K073091

FEB 29 2008

510(k) SUMMARY

VIDAS® NT-proBNP 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:	October 2007 *(revised February 2008)*

B. Device Name

Trade Name:	VIDAS® NT-proBNP
Common Name:	Endotoxin Assay
Classification Name:	21 CFR 862.1117 Product Code NBC B-type natriuretic peptide test system

C. Predicate Device Name

Trade Name:	Elecsys proBNP Assay

D. Device Description

The VIDAS® NT-proBNP assay is an automated quantitative test for use on the VIDAS instruments for the determination of N terminal fragment of B-type natriuretic peptide in human serum or plasma (lithium heparin) using the ELFA (Enzyme-Linked Fluorescent Assay) technique. The VIDAS NT-proBNP test is used as an aid in the diagnosis of suspected congestive heart failure.

The assay principle combines a one-step 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 in the 510(k) and in the package insert.

All of the assay steps are performed automatically by the VIDAS instrument. The sample is transferred into the well containing anti-NT-proBNP antibody (conjugate) labeled with alkaline phosphatase. 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 VIDAS instrument in relation to two calibration curves corresponding to the two detection steps stored in memory, and then printed out.

E. Intended Use

The VIDAS® NT-proBNP assay is an automated quantitative test for use on the VIDAS instruments for the determination of N terminal fragment of B-type natriuretic peptide in human serum or plasma (lithium heparin) using the ELFA (Enzyme-Linked Fluorescent Assay) technique. The VIDAS NT-proBNP test is used as an aid in the diagnosis of suspected congestive heart failure.

F. Technological Characteristics Summary

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

Item	Device [VIDAS NT-proBNP]	Predicate [Elecsys proBNP]
General Comparison		
Intended Use	Quantitative determination of N terminal fragment of B-type natriuretic peptide in human serum or plasma (lithium heparin). The VIDAS NT-proBNP test is used as an aid in the diagnosis of suspected congestive heart failure.	Same as initial claim [K022516]. *Roche obtained additional claims via other 510(k)s, "risk stratification" and "risk assessment " which bioMerieux is not pursuing at this time.*
Specimen	Human serum or plasma	Same
Analyte	Measures NT-proBNP	Same
Antibody	Anti-NT-proBNP antibody (polyclonal sheep)	Same
Assay Principle	Immunoassay based on sandwich principle	Same
Automated	Automated assay	Same
Assay Technique	Enzyme-Linked Fluorescent Assay (ELFA)	Electrochemiluminescent assay
Sample Volume	200 µl	20 µl
Assay Time	~20 minutes	18 minutes
Traceability/ Standardization	Traceable to proBNP Roche	Reference standard – purified synthetic NTG-proBNP (1-76) in human serum matrix
Measurement range	20-25,000 pg/mL	5-35,000 pg/mL

G. Performance Data

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

Test	Device [VIDAS NT-proBNP]	Predicate [Elecsys proBNP]
Non-clinical (Analytical) Comparison		
Matrix Comparison	Serum similar to Plasma *For patient follow-up, assays must be performed on the same type of sample tube.*	Same
Precision	5 samples tested in duplicate in 40 different runs (2 runs per day) repeatability (intra-run): 1.5 – 2.8 %CV inter-site: 3.4 –5.1 %CV inter-lot: 3.5 – 8.4 %CV	4 samples tested in 6 times daily for 10 days total precision: 2.2 – 3.2%CV within run precision: 1.8 – 2.7%CV
Detection Limits	< 20 pg/mL (LoB = 3.4 pg/mL, LoD = 6.7 pg/mL, LoQ = 13.9 pg/mL)	5 pg/ml
Interfering Substances Bilirubin Hemoglobin Triglycerides Albumin Human IgG Human IgM Rheumatoid Factors	No significant interference 30 mg/dl (510 µmol/L) 485 mg/dl (300 µmol/L) 30 g/l 100 g/L 17 g/L 6 g/L 1500 IU/mL	No significant interference 35 mg/dl 1.4 g/dl 4000 mg/dl Not tested Not tested Not tested 1500 IU/mL
Analytical Specificity Adrenomedullin Aldosterone Angiotensin I Angiotensin II Angiotensin III ANP_{28} Arg-Vasopressin BNP_{32} CNP_{22} Endothelin NT-proANP$_{1-30}$ NT-proANP$_{31-67}$ NT-proANP$_{79-98}$ Renin Urodilatin	 <0.1% <0.1% <0.1% <0.1% <0.1% <0.1% <0.1% <0.1% <0.1% <0.1% <0.1% <0.1% <0.1% <0.1% <0.1%	 <0.001% <0.001% <0.001% <0.001% <0.001% <0.001% <0.001% <0.001% <0.001% <0.001% <0.001% <0.001% <0.001% <0.001% <0.001%
Drug Interference	No interference was observed on 39 frequently administered drugs tested *in vitro*	No interference found on commonly used pharmaceuticals
Hook Effect	No hook effect found up to concentrations of 500,000 pg/mL	No hook effect found up to concentrations of 300,000 pg/mL
Clinical Comparison		
Cut-off	125 pg/mL for patients <75 years old 450 pg/mL for patients ≥ 75 years old	Same
Clinical Sensitivity/Specificity Studies		
Reference Group (without CHF)		
Number of patients	411 patients	1411 patients
Study Site(s)	US and Europe	unknown

Results	% < cut-off (males and females) <45 yrs: 92.4% 45-54 yrs: 90.3% 55-64 yrs: 95.4% 65-74 yrs: 89.5% <75 yrs: 92.2% ≥75+ yrs: 95.7%	% < 125 pg/mL (all) <45 yrs: 95.7% 45-54 yrs: 93.3% 55-64 yrs: 83.3% 65-74 yrs: 69.8% <75 yrs: 82.4% % < 450 pg/mL (all) 75+ yrs: 88.9%
Disease Group (with CHF)		
Number of patients	407 patients	721 patients
Study Site(s)	US and Europe	unknown
Results	% ≥ cut-off (males and females) <45 yrs: 85.0% 45-54 yrs: 85.3% 55-64 yrs: 88.1% 65-74 yrs: 100.0% <75 yrs: 92.3% ≥75+ yrs: 91.5%	% < 125 pg/mL (all) <45 yrs: 82.8% 45-54 yrs: 88.5% 55-64 yrs: 89.5% 65-74 yrs: 92.2% 75+ yrs: unknown <75 yrs: 89.3% % < 450 pg/mL (all) 75+ yrs: 84.7%

Sensitivity and Specificity vs. gender and age

European Site 1

Statistics	All patients	< 75 yrs.	≥ 75 yrs.
Sensitivity (%)	94.63 (89.64-97.29)	100 (94.81-100)	89.47 (80.36-94.64)
Specificity (%)	97.39 (93.36-99.00)	97.27 (92.14-99.09)	97.67 (87.63-99.6)

European Site 2

Statistics	All patients	< 75 yrs.	≥ 75 yrs.
Sensitivity (%)	94.96 (89.84-97.57)	94.23 (84.08-98.06)	95.4 (88.58-98.23)
Specificity (%)	96.69 (92.37-98.6)	96.36 (90.87-98.6)	97.56 (87.09-99.58)

US Site

Statistics	All patients	< 75 yrs.	≥ 75 yrs.
Sensitivity (%)	84.87 (77.18-90.3)	82.86 (72.14-90.02)	87.76 (75.46-94.35)
Specificity (%)	81.31 (72.69-87.67)	81.82 (72.88-88.28)	75 (40.31-93.02)

All Sites Combined

Statistics	All patients	< 75 yrs.	≥ 75 yrs.
Sensitivity (%)	91.89 (88.76-94.21)	92.31 (87.58-95.33)	91.51 (86.87-94.61)
Specificity (%)	92.94 (89.98-95.08)	92.16 (88.6-94.68)	95.65 (89.17-98.33)

Males: All Sites Combined

Statistics	Males	Males < 75 yrs.	Males ≥ 75 yrs.
Sensitivity (%)	92.92 (88.85-95.57)	94.07 (88.6-97.01)	91.43 (84.33-95.48)
Specificity (%)	95.67 (92.13-97.66)	95.31 (91.23-97.55)	97.44 (86.49-99.56)

Females: All Sites Combined

Statistics	Females	Females < 75 yrs.	Males ≥ 75 yrs.
Sensitivity (%)	90.42 (84.87-94.07)	88.33 (77.56-94.31)	91.59 (84.61-95.57)
Specificity (%)	89.44 (83.98-93.2)	87.4 (80.35-92.17)	94.34 (84.36-98.1)

H. Conclusion

The VIDAS® NT-proBNP Assay is substantially equivalent to the Roche Elecsys proBNp 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

bioMerieux, Inc
c/o Ms. Nikita Mapp
Senior Regulatory Affairs Specialist
595 Anglum Road
Hazelwood, MO 63042

FEB 29 2008

Re: k073091
Trade/Device Name: VIDAS NT-proBNP Assay
Regulation Number: 21 CFR 862.1117
Regulation Name: B-type natriuretic peptide test system
Regulatory Class: Class II
Product Code: NBC

Dated: February 04, 2008
Received: February 05, 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 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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): Not yet assigned K073091

Device Name: VIDAS NT-proBNP Assay

Indication For Use: VIDAS® NT-proBNP assay is an automated quantitative test for use on the VIDAS instruments for the determination of N terminal fragment of B-type natriuretic peptide in human serum or plasma (lithium heparin) using the ELFA (Enzyme-Linked Fluorescent Assay) technique. The VIDAS NT-proBNP test is used as an aid in the diagnosis of suspected congestive heart failure.

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)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K073091