



BBL™ CHROMagar™ MRSA II*

INTENDED USE

BBL™ CHROMagar™ MRSA II (CMRSAII) is a selective and differential medium for the qualitative direct detection of methicillin-resistant *Staphylococcus aureus* (MRSA) from clinical specimens. The test can be performed on respiratory, lower gastrointestinal (= GI), skin and wound specimens, on anterior nares specimens for the screening of nasal colonization to aid in the prevention and control of MRSA infections in healthcare settings and on positive blood culture bottles containing gram-positive cocci.

SUMMARY AND EXPLANATION

MRSA is a major cause of nosocomial and life threatening infections. MRSA infections have been associated with a significantly higher morbidity, mortality and cost compared to methicillin-susceptible *S. aureus* (MSSA) infections.¹ Selection of these organisms has been greatest in the healthcare setting; however, MRSA has also become more prevalent in the community.^{2,3}

To control the transmission of MRSA, the Society for Healthcare Epidemiology of America (SHEA) has published guidelines, which include an active surveillance program to identify potential reservoirs and a rigorous infection control program to control the spread of MRSA.¹

BBL CHROMagar MRSA II is a selective and differential medium, which incorporates ceftiofur for the detection of MRSA from respiratory (e.g., nares, throat and sputum), lower GI (e.g., rectal and stool), skin (e.g., groin/axilla and perineum/perianal), and wound specimens, and positive blood culture bottles containing gram-positive cocci.

BBL CHROMagar MRSA II is a modified version of the existing formulation of CHROMagar MRSA developed by A. Rambach and BD and is sold by BD under a licensing agreement with CHROMagar, Paris, France.

PRINCIPLES OF THE PROCEDURE

Microbiological Method

BBL CHROMagar MRSA II medium permits the direct detection and identification of MRSA through the incorporation of specific chromogenic substrates and ceftiofur. MRSA strains will grow in the presence of ceftiofur⁴ and produce mauve colonies resulting from hydrolysis of the chromogenic substrate. Additional selective agents are incorporated for the suppression of gram-negative organisms, yeast and some other gram-positive cocci. Bacteria other than MRSA may utilize other chromogenic substrates in the medium resulting in blue to blue/green colored colonies or if no chromogenic substrates are utilized, the colonies appear as white or colorless.

*European, U.S. & Canadian Patents Pending

REAGENTS

BBL CHROMagar MRSA II

Approximate Formula* Per Liter Purified Water

Chromopeptone	35.0 g
Chromogen Mix	0.5 g
Sodium Chloride	17.5 g
Inhibitory Agents	7.52 g
Cefoxitin	5.2 mg
Agar	14.0 g

pH: 7.0 +/- 0.2 at 25°C

*Adjusted and/or supplemented as required to meet performance criteria.

WARNINGS AND PRECAUTIONS

IVD

For professional use only. ⓧ

Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus may be present in clinical specimens. "Standard Precautions"⁵⁻⁸ and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids. After use, prepared plates, specimen containers, and other contaminated materials must be sterilized by autoclaving before discarding. For details, consult **GENERAL INSTRUCTIONS FOR USE** document.

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

Before using **BBL CHROMagar MRSA II** for the first time, training on the typical colony appearance of MRSA with defined strains; i.e., the strains mentioned under **USER QUALITY CONTROL**, is recommended.

STORAGE AND SHELF LIFE

On receipt, store plates in their original wrapping and box at 2-8°C until time of inoculation. Minimize exposure (< 4h) of **BBL CHROMagar MRSA II** to light both before and during incubation, as prolonged exposure may result in reduced recovery and/or coloration of isolates. Avoid freezing and overheating. The plates may be inoculated up to the expiration date (see plate imprint or package label) and incubated for the recommended incubation times. Plates from opened stacks of 10 plates can be used for one week when stored in a clean area at 2-8°C in the dark.

USER QUALITY CONTROL*

Examine plates for signs of deterioration as described under "Product Deterioration".

Check performance by inoculating representative samples with dilutions of the cultures as described below:

1. Streak plates for isolation. For *Staphylococcus aureus* ATCC™ 29213 and *Staphylococcus aureus* ATCC 43300, use direct inoculation.⁹
2. Incubate plates at 35-37°C in an aerobic atmosphere.
3. Include Columbia Agar with 5% Sheep Blood plates as nonselective controls for all organisms.
4. Examine plates after 20-26 h for recovery, colony size and color. See Table for expected results:

Test Strain	Expected Results
<i>Staphylococcus aureus</i> ATCC™ 43300 (MRSA)	Growth of mauve colonies
<i>Staphylococcus aureus</i> ATCC™ 29213 (MSSA)	No growth

* Quality control requirements must be performed in accordance with applicable local, state, federal or country regulations, accreditation requirements, and/or your laboratory's standard quality control procedures. The user may refer to CLSI guidance for appropriate quality control practices.

PROCEDURE

Materials Provided

BBL CHROMagar MRSA II (90 mm **Stacker™** plates). Microbiologically controlled.

Materials Required But Not Provided

Confirmatory test such as coagulase or *Staphylococcus* latex agglutination (e.g., **Staphyloslide™**) test reagents, quality control organisms, ancillary culture media and other laboratory equipment as required.

Specimen Types

The medium can be used for respiratory (e.g., throat, and sputum), lower GI (e.g., rectal and stool), skin (e.g., groin/axilla and perineum/perianal), nares and wound specimens, and positive blood culture bottles containing gram-positive cocci.

Specimen Collection and Handling

Use of transport devices approved for the collection of microbiological clinical specimens is recommended. Follow the transport device manufacturer's recommended procedures.

The user may also refer to appropriate texts for details of specimen collection and handling procedures.^{10, 11}

Test Procedure

Observe aseptic techniques. The agar surface should be smooth and moist, but without excessive moisture. Allow the medium to warm to room temperature before inoculation.

- **Anterior nares specimens:** As soon as possible after receipt in the laboratory, inoculate the specimen onto a **BBL CHROMagar MRSA II** plate and streak for isolation. Incubate plates aerobically at 35-37°C for 20-26 h in an inverted position.
- **Positive blood culture bottles containing gram-positive cocci:** As soon as the blood culture bottle is designated as positive and the Gram stain confirms the presence of gram-positive cocci, remove an aliquot, inoculate a **BBL CHROMagar MRSA II** plate and streak for isolation. Incubate plates aerobically at 35-37°C for 18-28 h in an inverted position. Incubation beyond 18-28 h is not required.
- **All other specimens (throat, sputum, lower GI, skin and wound specimens):** As soon as possible after receipt in the laboratory, inoculate a **BBL CHROMagar MRSA II** plate and streak for isolation. Incubate plates aerobically at 35-37°C for 18-28 h in an inverted position. If no mauve colonies are recovered, reincubate for a total of 36-52 h.

Do not incubate in an atmosphere supplemented with carbon dioxide. Minimize exposure (<4 h) of **BBL CHROMagar MRSA II** to light both before and during incubation, as prolonged exposure may result in reduced recovery and/or coloration of isolates. Exposure to light is permissible after colony color develops.

RESULTS

After the appropriate incubation, read plates against a white background. Colonies of MRSA will appear mauve on the **BBL CHROMagar MRSA II** medium. Other organisms (non-MRSA) will be inhibited or produce blue to blue/green, white or colorless colonies. Refer to Tables 1 - 3 for interpretation of results.

Table 1: Interpretation of results for anterior nares specimens

20-26 h Incubation	Interpretation/Recommended Action
Mauve colonies morphologically resembling staphylococci*	Positive - MRSA detected
Non-mauve colonies detected	Negative - No MRSA detected
No growth	Negative - No MRSA detected

* See LIMITATIONS OF THE PROCEDURE

Table 2: Interpretation of results for positive blood culture bottles containing gram-positive cocci

18-28 h Incubation	Interpretation/Recommended Action
Mauve colonies morphologically resembling staphylococci*	Positive - MRSA detected
No mauve colonies	Negative - No MRSA detected

* See LIMITATIONS OF THE PROCEDURE

Table 3: Interpretation of results for throat, sputum, lower GI, skin and wound specimens

18-28 h Incubation	Interpretation/Recommended Action	
Mauve colonies morphologically resembling staphylococci*	MRSA detected	
No mauve colonies	Reincubate for additional 18 to 24 h to achieve a total incubation time of 36 – 52 hours)	
36-52 h Incubation	Recommended Action	Interpretation
Mauve colonies*	Perform direct confirmatory test (e.g., coagulase or <i>Staphylococcus</i> latex agglutination)	If coagulase or <i>Staphylococcus</i> latex agglutination positive – MRSA detected If coagulase or <i>Staphylococcus</i> latex agglutination negative – No MRSA detected
No mauve colonies	N/A	No MRSA detected

* See LIMITATIONS OF THE PROCEDURE

N/A= not applicable

EXPECTED VALUES

The prevalence of MRSA infection has increased dramatically in medical institutional settings, and the carriage rate of MRSA is rising in the community. Recent publications suggest that *S. aureus* related hospitalizations have increased 62% and the estimated number of methicillin - resistant *S. aureus* hospitalizations more than doubled from 1999 through 2005.¹² Data from the NNIS (National Nosocomial Infections Surveillance System) indicate that in the intensive care patient setting, the proportion of MRSA among *S. aureus* infections has increased to 59.5-64.4%. Dramatic increases in the incidence of soft tissue and skin infections were found, suggesting community-associated MRSA is spreading in hospitals.^{12, 13}

PERFORMANCE CHARACTERISTICS

BBL™ CHROMagar™ MRSA II is a selective and differential medium for the qualitative direct detection of methicillin-resistant *Staphylococcus aureus* (MRSA) from clinical specimens. The test can be performed on respiratory, lower gastrointestinal (GI), skin and wound specimens after 18 to 52 hours incubation. The test can also be performed on anterior nares specimens for the screening of nasal colonization to aid in the prevention and control of MRSA infections in healthcare settings after 20 to 26 hours incubation, and on positive blood culture bottles containing gram-positive cocci after 18 to 28 hours incubation.

External Performance Evaluations

Two external performance evaluations were conducted:

- In the first evaluation, **BBL CHROMagar MRSA II** was evaluated at four diverse clinical laboratories with remnant, prospective respiratory (e.g., nares, throat, and sputum), lower GI (e.g., rectal and stool), skin (e.g., groin/axilla and perineum/perianal) and wound specimens, and positive blood culture bottles containing gram-positive cocci (Tables 4 and 5).¹⁴

Specimens were evaluated by comparing the recovery of MRSA on traditional culture media (e.g., Tryptic Soy Agar with 5% Sheep Blood, Columbia Agar with 5% Sheep Blood, or CNA (colistin nalidixic acid agar), depending upon specimen types) and **BBL CHROMagar MRSA II** plates. *S. aureus* recovered on the traditional culture media were tested by the cefoxitin disk diffusion test method. Cefoxitin disk diffusion test results followed CLSI interpretive criteria for the determination of methicillin resistance (R) and methicillin susceptibility (S), ($R \leq 21\text{mm}$ and $S \geq 22\text{ mm}$).^{4, 15} **BBL CHROMagar MRSA II** was interpreted as positive for MRSA at 18-28 h based on detection of mauve colonies or at 36 - 52 h based on detection of mauve colonies with confirmation as *S. aureus*.

The overall prevalence of MRSA from **BBL CHROMagar MRSA II** was 15% (778/5051), or about 65.6% (778/1186) of all *S. aureus*. For the traditional culture plate (e.g., Tryptic Soy Agar with 5% Sheep Blood, Columbia Agar with 5% Sheep Blood, and CNA) the MRSA recovery rate was 79.8% (621/778), while for **BBL CHROMagar MRSA II**, the MRSA recovery rate was 95.6% (744/778).

Table 4 MRSA Recovery: BBL CHROMagar MRSA II vs. Traditional Culture

		MRSA Recovery	
Specimen Category	Read Time ¹⁾	Traditional Culture	CMRSaII
Respiratory	24 h	79.8% (182/228)	85.5% (195/228)
	48 h	76.8% (182/237)	92.4% (219/237)
Lower GI	24 h	86.9% (93/107)	87.9% (94/107)
	48 h	77.5% (93/120)	98.3% (118/120)
Skin	24 h	68.6% (118/172)	88.4% (152/172)
	48 h	66.3% (118/178)	96.1% (171/178)
Wound	24 h	90.6% (115/127)	92.1% (117/127)
	48 h	88.5% (115/130)	94.6% (123/130)
Blood Culture ²⁾	24 h	100% (113/113)	100% (113/113)
Combined ³⁾	24 h	83.1% (621/747)	89.8% (671/747)
	48 h	79.8% (621/778)	95.6% (744/778)

¹⁾ 24 h represents a read range of 18-28 h with no confirmatory testing required and 48 h read range is 36-52 h with confirmatory testing.

²⁾ Positive blood culture containing gram-positive cocci

³⁾ Includes all specimen types (respiratory, lower GI, skin, wound and blood culture)

Table 5: BBL CHROMagar MRSA II Performance vs. Traditional Culture and Cefoxitin Disk by Specimen Type

Specimen Category	Read Time ¹⁾	Cefoxitin Disk	
		Sensitivity (95% CI)*	Specificity (95% CI)*
Respiratory	24 h	85.5% (195/228) (80.3%,89.8%)	99.8% (1216/1218) (99.4%,100%)
	48 h	92.4% (219/237) (88.3%,95.4%)	99.8% (1207/1209) (99.4%,100%)
Lower GI	24 h	87.9% (94/107) (80.1%,93.4%)	100% (587/587) (99.4%,100%)
	48 h	98.3% (118/120) (94.1%,99.8%)	100% (574/574) (99.4%,100%)
Skin	24 h	88.4% (152/172) (82.6%,92.8%)	100% (1103/1103) (99.7%,100%)
	48 h	96.1% (171/178) (92.1%,98.4%)	100% (1097/1097) (99.7%,100%)
Wound	24 h	92.1% (117/127) (86%,96.2%)	100% (821/821) (99.6%,100%)
	48 h	94.6% (123/130) (89.2%,97.8%)	100% (818/818) (99.6%,100%)
Blood Culture ²⁾	24 h	100% (113/113) (96.8%,100%)	100% (575/575) (99.4%,100%)
Combined ³⁾	24 h	89.8% (671/747) (87.4%,91.9%)	100% (4302/4304) (99.8%,100%)
	48 h	95.6% (744/778) (93.9%,97%)	100% (4271/4273) (99.8%,100%)

* CI= confidence interval

¹⁾ 24 h represents a read range of 18-28 h with no confirmatory testing required and 48 h read range is 36- 52 h with confirmatory testing.

²⁾ Positive blood culture containing gram positive cocci

³⁾ Includes all specimen types (respiratory, lower GI, skin, wound and blood culture)

Respiratory specimens:

A total of 1446 respiratory specimens were evaluated comparing the recovery of MRSA on traditional culture plates to **BBL CHROMagar MRSA II** plates. Overall recovery of MRSA on **BBL CHROMagar MRSA II** was higher at 92.4% (219/237), compared to a recovery of 76.8% (182/237) on traditional culture plates at 48 h. At the 18-28 h reading, two false positives were observed on **BBL CHROMagar MRSA II**, for a specificity of 99.8% (1216/1218). Using colony color at the 18-28 h reading for **BBL CHROMagar MRSA II**, and confirming all mauve colonies with a confirmatory test at the 36-52 h reading, the overall agreement of **BBL CHROMagar MRSA II** compared to the cefoxitin disk diffusion test for respiratory specimens was 98.6% (1426/1446).

Lower GI specimens:

A total of 694 lower GI specimens were evaluated comparing the recovery of MRSA on traditional culture plates to **BBL CHROMagar MRSA II** plates. Overall recovery of MRSA on **BBL CHROMagar MRSA II** was higher at 98.3% (118/120) compared to a recovery of

77.5% (93/120) on traditional culture plates at 48 h. There were no false positive specimens observed on **BBL CHROMagar MRSA II**. Using colony color at the 18-28 h reading for **BBL CHROMagar MRSA II** and confirming all mauve colonies with a confirmatory test at the 36-52 h reading, the overall agreement of **BBL CHROMagar MRSA II** compared to the ceftiofur disk diffusion test for lower GI specimens was 99.7% (692/694).

Skin specimens:

A total of 1275 skin specimens were evaluated comparing the recovery of MRSA on traditional culture plates to **BBL CHROMagar MRSA II** plates. Overall recovery of MRSA on **BBL CHROMagar MRSA II** was higher at 96.1% (171/178) compared to a recovery of 66.3% (118/178) on traditional culture plates at 48 h. There were no false positive specimens observed on **BBL CHROMagar MRSA II**. Using colony color at the 18-28 h reading for **BBL CHROMagar MRSA II**, and confirming all mauve colonies with confirmatory testing at the 36-52 h reading, the overall agreement of **BBL CHROMagar MRSA II** compared to the ceftiofur disk diffusion test for skin specimens was 99.5% (1268/1275).

Wound specimens:

A total of 948 wound specimens were evaluated comparing the recovery of MRSA on traditional culture plates to **BBL CHROMagar MRSA II** plates. Overall recovery of MRSA on **BBL CHROMagar MRSA II** was higher at 94.6% (123/130) compared to a recovery of 88.5% (115/130) on traditional culture plates at 48 h. There were no false positives observed on **BBL CHROMagar MRSA II**. Using colony color at the 18-28 h reading for **BBL CHROMagar MRSA II**, and confirming all mauve colonies with confirmatory testing at the 36-52 h reading, the overall agreement of **BBL CHROMagar MRSA II** compared to the ceftiofur disk diffusion test for wound specimens was 99.3% (941/948).

Positive blood culture bottles containing gram-positive cocci:

A total of 688 positive blood culture bottles containing gram-positive cocci were evaluated comparing the recovery of MRSA on traditional culture plates to **BBL CHROMagar MRSA II** plates. Overall recovery of MRSA on **BBL CHROMagar MRSA II** and traditional culture plates was equivalent at 100% (113/113) at 18-28 h. There were no false positives observed on **BBL CHROMagar MRSA II**. Using colony color at the 18-28 h reading for **BBL CHROMagar MRSA II**, the overall agreement of **BBL CHROMagar MRSA II** compared to the ceftiofur disk diffusion test for positive blood culture bottles was 100% (688/688).

Combined specimen types:

A combined overall total of 5051 specimens were evaluated comparing the recovery of MRSA on traditional culture plates to **BBL CHROMagar MRSA II** plates. Overall recovery of MRSA on **BBL CHROMagar MRSA II** was higher at 95.6% (744/778) compared to a recovery of 79.8% (621/778) on traditional culture plates for all specimen types combined (respiratory, lower GI, skin, wound and positive blood culture bottles containing gram-positive cocci). At the 18-28 h reading, there were 2 false positive mauve colonies observed on **BBL CHROMagar MRSA II**, for a specificity of 99.9% (4271/4273). Using colony color at the 18-28 h reading for **BBL CHROMagar MRSA II**, and confirming all mauve colonies with confirmatory testing at the 36-52 h reading, the combined overall agreement of **BBL CHROMagar MRSA II** compared to the ceftiofur disk diffusion test for all specimen types was 99.3% (5015/5051).

Challenge Testing

Testing of twenty (20) challenge strains of *S. aureus* was conducted at three clinical sites. The panel included 14 MRSA and 6 MSSA. Individual sites and combined site agreements were 100%.

- In the second evaluation, **BBL CHROMagar MRSA II** was evaluated at three geographically diverse clinical laboratories with surveillance specimens of the anterior nares. Specimens were evaluated by comparing the recovery of MRSA on Trypticase Soy Agar with 5% Sheep Blood (TSA II) plates and each site's routine procedure for identification of *S. aureus* (traditional culture) to **BBL CHROMagar MRSA II** plates. (The routine procedure for two sites included staphylococcal latex agglutination testing and the third site included coagulase testing. All *S. aureus* recovered were tested for *mec-A* mediated oxacillin resistance by the cefoxitin disk diffusion test.) Cefoxitin disk (30µg) diffusion test results followed CLSI methods and interpretive criteria.^{4, 15} **BBL CHROMagar MRSA II** was interpreted as positive for MRSA at 20-26 h based on detection of mauve colonies.

From both external evaluations, 1613 compliant anterior nares specimens were evaluated in total, comparing the recovery of MRSA on traditional culture plates to **BBL CHROMagar MRSA II** plates after 20 to 26 h incubation (Table 6). The positive percent agreement and negative percent agreement of **BBL CHROMagar MRSA II** at 20-26h to traditional culture was 87.9% and 98.6%, respectively. The sensitivity and specificity compared to the cefoxitin disk diffusion test was 88.8 and 99.8%, respectively.

Table 6: BBL CHROMagar MRSA II Performance vs. Traditional Culture and Cefoxitin Disk for Nares Specimens

Traditional culture			
Specimen Type	Read Time	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
Nares	24 h ¹	87.9% (181/206) (82.6%, 92.0%)	98.6% (1387/1407) (97.8%, 99.1%)

Cefoxitin disk diffusion test (CLSI)			
Specimen Type	Read Time	Sensitivity (95% CI)	Specificity (95% CI)
Nares	24 h ¹	88.8% (198/223) (83.9%, 92.6%)	99.8% (1387/1390) (99.4%, 100%)

¹24 h represents a read range of 20-26 h with no confirmatory testing required

Internal Performance Evaluation

Limits of Detection (LOD)

BBL CHROMagar MRSA II was evaluated to determine the limit of detection (LOD) of methicillin-resistant *S. aureus* recovery. Four test strains; representing two heterogeneous and two homogeneous MRSA were evaluated for recovery on **BBL CHROMagar MRSA II**.¹⁶ Non-selective Columbia Agar with 5% Sheep blood plates were used to determine the organism concentration expressed in colony forming units (CFU) for each dilution. The LOD for **BBL CHROMagar MRSA II** ranged from 4-116 CFU at 24 h and 4-24 CFU at 48 h¹⁷.

Interference Study

A total of 30 substances including commonly used medicinal substances, transport devices, enrichment broth, and blood culture media were evaluated for potential interference and inhibition of MRSA on **BBL CHROMagar MRSA II**. Some mouthwash, throat drops, acetylsalicylic acid, personal lubricants and ibuprofen may reduce recovery of MRSA. Nasal sprays containing fluticasone propionate, azelastine hydrochloride, phenylephrine hydrochloride and oxymetazoline hydrochloride as well as OTC throat drops containing menthol demonstrated antibacterial activity.

No other substances, devices or media tested interfered with recovery of MRSA on **BBL CHROMagar MRSA II**.¹⁷

LIMITATIONS OF THE PROCEDURE

- Minimize exposure of **BBL CHROMagar MRSA II** to light (<4 h) both before and during incubation, as prolonged exposure may result in reduced recovery and/or coloration of isolates.
- Incubation in CO₂ is not recommended and may result in false negative cultures.
- Incubation time beyond 36 - 52 h is not recommended.
- For anterior nares specimens, performance of **BBL CHROMagar MRSA II** has been optimized for incubation for 20-26 h at 35-37°C. Lower incubation temperatures (<35° C) and/or shorter incubation times (<20 h) may reduce the sensitivity of **BBL CHROMagar MRSA II**. Note that frequent opening of incubator doors may reduce the incubator temperature. It is therefore recommended to reduce opening of the incubator doors to a minimum and to keep the opening periods as short as possible.
- After 24 h or longer incubation, some strains of *Chryseobacterium meningosepticum*, *Corynebacterium jeikeium*, *Enterococcus faecalis* (VRE), *Rhodococcus equi*, and *Bacillus cereus* may produce mauve-colored colonies. If desired, a gram stain may be performed.
- After 24 h or longer incubation, *Staphylococcus simulans*, *S. epidermidis*, and methicillin-susceptible *Staphylococcus aureus* rarely may also produce mauve-colored colonies. If MRSA is not suspected, a coagulase test and antimicrobial susceptibility test (AST) may be performed.
- Rare strains of MRSA have demonstrated sensitivity to the **BBL CHROMagar MRSA II** base. This sensitivity is unrelated to methicillin resistance, but is due to a component in the base. As a result, these strains may appear as falsely susceptible to methicillin.
- There exist rare strains of MRSA that may produce non-mauve colonies on **BBL CHROMagar MRSA II**. If MRSA is suspected, subculture non-mauve colonies for further identification and susceptibility testing as necessary.
- A heavy bacterial load and/or some specimens may produce nonspecific coloring of the primary quadrant of the medium. This could result in the medium exhibiting mauve, purple, green or blue coloration or a slight haze on top of the medium, but lacking distinct colonies. Non-specific coloring of the medium should be interpreted as negative.
- *mecA*-negative *S. aureus* may grow if the oxacillin or ceftiofur MICs are at or near the resistant breakpoint.
- Resistance mechanisms other than *mecA* (i.e. borderline oxacillin-resistant *Staphylococcus aureus*-BORSA, and modified *Staphylococcus aureus*-MODSA), have not been extensively evaluated with the CMRSA II, therefore the performance of CMRSA II with such resistance mechanisms is unknown.
- Because the isolation of MRSA is dependent on the number of organisms present in the sample, reliable results are dependent on proper specimen collection, handling, and storage.
- A single negative result should not be used as the sole basis for diagnosis, treatment, or management decisions. Concomitant cultures may be necessary for organism identification, susceptibility testing or epidemiological typing.

Before using **BBL CHROMagar MRSA II** for the first time, training on the typical colony appearance of MRSA with defined strains; e.g., the strains mentioned under **User Quality Control**, is recommended.

AVAILABILITY

REF 257434 **BBL™ CHROMagar™ MRSA II** Ready-to-use Plated Media, cpu 20

REF 257435 **BBL™ CHROMagar™ MRSA II** Ready-to-use Plated Media, cpu 120

REFERENCES

1. Calfee, D. P., C. D. Salgado, D. Classen, K.M. Arias, K. Podgorny, D.J. Anderson, H. Burstin, S. E. Coffin, E. R. Dubberke, V. Fraser, D. N. Gerding, F. A. Griffin, P. Gross, K.S. Kaye, M. Klompas, E. Lo, J. Marschall, L. A. Mermel, L. Nicolle, D. A. Pegues, T. M. Perl, S. Saint, R. A. Weinstein, R. Wise, D. S. Yokoe. 2008. Supplement Article: SHEA/ IDSA Practice Recommendation Strategies to prevent Transmission of Methicillin-Resistant *Staphylococcus aureus* in Acute Care Hospitals. Infect. Control and Hospital Epidemiol. Oct: 29: supplement 1, 62-80.
2. Bannerman, T. L, and S. J. Peacock. 2007. *Staphylococcus, Micrococcus*, and other catalase-positive cocci. In P.R. Murray, E.J. Baron, J.H. Jorgensen, M. L. Landry and M.A. Pfaller (eds.), Manual of clinical microbiology, 9th ed. ASM, Washington DC.
3. Klein E., D. A. Smith, and R. Lazminarayan. 2007. Hospitalizations and deaths caused by methicillin-resistant *Staphylococcus aureus*, United States, 1999-2005. Emerging Infectious Diseases, (12) CDC website, <http://www.cdc.gov/ncidod>
4. Clinical and Laboratory Standards Institute. 2008. Performance standards for antimicrobial susceptibility testing; Eighteenth Informational Supplement, M100-S18. CLSI, Wayne, PA.
5. Clinical and Laboratory Standards Institute. 2005. Approved Guideline M29-A3. Protection of laboratory workers from occupationally acquired infections, 3rd ed., CLSI, Wayne, PA.
6. The Public Health Services, US Department of Health and Human Services, Centers for Disease Control and Prevention. Guideline for isolation precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007. CDC website, <http://www.cdc.gov/ncidod/dhqp/gl>.
7. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health. 2007. Biosafety in microbiological and biomedical laboratories (BMBL) 5th ed. U.S. Government Printing Office, Washington, DC. CDC website, <http://www.cdc.gov/print.do?url=http%3A/www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl15toc>
8. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC). Official Journal L262, 17/10/2000, p. 0021-0045.
9. Clinical and Laboratory Standards Institute. 2004. Approved Standard M22-A3. Quality control for commercially prepared microbiological culture media, 3rd ed., CLSI, Wayne, PA.
10. Linscott, A.J. 2007. Specimen collection and transport. In L.S. Gracia, and H.D. Isenberg, (eds.), Clinical microbiology procedures handbook, 2nd ed. ASM, Washington DC.
11. Miller, J.M., K. Krisner, and H.T. Holmes. 2007. General principles of specimen collection and handling. In P.R. Murray, E.J. Baron, J.H. Jorgensen, M.L. Landry and M.A. Pfaller (eds.), Manual of clinical microbiology. 9th ed., ASM, Washington DC.
12. Huckabee C.M., W.C. Huskins, and P.R. Murray. 2009. Predicting Clearance of Colonization with Vancomycin- Resistant Enterococci and Methicillin-Resistant *Staphylococcus aureus* by use of weekly surveillance cultures. J. Clin. Microbiol., 47: 1229-1230.
13. Kleven R. M., M. A. Morrison, and J. Nadle et al. Invasive methicillin-resistant *Staphylococcus aureus* infections in the US. JAMA, 298 (15) 1763-1771 (summary on MRSA – Methicillin Resistant *Staphylococcus aureus*: Fact Sheet. CDC website, <http://www.cdc.gov/ncidod/hip/Aresist/mrsaFAQ.htm>.)
14. Wendt C., N. L. Havill, and K. C. Chapin et al. Evaluation of a new selective medium, BD BBL CHROMagar MRSA II, for detection of methicillin-resistant *Staphylococcus aureus* in different specimens. J. Clin. Microbiol., 48: 2223-2227.
15. Clinical and Laboratory Standards Institute. 2006. Approved Standard M2-A9. Performance standards for antimicrobial disk susceptibility tests, 9th ed., CLSI, Wayne, PA.
16. Tomasz A., S. Nachman, and H. Leah 1991. Stable classes of phenotypic expression in methicillin resistant clinical isolates of staphylococci. Antimicro. Agents Chemother, 35:124-129.
17. Data on file, BD Diagnostics.

FURTHER INFORMATION

For further information please contact your local BD representative.



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