510(k) SUMMARY

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AUG 2 0 2010

CONTACT NAME: Paul Swift, Regulatory Affairs Specialist

DATE PREPARED: August 12, 2010

DEVICE TRADE NAME: BBL™ CHROMagar™ MRSA II

DEVICE COMMON NAME: Culture Medium

DEVICE CLASSIFICATION: 21 CFR§866.1700, Class II

PREDICATE DEVICES: BBL™ CHROMagar™ MRSA (K042812)
BBL™ Oxacillin Screen Agar (K863821)

INTENDED USE:

BBL™ CHROMagar™ MRSA II is a selective and differential chromogenic medium for the qualitative direct detection of nasal colonization by 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 to screen for MRSA colonization.

BBL CHROMagar MRSA II is not intended to diagnose, guide or monitor treatment for MRSA infections. A negative result does not preclude MRSA nasal colonization. Concomitant cultures are necessary for organism identification, susceptibility testing or epidemiological typing.

DEVICE DESCRIPTION:

BBL™ CHROMagar™ MRSA II (CMRSA II) permits the direct detection and identification of MRSA through the incorporation of specific chromogenic substrates and cefoxitin. MRSA strains will grow in the presence of cefoxitin[1] and produce mauve-colored colonies resulting from hydrolysis of the chromogenic substrate. Selective agents are incorporated for the suppression of gram-negative organisms, yeast and enterococci and some other gram-positive cocci. Bacteria other than MRSA may utilize other

[1] Clinical and Laboratory Standards Institute. 2009. Performance Standards for Antimicrobial Susceptibility Testing; Nineteenth Informational Supplement, M100-S19. Clinical and Laboratory Standards Institute, Wayne, PA.

chromogenic substrates in the medium resulting in the growth of colonies that are not mauve.

DEVICE COMPARISON:

The BBL™ CHROMagar™ MRSA II (CMRSA II) differs from the BBL CHROMagar MRSA (CMRSA) (K042812) in the following ways:

- CMRSA II detects and identifies MRSA within 20-26 hours; whereas, CMRSA detects and identifies MRSA at 24 ± 4 hours to 48 ± 4 hours.

The BBL™ CHROMagar™ MRSA II differs from the BBL™ Oxacillin Screen Agar (OSA) (K863821) in the following ways:

- CMRSA II is selective and differential culture medium for antimicrobial susceptibility testing of MRSA, whereas, OSA is a selective culture medium for antimicrobial susceptibility testing of MRSA.

- CMRSA II is intended to identify MRSA from nares specimens; whereas, OSA is cleared for the identification of MRSA from pure clinical isolates that were identified as *Staphylococcus aureus*.

- CMRSA II utilizes direct inoculation from specimen collection devices. OSA utilizes indirect inoculation from a broth suspension of pure *S. aureus* colonies isolated from18-24 hour culture.

- CMRSA II utilizes cefoxitin as a selective agent to differentiate MRSA from methicillin-susceptible *S. aureus* and other organisms; whereas, OSA utilizes oxacillin as a selective agent to identify MRSA from a pure *S. aureus* culture.

- CMRSA II utilizes chromogenic substances to facilitate the differentiation of MRSA from MSSA and other organisms; whereas, OSA does not contain chromogenic substances to differentiate growth on the plate.

- CMRSA II produces mauve colonies as an indicator of MRSA; whereas, any colony growth seen on OSA is an indicator of MRSA.

- CMRSA II detects and identifies MRSA in 20-26 hours; whereas, OSA identifies MRSA in 24 hours.

- CMRSA II utilizes incubation conditions at a temperature of 35-37°C; whereas, OSA utilizes incubation conditions at temperature of 30-35°C.

SUMMARY OF PERFORMANCE DATA:

Analytical Studies:

Interfering Substances
Commonly used transport devices, nasal spray and whole blood were evaluated for potential interference and inhibition of MRSA on CMRSA II.

Nasal sprays containing fluticasone propionate, azelastine hydrochloride and oxymetazoline hydrochloride as well as OTC throat drops containing menthol demonstrated antibacterial activity. No other substances or transport devices interfered with recovery of MRSA on CMRSA II.

Reproducibility
Reproducibility testing of the CMRSA II was evaluated using 20 test strains. Three different lots of CMRSA II were tested to determine that CMRSA II reliably detects MRSA within lots and across lots. Acceptance criteria for reproducibility of ≥95% for both inter-lot and overall testing intervals was met.

Recovery Rate (Limit of Detection)
BBL CROMagar MRSA II was evaluated to determine the recovery rate (limit of detection (LOD)) for recovery of methicillin-resistant *S. aureus*. Seven test strains, representing five heterogeneous and two homogeneous MRSA were evaluated for recovery on **BBL CHROMagar MRSA II.** 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. Analytical studies, including incubation time, analytical reactivity or sensitivity, interfering substances and reproducibility were all performed using an MRSA suspension of $1x10^5$ CFU/mL. Ten µl of this suspension was then inoculated on to **BBL CHROMagar MRSA II.**

Clinical Studies

Reproducibility Testing
Testing of ten (10) masked strains of *S. aureus* was conducted at three clinical sites. The panel included seven (7) MRSA and three (3) methicillin sensitive *S. aureus* (MSSA). Individual and combined site reproducibility agreements were 100% across three successive days.

Challenge Strain 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%.

Clinical Accuracy
The performance of **BBL™ CHROMagar™ MRSA II** was evaluated at three diverse clinical laboratories in the U.S. A total of 1187 compliant remnant, prospective, nares

specimens were enrolled. Specimens were evaluated by comparing the recovery of MRSA on traditional culture media and **BBL™ CHROMagar™ MRSA II** plates. *S. aureus* recovered on the traditional culture media was tested by the cefoxitin disk diffusion test method. **BBL™ CHROMagar™ MRSA II** was interpreted as positive for MRSA at 20-26 hours based on detection of mauve colonies.

A total of 162 specimens were found to be MRSA positive. The positive percent agreement of **BBL™ CHROMagar™ MRSA II** to cefoxitin disk was 92% (149/162). The negative percent agreement of BBL CHROMagar MRSA II compared to cefoxitin disk 99.9% (1024/1025) (**Table 1**).

Table 1: BBL™ CHROMagar™ MRSA II Performance versus Cefoxitin Disk

	Cefoxitin Disk		
CMRSA II Result	**MRSA**	**Not MRSA**	**Total**
MRSA	149	1	*150*
Not MRSA	13	1024	*1037*
	162	*1025*	*1187*
Reference Method: Cefoxitin Disk Positive Percent Agreement: 92% (86.7%, 95.7%) Negative Percent Agreement: 99.9% (99.5%, 100%)			

With combined data from two clinical trial sites, the positive percent agreement of **BBL™ CHROMagar™ MRSA II** compared to Traditional Culture was 92% at 20-26h and the negative percent agreement was 98.8% (**Table 2**).

Table 2: BBL™ CHROMagar™ MRSA II Performance vs. Traditional Culture at Two Clinical Trial Sites

	Traditional Culture		
CMRSA II Result	**MRSA**	**Not MRSA**	**Total**
MRSA	92	9*	*101*
Not MRSA	8	760	*768*
	100	*769*	*869*
Reference Method: Traditional Culture Positive Percent Agreement: 92% (84.8%, 96.5%) Negative Percent Agreement: 98.8% (97.8%, 99.5%)			

* Nine samples that were positive on **BBL™ CHROMagar™ MRSA II** and negative by Traditional Culture were confirmed as MRSA by cefoxitin disk diffusion testing.

At the third clinical trial site, the positive percent agreement of **BBL™ CHROMagar™ MRSA II** compared to Traditional Culture was 90.2% at 20-26h and the negative percent agreement was 98.9% (**Table 3**).

Table 3: BBL™ CHROMagar™ MRSA II Performance vs. Traditional Culture at Third Clinical Trial Site

	Traditional Culture		
CMRSA II Result	**MRSA**	**Not MRSA**	**Total**
MRSA	46	3*	*49*
Not MRSA	5	264	*269*
	51	*267*	*318*
Reference Method: Traditional Culture Positive Percent Agreement: 90.2% (78.6%, 96.7%) Negative Percent Agreement: 98.9% (96.8%, 99.8%)			

* Two samples that were positive on **BBL™ CHROMagar™ MRSA II** and negative by Traditional Culture were confirmed as MRSA by cefoxitin disk diffusion testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

Mr. Paul Swift
Regulatory Affairs Specialist
Becton Dickinson and Company
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Sparks, MD 21152

AUG 2 0 2010

Re: k092767
Trade/Device Name: BBL™ CHROMagar™ MRSA II
Regulation Number: 21 CFR §866.1700
Regulation Name: Culture Medium for Antimicrobial Susceptibility Tests
Regulatory Class: II
Product Code: JSO
Dated: August 18, 2010
Received: August 19, 2010

Dear Mr. Swift:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

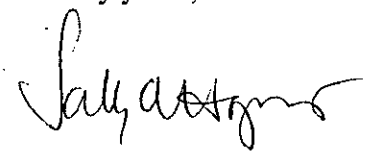
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

K092767

510(k) Number (if known): K092767

Device Name: BBL™ CHROMagar™ MRSA II

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Prescription Use __X____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092767