TRAINING UPDATE

Lab Location:	SGMC & WAH	**Date Distributed:**	8/27/2015
Department:	Core	**Due Date:**	8/31/2015
		Implementation:	**9/1/2015**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Urine Culture Screen SGAH.M918, WAH.M909 v1

Description of change(s):

Section 8:

Understand the changes to read times -

- Plates will be read by day shift at 0700, by evening shift at 1500, and by night shift at 2300.
- Day shift will read plates incubated before 1300 on the previous day. (0500-1300)
- Evening shift will read plates incubated before 2100 on the previous day. (1300-2100)
- Night shift will read plates incubated before 0500 that day. (2100-0500)

Add that plates must be sent to specimen processing at least 30 min prior to the next courier pickup to ensure transport on the earliest run.

Add plates must be read under reflected light with the lids removed. Any questionable colonies must be verified using a magnifier.

Plates must be saved in a refrigerator for 2 days after completion.
***Note**: no change to storage of urine specimens (store at hospital for at least 3 days after plating)*

This revised SOP will be implemented on September 1, 2015

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

Approved draft for training (version 1)

Technical SOP

Title	**Urine Culture Screen**
Prepared by	Ron Master Date: 05/28/2015
Owner	Ron Master Date: 05/28/2015

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

Review		
Print Name and Title	**Signature**	**Date**

Form revised 2/2/07

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Order Code
Culture, Urine, Routine (includes urine collected from indwelling catheter)	Calibrated Loop Technique	XURNC

Synonyms/Abbreviations
Culture, Urine, Clean Catch Culture, Urine, Midstream Culture, Urine, Voided Culture, Urine, Indwelling Catheter Culture, Cystoscopy Urine Culture, Bladder Urine Culture, Urine Straight Catheter Culture, Urine In/Out Catheter

Department
Microbiology

2. ANALYTICAL PRINCIPLE

The purpose of this document is to provide standard criteria for the culture; examination, reporting of negative urine cultures and the referral of positive cultures of urinary tract pathogens in voided, straight catheterized, cystoscopy and indwelling catheterized specimens. The quantitative count of bacterial colonies is used to judge the significance of any isolated organism(s). Urine specimens, when transported and handled properly, provide an accurate assessment of the number of bacteria present per milliliter (mL) in the bladder. The concentration of bacteria present per mL of urine is determined by multiplying the observed colony count by the inoculum size (0.001 mL or 0.01); (i.e. multiply by 1000 or 100).

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Specimen Collection	Refer to the Laboratory Test Directory (electronic) on the Adventist Healthcare intranet for details.
Timing Considerations	• Early morning specimens are preferred as there are increased bacteria in the bladder after overnight incubation. • The microbial load in urine may be influenced by fluid intake. Symptomatic patients may have lower colony counts if specimens are collected when diuresis is occurring.
Special Collection Procedures	N/A
Other	If Urine Collection Kit is not used, submit to Laboratory within 2 hours of collection.

3.2 Specimen Type & Handling

Criteria	
Type -Preferred	Clean-Catch Midstream urine Indwelling catheter collected urine Straight (in/out) catheter collected urine Cystoscopy collected urine
-Other Acceptable	None
Collection Container	Clean, non-sterile plastic are used to collect urine before transfer to a BD 5-mL Vacutainer™ gray top urine transport tube.

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Criteria	
Volume - Optimum **- Minimum**	Approximately 5 mL Approximately 4 mL (to fill line on 5-mL Vacutainer™ Brand Urine C&S Transport Tube) For < 4 mL, see Transport Container section.
Transport Container & Temperature	• BD 5-mL Vacutainer™ brand, Urine C&S Transport gray top tube. • A sterile, screw cap urine cup may only be used when less than 5 mL of urine can be obtained such as in pediatric specimens or from patients with renal abnormalities. • Room Temperature (18ºC to 30ºC) for 48 hours. • Refrigerated (2ºC to 8ºC) for 48 hours.
Stability & Storage Requirements	• Vacutainer™ Brand Urine C&S Transport Kits holds bacterial counts stable at room temperature or refrigerated for 48 hours. • Low volume specimens are stable in a sterile urine container for 48 hours when refrigerated.
Unacceptable Specimens & Actions to Take	**Reject:** • Unpreserved specimens with < 5mL of urine • Unpreserved specimens < 5mL not refrigerated received > 2 hours from collection time. • Unpreserved specimens < 5 mL refrigerated received >24 hours from collection time. • Under filled Vacutainer™ Brand Urine C&S Transport tubes • Specimens exceeding time limits in "Stability and Storage Requirements" • Specimens transported in urinalysis preservative • Requests for anaerobic culture • Frozen samples • Expired transport devices • 24-hour urine collections • Foley catheter tips • Leaking samples • Swabs 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.

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Criteria	
Compromising Physical Characteristics	Not Applicable
Other Considerations	Not Applicable

4. REAGENTS / MEDIA

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

Media:

Reagents / Kits	Supplier & Catalog Number
Trypticase Soy Agar (TSA) Plate with 5% Sheep Blood	BBL, Cat # 221261
MacConkey Agar Plate	BBL, Cat # 221270

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	Trypticase Soy Agar (TSA) Plate with 5% Sheep Blood and MacConkey Agar Plate
Container	Manufacturer's packaging
Storage	2-8°C
Stability	Stable until expiration date on package
Preparation	None

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

6.1 Controls Used

The Urine Culture Screening procedure describes the process used to isolate bacteria contained in urine samples. All media used in conjunction with this procedure shall be checked for proper reactivity using appropriate quality control procedures. Refer to specific test procedures or department QC plan for detailed quality control requirements.

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.

Refer to specific test procedures for preparation, storage and handling instructions.

6.3 Frequency

Refer to M11 Media Quality Control procedure for QC frequency requirements.

6.4 Review Patient Data

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

6.5 Documentation

Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.6 Quality Assurance Program

- 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

Not Applicable

7.2 Equipment

Equipment	Supplier
Incubator, 35 ± 2ºC, air or CO_2 atmosphere	Current Vendor

7.3 Supplies

Supplies	Supplier
1 µL loop, 1000/box	8175CS20 (Copan)
10 µL loop	8177CS20

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.

Step	Action
1.	Label plates with LIS label and write the **date and time the sample was plated** and tech code on the plate.
2.	Gently invert the urine sample 2-3 times to mix the specimen.
3.	**For urine collected by midstream, clean catch or indwelling catheter:** Use a 1 µL calibrated loop to inoculate 0.001 mL to each plate and streak for isolation as in SOP M.04. The same loop may be used for both the blood agar and MacConkey agar plates for the same specimen. **For urine collected by straight (in/out) catheter, cystoscopy, suprapubic aspirate or listed as bladder urine:** Use a 1 µL calibrated loop to inoculate 0.001 mL to one set of blood agar and MacConkey agar plates. Use a 10 µL calibrated loop to deliver 0.01 mL to a second set of blood agar and MacConkey plates. Label each plate with the inoculum size and plate and streak for isolation as in SOP M.04. Keep these plates in a separate canister since these are incubated for 48h.
4.	Incubate plates at 35 ± 2°C in ambient air or 4-8% CO_2 atmosphere.
5.	Save urine specimens at the hospital for at least 3 days after plating.

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Step	Action
6.	Plates will be read by day shift at 0700, by evening shift at 1500, and by night shift at 2300. • Day shift will read plates incubated before 1300 on the previous day (0500-1300). • Evening shift will read plates incubated before 2100 on the previous day (1300-2100). • Night shift will read plates incubated before 0500 that day (2100-0500). Plates must be sent to specimen processing at least 30 minutes prior to the next courier pickup to ensure transport on the earliest run.
7.	Plates must be read under reflected light with the lids removed. Any questionable colonies must be verified using a magnifier.
8.	Save plates in a refrigerator for 2 days after completion.
9.	**For urine collected by midstream, clean catch or indwelling catheter:** Report final "No growth" result after overnight incubation (minimum of 18 hours). **For urine collected by straight (in/out) catheter, cystoscopy, suprapubic aspirate or listed as bladder urine:** Read plates at 18-24 h and if no growth, report a preliminary report of "No growth at day 1" and incubate for an additional 24 h. Report final "No growth" result after 48 hours of incubation (minimum of 42 hours).
10.	Any specimens with growth must have ROB and FES performed before sending to Chantilly for further workup. Do NOT report any result.
11.	Do not discard plates until pending list is reviewed and any issues resolved. Use worksheet codes SMIT3 (SG), WMIT3 (WAH) and GMIT3 (GEC) to create LIS pending log. Discard the no growth plates after results are reported and pending list has been resolved.

9. CALCULATIONS

Not applicable

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

More than 95% of urinary tract infections (UTIs) are attributed to a single organism and have colony counts >100,000 colonies per mL (>10^5 CFU/mL of urine). In cases of UTI where more than one organism is present, the predominant organism is usually clinically significant and others are probable urethral or collection contaminants. When multiple organisms are isolated from patients with indwelling catheters, UTI is doubtful and colonization likely.

10.2 Rounding

Not applicable

10.3 Units of Measure

Not applicable

10.4 Clinically Reportable Range (CRR)

Qualitative test. Report only as No Growth.

10.5 Repeat Criteria and Resulting

None

10.6 LIS Resulting

Refer to addendum A

11. EXPECTED VALUES

11.1 Reference Ranges

No growth

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

Urinary tract infections (UTI) are among the most common infections of humans. Infections may involve the urethra, bladder, kidneys, other organs or adjacent tissues and may be complicated by bacteremia. In voiding, the urine must pass through sites containing normal flora. Quantitative culturing of urine is an established tool to differentiate significant bacteriuria from contamination introduced during voiding. However, studies have shown that when the calibrated method is performed, even perfectly, colony counts are only approximations. There can be approximately 50% to 150% variation in the colony count reported.

13. PROCEDURE NOTES

- **FDA Status:** Lab developed test, without message.
- **Validated Test Modifications:** Not applicable
- Colony counts may be inaccurate if the urine specimen is not mixed well in transport tube, or if the loop is held at an angle or dipped too deep.
- On occasion, specimens may contain high white blood cell counts and yield negative cultures. This may be due to factors such as antimicrobial therapy, but may also be due to chemical irritation of the bladder wall. Inflammation does not always indicate infection.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

The lower limit of detection of this test is about 1,000 CFU/mL when a 1 uL loop is used and 100 CFU/mL when a 10 uL loop is used. The upper limit of quantitation is >100,000 CFU/mL.

UTI caused by fastidious organisms such as *Haemophilus influenzae, Neisseria gonorrhoeae, Mycobacterium* spp., anaerobes, *Mycoplasma* spp., *Ureaplasma* spp., and intracellular pathogens such as *Chlamydia* spp. will not usually be detected by this method.

14.2 Precision

Not applicable

14.3 Interfering Substances

Use of antimicrobial agents may reduce the sensitivity of the test.

14.4 Clinical Sensitivity/Specificity/Predictive Values

Some fastidious organisms such as *Corynebacterium* species (e.g. *C. urealyticum, C. glucuronolyticum and C. pseudogenitalium*) and *Gardnerella vaginalis* may be uropathogens, but may not be detected or may require longer incubation time.

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 the learn 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 Quality Control Program
2. Laboratory Safety Manual
3. Material Safety Data Sheets (MSDS)
4. *Joint Directory of Services*, Specimen Collection section
5. SOP M.04 Specimen Processing for Microbiology
6. SOP M.11 Media Quality Control
7. How to Result a Urine Culture Job Aid (AG.F330)

17. REFERENCES

1. Culture, Urine, Routine (includes urine collected from indwelling catheter) QDMI715v2.4E

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
0	8/10/15	8.6	Changed read times, added read on third shift	R. Master	R. Master
0	8/10/15	8.7	Added detail on reading plates	R. Master	R. Master
0	8/10/15	8.8	Added to save plates for 2 days	R. Master	R. Master
0	8/10/15	16	Added job aid for resulting	L. Barrett	R. Master

19. ADDENDA

A. LIS Resulting

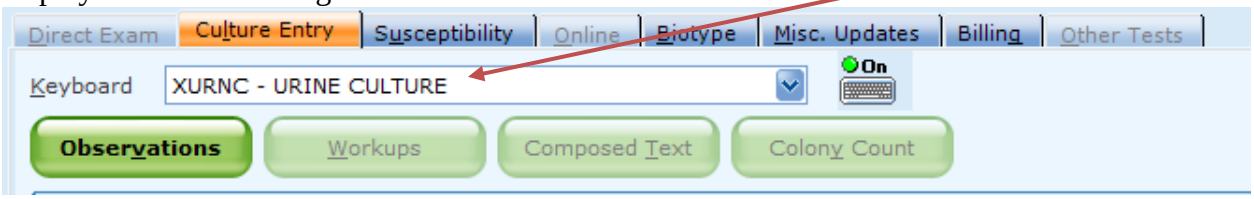
Addendum A

LIS resulting

1. Resulting is done via the Microbiology Result Entry (Misys GUI) application. Do **NOT** use function MEM in SmarTerm.

2. After accessing the application, type in the Accession number. Double click on the accession number in the 'Accession/Battery list' –**OR**– click on Select. This will bring up the culture for resulting.

The 'Microbiology Result Entry' box opens. A default keyboard called "XURNC- Urine Culture" displays. Do **NOT** change.



3. With your cursor in the result field, press **F8** to display the on-screen resulting keyboard. This will show what key is tied to an English text code for resulting.

4. Resulting (using the on-screen keyboard or keyboard attached to PC).
   a. **For urine collected by midstream, clean catch or indwelling catheter** - Report "No growth" final results.
      1) With the cursor in the Observation #1 **Result** field, select the **N** key, to result as **NG**. This code translates to No Growth.
      2) Press the Tab key 3 times; this takes you to the next **Result** field.
      3) Select the / key **fnl** to finalize the report. Pop-up displays letting you know that the culture has been finalized along with the tech code of who finalized it. Close the pop-up by clicking on **OK**.
      4) Click on **Save** twice.
      5) Report is now finalized with a result of No Growth.

   b. **For urine collected by straight (in/out) catheter, cystoscopy, suprapubic aspirate or listed as bladder urine**
      1) If reporting "No growth at day 1" as a **preliminary** report.
         - With the cursor in the **Result** field, select the **1** key to result as NGD. This code translates to No Growth Day 1.
         - Press the Tab key 3 times; this takes you to the next **Result** field.
         - Click on **Save** twice.
         - This saves the report as a **preliminary** report of No Growth Day 1.

2) To **finalize** a no growth report by changing result of NGD1 (No growth day 1) to NG (No growth).
   - With the cursor in the Observation #2 **Result** field below the NGD1 result, use either the mouse or up arrow key to move cursor to the NGD1 Result field. Press the **Delete** key, this will remove the results.
   - With the cursor still in the observation #1 **Result** field, press the **N** key, to result as **NG**. This code translates to No Growth.
   - Press the Tab key 3 times; this takes you to the Observation #2 Result field.
   - Press the / key **fnl** to finalize the report. Pop-up displays letting you know that the culture has been finalized along with the tech code of who finalized it.
   - Close the pop-up by clicking on **OK**.
   - Click on **Save** twice.

Note: Sterile sources are held for a minimum of 42 hours instead of a minimum of 18 hours. If the source is sterile, the following message will display reminding you to hold for a minimum of 42 hours.