MAY 18 2011

510(k) SUMMARY

VIDAS® TOXO IgG Avidity Assay

A. Submitter Information

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	John Albright
Phone Number:	314-731-8546
Fax Number:	314-731-8689
Date of Preparation:	July 2010

B. Device Name

Trade Name:	VIDAS® TOXO IgG Avidity Assay
Common Name:	TOXO IgG Avidity Assay
Classification Name:	21 CFR 866.3780 Product Code LGD Toxoplasma gondii serological readents

C. Predicate Device Name

Trade Name:	VIDAS® TOXO IgM Assay

D. Device Description

The VIDAS® TOXO IgG Avidity assay is an automated qualitative test for the determination of anti-toxoplasma IgG avidity in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS® TOXO IgG Avidity assay is intended for use in conjunction with results from the VIDAS TOXO IgG II and must have a positive titer (> 8 IU/mL); other laboratory findings and clinical information to aid in the presumptive exclusion of a recently acquired (< 4 months) Toxoplasma gondii infection in pregnant women and patients with lymphadenopathy.

The addition of a dissociating agent (such as urea) which disrupts the Ag-Ab link during an ELISA test has little effect on the high avidity Ag-Ab link, but great effect on that of weak avidity Ab. Comparison of results obtained with and without a dissociating agent corresponds to one measure of avidity.

The assay principle combines a two-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. Reagents for the assay are ready-to-use and pre-dispensed in the sealed reagent strips. VIDAS TOXO IgG Avidity uses a dual strip comprising one reference strip and one test strip. The sample to be tested, after dilution, is dispensed into both sample wells of the dual strip: reference and test.

Anti-toxoplasma IgG present in the sample forms complexes with antigen coated to the solid phase. In the reference strip, non-specific antibodies are eliminated by washing, whereas specific antibodies remain coated to the solid phase. In the test strip, washing with the dissociating agent changes antigen-antibody links: high avidity antibodies remain bound to the solid phase, whereas low avidity antibodies are eliminated.

Alkaline phosphatase labeled with human anti-IgG antibody (conjugate) is then cycled in and out of the SPR, and binds with any human IgG coated on the interior of the SPR. Unbound conjugate is removed by washing.

All of the assay steps are performed automatically by the instrument. The reaction medium is cycled in and out of the SPR several times. 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. Fluorescence is measured twice in the Reagent Strip's reading cuvette for each dual reagent strip. The first reading is a background reading of the substrate cuvette before the SPR is introduced into the substrate. The second reading is taken after incubating the substrate with the enzyme remaining on the interior of the SPR. The RFV (Relative Fluorescence Value) is calculated by subtracting the background reading from the final result. The RFV for the two assays (reference and test) appear on the result sheet. 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 and then printed out.

The ratio between the quantity of high avidity antibodies (test strip) and the quantity of total antibodies (reference strip) provides an index that indicates antibody avidity in the tested sample.

E. Intended Use

The VIDAS® TOXO IgG Avidity assay is an automated qualitative test for the determination of anti-toxoplasma IgG avidity in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS® TOXO IgG Avidity assay is intended for use in conjunction with results from the VIDAS TOXO IgG II and must have a positive titer ($\geq$ 8 IU/mL); other laboratory findings and clinical information to aid in the presumptive exclusion of a recently acquired ($\leq$ 4 months) Toxoplasma gondii infection in pregnant women and patients with lymphadenopathy.

VIDAS TOXO IgG Avidity assay performance has not been established for prenatal screening, for newborn testing, for use in immunocompromised patients and in cases of endogenous or exogenous reinfection by Toxoplasma gondii. This assay has not been cleared or approved by the FDA for blood/plasma donor screening.

F. Technological Characteristics Summary

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

Item	Device [VIDAS TOXO IgG Avidity Assay]	Predicate [VIDAS TOXO IgM Assay]
General Comparison		
Intended Use	The VIDAS® TOXO IgG Avidity assay is an automated qualitative test for the determination of anti-toxoplasma IgG avidity in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS® TOXO IgG Avidity assay is intended for use in conjunction with results from the VIDAS TOXO IgG II and must have a positive titer (≥ 8 IU/mL); other laboratory findings and clinical information to aid in the presumptive exclusion of a recently acquired (≤ 4 months) Toxoplasma gondii infection in pregnant women and patients with lymphadenopathy. VIDAS TOXO IgG Avidity assay performance has not been established for prenatal screening, for newborn testing, for use in immunocompromised patients and in cases of endogenous or exogenous reinfection by Toxoplasma gondii. This assay has not been cleared or approved by the FDA for blood/plasma donor screening.	VIDAS® TOXO IgM Assay is intended for use with a VIDAS (VITEK® ImmunoDiagnostic Assay System) instrument as an automated enzyme-linked fluorescent immunoassay (ELFA) for the presumptive qualitative detection of anti-*Toxoplasma gondii* IgM antibodies in human serum, as an aid in the diagnosis of acute, recent, or reactivated Toxoplasma gondii infection. This assay must be performed in conjunction with an anti-Toxoplasma gondii IgG antibody assay. VIDAS TXM assay performance has not been established for prenatal screening or newborn testing. This assay has not been cleared by the FDA for blood/plasma donor screening.
Specimen	Serum	Serum
Analyte	Anti-toxoplasma IgG avidity	Anti-toxoplasma IgM
Assay Principle	Immunoassay based on sandwich principle	Immunoassay based on sandwich principle
Automated	Yes	Yes
Assay Technique	Enzyme-linked fluorescent assay (ELFA)	Enzyme-linked fluorescent assay (ELFA)

G. Performance Data

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

Non-clinical (Analytical) Comparison		
Item	**VIDAS® TOXO IgG Avidity Assay**	**VIDAS® TOXO IgM assay (K923166)**
Within-run Precision	n = 80 replicates at each of the 3 sites Low avidity: Mean avidity index = 0.1196 CV = 7.9% Low avidity close to the clinical decision point (C_5): Mean avidity index =0.2620 CV = 7.8%	n = 22 replicates High positive: Mean test value = 1.93 CV = 4.8% Low positive: Mean test value = 1.10 CV = 6.7% Negative: Mean test value = 0.08

Non-clinical (Analytical) Comparison		
Item	**VIDAS® TOXO IgG Avidity Assay**	**VIDAS® TOXO IgM assay (K923166)**
	High avidity close to the clinical decision point (C_{95}): Mean avidity index =0.3209 CV = 5.7% High avidity (medium): Mean avidity index = 0.5352 CV = 6.1% High avidity (high): Mean avidity index = 0.6843 CV = 7.1%	CV = 6.1%
Between-Run Precision	n = 40 runs at each of the 3 sites Low avidity: Mean avidity index = 0.1196 CV ≤ 0.1% Low avidity close to the clinical decision point (C_5): Mean avidity index = 0.2620 CV ≤ 0.1% High avidity close to the clinical decision point (C_{95}): Mean avidity index = 0.3209 CV = 4.3% High avidity (medium): Mean avidity index = 0.5352 CV = 3.1% High avidity (high): Mean avidity index = 0.6843 CV = 2.1%	n = 3 replicates for 12 days High positive: Mean test value = 1.96 CV = 3.7% Low positive: Mean test value = 1.03 CV = 7.5% Negative: Mean test value = 0.07 CV = 6.4%
Total Precision (within-run, between-run, between-day, between-lot and between site)	n = 120 runs (2 runs per day, for 10 days with 2 reagent lots (10 days per lot), at 3 sites) Low avidity: Mean avidity index = 0.1196 CV = 8.4% Low avidity close to the clinical decision point (C_5): Mean avidity index = 0.2620 CV = 9.7% High avidity close to the clinical decision point (C_{95}): Mean avidity index = 0.3209 CV = 7.4% High avidity (medium): Mean avidity index = 0.5352 CV = 7.0% High avidity (high): Mean avidity index = 0.6843 CV = 7.4%	No claim
Cross-Reactivity	No clinically significant interference was observed for: • Samples from patients with Rheumatoid Factors	No cross-reactivity was observed for: • Samples from patients with Rheumatoid Factors • Samples from patient with

Non-clinical (Analytical) Comparison		
Item	**VIDAS® TOXO IgG Avidity Assay**	**VIDAS® TOXO IgM assay (K923166)**
	• Samples from patient with Antinuclear antibodies • Samples from patients with Epstein Bar virus infection. • Samples from patients with CMV • Samples from patients with HAMA • Samples from patients with HAV • Samples from patients with HBV • Samples from patients with HSV-2 • Samples from patients with Rubella • Samples from patients with VZV However, a clinically significant interference was observed with 1 of the 12 samples tested for HSV-1 disease.	Antinuclear antibodies • Samples from patients with Epstein Bar virus infection.
Interfering Substances	No interference from: • Hemoglobin up to 300 µmol/L • Triglycerides up to 30 mg/mL • Bilirubin up to 510 µmol/L • Human albumin up to 5 g/dL	No claim
Drug Interference	• No interference with Sulfamethoxazole was observed at a concentration of 1.58 mmol/L (400 µg/mL) • No interference with Sulfapyridine was observed at a concentration of 1.20 mmol/L (300 µg/mL) • No interference with Sulfasalazine was observed at a concentration of 754 µmol/L (300 µg/mL) • No interference with Spiramycin was observed at a concentration of 15.0 µg/mL • No interference with Clindamycin was observed at a concentration of 89.1 µmol/L (45 µg/mL) • No interference with Trimethoprim was observed at a concentration of 138 µmol/L (40 ug/mL) • No interference with Sulfamethoxazole and Trimethoprim was observed at a concentration of 1.58 mmol/L (400 µg/mL)and138 µmol/L (40 µg/mL), respectively • No interference with Pyrimethamine was observed at a concentration of 60 µg/mL)	No claim

Non-clinical (Analytical) Comparison		
Item	VIDAS® TOXO IgG Avidity Assay	VIDAS® TOXO IgM assay (K923166)

H. Conclusion

The VIDAS® TOXO IgG Avidity Assay is substantially equivalent to the bioMérieux TOXO IgM 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
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAY 18 2011

bioMérieux, Inc.
c/o John Albright
Sr. Regulatory Affairs Specialist
595 Anglum Road
Hazelwood, Missouri 63042-2320

Re: K101946
Trade/Device Name: VIDAS® Toxo IgG Avidity Assay
Regulation Number: 21 CFR 866.3780
Regulation Name: *Toxoplasma gondii* Serological Reagents
Regulatory Class: Class II
Product Code: LGD
Dated: May 13, 2011
Received: May 16, 2011

Dear Mr. Albright:

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 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): K101946

Device Name: VIDAS® TOXO IgG Avidity

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K101946