K061686

AUG 30 2006

510(k) SUMMARY

August 23, 2006

GeneOhm Sciences Canada, Inc. IDI-Van*R*™ Assay

Submitted by:

GeneOhm Sciences Canada, Inc.
2050, boul. René-Lévesque O, 4e étage
Sainte-Foy, Québec
Canada
G1V 2K8

Contact:

Patricia Dionne, Ph.D.

Name of Device:

Trade Name:	IDI-Van*R*™ Assay
Common Name:	Vancomycin-resistant Enterococci detection assay
Classification Name:	System, Nucleic Acid Amplification Test, DNA, Vancomycin Resistant Bacteria, Direct Specimen

Predicate Device:

Remel Bile Esculin Azide agar with 6 ug/mL vancomycin (BEAV) (K972359)

Device Description:

Intended Use:

The IDI-VanR® Assay is a qualitative in vitro test for the rapid detection of vancomycin-resistance (*vanA* and *vanB*) genes directly from rectal swabs. The IDI-vanR® Assay detects the presence of the *vanA* and *vanB* genes that can be associated with vancomycin-resistant enterococci (VRE). The assay is performed on an automated real-time PCR instrument with rectal swabs from patients at risk for VRE colonization. The IDI-VanR® Assay can be used as an aid to identify, prevent and control vancomycin-resistant colonization in healthcare settings. Concomitant cultures are necessary to recover organisms for epidemiological typing, susceptibility testing and for further confirmatory identification. The IDI-VanR® Assay is not intended to diagnose VRE infections nor to guide or monitor treatment for VRE infections.

Test Description:

Following specimen lysis, amplification of the *vanA* and *vanB* targets occurs. Amplification of the IC, a DNA fragment of 294-bp including a 254-bp sequence not found in VRE, will also take place unless there are PCR inhibitory substances.

The amplified DNA targets are detected with molecular beacons, a hairpin-forming single-stranded oligonucleotides labelled at one end with a quencher and at the other end with a fluorescent reporter dye (fluorophore). In the absence of target, the fluorescence is quenched. In the presence of target, the hairpin structure opens upon beacon/target hybridization, resulting in emission of fluorescence. For the detection of *vanA* amplicons, the molecular beacon contains the fluorophore FAM at the 5' end and the non-fluorescent quencher moiety DABCYL at the opposite end of the oligonucleotide. For the detection of the *vanB* amplicons, the molecular beacon contains the fluorophore Texas Red at the 5' end and the quencher DABCYL at the 3' end. For the detection of the Internal Control (IC) amplicons, the molecular beacon contains the fluorophore TET

at the 5' end and the quencher DABCYL at the 3' end. Each beacon-target hybrid fluoresces at a wavelength characteristic of the fluorophore used in the particular molecular beacon. The amount of fluorescence at any given cycle, or following cycling, depends on the amount of specific amplicons present at that time. The SmartCycler® software simultaneously monitors the fluorescence emitted by each beacon, interprets all data, and provides a final result at the end of the cycling program.

Substantial Equivalence:

The GeneOhm Sciences Canada, Inc. IDI-Van*R*™ Assay has been found to be substantially equivalent to the Remel Bile Esculin Azide agar with 6 ug/mL vancomycin (BEAV) (K972359) with phenotypic identification of presumptive *Enterococcus* colonies (MMWR, 1995; CDC, 1999) and determination of vancomycin and teicoplanin resistance (CLSI, M7-A6 and M100-S15) for the detection of vancomycin resistance in presumptively identified cultures of *Enterococcus faecalis* and *Enterococcus faecium.*

Clinical trial were performed at four sites to evaluate the performance of the IDI-VanR™ Assay to the Remel Bile Esculin Azide agar with 6 ug/mL vancomycin (BEAV) with phenotypic identification of presumptive *Enterococcus* colonies and determination of vancomycin and teicoplanin resistance. The results are summarized in Tables 1-3.

Table 1: Clinical Performance Obtained for vanA and van B with IDI-Van*R*™ Assay from Rectal Swabs for the Overall Study in Comparison with Culture Technique

		IDI-VANR™					
		VANA	VANB	VANA+B	NEGATIVE	UNRESOLVED	TOTAL
Culture	VanA	80	0	18	3	0	101
	VanB	0	4	3	0	0	7
	VanA + B	0	0	2	0	0	2
	Negative	14	58	2	783	1	858
	Total :	**94**	**62**	**25**	**786**	**1**	**968**

Sensitivity *VanA*[1]: 97.1% (91.6-99.4%) **Specificity: 91.4%**
Sensitivity *VanB*: 57.1% (1.8-90.1%)

[1] The vanA+B PCR results and culture vanA positive were considered as true positive and included in the calculation of the sensitivity of vanA target.

The low sensitivity associated with vanB detection is due to the low number of vanB positive specimens.

Table 2: Clinical Performance Obtained with IDI-Van*R*™ Assay from Rectal Swabs for the Overall Study in Comparison with Culture Technique

		IDI-VANR™			
		POSITIVE	NEGATIVE	UNRESOLVED	TOTAL
Culture	Positive	107	3	0	110
	Negative	74	783	1	858
	Total :	**181**	**786**	**1**	**968**

Sensitivity: 97.3 (92.2%-99.4%) **Specificity: 91.4% (89.3%-93.2%)**

Table 3: Clinical Performance Obtained with IDI-Van*R*™ From Rectal Swabs by Each Investigational Site and For the Overall Study In Comparison With Culture Technique

Site	Clinical sensitivity of IDI-VanR™	Clinical specificity IDI-VanR™ (95% CI) [A]	Rate of unresolved	
			Initial	After repeat testing
Site #1	98.4% (91.2%-100%)	87.1% (81.6%-91.5%)	0.8% (2/255)	0.4% (1/255)
Site #2	100% (2.5-100%)	87.3% (81.3%-92.0%)	0%	N/A
Site #3	100% (2.5-100%)	92.0% (87.4%-95.4%)	0%	N/A
Site #4	95.7% (85.5%-99.5%)	96.0% (93.0%-97.9%)	0%	N/A
Overall study	97.3% (92.2%-99.4%)	91.4% (89.3% - 93.2%)	0.2 % (2/968)	0.1% (1/968)

[A] Binomial 95% confidence intervals

For the population tested, the negative predictive value was 99.6% (98.9%-99.9%) and the positive predictive value was 59.1% (51.6%-66.4%).

The low PPV is associated with vanB detection which is due to the low number of vanB positive specimens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 3 0 2006

GeneOhm Sciences Canada, Inc.
c/o Ms. Judi Smith
Submission Correspondent
Sienna Partners, LLC
P.O. Box 103
Baldwin, Maryland 21082

Re: k061686
Trade/Device Name: IDI-VanR® Assay
Regulation Number: 21 CFR § 866.1640
Regulation Name: System test genotypic detection – resistant markers
Regulatory Class: II
Product Code: NIJ
Dated: August 23, 2006
Received: August 24, 2006

Dear Ms. Smith:

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.

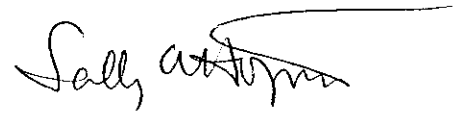
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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): K061686

Device Name: IDI-VanR® Assay

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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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