

K980811

MAY 12 1998

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® Anti-Sm/RNP

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

**Device Classification:** Class II (performance standards)

**Description:**

The SeraQuest Anti-Sm/RNP 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 Sm/RNP nuclear antigen (Anti-Sm/RNP), in human serum.

The Calibrators in the SeraQuest Anti-Sm/RNP 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 Sm/RNP antigen. Antibodies against Sm/RNP (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 Sm/RNP 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 Sm/RNP nuclear antigen human serum by enzyme immunoassay. For use as an aid in the diagnosis of systemic rheumatic

... disease, particularly mixed connective tissue disease. For manual use, or for use with the HyPrep System Plus. For In Vitro Diagnostic Use Only.

**Predicate Device:**

The SeraQuest Anti-Sm/RNP test is substantially equivalent in intended use and performance, to the Shield Diastat Anti-Sm/RNP test, Shield Diagnostics, Dundee, U.K.

**Summary of technological characteristics:**

<u>Characteristic</u>	<u>SeraQuest Anti-Sm/RNP</u>	<u>Shield Diastat Anti-Sm/RNP</u>
Description:	Enzyme Immunoassay	Enzyme Immunoassay
Intended Use:	The detection of antibodies against Sm/RNP in human serum.	The detection of antibodies against Sm/RNP in human serum.
Antigen Source:	Calf Thymus	Calf Thymus
Solid Phase:	Plastic Microwell	Plastic Microwell
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 µl	100 µl
Conjugate Incubation Duration:	30 minutes	30 minutes
Substrate:	p-Nitrophenyl phosphate	phenolphthalein monophosphate
Substrate Volume:	100 µl	100 µl

Substrate Incubation	30 minutes	30 minutes
Stop 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 252 specimens tested, 40 were positive, and 189 were negative in both the SeraQuest and Shield tests (please see Table C-3). Of the remaining specimens, 23 specimens which were negative by the Shield test, 20 were positive and 3 equivocal by the SeraQuest test. Please see Table 1 below.

**TABLE 1.**

**RESULTS OF SeraQuest Anti-Sm/RNP ASSAYS AND SHIELD Sm/Anti-RNP ASSAYS OF 252 SERUM SPECIMENS.**

Shield Anti-Sm/RNP	SeraQuest Anti-Sm/RNP				%	95 % CI <sup>√</sup>
	Positive	Equivocal	Negative			
Positive	40	0	0	Relative sensitivity	100	99.9 to 100
Negative	20	3	189	Relative specificity*	90.4	86.4 to 94.4
				Overall agreement*	95.4	88.6 to 95.3

<sup>√</sup> 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.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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Robert A. Cort  
Vice President, Quality Assurance  
QUEST INTERNATIONAL, INC.  
1938 N.E. 148th Terrace  
North Miami, FL 33181

Re: K980811  
Trade Name: SeraQuest® Anti-Sm/RNP  
Regulatory Class: II  
Product Code: LKP  
Dated: April 28, 1998  
Received: April 28, 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 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.

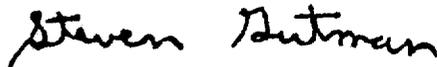
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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 (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large, prominent "S" and "G".

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

APPENDIX 8

510(k) Number (if known): K 9808 11

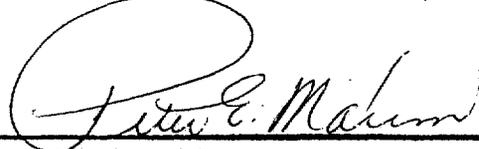
Device Name: SeraQuest Anti-Sm/RNP

Indications For Use:

1. For in vitro diagnostic use only.
2. For the qualitative and semi-quantitative detection of IgG antibodies to Sm/RNP in human serum by enzyme immunoassay.
3. For use as an aid in the diagnosis of systemic rheumatic disease, particularly mixed connective tissue disease (MCTD).
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

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Prescription Use  (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)