

JUN 15 1998

510(k) SUMMARY

K980639

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® Anti-SSB

Device Name: Antinuclear antibody immunological test system (21CFR § 866.5100)

Device Classification: Class II (performance standards)

Description:

The SeraQuest Anti-SSB 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 SSB nuclear antigen (Anti-SSB) , in human serum.

The Calibrators in the SeraQuest Anti-SSB 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 SSB antigen. Antibodies against SSB (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 SSB 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 qualitative and semi-quantitative detection of human antibodies to SSB nuclear antigen in human serum by enzyme immunoassay. For manual use, or for use with the HyPrep System Plus.
For In Vitro Diagnostic Use Only.

Indicate Device:

The SeraQuest Anti-SSB test is substantially equivalent in intended use and performance, to the Shield Diastat Anti-SSB test, Shield Diagnostics, Dundee, DD2 1SW.

Summary of technological characteristics:

<u>Characteristic</u>	<u>SeraQuest Anti-SSB</u>	<u>Shield Diastat Anti-SSB</u>
Description:	Enzyme Immunoassay	Enzyme Immunoassay
Intended Use:	The detection of antibodies against SSB in human serum.	The detection of antibodies against SSB in human serum.
Solid Phase:	Plastic Microwell	Plastic Microwell
Antigen Source:	Calf Thymus	Calf Thymus
Number of Incubation Periods:	Three	Three
Sample Dilution:	1:50	1:500
Sample Incubation Duration:	30 minutes	60 minutes
Incubation Temperature:	Room temperature	Room temperature
Ezyme-labeled Conjugate:		
Antibody	Goat anti-human IgG	Goat anti-human IgG
Enzyme	Alkaline phosphatase	Alkaline phosphatase
Conjugate Volume:	100 μ l	100 μ l
Conjugate Incubation Duration:	30 minutes	30 minutes
Substrate:	p-Nitrophenyl phosphate	phenolphthalein monophosphate
Substrate Volume:	100 μ l	100 μ l
Substrate Incubation Duration:	30 minutes	30 minutes

Top Reagent:	0.5 M Trisodium phosphate	Sodium Hydroxide
Stop Reagent Volume:	100 µl	100 µl
Readout:	Spectrophotometric 405 nm	Spectrophotometric 540-565 nm

Summary of Clinical Testing:

Of the 288 specimens tested, 27 were positive, and 252 were negative in both the SeraQuest and Shield tests (please see Table 1 below). Seven specimens which were negative by the Shield test, were positive in the SeraQuest test. One specimen which was negative in the Shield test, was equivocal in the SeraQuest test. One specimen which was positive in the Shield test, was negative in the SeraQuest test.

TABLE 1.

RESULTS OF SeraQuest Anti-SSB ASSAYS AND SHIELD Anti-SSB ASSAYS OF 288 SERUM SPECIMENS.

SHIELD Anti-SSB ASSAY	SeraQuest Anti-SSB				%	95 % CI
	Positive	Equivocal	Negative			
Positive	27	0	1	Relative sensitivity	96.4	89.6 to 100*
Negative	7	1	252	Relative specificity [√]	97.2	95.3 to 99.3*
				Overall agreement [√]	99.6	95.3 to 99.1*

[√] 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, 1986.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 15 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K980639/S1
Trade Name: SeraQuest® Anti-SSB Test System
Regulatory Class: II
Product Code: LLL
Dated: April 20, 1998
Received: April 24, 1998

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 (Pre-market 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 pre-market 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.

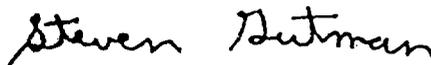
Page 2

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 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 8 (REVISED 4/17/98)

Page 1 of 1

510(k) Number (if known): K980639

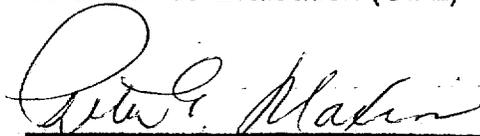
Device Name: SeraQuest Anti-SSB

Indications For Use:

1. For in vitro diagnostic use only.
2. For the qualitative and semi-quantitative detection of IgG antibodies to SSB antigen in human serum by enzyme immunoassay.
3. For use as an aid in the diagnosis of systemic rheumatic disease, particularly Sjogren's Syndrome.
4. 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)



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

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)