K092819

510(k) SUMMARY

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JUL 15 2010

Date Prepared: September 11, 2009

Device Trade Name: Spectra™ VRE

Predicate Device: Remel Bile Esculin Azide Agar with 6 µg/ml Vancomycin

Device Classification: 21 CFR 866.1700: Culture medium for antimicrobial susceptibility tests.

Intended Use: Remel Spectra™ VRE is a selective and differential chromogenic medium, containing 6 µg/ml of vancomycin, intended for use in the qualitative detection of gastrointestinal colonization with vancomycin-resistant *Enterococcus faecium* and *Enterococcus faecalis* (VRE) to aid in the prevention and control of VRE in healthcare settings. The test is performed with rectal swab and fecal specimens from patients to screen for VRE colonization. Spectra™ VRE is not intended to diagnose VRE infection or to guide or monitor treatment for infections. Subculture to non-selective media (e.g. Tryptic Soy Agar with 5% sheep blood) is needed for further identification, susceptibility testing, and epidemiological typing.

Device Description: Remel Spectra™ VRE is an opaque medium allowing differentiation of vancomycin-resistant *E. faecium* from vancomycin-resistant *E. faecalis* by incorporation of two chromogens that are targeted by phosphatase and α-galactosidase. The action of these enzymes on the chromogens results in a build-up of color within the colony. The presence of phosphatase enzymes in both *E. faecium* and *E. faecalis* results in a light blue or blue colony. However, *E. faecium* also produces α-galactosidase, resulting in a mix of blue and pink chromophores within the bacterium producing navy blue or pink-purple colonies, which are distinguished from the light blue or blue *E. faecalis* colonies. Additional antibiotics, in combination with vancomycin, are present to suppress the growth of competing flora including *E. gallinarum* and *E. casseliflavus*, both of which are intrinsically resistant to vancomycin, possessing the chromosomally encoded VanC resistance mechanism.

Device Comparison:

Characteristic	Remel Spectra™ VRE	Remel Bile Esculin Azide with Vancomycin
Similarities		
Intended Use	Remel Spectra™ VRE is a selective and differential chromogenic medium, containing 6 µg/ml of vancomycin, recommended for use in the qualitative detection of gastrointestinal colonization of vancomycin-resistant *Enterococcus* (VRE) to aid in the prevention and control of VRE in healthcare settings. The test is performed with rectal swabs and fecal specimens from patients to screen for VRE colonization. Spectra™ VRE is not intended to diagnose VRE infection or to guide or monitor treatment for infections. Subculture to non-selective media (e.g. Tryptic Soy Agar with 5% sheep blood) is needed for further identification, susceptibility testing, and epidemiological typing.	Remel Bile Esculin Azide Agar w/ 6 µg/ml Vancomycin is a solid medium recommended for use in qualitative procedures as a screening method for primary isolation and presumptive identification of vancomycin-resistant enterococci (VRE) from surveillance cultures.
Inoculation	Direct Specimen	Direct Specimen
Sample Type	Fecal specimens Rectal swabs	Fecal Specimens Urine specimens
Interpretation	Manual, visual	Manual, visual Additional confirmation required
Test Methodology	Enzymatic	Enzymatic
Incubation	24 hours	24–48 hours
Differences		
Target Enzyme	Phosphatase α-galactosidase	Esculin hydrolysis
Species Differentiation	Positive – Vancomycin-resistant *E. faecium* colonization: Navy blue or purple-pink colonies. Positive – Vancomycin-resistant *E. faecalis* colonization: Light blue to blue colonies. Negative – No VRE colonization: No colored colonies.	Positive – Dark brown to black color around colonies and diffusing into the medium. Negative – No blackening of the media.

Summary of Performance Data:

Clinical Accuracy:

The performance of Spectra™ VRE was evaluated at three geographically diverse regions of the United States. A total of six hundred twenty-three (623) prospective rectal swab and fecal surveillance specimens (yielding 629 data points) were evaluated. Results from Spectra™ VRE at 24 hours incubation were compared to results obtained from traditional culture on Bile Esculin Azide Agar with 6 µg/ml Vancomycin (BEAV) after 48 hours incubation. Two hundred twenty VRE with minimal inhibitory concentration MICs to vancomycin of >256 µg/ml were recovered from six hundred twenty three specimens (191 vancomycin-resistant *E. faecium* and 29

vancomycin-resistant *E. faecalis*). The overall recovery of VRE on Spectra™ VRE at 24 hours was 99.1% (218/220) compared to recovery of 95.5% (210/220) on BEAV at 48 hours.

Suspect isolates of VRE were evaluated using the Vitek® 2 system and biochemical tests, and an antibiotic gradient method for determination of vancomycin MIC. For detection of VRE by colored colonies isolated on Spectra™ VRE at 24 hours compared to identification and susceptibility testing as described, the overall agreement was 99.5% (626/629).

	Positive % Agreement	Negative % Agreement
Spectra™ VRE vs. conventional methods	99.1% (218/220) (95% CI = 96.8–99.9%)	99.8% (408/409) (95% CI = 98.6–100%)

Note : CI = Confidence Interval

Forty rectal swabs (eleven positive and twenty-eight negative) were tested which did not yield a statistically sound 95% lower bound confidence interval. The results are not included in the data.

Spectra™ VRE vs. Conventional Methods

	Positive % Agreement	Negative % Agreement
VR-*E. faecium*	99.0% (189/191)[a] (95% CI = 96.3–99.9%)	99.8% (437/438)[b] (95% CI = 98.7–100%)
VR-*E. faecalis*	100% (29/29) (95% CI = 88.1–100%)	100% (600/600) (95% CI = 99.4–100%)

Note : CI = Confidence Interval

[a] One isolate showed expected results at 28 hours and one isolate showed expected results at 48 hours.
[b] One isolate developed pink colonies and was identified as *Lactobacillus* sp.

Performance Compared to Commercially Available Devices:

Spectra™ VRE was compared to culture on Bile Esculin Azide with 6 µg/ml Vancomycin, with subsequent identification and susceptibility testing. There was 82.7% (520/629) agreement with six hundred twenty-nine isolates. The Bile Esculin Azide with 6 µg/ml Vancomycin demonstrated 95.5% (210/220) agreement for the recovery of VRE (acquired resistance) and 75.8% (310/409) agreement for non-VRE.

Interfering Substances:

The following substances were evaluated for potential interference of the chromogenic reaction of Spectra™ VRE. These substances were tested in combination with vancomycin-resistant *E. faecalis* and *E. faecium* isolates at a concentration of 50 CFU: blood, mucous, MYLANTA® Maximum Strength, Pepto-Bismol®, Imodium® A-D, Kaopectate®, Fletcher's Castoria®, PEPCID® AC Maximum Strength, Tagamet HB 200®, Prilosec OTC®, vancomycin, metronidazole, barium sulfate, Preparation H®, petroleum jelly, glycerin, bisacodyl, witch hazel, miconazole, nonoxynol-9, KY® Jelly. Hydrocortisone acetate was not evaluated. Blood, Pepto-Bismol®, glycerin, vancomycin, miconazole, and Preparation H® may reduce the recovery of vancomycin resistant *E. faecalis* and *E. faecium* strains.

Reproducibility:

Reproducibility testing was conducted at four sites on three separate days with twenty blinded strains including vancomycin susceptible and resistant *E. faecium* and *E. faecalis*, as well as quality control reference strains. The strains produced the expected result with Spectra™ VRE 100% of the time at 24 hours.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

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Re: K092819

Trade/Device Name:	Spectra™ VRE
Regulation Number:	21 CFR § 866.1700
Regulation Name:	Remel Spectra™ VRE Chromogenic VRE Media
Regulatory Class:	Class II
Product Code:	JSO
Dated:	July 13, 2010
Received:	July 14, 2010

Dear Ms. Silvius

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

INDICATIONS FOR USE

510(k) Number (if known): K092819

Device Name: Spectra™ VRE

Indications For Use: Remel Spectra™ VRE is a selective and differential chromogenic medium, containing 6 µg/ml of vancomycin, intended for use in the qualitative detection of gastrointestinal colonization with vancomycin-resistant *Enterococcus faecium and Enterococcus faecalis* (VRE) to aid in the prevention and control of VRE in healthcare settings. The test is performed with rectal swab and fecal specimens from patients to screen for VRE colonization. Spectra™ VRE is not intended to diagnose VRE infection or to guide or monitor treatment for infections. Subculture to non-selective media (e.g. Tryptic Soy Agar with 5% sheep blood) is needed for further identification, susceptibility testing, and epidemiological typing.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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