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K993319

bioMérieux

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: _____

Submitter:	bioMerieux, Inc. 1022 Hingham Street Rockland, MA 02370 Phone (781) 871-4442 Fax (781) 871-3470 Contact Name: Anna J. DeMarinis
Date:	September 30, 1999
Device Trade/Proprietary Name:	VIDAS TOXO IgG II (TXG) assay
Common or Usual Name:	Enzyme-linked Fluorescent Immunoassay (ELFA) for the quantitative determination of *Toxoplasma gondii*- specific IgG
Classification Name:	21 CFR 866.3780, *Toxoplasma gondii* serological reagents
Predicate Device:	Abbott IMx Toxo IgG 2.0 Antibody Assay

Device Description:

The VIDAS TOXO IgG II (TXG) assay is an automated quantitative test that is performed in a VIDAS instrument. All assay steps and assay temperature are controlled by the VIDAS instrument. 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.
All of the assay steps are performed automatically by the instrument. The VIDAS TXG kit contains 60 TXG Reagent Strips, 60 TXG SPRs, 1 bottle of calibrator, and 1 bottle each of Positive and Negative controls. Each VIDAS TXG assay requires one TXG Reagent Strip and one TXG SPR.

Intended Use:

VIDAS® TOXO IgG II (TXG) is an automated quantitative test for use on a VIDAS® analyser for the quantitative measurement of anti- *Toxoplasma gondii* IgG in human serum or plasma (EDTA, heparin). It is intended for use as an aid in determination of immune status. It is not intended for use in testing (screening) blood or plasma donors.

Summary/Comparison of Technological Characteristics

The VIDAS TXG assay is substantially equivalent to the Abbott IMx Toxo IgG 2.0 Antibody Assay.

Major similarities include:

1. Both are enzyme immunoassays which detect IgG antibodies to *Toxoplasma gondii* in human serum or plasma.
2. Both utilize 4-methylumbelliferyl phosphate substrate.

Major differences include:

1. The VIDAS TXG assay uses a Solid Phase Receptacle (SPR) to capture anti-*T. gondii* IgG. The IMx uses microparticles for capture.
2. The VIDAS TXG assay is a fully automated enzyme-linked fluorescent immunoassay (ELFA) which uses sealed reagent strips containing all reagents necessary for the assay. The IMx requires separate addition of reagents to the system.
3. The VIDAS TXG assay provides a factory created master curve which only requires running a single calibrator. The IMx requires running a set of calibrators.

Synopsis of Performance Testing

Nonclinical Testing:

1. Cross-reactivity/Interference: In two separate studies, a total of 85 samples from patients with a variety of disease states (and known anti-*T. gondii* IgG status) were tested in the VIDAS TXG assay. None of the samples tested yielded unexpected results.
2. Precision: Within-run precision calculations as described by NCCLS EP5-T2 yielded % CV ranging from 5.13 % to 7.21 % over the reportable range of the assay. Total precision calculations as described by NCCLS EP5-T2 yielded % CV ranging from 6.70 % to 11.52 % over the reportable range of the assay.
3. Linearity: Dilutions of 4 serum samples and the WHO standard were tested using the VIDAS TXG assay. Linear regression analysis of the results yielded correlation coefficients of 0.98 or greater.

Clinical Testing:

1. Sensitivity and Specificity (relative to predicate device): One thousand nine hundred forty serum samples were tested using the VIDAS TXG assay and the Abbott IMx Toxo IgG Antibody Assay. After retesting of initial VIDAS equivocal samples (as directed in the package insert), there were 30 VIDAS equivocal results and 19 Abbott equivocal results. For the remaining 1891 samples, the VIDAS TXG assay showed a relative sensitivity of 98.45% (95% confidence interval 97.06%-99.29%) and a relative specificity of 99.77% (95% confidence interval 99.33%-99.95%).

These results support a determination of substantial equivalence. When the VIDAS TXG assay is used as instructed in the package insert, the above statements are true. The package insert should always be consulted along with a VIDAS Procedures Manual to ensure that the assay is being performed properly. For additional information, references are listed in the package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 22 2000

Ms. Sandra L. Perreand
Manager, Regulatory Affairs
BioMérieux, Inc.
595 Anglum Drive
Hazelwood, Missouri 63042

Re: K993319
Trade Name: VIDAS® TOXO IgG II (TXG) Assay
Regulatory Class: II
Product Code: LGD
Dated: May 4, 2000
Received: May 11, 2000

Dear Ms. Perreand:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: VIDAS TOXO IgG II (TXG) Assay

Indications for Use:

The VIDAS® TOXO IgG II (TXG) assay is intended for use with a VIDAS® (Vitek ImmunoDiagnostic Assay System) instrument as a quantitative automated enzyme-linked fluorescent immunoassay (ELFA) for the measurement of *Toxoplasma gondii*-specific IgG in human serum or plasma (EDTA, heparin). It is intended for use as an aid in determination of immune status. It is not intended for use in testing (screening) blood or plasma donors.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993319

Prescription Use X or Over-the-Counter Use_____