

K081212

JUN 13 2008

510(k) SUMMARY

Date of Summary

April 28, 2008

Product Name

Bio-Rad MRSASelect
A selective medium for the detection and direct identification of methicillin-resistant *Staphylococcus aureus*. Results can be interpreted after 18 - 28 hours incubation.

Sponsor

Bio-Rad
3 Boulevard Raymond Poincaré
92430 Marnes-la-Coquette
France

Correspondent

MDC Associates, LLC
Fran White, Regulatory Consultant
163 Cabot Street
Beverly, MA 01915

Substantially Equivalent Device

MRSASelect with extended incubation times is substantially equivalent to MRSASelect (reference 510(k) K070361).

Manufacturer: Bio-Rad
Product: MRSASelect

Product Attribute	Bio-Rad MRSASelect™ (18 - 28 hours incubation)	Bio-Rad MRSASelect™ (24 hours incubation)	Substantially Equivalent?
Intended use	MRSASelect is a selective and differential chromogenic medium for the qualitative detection of nasal colonization of methicillin-resistant <i>Staphylococcus aureus</i> (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. MRSASelect is not intended to diagnose MRSA infection nor to guide or monitor treatment of infection. Results can be interpreted after 18 - 28 hours incubation.	MRSASelect is a selective and differential chromogenic medium for the qualitative detection of nasal colonization of methicillin-resistant <i>Staphylococcus aureus</i> (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. MRSASelect is not intended to diagnose MRSA infection nor to guide or monitor treatment of infection.	√
Sample	Nasal swabs	Nasal swabs	√
Test methodology	Chromogenic Media	Chromogenic Media	√

PRODUCT DESCRIPTION:

Methicillin-resistant *Staphylococcus aureus* is a major cause of nosocomial and life threatening infections which have been associated with significantly higher rates of mortality and morbidity.

The Bio-Rad MRSASelect is a selective and differential chromogenic culture medium for the qualitative detection of MRSA from anterior nares specimens. Results can be interpreted after 18 - 28 hours incubation.

INTENDED USE:

MRSASelect 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. MRSASelect is not intended to diagnose MRSA infection nor to guide or monitor treatment of infection. Results can be interpreted after 18 - 28 hours incubation.

SUMMARY OF TECHNOLOGY:

MRSASelect is a selective medium for the detection and direct identification of MRSA. The selectivity of this medium is based on the presence of an antibiotic/antifungal mixture and an optimized salt concentration and that inhibits the growth of yeast and the majority of Gram negative and Gram positive bacteria with the exception of methicillin-resistant staphylococci. Identification is based on the cleavage of a chromogenic substrate by a specific enzymatic activity of *Staphylococcus aureus* leading to a strong pink coloration of the *Staphylococcus aureus* colonies.

Within 18 – 28 hours incubation time methicillin-resistant *Staphylococcus aureus* produce small pink colonies on MRSASelect. Coagulase negative methicillin-resistant staphylococci that do not metabolize the chromogenic substrate appear as colorless or white colonies (possibly light pink). Methicillin sensitive staphylococci (MSS) are inhibited.

PERFORMANCE DATA:

Performance of MRSASelect Extended Incubation was evaluated at two geographically diverse hospitals with fresh anterior nares surveillance specimens. A total of 200 surveillance samples were evaluated. MRSA on routine culture was defined as isolation of Staphylococci on Trypticase Soy Agar with 5% blood, with identification confirmed by coagulase and Oxacillin susceptibility using E-Test. MRSASelect plates were incubated at 35 - 37°C at ambient conditions. Plates were read after 18, 20, 24, 28 hours incubation. No difference in performance was noted at the defined incubation times.

Summary Performance Data

A total of 200 samples were tested at two sites against routine culture (blood agar plate, coagulase and susceptibility), and MRSASelect. MRSASelect plates were read and results read at 18, 20, 24 and 28 hours incubation.

Comparison with Routine Culture

		Routine Culture		total		
		pos	neg		sen	100%
MRSA Select 18 hours	Pos	18	3	21	spec	98%
	Neg	0	179	179	ppv	86%
		18	182	200	npv	100%

		Routine Culture		total		
		pos	neg		sen	100%
MRSA Select 20 hours	Pos	18	3	21	spec	98%
	Neg	0	179	179	ppv	86%
		18	182	200	npv	100%

		Routine Culture		total		
		pos	neg		sen	100%
MRSA Select 24 hours	Pos	18	3	21	spec	98%
	Neg	0	179	179	ppv	86%
		18	182	200	npv	100%

		Routine Culture		total		
		pos	neg		sen	100%
MRSA Select 28 hours	Pos	18	3	21	spec	98%
	Neg	0	179	179	ppv	86%
		18	182	200	npv	100%

STATEMENT OF SAFETY AND EFFICACY:

200 nasal swabs (surveillance samples) were tested on MRSASelect and routine culture (Trypticase Soy Agar w/5% blood, coagulase and susceptibility). Performance of MRSASelect was noted after 18, 20, 24 and 28 hours incubation, comparing results to culture

results. MRSASelect Sensitivity was 100%, with Specificity at 98% at all incubation time intervals noted. Bio-Rad confirms that any/all data provided in this submission may be released upon request.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Bio-Rad
c/o Ms. Fran White
Regulatory Consultant
MDC Associates, LLC
163 Cabot Street
Beverly, MA 01915

JUN 18 2008

Re: k081212
Trade/Device Name: Bio- Rad MRSASelect
Regulation Number: 21 CFR § 866.1700
Regulation Name: Culture medium for antimicrobial susceptibility test
Regulatory Class: Class II
Product Code: JSO
Dated: April 28th, 2008
Received: April 29th, 2008

Dear Ms. White:

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.

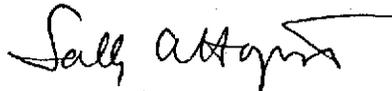
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

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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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

Indications for Use

510(k) Number (if known): K081212

Device Name: MRSASelect

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF 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) _____