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OCT 21 1997
K971672

510(k) SUMMARY

Applicant: Quest International, Inc.
1938 N.E. 148th Terrace
North Miami, FL 33181

Date prepared: May 1, 1997

Contact person: Robert A. Cort, President

Telephone: (305) 948-8788

Telefax: (305) 948-4876

Device: SeraQuest Toxoplasma IgM

Device Classification: Class II (performance standards)

Device Name: Toxoplasma serological reagents (21CFR § 866.3780)

Description:

The SeraQuest Toxoplasma IgM test is a solid-phase enzyme immunoassay (EIA), which is performed in microwells, at room temperature, in three thirty minute incubations. It has been developed to detect IgM antibodies which are directed against Toxoplasma gondii, in human serum. The Calibrators in the SeraQuest Toxoplasma IgM test set have been assigned Index values based on an in-house standard, and International Units (IU/ml) based on the WHO Anti-toxoplasma Serum, Human, (3rd international standard preparation). Test results are reported as Index values, or IU/ml.

Principle:

Diluted samples are incubated in wells coated with Toxoplasma gondii antigen. Antibodies directed against toxoplasma (if present) are immobilized in the wells. Residual sample is eliminated by washing and draining, and conjugate (enzyme-labeled antibodies to human IgM) is added and incubated. If IgM antibodies to Toxoplasma are present, the conjugate will be immobilized in the wells. Residual conjugate is eliminated by washing and draining, and the enzyme substrate is added and incubated. In the presence of the enzyme, the substrate is converted to a yellow end-product which is read photometrically at 405 nm.

Intended Use:

For the quantitative, semi-quantitative and qualitative detection of human IgM antibodies to Toxoplasma in human serum by enzyme immunoassay, to aid in the diagnosis of Toxoplasma infection. A positive result is presumptive for the detection of anti-*Toxoplasma gondii* antibodies and presumptive for the diagnosis of acute, recent, or reactivated *Toxoplasma gondii* infection. Patient testing with the anti-Toxoplasma gondi IgM antibody assay, must be accompanied by a anti-

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oxoplasma gondi IgG antibody assay. For manual use, or for use with the HyPrep System Plus. This assay has not been cleared / approved by the FDA for blood / plasma donor screening. For In Vitro Diagnostic Use Only. Please see Indications for Use form, Appendix 11.

Predicate device:

The SeraQuest Toxoplasma IgM test has been shown to be substantially equivalent to the Toxoplasma IgM Clin-ELISA™ kit, INCSTAR Corporation, Stillwater Minnesota.

Summary of technological characteristics:

Characteristic	SeraQuest Toxoplasma IgM	INCSTAR Toxo IgM Clin-ELISA™
Description:	Enzyme Immunoassay	Enzyme Immunoassay
Intended Use:	The detection of IgM antibodies against Toxoplasma gondii in human serum.	The detection of IgM antibodies against Toxoplasma gondii in human serum.
Antigen Strain	RH	RH
Solid Phase:	Plastic Microwell	Plastic Microwell
umber of Incubation Periods:	Three	Three
Sample Dilution:	1:26	1:51
Sample Volume:	100 µl	200 µl
Sample Pretreatment Duration:	None	30 minutes
Sample Incubation Duration:	30 minutes	30 minutes
Incubation Temperature:	Room temperature	Room temperature
Ezyme-labeled Conjugate:		
Antibody	Goat anti-human IgM	Goat or Sheep anti-human IgM
Enzyme	Alkaline phosphatase	Alkaline phosphatase
Conjugate Volume:	100 µl	200 µl
Conjugate Incubation Duration:	30 minutes	30 minutes

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Substrate:	p-Nitrophenyl phosphate	p-Nitrophenyl phosphate
Subtrate Volume:	100 µl	200 µl
Substrate Incubation Duration:	30 minutes	45 minutes
Stop Reagent:	0.5 M Trisodium phosphate	3 N Sodium Hydroxide
Stop Reagent Volume:	100 µl	50 µl
Readout:	Spectrophotometric 405 nm	Spectrophotometric 405 nm

Summary of Clinical Testing:

Experimental Procedure

One hundred and twenty-eight archival serum specimens including: 24 specimens from normal, asymptomatic donors, 38 specimens from women being tested prenatally for antibodies to toxoplasma and 16 specimens reported to be positive for IgM antibodies to toxoplasma which were obtained from serum brokers, and 50 specimens from acute toxoplasma infections, were tested at Quest International, Inc., concurrently by the SeraQuest Toxoplasma IgM test and the INCSTAR Toxoplasma IgM Clin-ELISA™ test. The assays were performed and interpreted according to the manufacturers package inserts. Specimens giving discordant results were tested with a second legally marketed device, along with a representative number of positive and negative samples which gave concordant results by both test methods.

Results and Conclusion

Of the 128 specimens tested, 51 were positive, and 55 were negative in both the SeraQuest and Incstar tests (please see Table 1). Of the 22 remaining specimens, 4 specimens which were negative by the Incstar test were positive by the SeraQuest test, and 10 specimens which were positive by the Incstar test were negative in the SeraQuest test. The remaining 8 specimens gave equivocal results in one or both of the assays being compared. Of 5 specimens which were equivocal in the SeraQuest assay 4 were positive and 1 was negative in the Incstar assay, and of 3 specimens which were equivocal in the Incstar assay, 1 was positive and 2 were negative by the SeraQuest test.

Excluding the equivocal results, the sensitivity and specificity expressed as 95% confidence intervals (95% CI), of the SeraQuest Toxoplasma IgM test relative to the INCSTAR Toxoplasma IgM Clin-ELISA™ test, were 74.3 to 92.9% and 86.8 to 99.6% respectively. The overall agreement was 82.6 to 94.1%.

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RESULTS OF SeraQuest TOXOPLASMA IgM ASSAYS, AND INCSTAR TOXOPLASMA IgM Clin-ELISA ASSAYS, OF 128 SERUM SPECIMENS. THE SPECIMENS INCLUDED: 24 SPECIMENS FROM FROM NORMAL ASYMPTOMATIC DONORS; 38 SPECIMENS FROM WOMEN BEING SCREENED PRENATALLY FOR TOXOPLASMA ANTIBODIES; 16 SPECIMENS REPORTED TO BE POSITIVE FOR IgM ANTIBODIES TO TOXOPLASMA, WHICH WERE OBTAINED FROM SERUM BROKERS; AND 50 ACUTE PHASE SPECIMENS OBTAINED FROM TOXOPLASMA INFECTIONS. THESE TESTS WERE PERFORMED IN-HOUSE AT QUEST INTERNATIONAL, INC., MIAMI, FL.

	SeraQuest Toxoplasma IgM			
INCSTAR Toxoplasma IgM	Positive	Equivocal	Negative	95 % Confidence Interval
Positive	51	4	10	Relative sensitivity* 74.3 to 92.9√√
Equivocal	1	0	2	
Negative	4	1	55	Relative specificity* 86.8 to 99.6√√
				Overall agreement* 82.6 to 94.1√√

* Excluding equivocal results.

√√ Calculated by the normal method. (see Reference below).

Reference: Gardner, M.J. and Altman, D.G., Confidence Intervals Rather Than Hypothesis Testing. Brit. Med. J., 292: 746-750, 1986.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 21 1997

Robert A. Cort
Vice President, Quality Assurance
Quest International
1938 N.E. 148th Terrace
North Miami, FL 33181

Re: K971672
Trade Name: SeraQuest Toxoplasma IgM
Regulatory Class: II
Product Code: LGD
Dated: August 6, 1997
Received: August 6, 1997

Dear Mr. Cort:

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 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 requirement, 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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" (21 CFR 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

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510(k) Number (if known): K971672

Device Name: SeraQuest Toxoplasma IgM

Indications For Use:

1. For the qualitative, semi-quantitative, and quantitative detection of IgM antibodies to *Toxoplasma gondii* in human serum by enzyme immunoassay, to aid in the diagnosis of Toxoplasma infection.

2. A positive result is presumptive for the detection of anti-*Toxoplasma gondii* antibodies and presumptive for the diagnosis of acute, recent or reactivated *Toxoplasma gondii* infection.

3. Patient testing with the SeraQuest Toxoplasma IgM assay must be accompanied by an anti-toxoplasma IgG antibody assay.

4. Useful for the above indications, with specimens obtained from women of childbearing age and during pregnancy.

5. For manual use, or for use with the HyPrep System Plus semi-automated fluid handler.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971672

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)