NOV - 2 1999

510(k) SUMMARY

K991975

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

Registration No. 1061839

Contact Person: Robert A. Cort, V.P. , Quality Assurance

Telephone: (305) 948-8788

Telefax: (305) 948-4876

Manufacturing Site: Same as above

Device: SeraQuest® EB NA IgG

Device Name: Epstein-Barr virus serological reagents (21CFR § 866.3235)

Device Classification: Class I (general controls)

Description:

The SeraQuest EB NA IgG 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 IgG antibodies which are directed against Epstein-Barr virus nuclear antigen, in human serum.

The Calibrators in the SeraQuest EB NA IgG test set have been assigned Index values based on an in-house standard. Test results are reported as Index values.

Principle:

Diluted samples are incubated in wells coated with Epstein-Barr nuclear antigen. Antibodies directed against Epstein-Barr nuclear antigen (if present) are immobilized in the wells. Residual sample is eliminated by washing and draining, and conjugate (enzyme-labeled antibodies to human IgG) is added and incubated. If IgG antibodies to Epstein-Barr nuclear antigen 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:

Intended Use: The SeraQuest EB NA IgG test is intended for the qualitive and semi-quantative detection of human IgG antibodies to Epstein-Barr nuclear antigen, in human serum by enzyme

immunoassay. The test may be used in conjunction with other EBV serologicals as an aid in the diagnosis of infectious mononucleosis. For In Vitro Diagnostic Use Only.

Predicate Device:

The SeraQuest EB NA IgG test is substantially equivalent in intended use and performance, to the Gull Laboratories' EBNA IgG ELISA test, Gull Laboratories, Inc., Salt Lake City, Utah.

Summary of technological characteristics:

Characteristic	SeraQuest EB VCA IgG	Gull Laboratories ' EBV IgG ELISA
Description:	Enzyme Immunoassay	Enzyme Immunoassay
Intended Use:	The detection of IgG antibodies against Epstein-Barr virus capsid antigen in human serum.	The detection of IgG antibodies against Epstein-Barr virus capsid antigen in human serum.
Solid Phase:	Plastic Microwell	Plastic Microwell
Antigen :	Recombinant EBNA-1	Recombinant EBNA-1
Number of Incubation Periods:	Three	Three
Sample Dilution:	1:50	1:21
Sample Incubation Duration:	30 minutes	30 minutes
Incubation Temperature:	Room temperature	37 ºC.
Ezyme-labeled Conjugate:		
Antibody	Goat anti-human IgG	Goat anti-human IgG
Enzyme	Alkaline phosphatase	Alkaline phosphatase
Conjugate Volume:	100 µl	100 µl
Conjugate Incubation Duration:	30 minutes	30 minutes
Substrate:	p-Nitrophenyl phosphate	p-Nitrophenyl phosphate

Subtrate Volume:	100 µl	100 µl
Substrate Incubation Duration:	30 minutes	30 minutes
Stop Reagent:	0.5 M Trisodium phosphate	1.5 N Sodium hydroxide
Stop Reagent Volume:	100 µl	100 µl
Readout:	Spectrophotometric 405 nm	Spectrophotometric 405 nm

Summary of Clinical Testing:

Experimental Procedure

To challenge the cutoff values, 157 archival serum specimens were tested at Quest International, Inc., concurrently by the SeraQuest EB NA IgG test and Gull Laboratories' EBNA IgG test. The test specimens included: 80 from patients whose sera were submitted to a clinical laboratory for EBV serological testing, 11 from donors reported to be positive for EBV antibodies, which were obtained through serum brokers, and 66 from normal serum donors. The assays were performed and interpreted according to the manufacturers package inserts.

Results and Conclusion

Of the 157 specimens tested, 105 were positive, and 44 were negative in both the SeraQuest and Gull Laboratories' tests (please see Table 1). Of the 8 remaining specimens, 2 specimens which were negative by the Gull test, were positive by the SeraQuest test, and 1 specimen which was positive by the Gull test, was negative by the SeraQuest test. Five specimens which gave equivocal results in the SeraQuest test were negative in the Gull test. The Gull test has no equivocal interpretation.

Excluding the equivocal results, the sensitivity of the SeraQuest EB NA IgG test relative to Gull Laboratories NA IgG test was 99.0 %, or 97.2 % to 100 % (95% C.I.); the specificity was 95.6 %, or 89.48% to 100 % (95% C.I.); respectively. The overall agreement was 98.0%, or 95.8 to 100% (95% C.I.) (please see Table C-3).

TABLE 1.

RESULTS OF SeraQuest EBNA IgG ASSAYS, AND GULL EBNA IgG ELISA TESTS OF 157 SERUM SPECIMENS.

	SeraQuest EBNA IgG					
GULL EBNA IgG	Positive	Negative	Equivocal			
					%	95% CI√
Positive	105	1	0	Relative Sensitivity	99.0	97.2 to 100
Negative	2	44	5	Relative specificity*	95.6	89.8 to 100
				Overall agreement*	98.0	95.8 to 100

* Excluding equivocals.
√ Calculated by the normal method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 2 1999

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

Re: K991975
Trade Name: SeraQuest EB NA IgG
Regulatory Class: I
Product Code: LSE
Dated: September 10, 1999
Received: September 13, 1999

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 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.

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

APPENDIX 5 (REVISED)

Page 1 of 1

510(k) Number (if known): K991975

Device Name: SeraQuest EB NA IgG

Indications For Use:

1. For in vitro diagnostic use only.

2. For the qualitative and semi-quantitative detection of IgG antibodies to Epstein-Barr virus nuclear antigen in human serum by enzyme immunoassay.

3. May be used in conjunction with other EBV serologicals as an aid in the diagnosis of infectious mononucleosis.

(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 K991975

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)