APR 23 1998

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K980759

Applicant Information:

Date Prepared:	April 10, 1998
Name:	Diamedix Corporation
Address:	2140 N. Miami Avenue Miami, FL 33127
Contact Person:	Dr. Lynne Stirling
Phone Number:	305-324-2354
Fax Number:	305-324-2585

Device Information:

Trade Name:	Is-ENA-6 Screen Test System
Common Name:	ENA Screening Test
Classification Name:	Antinuclear Antibody Immunological Test System (866.5100), product code LLL

Equivalent Device:
Zeus Scientific ENA Screen, ELISA Test System

Device Description: The Is-ENA-6 Screen Test Kit System is an enzyme-linked immunosorbent assay (ELISA) for the detection of IgG to six extractable nuclear antigens (ENAs), in human serum.

Intended Use: The assay is intended for use in detecting IgG antibodies to ENA's (SSA, SSB, Sm, Sm/RNP, Scl-70 and Jo-1 in one well) in a single human serum sample. The results of the assay can be used as an aid in the diagnosis of autoimmune disorders.

Principle of the Procedure:

The Is-ENA-6 Screen Test System is an enzyme-linked immunosorbent assay to detect IgG to six ENAs in human serum. Purified antigens are attached to a solid phase microtiter well. Diluted test sera are added to each well. If antibodies which recognize the antigens are present in the patient sample they will bind to the antigens in the well. After incubation, the wells are washed to remove unbound antibody. An enzyme labeled anti-human immunoglobulin (conjugate) is added to each test well. If antibody is present the enzyme-linked antibody will bind to it. After incubation, the wells are washed to remove unbound conjugate. A substrate solution is then added to each well. If enzyme is present from prior step, the reaction is stopped and the color intensity is measured photometrically producing an indirect measure of the specific antibodies present in the patient sample.

SUMMARY OF SAFETY AND EFFECTIVENESS

Performance Characteristics

A. Comparison Testing

The Diamedix Is-ENA-6 Screen Test Kit was evaluated relative to another commercially available ENA Screen test kit. One hundred and fifty sera from normal blood donors and eighty-eight sera from clinical patients were tested by the Is-ENA-6 Screen Test Kit and the comparative method. Testing was performed manually and using the MAGO and MAGO PLUS Automated Processors. The results obtained are shown in Table 1.

TABLE 1.	Manual			MAGO			MAGO PLUS		
	# of Sera	%	95%CI	# of Sera	%	95% CI	# of Sera	%	95% CI
Relative Sensitivity	81/88	92.0	84.3-96.7	82/89	92.1	84.5-96.8	82/89	92.1	84.5-96.8
Relative Specificity	143/146	97.9	94.1-99.6	142/146	97.2	93.1-99.2	143/146	97.9	94.1-99.6
Overall Agreement	224/234*	95.7	92.3-97.9	224/235**	95.3	91.8-97.6	225/235**	95.7	92.3-97.9

* Four equivocal samples were exluded from calculations; ** Three equivocal samples were excluded from calculations. Ten sera were discordant in the manual and MAGO PLUS testing; an additional sample was discordant in the MAGO testing. All discordant samples were tested in 6 specific commercially available ENA test kits for anti-SSA, -SSB, -Sm, -Sm/RNP, Scl-70 and Jo-1. The resolution of discordant samples is summarized in Table 2.

TABLE 2.

Sample #	Is-ENA-6 Screen Result	Other ENA Screen Result	Resolution
82-normal	POS	NEG	NEG in all 6 specific ENA tests
84-normal	NEG	POS	NEG in all 6 specific ENA tests
90-normal*	POS	NEG	NEG in all 6 specific ENA tests
91-normal	NEG	POS	NEG in all 6 specific ENA tests
112-clinical	POS	NEG	POS for anti-SSA
128-clinical	NEG	POS	NEG in all 6 specific ENA tests
138-clinical	NEG	POS	POS for anti-Jo-1
140-clinical	NEG	POS	NEG in all 6 specific ENA tests
173-clinical	POS	NEG	POS for anti-SSA
205-normal	NEG	POS	NEG in all 6 specific ENA tests
225-normal	NEG	POS	NEG in all 6 specific ENA tests

* This sample was a weak positive (Index 1.2) during MAGO testing only.

B. Precision

The precision of the Is-ENA-6 Screen test kit was determined by testing six different sera (2 negative and 4 positive) and the kit calibrator and controls in triplicate in two different runs on three different days. Precision was evaluated manually and using the MAGO and MAGO PLUS Processors. The intra- and interassay precision is shown in Table3.

TABLE 3.	Overall	MANUAL		MAGO		MAGO PLUS	
SERUM	Mean Abs.	Intra-CV%	Inter CV%	Intra-CV%	Inter-CV%	Intra-CV%	Inter-CV%
A (NEG)	0.024	10.3	15.1	44.8	47.0	26.1	25.1
B (NEG)	0.044	4.7	9.3	10.1	28.6	5.8	15.3
C (POS)	0.600	7.0	8.4	7.3	12.0	5.9	11.6
D (POS)	0.927	4.0	10.4	7.1	11.0	6.3	8.3
E (POS)	1.004	3.0	9.3	6.6	9.9	6.7	9.9
F (POS)	1.488	4.9	8.5	6.7	10.4	4.9	7.9
c/o CAL	0.368	6.6	11.2	3.7	9.2	3.3	5.0
POS	0.487	3.1	7.7	5.6	9.1	3.6	7.0
NEG	0.060	9.0	12.9	18.1	23.0	10.7	13.7

C. Expected Values

The expected value for a normal patient is a negative result. However, positive results for autoantibodies may be found in some apparently healthy individuals. Patient sera containing autoantibodies to those antigens represented in the Is-ENA-6 Screen test will give positive results which can be further evaluated in specific tests. The number of positive samples detected is dependent upon the populations being tested. The expected values in a normal S. Florida blood donor population were evaluated by assaying 150 sera both manually and using the MAGO and MAGO PLUS Automated Processors. Figures 1, 3 and 5 show the distribution of results in this normal population. For manual and MAGO PLUS testing 98.6% of the normals gave negative results; for MAGO 98% gave negative results. Two normal samples positive in the Is-ENA-6 Screen were subsequently shown to be strongly positive for SSA antibodies.

In the present studies 88 sera obtained from patients with an autoimmune disease or with a known autoantibody reactivity were evaluated in the Is-ENA-6 Screen. Figures 2, 4 and 6 show the distribution of results for this population.

Figure 1. Expected Values
Normal Samples - Manual

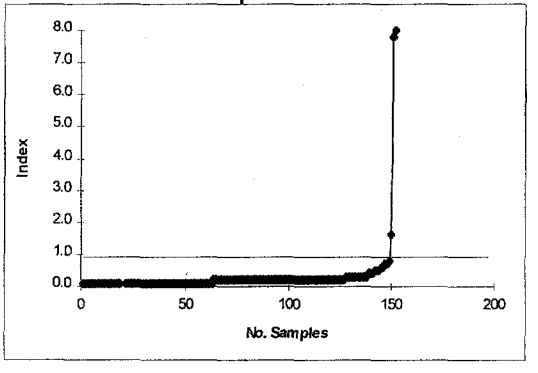


Figure 2. Expected Values
Clinical Samples - Manual

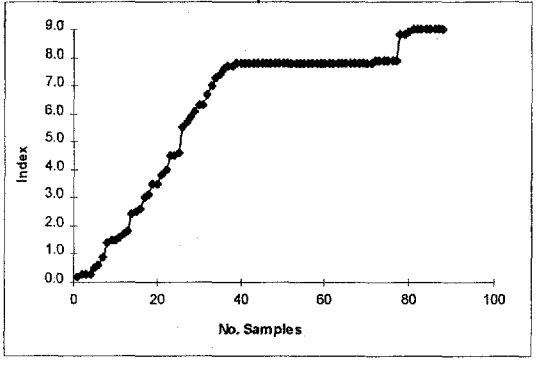


Figure 3. Expected Values
Normal Samples - MAGO

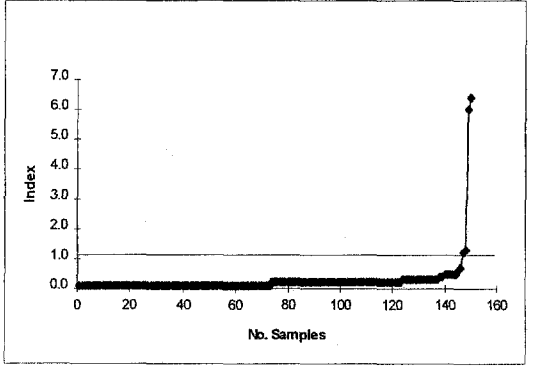


Figure 4. Expected Values
Clinical Samples - MAGO

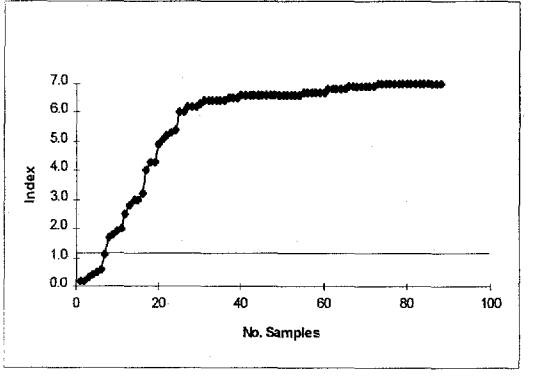


Figure 5. Expected Values
Normal Samples - MAGO PLUS

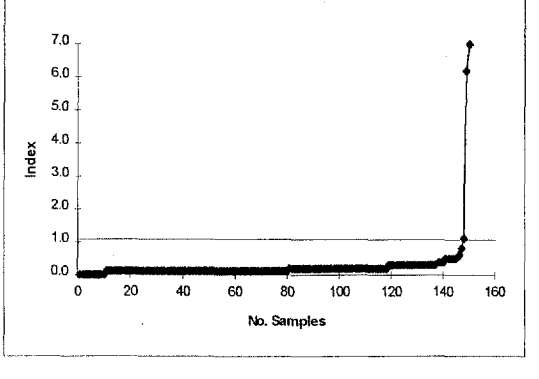
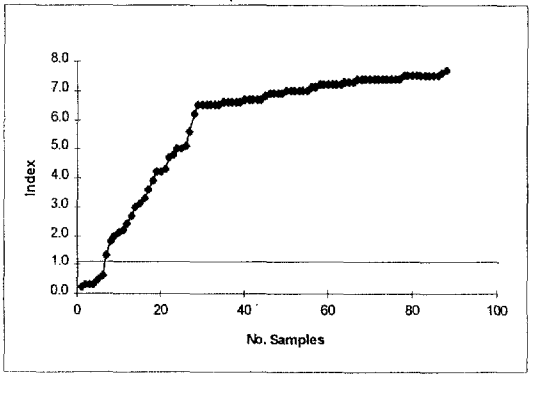


Figure 6. Expected Values
Clinical Samples - MAGO PLUS



D. Correlation of Manual, MAGO and MAGO PLUS Results

Correlation of manual, MAGO and MAGO PLUS Index Values for the 238 samples tested in the Is-ENA-6 Screen Test Kit is shown in Figures 7, 8 and 9.

Figure 7. Manual vs MAGO Correlation

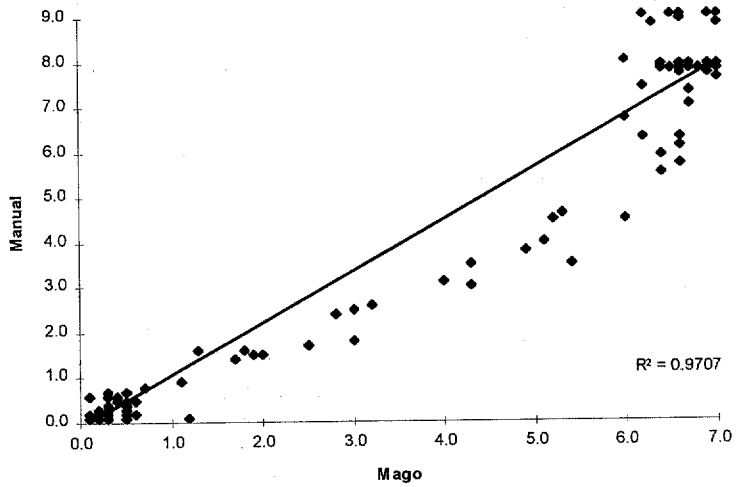


Figure 8. Manual vs MAGO PLUS Correlation

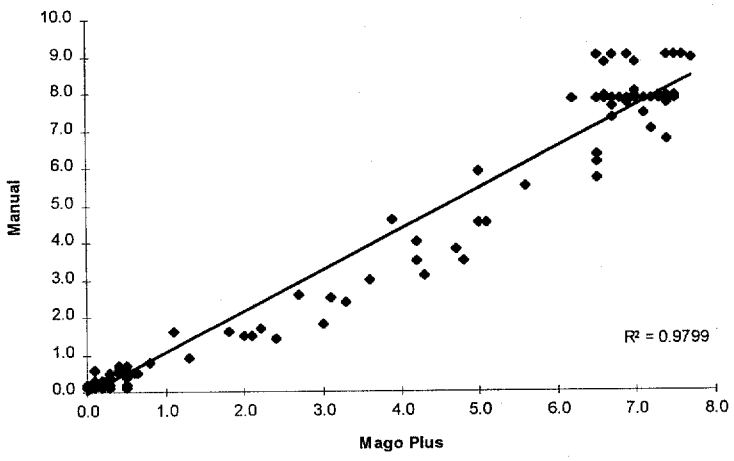
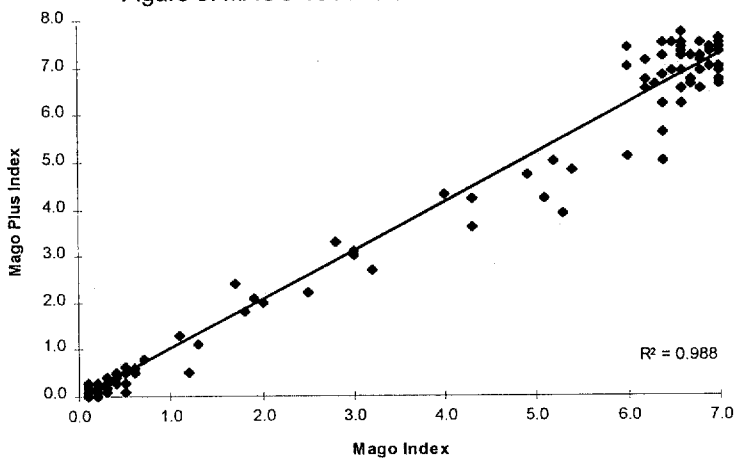


Figure 9. MAGO vs MAGO PLUS Correlation



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 23 1998

Lynne Stirling, Ph.D.
Diamedix Corporation
2140 N. Miami Avenue
Miami, Florida 33127

Re: K980759
Trade Name: Diamedix Is-ENA-6 Screen Test System
Regulatory Class: II
Product Code: LLL
Dated: February 26, 1998
Received: February 27, 1998

Dear Dr. Stirling:

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

Appendix G. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(K) NUMBER : K980759

DEVICE NAME : Is-ENA-6 Screen Test System

Indications for Use : For the qualitative screening of human IgG antibodies to extractable nuclear antigens (ENA) in human serum by indirect enzyme immunoassay as an aid in the diagnosis of certain autoimmune disorders.This test system screens for antibodies to Sm, Sm/RNP, SSA, SSB, Scl-70 and Jo-1 in one well. Positive samples should be evaluated further using tests designed for each ENA antibody. These reagents can be used either manually or in conjunction with the MAGO® or MAGO® PLUS Automated EIA Processors.

prescription use

✓

CA 4/23/98

Peter E. Maksim

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K980759