TRAINING UPDATE

Lab Location:	SGMC & WAH	**Date Distributed:**	8/13/2015
Department:	Core	**Due Date:**	8/31/2015
		Implementation:	**9/1/2015**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Remel Spectra™ MRSA Screen SGAH.M39, WAH.M36 v3
Description of change(s):
Addendum A - Specify callback documentation must be entered on a separate line 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 3)

Technical SOP

Title	**Remel Spectra™ MRSA Screen**	
Prepared by	Ron Master	Date: 12/03/2012
Owner	Ron Master	Date: 12/03/2012

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**

Form revised 2/02/2007

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Culture	Manual	MRSAS

Synonyms/Abbreviations
MRSA Surveillance Culture Nasal, MRSA Nasal Screen, MRSA Nasal Culture

Department
Microbiology

Form revised 2/02/2007

2. ANALYTICAL PRINCIPLE

Remel Spectra™ MRSA is a selective and differential chromogenic medium recommended for use in the qualitative detection of nasal colonization of methicillin-resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA in healthcare settings. The test is performed with anterior nares swab specimens from patients and healthcare workers to screen for MRSA colonization. Spectra™ MRSA is not intended to diagnose MRSA infection or to guide or monitor treatment for infections.

Spectra™ MRSA is an opaque medium, which uses a novel chromogen that yields a denim blue color as a result of phosphatase activity. This enzyme is present in all MRSA. To allow the medium to differentiate MRSA accurately, it contains a combination of antibacterial compounds designed to inhibit the growth of a wide variety of competitor organisms. Also included are compounds that encourage the production of MRSA pathogenicity marker, ensuring expression of the phosphatase enzyme and so providing enhanced sensitivity and specificity.

3. SPECIMEN REQUIREMENTS

CAUTION: Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus may be present in clinical specimens. "Standard Precautions" and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Use of transport devices approved for the collection of anterior nares specimens is recommended. Follow the transport device manufacturer's recommended procedures.
Special Collection Procedures	None
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred	Anterior nares specimen
-Other Acceptable	None
Collection Container	Swab
Volume - Optimum	1 swab
- Minimum	1 swab
Transport Container and Temperature	Use of transport devices approved for the collection of anterior nares specimens is recommended. Follow the transport device manufacturer's recommended procedures.
Stability & Storage Requirements	Room Temperature: Acceptable: 18-25ºC for 48 hours
	Refrigerated: Acceptable: 2-8ºC for 48 hours
	Frozen: Not recommended
Timing Considerations	N/A
Unacceptable Specimens & Actions to Take	Frozen; Not acceptable. Notify client and cancel test.
Compromising Physical Characteristics	N/A
Other Considerations	N/A

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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 Medium / Reagent Summary

Medium	Supplier & Catalog Number
Remel Spectra™ MRSA	Remel Catalog # Cat. No. R01821, Pkg of 10 plates Remel Catalog # Cat. No. R01822, Pkg of 100 plates

4.2 Reagent Preparations 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.

Product Deterioration: This product should not be used if (1) there is evidence of dehydration, (2) the product is contaminated, (3) the color has changed, (4) the expiration date has passed, or (5) there are other signs of deterioration.

Reagent	Spectra™ MRSA agar
Container	10 plates/box, 100 plates/carton
Storage	Store product in its original container at 2-8°C until used. Allow product to equilibrate to room temperature before use. Do not incubate prior to use.

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Stability	Stable until date of expiration on label
Preparation	This product is ready for use and no further preparation is necessary.

Warnings and Precautions:

- For in vitro Diagnostic Use.
- Observe aseptic techniques and established precautions against microbiological hazards throughout all procedures.

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

6.1 Controls Used

Examine plates for signs of deterioration as described under "Product Deterioration" in section 4.2. Check performance by inoculating plates with pure culture of stable control organisms that produce known, desired reactions.

Controls	Supplier and Catalog Number
Positive Control	*S. aureus* ATCC 43300
Negative Control	*S. aureus* ATCC 25923

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) check for visible signs of degradation on of all items received.
N/A

6.3 Frequency

Quality Control should be run with each new lot/shipment of media.
A positive (*S. aureus* ATCC 43300) and a negative control (*S. aureus* ATCC 25923) must be performed daily. Record QC results in the appropriate QC chart.

6.4 Tolerance Limits

Test Strain	Expected Growth
S. aureus ATCC 25923	No growth
S. aureus ATCC 43300	Growth with denim blue colonies

If expected results are not obtained, do not release patient result. Do not use the media. Notify Supervisor and document corrective action in the QC Failure Action Log.

6.5 Review Patient Data

N/A

6.6 Documentation

Refer to local policies and procedures for QC documentation and to Quest Diagnostics records management program for record retention requirements.

6.7 Quality Assurance Program

Each case of media has a manufacturer's Quality Control certificate indicating the organisms tested and the acceptability of those tests. These certificates must be maintained as quality assurance/quality control documentation

Do not use plates if they show evidence of microbial contamination, discoloration, drying, cracking or other signs of deterioration.

Each shipment of media must be tested to verify that the shipment was not subject to adverse storage or shipping conditions.

If expected results are not obtained, do not use the media. Contact Technical Services.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

N/A

7.2 Equipment

Incubator (aerobic) 35-37°C

7.3 Supplies

Swab
Disposable inoculating loop

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.

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	Medium Preparation
1.	Observe aseptic techniques.
2.	The agar surface should be smooth and moist, but without excessive moisture.
3.	Allow the medium to warm to room temperature prior to inoculation.

8.2	Procedure
1.	**Media inoculation times must be concurrent with read times to ensure 24 hour incubation**. Media will be inoculated once per shift at the designated times. Inoculate the specimen by rolling swab onto a Remel Spectra™ MRSA plate and streak plate in 4 quadrants to obtain isolated colonies. Write the date and time inoculated on the plate.
2.	Incubate plates aerobically at 35-37°C for 24 h in an inverted position. Plates should be placed in the incubator as soon as they are accessioned and plated. Do not incubate in an atmosphere supplemented with carbon dioxide.
3.	**Read plates after 24 hours of incubation**. Observe colony characteristics, morphology, and color reactions. Read plates against a white background. Colonies of MRSA will appear denim blue on the Remel Spectra MRSA medium. Other organisms (non-MRSA) will exhibit marked inhibition or produce white colonies. Refer to table in section 10.1 for interpretation of results.
4.	If after 24 hours of incubation no denim blue colonies are observed, the culture is considered negative and plates should be discarded.
5.	Pinpoint denim blue colonies should not be interpreted as positive. If in doubt, confirm the identity of the colonies with another method. Call Chantilly microbiology and speak to a supervisor and tell them that MRSA confirmation is requested. Send the plate with a note which mentions what is needed, the contact person at the hospital, and the person in Chantilly that was contacted.

9. CALCULATIONS
N/A

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Results

After 24 hours incubation, MRSA will appear as small to medium denim blue colonies against a white background. The colonies are typically smaller than on non-selective media. Other organisms (non-MRSA) will exhibit marked inhibition or produce white colonies. If after 24 hours incubation no denim blue colonies are observed, the specimen is considered negative and plates should be discarded.

24 h Incubation	Interpretation
Small to medium denim blue colonies	Methicillin-resistant *Staphylococcus aureus* (MRSA) detected
No denim blue colonies	No Methicillin-resistant *Staphylococcus aureus* (MRSA) detected

Appearance of MRSA on Spectra agar

10.2 Rounding / Units of Measure / Clinically Reportable Range (CRR)

N/A

10.3 Resulting

Message	Code
No Methicillin-resistant *Staphylococcus aureus* (MRSA) detected	NMRSA
Methicillin-resistant *Staphylococcus aureus* (MRSA)	SARMET

NOTE: All MRSA screen positive results <u>MUST</u> be called to the floor and documented as per the Critical Values policy.

Refer to Addendum A for details on LIS Resulting.

11. EXPECTED VALUES

11.1 Reference Ranges

Not detected

11.2 Critical Values

Methicillin-resistant *Staphylococcus aureus* (MRSA)

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

MRSA are a major cause of nosocomial and life threatening infections. Infections with MRSA have been associated with a significantly higher morbidity, mortality and costs than methicillin-susceptible *S. aureus* (MSSA). Selection of these organisms has been greatest in the healthcare setting; however, MRSA have also become more prevalent in the community.

To control the transmission of MRSA, the Society for Healthcare Epidemiology of America (SHEA) has recommended guidelines, which include an active surveillance program to identify potential reservoirs and a rigorous infection control program to control the spread of MRSA.

Remel Spectra™ MRSA is a selective and differential medium for the detection of MRSA from anterior nares specimens.

13. PROCEDURE NOTES

- **FDA Status**: Approved
- **Validated Test Modifications:** None

1. This product is For InVitro Diagnostic Use and should be used by properly trained individuals.
2. Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers, and media after use.
3. Directions should be read and followed carefully.

14. LIMITATIONS OF METHOD

- Organisms with atypical enzyme patterns may give anomalous results.
- Incubation in CO_2 may reduce recovery and potentially result in a false negative reaction.
- The growth requirements of certain MRSA can lead to their partial or complete inhibition in culture. Borderline oxacillin-resistant strains of *S. aureus* (BORSA) demonstrate variable results on this media.

- Rare strains of *Staphylococcus cohnii* and methicillin-resistant *Staphylococcus epidermidis* may grow and produce very dark, navy-blue and pale-blue colonies respectively. The intensity of the color reaction enables differentiation from MRSA.
- Few pinpoint denim blue colonies rarely occur in the presence of excessive blood and should not be interpreted as positive. If in doubt, confirm with a latex agglutination test directly from the Spectra™ MRSA plate.
- Surveillance testing determines the colonization status at a given time and can vary depending on patient treatment, patient status (actively shedding), or exposure to high-risk environments. Monitoring of colonization status should be performed in accordance with hospital policies and procedures.
- Some *Bacillus* species may produce flat, blue colonies with a feathery edge. A Gram stain will differentiate these colonies from staphylococci.

14.1 Analytical Measurement Range (AMR)

N/A

14.2 Precision

N/A

14.3 Interfering Substances

Commonly used medicinal substances and transport media, as well as human blood and mucous were evaluated for potential interference of the chromogenic reaction of Spectra™ MRSA. No interference was observed.

14.4 Clinical Sensitivity/Specificity/Predictive Values/Performance Characteristics

Refer to Remel Spectra™ MRSA package insert.

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. Critical Values (Lab policy)
3. Current Package Insert
4. Spectra MRSA Quality Control Chart (AG.F228)

17. REFERENCES

Product Information Remel Spectra™ MRSA package insert, IFU 1821, Revised April 16, 2013.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	6/4/13	10.3	Add reference to addendum B	L Barrett	R Master
000	6/4/13	19	Add addendum B	L Barrett	R Master
001	6/25/15	16	Move form from section 19	L Barrett	R Master
001	6/25/15	17	Update package insert revision date	L Barrett	R Master
001	6/25/15	19	Re-numbered addendum B to A	L Barrett	R Master
001	6/25/15	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R Master
2	7/29/15	Add. A	Specify callback documentation must be entered on a separate line	M Sabonis	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. Once you are in the application, type in the Accession number. Double click on the accession number in the 'Accession/Battery list'. This will bring up the culture for resulting.

3. The 'Microbiology Result Entry' box opens, select **OK**.

4. From the keyboard drop down box choose **CHROM- MRSA SCREEN**.

5. 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.

6. Resulting (using the on-screen keyboard or keyboard attached to PC).
   a. Select the **D** key, to result as **SARMET**. This code translates to Methicillin-resistant Staph aureus (MRSA). Press the **TAB** key three (3) times until you get to the next observation line. Then select the **C** key (CBACK) to document calling the results to the floor.
      Note: SARMET and CBACK documentation **MUST NOT be reported on the same line.** The example below shows proper documentation:

These are observation lines

Observations ☐ Suppress test

#	S	H	O	B	SIG	HLD	SUP	Result	Description
1.	☐	☐	☐	☐	☐	☐	☐	SARMET	Staphylococcus aureus (MRSA)
2.	☐	☐	☐	☐	☐	☐	☐	CBACK-;JACK SMITH 072915 1025	Called to and read back by:-;JACK SMITH 072915 1025

   b. Select the **N** key, to result as **NMRSA**. This code translates to No Methicillin-resistant Staph aureus (MRSA) detected.

7. When you are done with the on-screen keyboard, press **F8** to turn it off.

8. To finalize the culture, make sure that you are in a result field with no results reported and then select the / (forward slash) key. This will finalize the results. Then select **Save** twice to save results.

9. The LIS will prompt to enter another accession number to result. If you are done, select **Exit** to exit the Microbiology Result Entry application.