K080766 510(k) SUMMARY

VIDAS® RUB IgG Assay

DEC 23 2008

A. Submitter Information

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Sandra Perreand Sr. Director, North American Regulatory Affairs
Phone Number:	314-731-8594
Fax Number:	314-731-8689
Date of Preparation:	December 2008

B. Device Name

Trade Name:	VIDAS® RUB IgG Assay
Common Name:	Rubella IgG Antibody
Classification Name:	Enzyme Linked Immunoabsorbent Assay, Rubella

C. Predicate Device Name

Trade Name:	AxSYM Rubella IgG Antibody Assay

D. Device Description

The assay principle combines a 2-step enzyme 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. It is coated with Rubella antigen. The other reagents for the assay are ready-to-use and pre-dispensed in the sealed reagent strips. The individual kit components are described in detail on the following pages.

All of the assay steps are performed automatically by the instrument. The reaction medium is cycled in and out of the SPR several times. This operation enables the Rubella antigen fixed onto the interior wall of the SPR to capture the Rubella antibodies present in the sample. After dilution, the sample is incubated with the SPR. Rubella IgG antibodies present in the specimen bind to the Rubella antigen coating the interior of the SPR. Unbound components are eliminated during the preliminary wash step.

A second incubation step is then performed using alkaline phosphatase labeled monoclonal anti-human IgG antibodies (mouse), followed by a second wash step.

During the final detection 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 antibodies present in the sample. At the end of the assay, results are automatically calculated by the instrument in relation to the calibration curve stored in memory, and then printed out.

E. Intended Use

The VIDAS® RUB IgG (RBG) assay uses Enzyme Linked Fluorescent Assay (ELFA) technology on the VIDAS® automated instruments for the *in vitro* quantitative and qualitative measurement of IgG antibodies to rubella virus in human serum. The VIDAS® RUB IgG assay is intended as an aid in the determination of immune status to rubella. The performance of this device has not been established for screening of cord blood, or for neonatal samples. Likewise, performance characteristics of the assay have not been established for immunocompromised or immunosuppressed individuals.

F. Technological Characteristics Summary

A general comparison of the similarities and differences of the VIDAS RUB IgG assay to the predicate device is presented in the table below.

Item	VIDAS® RUB IgG Assay	Abbott's AxSYM Rubella IgG Antibody Assay (K954045)
General Comparison		
Intended Use	The VIDAS® RUB IgG (RBG) assay uses Enzyme Linked Fluorescent Assay (ELFA) technology on the VIDAS® automated instruments for the *in vitro* quantitative and qualitative measurement of IgG antibodies to rubella virus in human serum. The VIDAS® RUB IgG assay is intended as an aid in the determination of immune status to rubella. The performance of this device has not been established for screening of cord blood, or for neonatal samples. Likewise, performance characteristics of the assay have not been established for immunocompromised or immunosuppressed individuals.	The AxSYM Rubella IgG assay is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative and qualitative measurement of IgG antibodies to rubella virus in human serum or plasma (EDTA, heparin or sodium citrate) to aid in the determination of immune status to rubella.
Specimen	Serum	Serum or plasma (EDTA, heparin or sodium citrate)
Analyte	Rubella IgG	Rubella IgG
Antibody	Mouse monoclonal anti-human IgG	Goat anti-human IgG
Assay Principle	Two step antibody binding of Rubella antibodies. An antigen is bound to a solid phase and anti-human IgG is in liquid form and is labeled with fluorescent compound	Twostep antibody binding of Rubella antibodies. An antigen is bound to a solid phase and anti-human IgG is in liquid form and is labeled with fluorescent compound
Automated	Yes	Yes
Assay Technique	Enzyme-linked fluorescent assay (ELFA)	Microparticle enzyme immunoassay (MEIA)
Sample Volume	100 µL	180 µL
Traceability/ Standardization	Master curve for each kit lot and each calibrator lot are traceable to the 2nd preparation of the World Health Organization (WHO) 1st International Rubella Reference Standard	Each calibrator lot is traceable to the World Health Organization (W.H.O.) 2nd International Standard for Anti-Rubella Immunoglobulin
Measurement range	0 – 400 IU/mL	0 – 500.0 IU/mL

G. Performance Data

Precision

Four serum samples were tested in duplicate twice a day (2 runs per day over 10 days) on each of the 2 reagent lots using a single instrument at each of three sites (N = 240). The repeatability (intra-run precision), inter-run precision, between-site precision and total precision were calculated according to the CLSI® EP5-A2 document:

		Repeatability		Inter-run precision		Between site precision		Total precision	
Sample	Mean concentration IU/mL	Standard deviation	CV (%)	Standard deviation	CV (%)	Standard deviation	CV (%)	Standard deviation	CV (%)
Sample 1	7.8	0.58	7.4	0.58	7.4	0.20	2.5	0.84	10.8
Sample 2	8.8	0.57	6.4	0.66	7.4	0.22	2.5	0.89	10.2
Sample 3	29.8	1.46	4.9	2.62	8.8	0.95	3.2	3.14	10.6
Sample 4	154.6	10.58	6.8	18.49	12.0	0.00	0.0	21.30	13.8

Clinical Performance

The following tables compare the results of the VIDAS® RUB IgG assay to the consensus comparator

Prospective populations

	Prospective Pregnant Women 2/3 Consensus				Prospective General 2/3 Consensus			
VIDAS®	Pos	Equiv	Neg	Total	Pos	Equiv	Neg	Total
Pos	309	1	0	310	170	1	0	171
Equiv	10	3	0	13	3	1	0	4
Neg	0	0	2	2	0	2	2	4
Total	319	4	2	325	173	4	2	179*

	% Agreement	95% CI	% Agreement	95% CI
Positive	96.9% (309/319)	94.3 – 98.5	97.1% (170/175)	93.5 – 99.1
Negative	66.7% (2/3)	9.4 – 99.2	66.7% (2/3)	9.4 – 99.2

*One sample was defined as QNS (quantity not sufficient) and excluded from the analysis.

Retrospective populations

	Retrospective Pregnant Women 2/3 Consensus				Retrospective General 2/3 Consensus			
VIDAS®	Pos	Equiv	Neg	Total	Pos	Equiv	Neg	Total
Pos	179	0	0	179	169	0	0	169
Equiv	9	4	0	13	7	4	0	11
Neg	0	5	3	8	1	6	104	111
Total	188	9	3	200	177	10	104	291*

	% Agreement	95% CI	% Agreement	95% CI
Positive	92.7% (179/193)	88.1 – 96.0	92.3% (169/183)	87.5 – 95.8
Negative	100% (3/3)	29.2 – 100.0	100% (104/104)	96.5 – 100.0

*Five samples were defined as QNS (quantity not sufficient) and excluded from the analysis

Pre-selected Pregnant Women Population

	Pre-selected Pregnant Women 2/3 Consensus Method			
VIDAS®	Pos	Equiv	Neg	Total
Pos	23	0	0	23
Equiv	0	0	0	0
Neg	0	2	102	104
Total	23	2	102	127*

	% Agreement	95% CI
Positive	92.0% (23/25)	74.0 – 99.0
Negative	100% (102/102)	96.4 – 100.0

*Two samples were defined as QNS (quantity not sufficient) and excluded from the analysis.

H. Conclusion

The VIDAS® RUB IgG Assay is substantially equivalent to Abbott Laboratories AxSYM Rubella IgG Antibody 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

Sandra Perreand
Sr. Director, N.A. Regulatory Affairs
bioMérieux, Inc.
595 Anglum Road
Hazelwood, MO 63042

DEC 23 2008

Re: K080766

Trade/Device Name:	VIDAS® RUB IgG Assay
Regulation Number:	21CFR §866.3510
Regulation Name:	Rubella virus serological reagents
Regulatory Class:	Class II
Product Code:	LFX
Dated:	December 19, 2008
Received:	December 22, 2008

Dear Ms. Perreand:

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): K080766

Device Name: VIDAS® RUB IgG

Indications For Use:

The VIDAS® RUB IgG (RBG) assay uses Enzyme Linked Fluorescent Assay (ELFA) technology on the VIDAS® automated instruments for the *in vitro* quantitative and qualitative measurement of IgG antibodies to rubella virus in human serum. The VIDAS® RUB IgG assay is intended as an aid in the determination of immune status to rubella. The performance of this device has not been established for screening of cord blood, or for neonatal samples. Likewise, performance characteristics of the assay have not been established for immunocompromised or immunosuppressed individuals.

Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (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) K080766