K071146

OCT 11 2007

510(k) SUMMARY

VIDAS® B•R•A•H•M•S PCT Assay

A. Submitter Information

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Nikita S. Mapp
Phone Number:	314-731-7474
Fax Number:	314-731-8689
Date of Preparation:	March 1, 2007

B. Device Name

Trade Name:	VIDAS® BRAHMS PCT
Common Name:	Endotoxin Assay
Classification Name:	21 CFR 866.3210, Product Code NTM Antigen, Inflammatory Response Marker, Sepsis

C. Predicate Device Name

Trade Name:	BRAHMS PCT LIA Assay

D. Device Description

The VIDAS BRAHMS PCT Assay is an enzyme-linked fluorescent immunoassay (ELFA) performed in an automated VIDAS® instrument.

The assay principle combines a one-step immunoassay sandwich method with a final fluorescent detection (ELFA). The Solid Phase Receptacle (SPR), serves as the solid phase as well as the pipetting device for the assay. Reagents for the assay are ready-to-use and pre-dispensed in the sealed reagent strips.

All of the assay steps are performed automatically by the instrument. The sample is transferred into the wells containing anti-procalcitonin antibodies labeled with alkaline phosphatase (conjugate). The sample/conjugate mixture is cycled in and out of the SPR several times. This operation enables the antigen to bind with the immunoglobulins fixed to the interior wall of the SPR and the conjugate to form a sandwich. Unbound compounds are eliminated during washing steps.
Two detection steps are performed successively. During each step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the

hydrolysis of this substrate 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 concentration of antigen present in the sample.

At the end of the assay, results are automatically calculated by the instrument in relation to two calibration curves corresponding to the two revelation steps and stored in memory, and then printed out.

E. Intended Use

VIDAS BRAHMS PCT is an automated test for use on the VIDAS instruments for the determination of human procalcitonin in human serum or plasma (lithium heparin) using the ELFA (Enzyme-Linked Fluorescent Assay). VIDAS BRAHMS PCT is intended for use in conjunction with othe laboratory findings and clinical assessments to aid in the risk assessment of critically ill patients on their first day of ICU admission, for progression to severe sepsis and septic shock.

F. Technological Characteristics Summary

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

Item	Device [VIDAS BRAHMS PCT]	Predicate [BRAHMS PCT LIA]
Intended Use	Determination of human procalcitonin in human serum or plasma (lithium heparin)	Same
Indications for Use	For use in conjunction with other laboratory findings and clinical assessments to aid in the risk assessment of critically ill patients on their first day of ICU admission, for progression to severe sepsis and septic shock	Same
Specimen	Human serum or plasma (lithium heparin)	Same
Analyte	Measures procalcitonin concentration	Same
Antibody	Anti-PCT antibody (monoclonal mouse)	Same
Assay Principle	Immunoassay based on sandwich principle	Immunoluminometric assay based on sandwich principle
Automated	Automated assay	Non-automated assay
Final Detection of PCT antigen	Fluorescence (ELFA) of 4-methyl-umbelliferyl measured at 450 nm	Luminescence signal measurement via luminometer
Assay Technique	Enzyme-Linked Fluorescent Assay(ELFA)	Immunoluminometric assay (ILMA)
Special instrument requirements	None	Luminometer required
Sample Volume	200 µl	20 µl
Assay Time	~20 minutes	~90 minutes
Measurement range	0.05 to 200 ng/ml	0.3 – 500 ng/ml

G. Performance Data

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

Test	Device [VIDAS BRAHMS PCT]	Predicate [BRAHMS PCT LIA]
Non-clinical (Analytical) Comparison		
Matrix Comparison	Serum similar to Plasma For a given patient, the same type of sample tube must be performed for each patient	Same
Precision/ Reproducibility	6 samples tested in duplicate over 20 days total precision: 6.17 – 15.31% CV intra-run precision: 1.93 – 4.61% CV inter-run precision: 3.57 – 7.04% CV inter-site precision: 4.21 – 11.40% CV	14 samples tested in duplicate over 20 days total precision: 5.3 - 16.6% CV within run precision: 2.4-10% CV
Analytical Detection Limit	<0.05 ng/ml	1.0 ng/ml
Functional Detection Limit	0.09 ng/ml	0.3 ng/ml
Interfering Substances	No significant interference	No significant interference
Bilirubin	574 µmol/l	40 mg/dl
Hemoglobin	347 µmol/l	500 mg/dl
Triglycerides	30 g/l	634 mg/dl
Analytical Specificity	No significant interference	No significant interference
Protein (albumin)	4 g/dl	1 g/dl
Human calcitonin	60 ng/ml	8 ng/ml
Human katacalcin	10 ng/ml	30 ng/ml
Human alpha-CGRP	10 µg/ml	30 ng/ml
Human beta-CGRP	10 µg/ml	30 ng/ml
Drug Interference	No significant interference	No significant interference
Imipenem	0.5 mg/ml	1.18 mg/ml
Cefotaxime	180 mg/dl	90 mg/dl
Vancomycin	3 mg/ml	3.5 mg/ml
Dopamine	26 mg/dl	13 mg/dl
Noradrenalin	4 µg/ml	2 µg /ml
Dobutamine	22.4 µg/ml	11.2 µg /ml
Heparin	16,000 U/L	8000 U/l
Furosemide	4 mg/dl	2 mg/dl
Hook Effect	No hook effect found up to concentrations of 2600 ng/ml	No hook effect found up to concentrations of 4000 µg/L
Clinical Comparison		
Cut-off	>2 ng/ml = high risk of severe sepsis and/or septic shock <0.5 ng/ml = low risk of severe sepsis and/or septic shock	Same
Clinical Sensitivity/Specificity Studies		
Number of patients	232 patients	179 patients
Study Site(s)	US and Europe	Europe
Results	→ In 92 patients with PCT level ≤0.5 ng/ml, 18 patients had severe sepsis or septic shock → In 104 patients with severe sepsis or septic shock, 37 patients had PCT level ≤ 2.0 ng/ml	→ In 44 patients with PCT level <0.5 ng/ml, no patient had severe sepsis or septic shock → In 77 patients with severe sepsis or septic shock, one patient had PCT level ≤ 2.0

Test	Device [VIDAS BRAHMS PCT]	Predicate [BRAHMS PCT LIA]
		ng/ml
Clinical Specificity Study on U.S. Healthy Subjects (normal values)		
Number of patients	200 healthy subjects	144 healthy subjects
Study Site(s)	US	US
Results	200 healthy subjects; 95th percentile: <0.05 ng/ml cut-off 99th percentile: 0.09 ng/ml	143 out of 144 healthy subjects had PCT values of <0.3 ng/ml

H. Conclusion

The VIDAS® BRAHMS PCT Assay is substantially equivalent to the BRAHMS PCT LIA Assay.

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

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

OCT 11 2007

Re: k071146
Trade/Device Name: VIDAS® BRAHMS PCT
Regulation Number: 21 CFR 866.3210
Regulation Name: Endotoxin Assay
Regulatory Class: Class II
Product Code: NTM
Dated: August 30, 2007
Received: September 4, 2007

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): K071146

Device Name: VIDAS BRAHMS PCT Assay

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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 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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