TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	7/21/2016
Department:	Core	**Due Date:**	8/10/2016
		Implementation:	**8/10/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Wet Prep SGAH.M23 v4

Note: this has been converted to a system SOP

Description of change(s):

Section	Reason
Header	Add other sites
3.2	Specify saline concentration
11.3	Corrected reference range

This revised SOP will be implemented on August 10, 2016

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

Technical SOP

Title	**Wet Prep**	
Prepared by	Ron Master	Date: 8/25/2009
Owner	Ron Master	Date: 8/25/2009

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
Wet Prep	N/A	WETP

Synonyms/Abbreviations
N/A

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2. ANALYTICAL PRINCIPLE

Yeast and *Trichomonas* sp. can be found in urine or vaginal discharges. *Trichomonas* move by a progressive undulating, whipping of flagella and pseudopodial movement. Outside the body *Trichomonas* rapidly succumbs at temperatures higher than 40°C; therefore it is imperative to examine specimens requested for *Trichomonas* immediately upon arrival in the Laboratory. Yeast and clue cells can also be detected from vaginal discharge.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Specimen should be obtained on a swab and submitted in a tube containing 0.5 mL 0.85-0.9% saline (0.85-0.9% sodium chloride). A red top vacutainer tube (without additives) may be used. Deliver to Laboratory immediately.
Special Collection Procedures	N/A
Other	N/A

3.2 Specimen Type & Handling

Criteria		
Type	**-Preferred**	Vaginal discharges.
	-Other Acceptable	None
Collection Container		Swab in tube or a red-top vacutainer (without additives) containing 0.5 mL 0.85-0.9% saline
Volume	**- Optimum**	Swab in 0.5mL 0.85-0.9% saline
	- Minimum	Swab in 0.5mL 0.85-0.9% saline
Transport Container and Temperature		Collection container at room temperature
Stability & Storage Requirements	Room Temperature:	Do not let stand, test immediately.
	Refrigerated:	Unacceptable
	Frozen:	Unacceptable
Timing Considerations		Process immediately.
Unacceptable Specimens & Actions to Take		Dry swab. Call and request another sample
Compromising Physical Characteristics		N/A
Other Considerations		N/A

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4. REAGENTS

N/A

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

6.1 Controls Used

N/A

6.2 Control Preparations and Storage

N/A

6.3 Frequency

N/A

6.4 Tolerance Limits and Corrective Action Policy

N/A

6.5 Review Patient Data

N/A

6.5 Documentation

N/A

6.7 Quality Assurance Program

N/A

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

N/A

7.2 Equipment

Microscope

7.3 Supplies

Sterile transfer pipette
Paper towels
Glass slide
Coverslip
Gloves

8. PROCEDURE

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

8.1	Action
1.	Check order and verify patient name in the LIS matches name on specimen.
2.	Place a drop or two of the specimen on a slide using a plastic transfer pipette.
3.	Gently place a coverslip over the surface of the material on the slide.
4.	Examine with low (10x objective) and high dry (40x objective) power objectives.
5.	Enter results in computer utilizing Microbiology Result Entry.

9. CALCULATIONS

N/A

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Reporting of Results

Report the presence or absence of *Trichomonas*, yeast and clue cells.

DO NOT REPORT SPERMATOZOA.

11. EXPECTED VALUES

11.1 Reference Ranges

No Trichomonas, yeast, or clue cells seen
~~None established~~

11.2 Critical Values

None established

11.3 Standard Required Messages

None established

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12. CLINICAL SIGNIFICANCE

Trichomonas vaginalis is a parasite that is distinguished by its rapid movement and flagella. Motile *Trichomonas* trophozoites may be identified in a vaginal sample by its characteristic structure.

Bacterial vaginosis is the most common type of vaginal infection and can sometimes be detected by the presence of "clue cells". Clue cells are epithelial cells entirely covered with bacteria giving them a "furlike" appearance. If the organisms sticking to the edges or on top of the cell, without extending past the cytoplasmic margins, a diagnosis of clue cells cannot be made. Note: Certain anaerobic, non-pathogenic, species tend to adhere to the epithelial surface.

Yeast vaginitis is primarily caused by *Candida albicans*, although other *Candida* species are becoming increasingly important as disease agents. *Candida albicans*, in low numbers, is considered part of the normal vaginal flora, but may proliferate to cause an infection.

13. PROCEDURE NOTES

- **FDA Status:** LDT without message
- **Validated Test Modifications:** None

1. Examine wet preparation immediately as motility disappears rather rapidly (within 35-40 minutes) making it impossible to detect the parasite in wet preparations.

2. *Trichomonas vaginalis* can also be observed on Gram stain of the specific discharge or sedimented urine. Here the *Trichomonas* appear larger than the polymorphonucleated white cells, but smaller than epithelial cells. *Trichomonas* cytoplasm is typically foamy in appearance; the parasite stains slightly pink, demonstrating its typical pear to oval or any shape. The elliptical nucleus is clearly visible as it stains darker than the cytoplasm of the organism. Flagella are sometimes visible but not always.

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

You, the employee, have 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 Safety 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 needle sticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.
- Warnings of other specific hazards are noted in this procedure. Please comply with the requirements to reduce your risk of injury."

Report all accidents and injuries to your supervisor or the Safety Officer.

16. RELATED DOCUMENTS

Resulting Microbiology Direct Exams, Microbiology procedure

17. REFERENCES

- Baron, Ellen Jo, Sydney Finegold, Bailey and Scott's Diagnostic Microbiology, C.V. Mosby Co., St. Louis, .2002.
- P.C. Beaver, R.C. Jung, E.W. Cupp. *Clinical Parasitology*, 9th Edition, p. 49-51, Lee and Febiger Publishers, Philadelphia, PA, 1984.
- Henry, J.B, Clinical Diagnosis and Management by Laboratory methods, 19th ed., W. B. Saunders Company, Philadelphia, 1996

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SOP M010.002		
000	10/12/09	8.1	LIS update to GUI system	A. Sears	R. Master
000	10/12/09	16	Added procedure for resulting	L. Barrett	R. Master
001	10/4/2011	3.2	Deleted sources other than vaginal	R. Master	R. Master
002	5/16/2012	10.1	Deleted hyphae, deleted redundant report comments	R. Master	R. Master

003	7/6/16	Header	Added other sites	L. Barrett	R. Master
003	7/6/16	3.2	Specify saline concentration	R. Master	R. Master
003	7/6/16	11.1	Corrected reference range	R. Master	R. Master
003	7/6/16	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L. Barrett	R. Master

19. ADDENDA

None