Location: Department: GEC, SGAH & WAH Core
 Date Distributed:
 11/6/2014

 Due Date:
 12/8/2014

 Implementation:
 12/9/2014

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:				
Stool for WBC's GEC.U10, SGAH.U12, WAH.U13 v2				
Descri	iption of chang	ge(s):		
	Section	Reason		
	10.1	Replace Misys with LIS		
Th	is SOP wil	1 be implemented on December 9, 2014		

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

Technical SOP

Title	Stool for WBC's		
Prepared by	Cynthia Reidenauer	Date:	11/17/2011
Owner	Robert SanLuis	Date:	10/17/2012

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	2
2.	Analytical Principle	3
3.	Specimen Requirements	3
4.	Reagents	4
5.	Calibrators/Standards	4
6.	Quality Control	5
7.	Equipment And Supplies	5
8.	Procedure	5
9.	Calculations	5
10.	Reporting Results And Repeat Criteria	6
11.	Expected Values	6
12.	Clinical Significance	7
13.	Procedure Notes	7
14.	Limitations Of Method	7
15.	Safety	7
16.	Related Documents	8
17.	References	8
18.	Revision History	8
19.	Addenda	8

1. TEST INFORMATION

Assay	Method/Instrument	Local Code	
Stool for WBC's	Manual method	STWBC	

Synonyms/Abbreviations

Fecal Leukocytes

Department

Core Lab

2. ANALYTICAL PRINCIPLE

The correlation between the presence of large numbers of polymorphonuclear cells (PMN's) in stool and a patient's clinical symptoms can provide the clinician with a rapid presumptive diagnosis.

Although small numbers of PMN's may be found in the mucous from a normal stool, the total counts are greatly increased in conditions such as ulcerative colitis, chronic bacillary dysentery, and other inflammatory states.

Certain parasitic infestation present with increased eosinophilia and on rare occasion there may be intact eosinophils present in the stool.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	None
Specimen Collection and/or Timing	None
Special Collection Procedures	None
Other	None

3.2 Specimen Type & Handling

Criteria			
Type -Preferred	Random raw stool		
-Other Acceptable	Stool smear on slide		
Collection Container	Any clean dry container		
Volume - Optimum	N/A		
- Minimum	N/A		
Transport Container and	Collection container at room temperature		
Temperature			
Stability & Storage	Room Temperature:	4 hours	
Requirements	Refrigerated:	48 hours	
	Frozen:	Unacceptable	
Timing Considerations	None		

Criteria			
Unacceptable Specimens	Specimens that are unlabeled, improperly labeled, or those		
& Actions to Take	that do not meet the stated criteria are unacceptable.		
	Reject specimens greater then 2 days old.		
	Contact patient, unit or physician to obtain a new sample.		
	Request a recollection and credit the test with the		
	appropriate LIS English text code for "test not performed"		
	message. Examples: Quantity not sufficient-QNS; Wron		
	collection-UNAC. Document the request for recollection in		
	the LIS.		
Compromising Physical	N/A		
Characteristics			
Other Considerations	N/A		

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

Wright Stain, refer to the current Hematology Wright Staining system, either automated or manual method.

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.

Wright Stain, refer to the current Hematology Wright Stain in use, either automated or manual method.

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

A blood smear must be reviewed on a daily basis to verify that the staining is adequate for differential of the various cells. The result of this review is documented in the manual hematology QC book.

Refer to the appropriate hematology Stain procedure for QC requirements depending on the method used (automated stainer or manual stain).

- For automated stain see the current automated Hematology Staining system
- For manual method see the current manual Hematology Staining system

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

N/A

7.2 Equipment

Automatic Hematology Slide stainer or Manual Dip stain Microscope

7.3 Supplies

Glass slide Cotton-tipped applicator Coplin jars (if manual stain used)

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	Test Run
1.	Use a cotton-tipped applicator or wooden stick to roll a portion of the raw stool onto a glass slide
-	
2.	Air-dry the slide.
3.	Place slide onto the hematology slide stainer and stain, or use manual stain method.
	Examine under oil immersion at 100X.
4.	Count only polys on high power field. If other cells besides polys are noted, result
	these cells using a free text comment. See section 10.1

9. CALCULATIONS

N/A

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

Report the range per high power field i.e. 1-2/hpf, using the predefined LIS Result Code (see below).

**Do not enter range in the LIS using free text.

LIS Result code	Translation
NONE	None
ONET3	1-3
TT5	3-5
FT10	5-10
TT15	10-15
FT20	15-20
GT20	>20

Note: If the cells are other than PMN's a comment about the specific cell seen should be included in the report. Enter in the LIS using the following format below.

Example: English text code -; free text comment FT10-; 50% lymps

10.2 Rounding

N/A

10.3 Units of Measure

/hpf

10.4 Clinically Reportable Range (CRR)

N/A

10.5 Repeat Criteria and Resulting

N/A

11. EXPECTED VALUES

11.1 Reference Ranges

None established

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

Assist in the differential diagnosis of diarrheal disease.

13. PROCEDURE NOTES

- **FDA Status:** LDT without message
- Validated Test Modifications: None
- 1. 10 to 15% of stools, which yield invasive bacterial pathogen, have an absence of fecal leukocytes.
- 2. Fecal Leukocytes are present in idiopathic inflammatory bowel disease.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

N/A

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 <u>immediately</u> to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

Hematology Slide Stainer Cytocentrifuge, Hematology procedure Diff-Quik Stain Kit, Hematology procedure

17. REFERENCES

- 1. Laboratory Test Handbook: Jacobs, Demott, Finely, Horvat, Kasten, Tilzer 3rd edition 1994
- Clinical Diagnosis and Management by Laboratory Methods: Henry, p. 788, 16th Edition, 1979

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes U016.001		
000	10/17/12		Update owner	L Barrett	R SanLuis
000	10/17/12	4 & 6	Removed reference to specific staining procedure numbers and replaced with 'current' staining system.	C Reidenauer	R SanLuis
001	10/23/14	10.1	Replace Misys with LIS	A Chini	R SanLuis
001	10/23/14	Footer	version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis

19. ADDENDA

None