K080931

JUN 11 2008

510(k) SUMMARY

VIDAS® CDAB Assay

A. Submitter Information

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Nikita S. Mapp Associate Staff Regulatory Affairs Specialist
Phone Number:	314-731-7474
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Date of Preparation:	April 1, 2008

B. Device Name

Trade Name:	VIDAS® CDAB
Common Name:	*Clostridium difficile* Enzyme Immunoassay
Classification Name:	21 CFR 866.2660, Product Code LLH Reagents, Clostridium Difficile Toxin

C. Predicate Device Name

Trade Name:	VIDAS® *C. difficile* Toxin A & B (CDAB) assay [K072138]

D. Device Description

VIDAS® C. difficile Toxin A & B (CDAB) assay is an automated test for use on the VIDAS instruments for the qualitative detection of Clostridium difficile toxin A and toxin B in stool specimens using the ELFA technique (Enzyme-Linked Fluorescent Assay).

The assay principle combines a two-step enzyme immunoassay sandwich method with a final fluorescent detection (ELFA). The Solid Phase Receptacle (SPR), a pipette tip-like device, serves as the solid phase as well as the pipetting device for the assay. The assay reagents are ready-to-use and pre-dispensed in the sealed reagent strips (STRs). The individual kit components are described in detail on the following pages.

Each of the four reaction steps are performed automatically by the VIDAS instrument. The reaction medium (sample/conjugate mixture) is cycled in and out of the SPR several times. Each step is followed by a wash cycle which eliminates unbound components.

Step 1: Toxin A and/or toxin B present in the sample binds with the anti-toxin A antibodies (rabbit polyclonal) and anti-toxin B antibodies (mouse monoclonal) coated on the interior wall of the SPR.

Step 2: Binding between toxin A and anti-toxin A antibodies (mouse monoclonal) conjugated with biotin.
Binding between toxin B and anti-toxin B antibodies (mouse monoclonal) conjugated with biotin.

Step 3: The presence of biotin is detected by incubation with streptavidin conjugated with alkaline phosphatase.

Step 4: Two detection steps are performed successively Alkaline phosphatase catalyzes the hydrolysis of the substrate (4-Methyl-umbelliferyl phosphate) into a fluorescent product (4-Methyl-umbelliferone) the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is proportional to the quantity of toxin A and/or toxin B present in the sample.

At the end of the VIDAS CDAB assay, results are automatically calculated by the VIDAS instrument. A test value as well as the qualitative result (positive, negative or equivocal) are provided on the result sheet for each sample.

E. Intended Use

VIDAS® *C. difficile* Toxin A & B (CDAB) assay is an automated test for use on the VIDAS instruments for the qualitative detection of Clostridium difficile toxin A and toxin B in stool specimens using the ELFA technique (Enzyme-Linked Fluorescent Assay). The VIDAS *C. difficile* toxin A & toxin B (CDAB) assay is an aid for diagnosing *Clostridium difficile* associated disease (CDAD).

F. Technological Characteristics Summary

A comparison of the similarities and differences of the assays is presented in the table below.

Item	Device [VIDAS CDAB Assay – Claim Extension]	Predicate [VIDAS CDAB Assay – K072138]
Intended Use	An automated test for use on the VIDAS instruments for the qualitative detection of *Clostridium difficile* toxin A and toxin B in stool specimens using the ELFA technique (Enzyme-Linked Fluorescent Assay). The VIDAS *C. difficile* toxin A & toxin B (CDAB) assay is an aid for diagnosing *Clostridium difficile* associated disease (CDAD).	An automated test for use on the VIDAS instruments for the qualitative detection of *Clostridium difficile* toxin A and toxin B in stool specimens using the ELFA technique (Enzyme-Linked Fluorescent Assay).
Indications for Use	Interpretation of test results should be made taking into consideration the patient history and any other tests performed.	Same
Specimen	Stool	Same
Assay Principle	Enzyme immunoassay	Same
Automated	Automated assay	Same
Assay Technique	Enzyme-Linked Fluorescent Assay (ELFA)	Same
Antibodies **capture** **detection**	Anti-Toxin A (rabbit polyclonal) Anti-Toxin B (mouse monoclonal) Anti-Toxin A (mouse monoclonal) Anti-Toxin B (mouse monoclonal)	Same

Item	Device [VIDAS CDAB Assay – Claim Extension]	Predicate [VIDAS CDAB Assay – K072138]
Conjugate	Mouse monoclonal anti-toxin A and anti-toxin B antibodies conjugated with biotin	Same
Sample Volume	200 µl (liquid stool) 200 mg (semi-solid & solid stools)	Same
Assay Time	~75 minutes	Same

G. Performance Data

A summary of the non-clinical and clinical test results are presented in the table below.

Item	Device [VIDAS CDAB]	Predicate [Premier Toxins A&B]
Non-clinical (Analytical) Comparison		
Precision/ Reproducibility	6 pools of samples tested in duplicate over 6 days total precision: 7.4 – 37.6% CV inter-assay precision: 6.8 – 26.8% CV intra-assay precision: 2.9 – 26.3% CV	Same
***C. difficile* strain types**	A+/B+ 100% (23/23) A-/B+ 83% (15/18*) ** 3 of the A-/B+ strains gave equivocal results*	Same
Limit of Detection (stool)	Toxin A at level of ≥ 7.73 ng/mL; Toxin B at level of ≥ 4.55 ng/mL	Same
Drug Interference	Vancomycin; Metronidazole; Loperamide; Bismuth subsalicylate; Salicylate; Barium sulfate; Imodium tablet & liquid; Pepto-Bismol tablet & liquid	Not evaluated in K072138
Clinical Studies Comparison		
Number of specimen	1011 specimens	Same
Study Site(s)	USA and Europe	Same
Results Sensitivity: Specificity: PPV: NPV: *additional testing w/external site* Sensitivity: Specificity: Total Agreement:	*versus CTA (all sites)* 88.3%; 95% CI: 81.2 – 93.5% 99.8 %; 95% CI: 99.2 – 99.9% 98.1%; 95% CI: 93.5 – 99.8% 98.4 %; 95% CI: 97.3 – 99.1% 88.0%; 95% CI: 68.8 – 97.5% 95.1%; 95% CI: 86.3 – 99.0% 93.0%; 95% CI: 85.4 – 97.4%	Submitted in K072138 N/A
Results Positive Agreement: Negative Agreement: Global Agreement:	*versus Predicate (all sites)* 81.3%; 95% CI: 73.4 – 87.6% 99.5%; 95% CI: 98.8 – 99.9% 97.1%; 95% CI: 95.9 – 98.1%	Same

H. Conclusion

The VIDAS® CDAB Assay is substantially equivalent to the VIDAS CDAB Assay [K072138].

The 510(k) summary includes only information that is also covered in the body of the 510(k). The summary does not contain any puffery or unsubstantiated labeling claims. The summary does not contain any raw data, i.e., contains only summary data. The summary does not contain any trade secret or confidential commercial information. The summary does not contain any patient identification information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 11 2008

Ms. Nikita S. Mapp
Associate Staff Regulatory Affairs Specialist
bioMérieux, Inc.
595 Anglum Road
Hazelwood, MO 63042

Re: k080931
Trade/Device Name: VIDAS® CDAB Assay
Regulation Number: 21 CFR § 866.2660
Regulation Name: Microorganism Differentiation and Identification Device
Regulatory Class: I
Product Code: LLH
Dated: April 1st, 2008
Received: April 2nd, 2008

Dear Ms. Mapp:

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 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): K080931

Device Name: VIDAS® *C. difficile* Toxin A & B (CDAB) Assay

Indications For Use: VIDAS® *C. difficile* Toxin A & B (CDAB) assay is an automated test for use on the VIDAS instruments for the qualitative detection of *Clostridium difficile* toxin A and toxin B in stool specimens using the ELFA technique (Enzyme-Linked Flurorescent Assay). The VIDAS *C. difficile* toxin A & toxin B (CDAB) assay is an aid for diagnosing *Clostridium difficile* associated disease (CDAD).

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) K080931