K081920

510(k) SUMMARY

DEC 19 2008

December 17, 2008

BD Diagnostics BD GeneOhm™ Cdiff Assay

Submitted by:
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Name of Device:

Trade Name: BD GeneOhm™ Cdiff Assay
Common Name: *Clostridium difficile tcdB* detection assay
Classification Name: System, Test, Genotypic Detection, *Clostridium difficile* Toxin B

Predicate Device: Techlab *C. difficile* Tox-B Test (K935296)
Techlab *Clostridium difficile* Toxin/Antitoxin Kit (K923463)

Device Description:

Intended Use:
The BD GeneOhm™ Cdiff Assay is a rapid *in vitro* diagnostic test for the direct, qualitative detection of *C. difficile* toxin B gene (*tcdB*) in human liquid or soft stool specimens from patients suspected of having *Clostridium difficile*-associated disease (CDAD). The test, based on real-time PCR, is intended for use as an aid in diagnosis of CDAD. The test is performed directly on the specimen, utilizing polymerase chain reaction (PCR) for the amplification of specific targets and fluorogenic target-specific hybridization probes for the detection of the amplified DNA.

Test Description:
A liquid or soft stool specimen is collected and transported to the laboratory. A sterile dry swab is dipped into the liquid or soft stool material and processed. For testing, the swab is eluted in sample buffer and the specimen is lysed. An aliquot of the lysate is added to PCR reagents which contain the *tcdB* specific primers used to amplify the genetic target of *Clostridium difficile*, if present. The assay also includes an internal control (IC) to detect PCR inhibited specimens and to confirm the integrity of assay reagents. Amplified targets are detected with hybridization probes labelled with quenched fluorophores (molecular beacons). The amplification, detection and interpretation of the signals are done automatically by the Cepheid SmartCycler® software. The entire procedure takes about 75 to 90 minutes, depending on the number of specimens processed.

The amplified DNA target is detected with a molecular beacon, a hairpin-forming single-stranded oligonucleotide 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 *tcdB* amplicons, the molecular beacon contains the fluorophore FAM at the 5' end and the non-fluorescent quencher DABCYL at the opposite 3' end of the oligonucleotide. For the detection of the IC amplicons, the molecular beacon contains the fluorophore TET at the 5' end and the quencher moiety 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 molecular beacon, interprets all data, and provides a final result at the end of the cycling program.

Substantial Equivalence:

The BD GeneOhm™ Cdiff Assay has been found to be substantially equivalent to the Techlab *C. difficile* Tox-B Test (K935296) and the Techlab *Clostridium difficile* Toxin/Antitoxin Kit (K923463). These methods were used as the reference methods in the clinical trials.

Performance Characteristics:

Performance characteristics of the BD GeneOhm™ Cdiff Assay were determined in a multi-site prospective investigational study. Four (4) medical centers, two (2) in Canada and two (2) in the United States, participated in the study. To be enrolled in the study, specimens had to be from individuals for whom *Clostridium difficile* testing was indicated and/or ordered, according to institutional policies.

The Reference Cytotoxicity Assay was performed using a tissue culture Cytotoxicity assay on liquid or soft stool specimens within 48 hours of collection. The procedure was performed according to the Manufacturer's Instructions for Use.

A total of 1108 specimens were tested with both the Reference Assay described above and the BD GeneOhm™ Cdiff Assay, producing 1090 reportable results. The first dataset includes 835 fresh specimens tested at three (3) of the four (4) clinical sites (Table 1). In comparison to the Reference Assay, the BD GeneOhm™ Cdiff Assay identified 93.8% of the *C. difficile* positive specimens and 95.5% of the negative specimens (Table 2). For the population tested this resulted in a Negative Predictive Value (NPV) of 99.1% and a Positive Predictive Value (PPV) of 67.3%.

Testing at the fourth clinical site revealed that the Reference Cytotoxicity Assay was not reporting accurate results. Due to the high number of inaccurate reference assay results, samples were retested from aliquots of the original stool specimens which had been frozen after the initial testing. These frozen aliquots were tested with both the Reference Assay and the BD GeneOhm™ Cdiff Assay. The second dataset includes results from 255 frozen stool specimens available for analysis (Table 3).

In comparison to the Reference Assay, the BD GeneOhm™ Cdiff Assay identified 100% of the C. difficile positive specimens and 97.7% of the negative specimens in the frozen dataset; resulting in a NPV of 99.2% and PPV of 81.5% (Table 4).

Out of 852 fresh specimens tested with the BD GeneOhm™ Cdiff Assay, 39 were initially reported as unresolved (4.6%). Upon repeat testing from the frozen lysates, 22 were resolved and 17 remained unresolved (2.0%) (Table 5). Out of 256 frozen specimens tested with the BD GeneOhm™ Cdiff Assay, only one (1) specimen (0.4%) was initially reported unresolved. The specimen remained unresolved upon repeat testing from the frozen lysate (0.4%) (Table 6). One (1) run was reported invalid due to Run Control failure (0.6%). The run was reported valid upon repeat testing of the specimen lysates (Table 7).

Table 1: Fresh Stool Results Obtained with the BD GeneOhm™ Cdiff Assay in Comparison with the Reference Assay

		Reference Cytotoxicity Assay +	Reference Cytotoxicity Assay -	
BD GeneOhm™ Cdiff Assay	+	76	34[†]	110
	-	5[‡]	720	725
		81	754	835

[†] Cytotoxicity Assay on isolated strains was positive for 21 out of the 34 samples, verifying the presence of toxigenic *C. difficile*. For the remaining 13 samples, standard PCR with alternative primers followed by bi-directional sequencing revealed that 11 out of the 13 samples contained the expected *tcdB* gene.
[‡] For two (2) of the five (5) false negative specimens, *C. difficile* was recovered by culture, and only one (1) of these two (2) was reported as toxigenic. Of the remaining three (3) false negative PCR specimens, no *C. difficile* was recovered by culture.

Table 2: Performance Obtained with Fresh Stools using the BD GeneOhm™ Cdiff Assay in Comparison with the Reference Method

Clinical Sites	Prevalence	Sensitivity with 95% CI*	Specificity with 95% CI*
Site 1	11.0% (40/365)	90.5% (38/42) (77.4% - 97.3%)	95.7% (309/323) (92.8% - 97.6%)
Site 2	6.7% (16/240)	94.4% (17/18) (72.7% - 99.9%)	96.4% (240/249) (93.2% - 98.3%)
Site 3	11.1% (18/162)	100% (21/21) (83.9% - 100%)	94.0% (171/182) (89.4% - 96.9%)
Overall	9.6% (74/767)	93.8% (76/81) (86.2% - 98.0%)	95.5% (720/754) (93.8% - 96.9%)

* CI: Confidence Intervals

Table 3: Frozen Stool Results Obtained with the BD GeneOhm™ Cdiff Assay in Comparison with the Reference Assay

		Reference Cytotoxicity Assay +	-	
BD GeneOhm™ Cdiff Assay	+	34	5	39
	-	0	216	216
		34	221	255

Table 4: Performance Obtained with Frozen Stools using the BD GeneOhm™ Cdiff Assay in Comparison with the Reference Method

Clinical Site	Prevalence	Sensitivity with 95% CI*	Specificity with 95% CI*
Site 4	12.7% (34/267)	100.0% (34/34) (89.7% - 100%)	97.7% (216/221) (94.8% - 99.3%)

* CI: Confidence Intervals

Table 5: Fresh Stool Unresolved Rates

Clinical Sites	Initial unresolved rate with 95% CI*		Unresolved rate after repeat with 95% CI*	
Site 1	0.8% (3/367)	(0.2% - 2.4%)	0.5% (2/367)	(0.1% - 2.0%)
Site 2	6.6% (18/273)	(4.0% - 10.2%)	2.2% (6/273)	(0.8% - 4.7%)
Site 3	8.5% (18/212)	(5.1% - 13.1%)	4.2% (9/212)	(2.0% - 7.9%)
Overall	4.6% (39/852)	(3.3% - 6.2%)	2.0% (17/852)	(1.2% - 3.2%)

* CI: Confidence Intervals

Table 6: Frozen Stool Unresolved Rates

Clinical Site	Initial unresolved rate with 95% CI*		Unresolved rate after repeat with 95% CI*	
Site 4	0.4% (1/256)	(0.0% - 2.2%)	0.4% (1/256)	(0.0% - 2.2%)

* CI: Confidence Intervals

Table 7: Overall Invalid Run Rates

Site	Invalid Run Rates with 95% CI*	
Site 1	2.6% (1/38)	(0.1% - 13.8%)
Site 2	0.0% (0/41)	(0.0% - 8.6%)
Site 3	0.0% (0/58)	(0.0% - 6.2%)
Site 4	0.0% (0/23)	(0.0% - 14.8%)
Overall	0.6% (1/160)	(0.0% - 3.4%)

* CI: Confidence Intervals

Analytical Specificity

Genomic DNA from one non toxigenic *C. difficile* strain, two strains of Toxinotype XI lacking *tcdB* gene and 29 other-*Clostridium* strains (including one strain of *C. sordellii*), along with 99 closely related organisms and other pathogenic and commensal flora found in the intestine and stools (representing 96 species) were tested. All strains were tested at a concentration of approximately $1X10^8$ CFU/mL or $1X10^8$ target copies/mL. None of these species tested positive with the BD GeneOhm™ Cdiff Assay (Attachment 1).

Analytical Sensitivity

Quantitated culture and purified genomic DNA diluted in BD GeneOhm™ Cdiff Assay sample buffer were tested in five (5) replicates. The LOD was defined as the lowest concentration, in DNA copy number per reaction and CFU per reaction, at which five replicates out of five were found positive.

The analytical sensitivity (limit of detection or LOD) of the BD GeneOhm™ Cdiff Assay was determined with one strain of Toxinotype 0 *Clostridium difficile* carrying the *tcdB* gene (ATCC 43255).

The BD GeneOhm™ Cdiff Assay LOD is 10 DNA copies per reaction. The LOD in Colony Forming Units (CFU) is established at 4 CFU per reaction.

The analytical sensitivity in CFU per reaction was confirmed with a second Toxinotype 0 (ATCC 9689) and with Toxinotypes IIIa (SE844), V (SE881), VII (57267) and VIII (1470) *Clostridium difficile* toxigenic strains.

In addition to strains used for LOD determination, one hundred (100) other toxigenic *C. difficile* strains (including 17 other Toxinotypes), representing 21 countries, from well-characterized clinical isolates or public collections were evaluated using the BD GeneOhm™ Cdiff Assay. *C. difficile* strains were tested at a concentration of approximately 6.7 DNA copies/µL or 1 CFU/µL. The assay correctly identified all 100 *C. difficile* strains carrying the *tcdB* gene.

Reproducibility

The reproducibility panel consisted of three (3) simulated specimen categories where each tube contained 100 µL of simulated bowel flora; the two positive panel members were also inoculated with *C. difficile* (ATCC 43255). Additionally, two (2) Specimen Processing Controls (ATCC 9689 and ATCC 25922) and, two (2) Run Controls (Positive and Negative) were included. The specimens were tested in triplicate per panel run, on five (5) distinct days (consecutive or not), wherein each day two (2) panels were tested, one for each of two (2) technologists, at three (3) clinical sites with one (1) lot of reagents. One (1) of these clinical sites participated in the extended study where two (2) additional lots of reagents were tested.

The overall percent agreement for the low positive *C. difficile* specimen category is 96.7%; the moderate positive *C. difficile* specimen category is 100% and the negative specimen category is 100% for the Site-to-Site Reproducibility (Table 8).

The overall percent agreement for the low positive *C. difficile* specimen category is 100%; the moderate positive *C. difficile* specimen category is 97.8% and the negative specimen category is 100% for the Lot-to-Lot Reproducibility (Table 9).
Cycle threshold (Ct), an internal criteria used to determine a final assay result, was selected as an additional means of assessing assay reproducibility. Overall mean Ct values with variance components (SD and %CV) are shown in Tables 8 and 9.

An additional reproducibility study was performed, in accordance with the original reproducibility study protocol, to assess high negative specimens below the BD GeneOhm™ Cdiff Assay limit of detection (LOD). A sample containing simulated bowel flora was inoculated with *C. difficile* (ATCC 43255) at a concentration equivalent to the assay LOD. 100-fold and 10-fold dilutions of this sample were prepared, respectively, to obtain the two (2) high negative panel members. Overall percent agreement for negative test results and overall mean Ct values with variance components (SD and %CV) are shown in Table 10. As expected, the more dilute panel member (100-fold below the LOD) containing lower levels of target, demonstrates a higher percent agreement for negative test results than the less dilute panel member (10-fold below the LOD) which contains higher levels of target. Although high negative panel members are below the analytical LOD of the assay, positive test results may still be observed due to the presence of target in these specimens.

Table 8: Site-To-Site Reproducibility Study Results using One Lot

Category	SITE						Overall Percent Agreement		Ct Values		
	Site 1		Site 2		Site 3						
	Percent Agreement		Percent Agreement		Percent Agreement				Overall Mean	SD	%CV
NEG	30/30	100.0%	30/30	100.0%	30/30	100.0%	90/90	100.0%	36.2[†]	0.3[†]	0.8%[†]
LOW POS	28/30	93.3%	29/30	96.7%	30/30	100.0%	87/90	96.7%	38.8	0.9	2.3%
MOD POS	30/30	100.0%	30/30	100.0%	30/30	100.0%	90/90	100.0%	38.3	1.0	2.7%

[†] **Data represent values from the internal control.**

Table 9: Lot-To-Lot Reproducibility Study Results using Three Lots

Category	LOT						Overall Percent Agreement		Ct Values		
	Lot 1		Lot 2		Lot 3						
	Percent Agreement		Percent Agreement		Percent Agreement				Overall Mean	SD	%CV
NEG	30/30	100.0%	30/30	100.0%	30/30	100.0%	90/90	100.0%	36.1[‡]	0.3[‡]	0.8%[‡]
LOW POS	30/30	100.0%	30/30	100.0%	30/30	100.0%	90/90	100.0%	38.6	1.0	2.5%
MOD POS	29/30	96.7%	29/30	96.7%	30/30	100.0%	88/90	97.8%	37.8	1.1	2.8%

[‡] **Data represent values from the internal control.**

Table 10: Additional Reproducibility Study Using a High Negative Sample Panel

High Negative Panel Member	Site 1		Site 2		Site 3		Overall Percent Agreement*		Ct Values		
	Percent Agreement*		Percent Agreement*		Percent Agreement*				Overall Mean	SD	%CV
1:100 dilution	25/30	83.3%	21/30	70.0%	26/30	86.7%	72/90	80.0%	41.3	0.9	2.1%
1:10 dilution	11/30	36.7%	5/30	16.7%	5/30	16.7%	21/90	23.3%	40.2	1.4	3.4%

*Percent agreement for a negative result.

Precision

Within-laboratory precision was evaluated for the BD GeneOhm Cdiff Assay at one (1) site. The study was performed over 12 days, with two (2) runs per day and two (2) sample replicates per run. Samples included simulated specimens representing low and moderate positive *C. difficile* as well as negative *C. difficile*. One (1) out of 24 runs was excluded due to failure of the positive control (PC). One (1) moderate positive sample produced an unresolved result. All remaining samples and controls produced reportable results for a total of 46 replicates. Precision study results for low and moderate positive samples demonstrated agreement for (46/46) and (45/46) replicates, respectively; negative sample results demonstrated agreement for (46/46) replicates.

Interfering Substances

Twenty-six (26) biological and chemical substances occasionally used or found in perianal, rectal and/or stool specimens were evaluated for interference with the BD GeneOhm™ Cdiff Assay. Potentially interfering substances include, but are not limited to, blood and mucus. The presence of excessive blood may inhibit PCR and may give unresolved results. The remaining twenty-four (24) substances illustrated in the table below showed no detectable interference with the BD GeneOhm™ Cdiff Assay.

Endogenous and Commercial Exogenous Substances Tested with the BD GeneOhm Cdiff Assay

Substance	Result
Anusol MC Plus *	NI**
Atlas Ihle's Paste * Zinc oxide 25 % w/w paste (Laboratoire Atlas Inc.)	NI
Barium sulfate Fresh solution from powder form (LabMat)	NI
Exact™ Hydrocortisone acetate * Cream USP 0.5 % (Taro Pharmaceuticals Inc.)	NI
Exact™ stomach relief Bismuth subsalicylate liquid (Perrigo®)	NI
Fecal fat	NI
Fresh control® Moist towelettes pH 5,5 (Blue Skin)	NI
Gyne Moistrin® Vaginal moisturizing gel (Schering)	NI
Imodium AD® * Loperamide hydrochloride oral solution (McNeil)	NI
Kaopectate® Oral attaplugite suspension (Pharmacia & Upjohn)	NI
K-Y® Jelly (Johnson & Johnson Inc.)	NI
Metronidazole Fresh solution from powder form (Acros Organics)	NI

Substance	Result
Monistat™ Derm Miconazole nitrate cream USP 2% (McNeil)	NI
Palmitic acid * Fresh solution from powder (LabMat)	NI
Preparation H® with Bio-Dyne® * Cream (Wyeth)	NI
Preparation H® with Bio-Dyne® * Ointment (Wyeth)	NI
Rougier Neo-Laryngobis *Suppositories (Rougier Pharma)	NI
SAB-Dimenhydrinate® * Suppositories (SABEX®)	NI
Steric acid * Fresh solution from powder (LabMat)	NI
Trojan® latex condoms (with nonoxynol-9) Spermicidal lubricant (Church & Dwight Co., Inc.)	NI
Tucks MC personal cleansing pads Moist, soft clothpads (Pfizer)	NI
Vagisil® Anti-itch cream (Combe Incorporated)	NI
Vancomycin Liquid (MP Biomedicals, LLC)	NI
Vaseline™ * White petroleum jelly U.S.P. (Lever Pond's)	NI

* Substance tested with two strains of C. difficile (Tox 0 and Tox VIII)
** NI: No detectable interference with the BD GeneOhm Cdiff Assay

Attachment 1: BD GeneOhm™ Cdiff Assay Reactivity Study using DNA and Lysates from Various Species

Genera and Species	Strain	BD GeneOhm™ Cdiff Assay
Abiotrophia defective	ATCC 49176	neg
Acinetobacter baumannii	ATCC 19606	neg
Acinetobacter lwoffii	CDCF 3697	neg
Aeromonas hydrophila	ATCC 7966/ CCRI-10071	neg
Alcaligenes faecalis subsp. Faecalis	ATCC 15554	neg
Anaerococcus tetradius	ATCC 35098	neg
Bacillus cereus	ATCC 13472	neg
Bacillus cereus	HER 1414	neg
Bacteroides caccae	ATCC 43185	neg
Bacteroides merdae	ATCC 43184	neg
Bacteroides stercoris	ATCC 43183	neg
Bifidobacterium adolescentis	ATCC 15703	neg
Bifidobacterium longum	ATCC 15707	neg
Campylobacter coli	ATCC 43479	neg
Campylobacter jejuni subsp. jejuni	ATCC 33292	neg
Candida albicans	ATCC 10231	neg
Candida catenulate	IDI-1729	neg
Cedecea davisae	ATCC 33431	neg
Chlamydia trachomatis	ABI 08-901-000	neg
Citrobacter amalonaticus	ATCC 25405	neg
Citrobacter freundii	ATCC 8090	neg
Citrobacter koseri	ATCC 27028	neg
Citrobacter sedlakii	ATCC 51115 (IDI-2178)	neg
Clostridium beijerinckii	ATCC 8260	neg
Clostridium bifermentans	ATCC 638	neg
Clostridium bolteae	BAA-613	neg
Clostridium botulinum	Hall A	neg
Clostridium butyricum	CCRI-11128	neg
Clostridium chauvoei	ATCC 11957	neg
Clostridium difficile non-toxigenic	ATCC-700057	neg
Clostridium difficile XIa (A-B-tox bin+)	IS58	neg
Clostridium difficile XIb (A-B-tox bin+)	R11402	neg
Clostridium fallax	ATCC 19400	neg
Clostridium haemolyticum	ATCC 9650	neg
Clostridium histolyticum	ATCC 19401	neg
Clostridium innocuum	CCRI-9927 / IDI 1986	neg
Clostridium methylpentosum	ATCC 43829	neg
Clostridium nexile	ATCC 27757	neg
Clostridium novyi	ATCC 19402	neg
Clostridium orbiscindens	ATCC 49531	neg
Clostridium paraputrificum	ATCC 25780	neg
Clostridium perfringens	ATCC 13124	neg
Clostridium ramosum	ATCC 25582	neg
Clostridium scindens	ATCC 35704	Neg[1]
Clostridium septicum	ATCC 12464	neg

Genera and Species	Strain	BD GeneOhm™ Cdiff Assay
Clostridium sordellii	ATCC 9714	neg
Clostridium sp	CCRI-9842 / IDI 1987	neg
Clostridium sp	CCRI-9929 / IDI-1988	neg
Clostridium sphenoides	ATCC 19403	neg
Clostridium spiroforme	ATCC 29899	neg
Clostridium sporogenes	ATCC 15579	neg
Clostridium symbiosum	CCRI-9928 / IDI 1989	neg
Clostridium symbiosum	ATCC 14940	neg
Clostridium tertium	ATCC 14573	neg
Clostridium tetani	ATCC 19406	neg
Collinsella aerofaciens	ATCC 25986	neg
Corynebacterium genitalium	LSPQ 3583	neg
Desulfovibrio piger	ATCC 29098	neg
Edwardsiella tarda	ATCC 15947	neg
Eggerthella lenta	CCRI-9926 / IDI 1990	neg
Enterobacter aerogenes	ATCC 13048	neg
Enterobacter cloacae	ATCC 13047	neg
Enterococcus casseliflavus (vanC2)	CCRI-1566 / IDI 1981	neg
Enterococcus cecorum	ATCC 43198	neg
Enterococcus dispar	ATCC 51266	neg
Enterococcus faecalis vanB	ATCC 51299	neg
Enterococcus faecium vanA	ATCC 700221	neg
Enterococcus gallinarum vanC	CCRI-1561 / IDI 1982	neg
Enterococcus hirae	ATCC 8043	neg
Enterococcus raffinosus	ATCC 49427	neg
Escherichia coli	ATCC 23511	neg
Escherichia coli	Top10 (IDI-266)	neg
Escherichia fergusonii	ATCC 35469	neg
Escherichia hermannii	ATCC 33650	neg
Fusobacterium varium	ATCC 8501	neg
Gardnerella vaginalis	ATCC 14019	neg
Gemella morbillorum	ATCC 27824	neg
Hafnia alvei	ATCC 13337	neg
Helicobacter fennelliae	ATCC 35683 / IDI-2180	neg
Helicobacter pylori	ATCC 43504	neg
Homo sapiens	ATCC MGC-15492 / 2.16	neg
Klebsiella oxytoca	ATCC 33496	neg
Klebsiella oxytoca	ATCC 33497	neg
Klebsiella pneumoniae subsp. Pneumoniae	ATCC 13883	neg
Lactobacillus acidophilus	ATCC 4356	neg
Lactobacillus reuteri	ATCC 23272	neg
Lactococcus lactis	ATCC 11454	neg
Leminorella grimontii	ATCC 33999	neg
Listeria grayi	ATCC 19120	neg
Listeria innocua	ATCC 33090	neg
Listeria monocytogenes	L374	neg
Mitsuokella multacida	ATCC 27723	neg
Mobiluncus curtisii subsp. Holmesii	ATCC 35242	neg
Moellerella wisconsensis	ATCC 35017	neg
Morganella morganii subsp. morganii	ATCC 25830	neg
Neisseria gonorrhoeae	ATCC 35201	neg

Genera and Species	Strain	BD GeneOhm™ Cdiff Assay
Peptoniphilus asaccharolyticus	ATCC 14963	neg
Peptostreptococcus anaerobius	ATCC 27337	neg
Plesiomonas shigelloides	ATCC 14029	neg
Porphyromonas asaccharolytica	ATCC 25260	neg
Prevotella melaninogenica	ATCC 25845	neg
Proteus mirabilis	ATCC 25933	neg
Proteus penneri	ATCC 35198	neg
Providencia alcalifaciens	ATCC 9886	neg
Providencia rettgeri	ATCC 9250	neg
Providencia stuartii	ATCC 33672	neg
Pseudomonas aeruginosa	ATCC 35554	neg
Pseudomonas putida	LCDC D7172	neg
Ruminococcus bromii	ATCC 27255	neg
Salmonella choleraesuis (typhimurium)	ATCC 14028	neg
Salmonella enterica subsp. Arizonae (formerly *choleraesuis arizonae)*	ATCC 13314	neg
Salmonella enterica subsp. Enterica (formerly *Salmonella choleraesuis subsp. choleraesuis)*	ATCC 7001	neg
Serratia liquefaciens	ATCC 27592	neg
Serratia marcescens[2]	ATCC 13880	neg
Shigella boydii	ATCC 9207	neg
Shigella dysenteriae	ATCC 11835	neg
Shigella sonnei	ATCC 29930	neg
Staphylococcus aureus[3]	ATCC 43300	neg
Staphylococcus epidermidis	ATCC 14990	neg
Stenotrophomonas maltophilia	ATCC 13637	neg
Streptococcus agalactiae	ATCC 12973	neg
Streptococcus dysgalactiae	ATCC 43078	neg
Streptococcus intermedius	ATCC 27335	neg
Streptococcus uberis	ATCC 19436	neg
Trabulsiella guamensis	ATCC 49490	neg
Veillonella parvula	ATCC 10790	neg
Vibrio cholerae	ATCC 25870	neg
Vibrio parahaemolyticus	ATCC 17802	neg
Yersinia bercovieri	ATCC 43970	neg
Yersinia rohdei	ATCC 43380	neg
Yokenella regensburgei	ATCC 35313	neg

[1] A SC curve with a strong background was obtained at the first testing leading to a positive status. Retest in triplicate generated a final negative result.
[2]Two lysates were prepared because the first one gave an appearance of degradation on agarose gel.
[3]Tested with two lots of isolated DNA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Raymond J Boule
Senior Director, Regulatory Affairs, Quality Assurance
BD Diagnostics (GeneOhm Sciences Inc.)
6146 Nancy Ridge Drive
San Diego, CA 92121

DEC 19 2008

Re: k081920
Trade/Device Name: BD GeneOhm™ Cdiff Assay
Regulation Number: 21 CFR § 866.2660
Regulation Name: Clostridium difficile toxin
Regulatory Class: I
Product Code: LLH
Dated: July 2, 2008
Received: July 3, 2008

Dear Mr. Boule:

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

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 Statement

510(k) Number (if known): K081920

Device Name: BD GeneOhm™ Cdiff Assay

Indications For Use

Intended Use:

The BD GeneOhm™ Cdiff Assay is a rapid *in vitro* diagnostic test for the direct, qualitative detection of *C. difficile* toxin B gene (*tcdB*) in human liquid or soft stool specimens from patients suspected of having *Clostridium difficile*-associated disease (CDAD). The test, based on real-time PCR, is intended for use as an aid in diagnosis of CDAD. The test is performed directly on the specimen, utilizing polymerase chain reaction (PCR) for the amplification of specific targets and fluorogenic target-specific hybridization probes for the detection of the amplified DNA.

Prescription Use XXX OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

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

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K081920