TRAINING UPDATE

Lab Location:	SGMC & WAH	**Date Distributed:**	1/3/2017
Department:	Core Lab	**Due Date:**	1/31/2017
		Implementation:	**2/1/2017**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Stool for WBC's SGAH.U12 v3

Note: this has been converted to a system SOP

Description of change(s):

Section	Reason
4	Update labeling instruction to new standard wording
10.1	Change code NONE to NDET
11.1	Update to None detected
12	Add more detailed explanation
15	Update to new standard wording
16	Add stain package insert

This revised SOP will be implemented on February 1, 2017

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

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

Synonyms/Abbreviations
Fecal Leukocytes, Fecal WBC

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

Form revised 2/02/2007

Criteria	
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those 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; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	N/A
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

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.

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

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

Automated Hematology Slide stainer or Manual Dip stain
Microscope

7.3 Supplies

Glass slide
Cotton-tipped applicator
Coplin jars or sterile urine cups (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 Codes (see below).
**Do NOT enter range in the LIS using free text.

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

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

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

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 detected ~~None established~~

11.2 Critical Values

None established

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

~~Assist in the differential diagnosis of diarrheal disease.~~
The presence of leukocytes is an indicator of inflammation which is usually a product of bacteria-host interaction.

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

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

Hematology Slide Stainer Cytocentrifuge, Hematology procedure
Diff-Quik Stain Kit, Hematology procedure
Current package insert for stain

17. REFERENCES

1. Laboratory Test Handbook: Jacobs, Demott, Finely, Horvat, Kasten, Tilzer 3rd edition 1994
2. 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
2	12/5/16	Header	Add WAH	L Barrett	R SanLuis
2	12/5/16	4	Update labeling instruction to new standard wording	L Barrett	R SanLuis
2	12/5/16	10.1	Change code NONE to NDET	L Barrett	R SanLuis
2	12/5/16	11.1	Update to None detected	L Barrett	R SanLuis
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19. ADDENDA

None