

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k073027

B. Purpose for Submission:

Premarket notification

C. Measurand:

Methicillin Resistant *Staphylococcus aureus* (MRSA)

D. Type of Test:

Detection of MRSA using a selective and differential chromogenic media

E. Applicant:

Thermo Fisher Scientific

F. Proprietary and Established Names:

Remel Spectra™ MRSA

G. Regulatory Information:

1. Regulation section:

21 CFR 866.1700

2. Classification:

Class II

3. Product code:

JSO Culture media, Antimicrobial susceptibility test, excluding Mueller Hinton Agar

4. Panel:

Microbiology

H. Intended Use:

1. Intended use(s):

Remel Spectra™ MRSA is a selective and differential chromogenic medium for the qualitative detection of nasal colonization of methicillin resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings. The test can be performed on anterior nares specimens from patients and healthcare workers to screen for MRSA colonization. Spectra™ MRSA is not intended to diagnose MRSA infection nor to guide or monitor treatment of infection.

2. Indication(s) for use:

Remel Spectra™ MRSA can be used to establish MRSA colonization.

3. Special conditions for use statement(s):

Prescription use

4. Special instrument requirements:

Not applicable

I. Device Description:

Remel Spectra™ MRSA is a selective culture medium that uses chromogenic technology to detect phosphatase activity. Although phosphatase is produced by a wide range of bacteria, including *S. aureus*, non-target organisms are inhibited by a combination of antibiotics and other inhibitory agents contained in the medium.

In addition to nutrients required for growth and other growth promoting compounds, the medium contains several inhibitory agents to reduce or eliminate non-target organisms. Gram negative bacteria and most commonly encountered yeast and molds are eliminated by the inclusion of antibiotics.

J. Substantial Equivalence Information:

1. Predicate device name(s):

BBL™ CHROMagar™ MRSA

2. Predicate K number(s):

k042812

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	For MRSA detection	For MRSA detection
Reporting	MRSA	MRSA
Reading	Manual	Manual
Test Methodology	selective and differential chromogenic prepared culture medium	selective and differential chromogenic prepared culture medium

Differences		
Item	Device	Predicate
Inoculum	Anterior nares culture	Anterior nares
Incubation	24 hours	24 hours, reincubate to 48 hours if negative

K. Standard/Guidance Document Referenced (if applicable):

Not applicable

L. Test Principle:

Remel 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 enhance the production of the MRSA pathogenicity marker, ensuring expression of the phosphatase enzyme and so providing enhanced sensitivity and specificity.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility was demonstrated at four sites using 20 *S. aureus* strains including MRSA, MSSA, and borderline oxacillin-resistant *S. aureus* (BORSA) isolates. Reproducibility was >95%, however, the BORSA strain demonstrated variable results. A limitation has been included in the package insert to address this variability.

b. Linearity/assay reportable range:

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The recommended quality control (QC) organisms, *S. aureus* ATCC 43300 as positive control, and *S. aureus* ATCC 25923 as negative control were used. QC data was compiled across all four sites and all QC results were acceptable.

d. *Detection limit:*

Not applicable

e. *Analytical specificity:*

A Cross Reactivity Study was performed using 280 organisms (MRSA, MSSA, coagulase negative *Staphylococci*, and other organisms). No cross reactivity was observed when these organisms were tested on the Spectra™ MRSA.

Interference Study

Nine commonly used medicinal substances, human blood, mucous, and six types of transport media were evaluated for potential interference of the chromogenic reaction on the Spectra™ MRSA medium. No interference was observed except for human blood which grew pinpoint denim blue colonies.

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

The Remel Spectra™ MRSA was evaluated at four independent trial sites testing 767 prospective anterior nare surveillance specimens. Results from the Remel Spectra™ MRSA at 24 hour incubation were compared to results obtained from traditional culture on Tryptic Soy Agar with 5% sheep Blood (Blood Agar) after 48 hours incubation. Isolates of *S. aureus* were identified using a latex agglutination test or a biochemical identification system. Susceptibility testing of *S. aureus* isolates was performed using an antibiotic gradient method for oxacillin and the Oxoid PBP2' test for detection of the penicillin-binding protein 2a.

Percent agreement with each method as compared to the Remel Spectra™ MRSA is presented in the table below.

Method compared to	% Agreement MRSA	% Agreement MSSA
Traditional Culture	95.2% (100/105) (95% CI = 89.6 – 98.5%)	99.1% (656/662) (95% CI = 98.9 – 100%)
Oxacillin MIC	95.4% (104/109) (95% CI = 89.6 – 98.5%)	99.7% (656/658) (95% CI = 98.9 – 100%)
PBP2'	95.4% (104/109) (95% CI = 89.6 – 98.5%)	99.7% (656/658) (95% CI = 98.9 – 100%)

A challenge set of 20 *S. aureus* isolates which included 15 well-characterized strains of MRSA representing Pulse-Field Types (PFT) USA100, USA200, USA300, USA400, USA500, USA600, USA700, USA800, USA1000, and USA1100; one MRSA, and four MSSA were evaluated on the Remel Spectra™ MRSA and produced expected results.

b. Matrix comparison:

Not Applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable

b. Clinical specificity:

Not Applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not Applicable

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:

Not Applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.