

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

A. 510(k) Number:

k091024

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:

bioMérieux, Inc.

F. Proprietary and Established Names:

chromID™ MRSA Agar

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):

chromID™ MRSA agar 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 is performed on anterior nares swab specimens from patients and healthcare workers to screen for MRSA colonization. chromID™ MRSA agar is not intended to diagnose MRSA infection nor to guide or monitor treatment of infection.

2. Indication(s) for use:

The chromID™ MRSA agar is not intended to diagnose MRSA infection nor to guide or monitor treatment of infection.

3. Special conditions for use statement(s):

Prescription use

4. Special instrument requirements:

Not applicable

I. Device Description:

The chromID™ MRSA agar is translucent and a light tan color. After the plates are inoculated and incubated, colonies growing on the plates will have either a green appearance, which indicates a positive MRSA status or a colorless appearance which indicates a negative MRSA status. The green color is more vivid if the colonies are observed through the agar from the bottom of the plate.

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
Inoculum	Anterior nares specimens	Anterior nares specimens
Test Methodology	selective and differential chromogenic prepared culture medium	selective and differential chromogenic prepared culture medium

Differences		
Item	Device	Predicate
Detection Method	chromID™ contains a chromogenic substrate and a combination of several antibiotics including cefoxitin. The chromogenic substrate provides for the direct detection of MRSA by revealing β-glucosidase activity which produces green colonies (patent registered).	BBL™ CHROMagar™ MRSA contains specific chromogenic substrates and cefoxitin. MRSA strains growing in the presence of these substrates will produce mauve-colored colonies resulting from hydrolysis of the chromogenic substrate
Incubation	24 hours at 35 - 37°C in aerobic conditions	24 - 48 hours in 33 - 37° C in aerobic conditions

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

Not applicable

L. Test Principle:

The chromID™ MRSA agar consists of a rich nutritive base combining different peptones. It also contains a chromogenic substrate of α -glucosidase and a combination of several antibiotics including ceftiofur, which favor

- the growth of methicillin-resistant *staphylococci* (MRSA) including hetero-resistant strains,
- the direct detection of MRSA strains by revealing α -glucosidase (patent registered): green colonies

The selective mixture inhibits most bacteria not belonging to the genus *Staphylococcus*, as well as yeasts.

The MRSA strains are identified by the presence of green colonies that result from the chromogen incorporated in the medium. The chromogen targets the α -glucosidase activity of *S. aureus*. The α -glucosidase produced by *S. aureus* cleaves the chromogenic substrate, which gives a green color to the *S. aureus* colonies growing on the medium.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Reproducibility was demonstrated at three sites using 10 *S. aureus* strains including MRSA, MSSA, and borderline oxacillin-resistant *S. aureus* (BORSA) isolates. Reproducibility was >95%. The BORSA strain demonstrated a negative result.

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. Quality control data was compiled across all three sites and all QC results were acceptable.

QC Data summary at 24 hours

Organism	PCR Result	cMRSA Positive	cMRSA Negative
<i>S. aureus</i> ATCC® 29213 – <i>mecA</i> negative Expected Result: Neg	Neg	0	Neg
<i>S. aureus</i> ATCC® 43300 – <i>mecA</i> positive Expected Results : Pos	Pos	Pos	0

d. *Detection limit:*

Not applicable

e. *Analytical specificity:*

Cross Reactivity

Cross Reactivity Study was initially performed on 76 isolates during the development of the media in 2004. In 2009, 34 additional strains were tested. Certain organisms other than *S. aureus*, i.e. *Acinetobacter baumannii*, *Bacillus cereus*, *Enterobacter cloacae*, *Pseudomonas aeruginosa*, *Pseudomonas putida*, *Staphylococcus haemolyticus*, *Staphylococcus epidermidis*, and *Micrococcus* spp. showed growth at 24 hours but did not produce green pigmented colonies. Certain ESBL producers with heavy inoculum gave characteristic green color at the point of inoculation after 24 hours of incubation.

Interference Study

The human blood and mucin do not demonstrate interference with the chromID™MRSA agar. The medicines that contain antiseptic agents (benzalkonium chloride, phenyl ethylic alcohol, sodium edetate, chlorhexidine gluconate, amylmetacresol, menthol, bismuth) demonstrated an effect on the growth and on the color of the agar in comparison to the control.

Interference study was also performed on transport media i.e., Amies Gel Medium, Liquid Amies Medium, Stuart Gel Medium, Liquid Stuart Medium, and Cary-Blair Transport Media. The transport media tested did not affect the characteristics of chromID MRSA medium.

Expression of Resistance

Ten well-characterized *S. aureus ssp. aureus* strains having low level resistance to methicillin were evaluated with chromID™ MRSA. These strains were detected when the oxacillin MIC is equal to or greater than 2 mg/l. MRSA strains with an oxacillin MIC less than or equal to 1 mg/l may be not detected when the inoculum is very low.

f. Analytical sensitivity

Recovery study

Recovery study was performed using one strain of *S. aureus* (MRSA) ATCC 43300. The lowest number of CFU that can be detected on chromID MRSA is equivalent to 10 CFU per 100µL of sample.

g. Assay cut-off:

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

The performance of the chromID™ MRSA agar was evaluated at three sites using 1260 nasal swab specimens. Results from the chromID™ MRSA at 24 hour incubation were compared to results obtained from traditional culture on Tryptic Soy Agar with 5% sheep Blood (Blood Agar) after 24 hour incubation. Isolates of *S. aureus* were identified as MRSA using latex agglutination and cefoxitin screen.

Percent agreement to the Cefoxitin Disk Diffusion Test (30µg) as compared to the chromID™ MRSA agar is presented in the table below.

	TSAB Cefoxitin Disk Diffusion Test (30µg) 24h		
	Pos	Neg	Total
chromID™ MRSA Result in 24h			
Pos	277	*27	304
Neg	17	938	955
Total	294	965	1259

*27/27 of the TSAB negative specimens were confirmed as MRSA positive by cefoxitin disk diffusion.

Positive Percent Agreement: 94.22% (90.90%, 96.60%)

Negative Percent Agreement: 97.20% (95.96%, 98.15%)

Positive Predictive Value: 91.12% (87.34%, 94.07%)

Negative Predictive Value: 98.22% (97.17%, 98.96%)

A challenge set of 20 well characterized *S. aureus* isolates were tested at one external site. The challenge isolates included 14 *mecA* positive of which ten came from the Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) and four additional MRSA strains, five *mecA* negative methicillin-susceptible *S. aureus* (MSSA), and one borderline oxacillin resistant *S. aureus* (BORSA). All isolates showed expected results except for the USA600 strain from NARSA. This specific strain demonstrated pinpoint pale green colonies after 24 hours incubation.

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.

