ATTACHMENT 5

K033780

JAN 15 2004

510(k) SUMMARY

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® VCA IgM

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

Device Classification: Class I (general controls)

Description:

The SeraQuest VCA 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 Epstein-Barr virus capsid antigen, in human serum.

The Calibrators in the SeraQuest VCA IgM 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 virus capsid antigen. *Absorbents have been included in the Diluent to neutralize the affects of rheumatoid factor and IgG antibody.* Antibodies directed against Epstein-Barr virus capsid antigen (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 Epstein-Barr virus capsid 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.

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Intended Use:

For the qualitative detection of IgM antibodies to Epstein-Barr (EB), viral capsid antigen (VCA) in human serum by enzyme immunoassay, as an aid in differentiating active or recent Epstein-Barr virus infection from past infection. For in vitro diagnostic use only.

Predicate Device:

The SeraQuest VCA IgM test is substantially equivalent in intended use and performance, to the Zeus' EBV IgM ELISA test, Zeus Scientific, Inc., Raritan, New Jersey. 08869.

Summary of technological characteristics:

Characteristic	SeraQuest VCA IgM	Zeus' EBV-VCA IgM ELISA
Description:	Enzyme Immunoassay	Enzyme Immunoassay
Intended Use:	The detection of IgM antibodies against Epstein-Barr virus capsid antigen in human serum.	The detection of IgM antibodies against Epstein-Barr virus capsid antigen in human serum.
Solid Phase:	Plastic Microwell	Plastic Microwell
Antigen :	Purified gp125	Purified gp 125
Number of Incubation Periods:	Three	Three
Sample Dilution:	1:51	1:21
Sample Incubation Duration:	30 minutes	25 minutes
Incubation Temperature:	Room temperature	Room temperature
Ezyme-labeled Conjugate:		
Antibody	Goat anti-human IgM	Goat anti-human IgM
Label	Alkaline phosphatase	Horseradish Peroxidase
Conjugate Volume:	100 µl	100 µl
Conjugate Incubation Duration:	30 minutes	25 minutes

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Substrate:	p-Nitrophenyl phosphate	TMB
Subtrate Volume:	100 µl	100 µl
Substrate Incubation Duration:	30 minutes	10 minutes
Stop Reagent:	0.5 M Trisodium phosphate	1M H2SO4,0.7M HCL
Stop Reagent Volume:	100 µl	50 µl
Readout:	Spectrophotometric 405 nm	Spectrophotometric 450 nm

Summary of Clinical Testing:

Of the 113 specimens tested, 18 were positive, and 91 were negative in both the SeraQuest and Zeus' VCA IgM tests (please see Table 1). Of the 4 remaining specimens, 2 specimens which were positive by the Zeus' test, one was negative and the other equivocal by the SeraQuest test. One specimen which was equivocal by the Zeus' test, was negative by the SeraQuest test. One specimen which was negative by the Zeus' test, was equivocal by the SeraQuest test.

Table 1.

Results of Tests of 113 Archival Patient Specimens Tested at SeraQuest, Miami, FL, Using the SeraQuest EB VCA IgM Test and the Zeus EBV VCA IgM EIA Test.

	SeraQuest VCA IgM			
Zeus EBV-VCA IgM	Positive	Negative	Equivocal	Total
Positive	18	1	1	20
Negative	0	91	1	92
Equivocal	-	1	-	1
Total	18	93	2	113

Overall agreement [(TP + TN) / (TP + TN + FP + FN)] = 99.0 % *
95 % CI = 97.3 to 100 % **

* Excluding equivocal results
** Calculated by the normal method.

Reference: Gardner, M.J. and Altman, D.G., Confidence Intervals Rather Than Hypothesis Testing Brit. Med. J., 292: 746-750, 198

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 15 2004

Mr. Robert A. Cort
V. P., Quality Assurance
Quest International, Inc.
1938 N.E. 148th Terrace
North Miami, FL 33181

Re: k033780
Trade/Device Name: SeraQuest® VCA IgM
Regulation Number: 21 CFR 866.3235
Regulation Name: Epstein-Barr virus serological reagents
Regulatory Class: Class I
Product Code: LJN
Dated: November 26, 2003
Received: December 16, 2003

Dear Mr. Cort:

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.

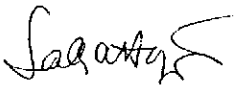
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Attachment 6

Indications for Use

510(k) Number _____ K033780

Device Name SeraQuest EB VCA IgM

Indications for Use:

1. For In Vitro Diagnostic Use
2. For the qualitative detection of human IgM antibodies to Epstein-Barr (EB) viral capsid antigen (VCA) in human serum by enzyme immunoassay, as an aid in differentiating active or recent Epstein-Barr virus infection from past infection.

A positive result is presumptive for the detection of anti-Epstein-Barr virus IgM antibodies and presumptive for the diagnosis of acute or recent Epstein-Barr virus infection.

Prescription Use ✓ (Part 21 CFR Subpart D) OR Over-The-Counter-Use _____ (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

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