FEB 1 8 2000

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: K994424

Applicant Information:

Date Prepared:	December 29, 1999
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-anti-dsDNA Test System
Common Name:	Anti-DNA EIA Test
Classification Name:	Anti-DNA Antibody

Equivalent Device:
Enzyme Immunoassay Anti-dsDNA Test

Device Description: The Is-anti-dsDNA Test Kit System is an enzyme-linked immunosorbent assay (ELISA) for the detection and quantitation of IgG antibodies to DNA in human serum.

Intended Use: The assay is intended for use in detecting IgG antibodies to dsDNA in a single human serum sample. The results of the assay are to be used as an aid in the diagnosis of SLE.

Principle of the Procedure:

The Is-anti-dsDNA Test System is an enzyme-linked immunosorbent assay to detect IgG antibdies to dsDNA in human serum. Purified plasmid DNA is attached to a solid phase microtiter well. Diluted test sera are added to each well. If antibodies which recognize the DNA antigen are present in the patient sample they will bind to the antigen 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 antibody present in the patient sample.

K994424

SUMMARY OF SAFETY AND EFFECTIVENESS

Performance Characteristics

A. Comparison Studies : Relative Sensitivity and Specificity

The Diamedix Is-anti-dsDNA Test Kit was evaluated relative to another commercially available anti-dsDNA ELISA test with traceability to the WHO Standard. A total of 413 samples were tested by both methods. These samples were comprised of two hundred sera from normal blood donors, two hundred and nine sera from clinical patients with either a diagnosis of SLE or another autoimmune disease and four sera from patients whose status was unknown. Performance is summarized in TABLE 1 for both 6-Point and Single Point Calibration using the manual method of testing. Similar results were obtained using the MAGO Plus automated testing method.

TABLE 1

	6-Point Calibration			Single Point Calibration		
	# of sera	%	95% CI	# of sera	%	95% CI
Relative Sensitivity	104/108	96.3	90.8-99.0	111/112	99.1	95.1-100.0
Relative Specificity	264/275	96.0	93.0-98.0	251/271	92.6	88.8-95.4
Overall Agreement*	368/383	96.1	93.6-97.8	362/383	94.5	91.7-96.6

* Equivocal and QNS samples were excluded from calculations

NOTE : Please be advised that 'relative' refers to the comparison of the assay's results to that of a similar assay. There was not an attempt to correlate the assay's results with disease presence or absence. No judgment can be made on the comparison's accuracy to predict disease.

B. Clinical Sensitivity and Specificity Using Characterized Sera

Clinical sensitivity and specificity was assessed by evaluating the results from each patient group . The groups consisted of 200 normal samples, 70 sera from patients with a diagnosis of SLE and 138 sera from patients with suspected autoimmune disease. The results presented in TABLE 2 were obtained manually using the 6-Point calibration method.

TABLE 2

Patient Group:	Positive	Equivocal*	Negative	Total
Normals	0	3	197	200
SLE	56	4	10	70
Autoimmune Disease	63	5	70	138

Clinical Specificity:		**95% CI**
Normals	= 197/197 = 100.0%	98.1-100.0
Clinical Sensitivity:		**95% CI**
SLE patients	= 56/66 = 84.8%	73.9-92.5
Autoimmune disease patients	= 63/133 = 47.4%	38.9-55.9

* Equivocal results were excluded from calculations

C. Precision

The precision of the Is-anti-dsDNA Test Kit when performed either manually or on the MAGO Plus Automated EIA Processor using the 6-Point calibration method was determined by assaying six sera and the kit positive and negative controls in triplicate in two runs per day for three days. TABLES 3 and 4 show the intra-and interassay precision obtained. Comparable CVs for positive samples were also obtained when precision testing was performed using the Single Point calibration method (data on file).

TABLE 3: Intra-Assay and Interassay Precision- Manual Testing

SERUM	INTRA-ASSAY DAY 1			INTRA-ASSAY DAY 2			INTRA-ASSAY DAY 3			INTERASSAY		
	MEAN IU/ml	SD	CV%	MEAN IU/ml	SD	CV%	MEAN IU/ml	SD	CV%	MEAN IU/ml	SD	CV%
A (NEG)	0.0	0.00	N/A	0.0	0.00	N/A	0.0	0.00	N/A	0.0	0.00	N/A
B (NEG)	0.0	0.00	N/A	0.0	0.00	N/A	0.0	0.00	N/A	0.0	0.00	N/A
C (POS)	49.3	5.17	10.5	48.5	7.12	14.7	45.1	0.95	2.1	47.6	5.17	10.9
D (POS)	68.5	6.88	10.0	62.3	5.45	8.8	66.9	1.95	2.9	65.9	5.59	8.5
E (POS)	96.6	5.89	6.1	90.5	8.16	9.0	79.2	4.51	5.7	88.7	9.53	10.7
F (POS)	152.4	4.06	2.7	156.9	8.61	5.5	150.3	1.59	1.1	153.2	5.95	3.9
POS CTRL	69.1	5.57	8.1	70.3	2.99	4.3	66.4	2.20	3.3	68.6	4.00	5.8
NEG CTRL	0.0	0.00	N/A	0.0	0.00	N/A	0.0	0.00	N/A	0.0	0.00	N/A

TABLE 4 : Intra-Assay and Interassay Precision - MAGO Plus Testing

SERUM	INTRA-ASSAY DAY 1			INTRA-ASSAY DAY 2			INTRA-ASSAY DAY 3			INTERASSAY		
	MEAN IU/ml	SD	CV%	MEAN IU/ml	SD	CV%	MEAN IU/ml	SD	CV%	MEAN IU/ml	SD	CV%
A (NEG)	0.0	0.00	0.0	0.0	0.00	0.0	0.0	0.00	0.0	0.0	0.00	0.0
B (NEG)	0.0	0.00	0.0	2.1	2.90	0.0	0.0	0.00	0.0	0.0	0.00	0.0
C (POS)	52.9	3.55	6.7	51.3	2.80	5.5	52.6	3.26	6.2	52.3	3.11	5.9
D (POS)	76.0	5.02	6.6	76.8	3.14	4.1	72.9	5.19	7.1	75.2	4.61	6.1
E (POS)	80.0	9.54	11.9	81.6	6.58	8.1	89.7	7.36	8.2	83.8	8.63	10.3
F (POS)	164.6	7.49	4.6	158.1	11.40	7.2	162.0	11.40	7.0	161.6	10.00	6.2
POS CTRL	76.5	2.28	3.0	75.6	2.04	2.7	74.2	3.08	4.1	75.4	2.54	3.4
NEG CTRL	0.0	0.00	0.0	0.0	0.00	0.0	0.0	0.00	0.0	0.0	0.00	0.0

D. Linearity

The dose response curve for the Is-anti-dsDNA test kit is sufficiently linear to allow for the use of either 6-Point or Single Point calibration systems. This linearity is illustrated in FIGURES 1 and 2. These figures depict samples that have been serially diluted in Sample Diluent and then each dilution tested and results determined using either calculation method. The samples selected were the WHO Reference preparation, the kit 200 IU/ml Standard and the in-house reference 200 IU/ml Standard. Recovered IU/ml values for each dilution were determined using either the 6-Point (FIGURE 1) or Single Point (FIGURE 2) calibration methods. The linearity data shown was obtained using the manual method of testing. Similar results were obtained using the MAGO Plus automated method.

FIGURE 1

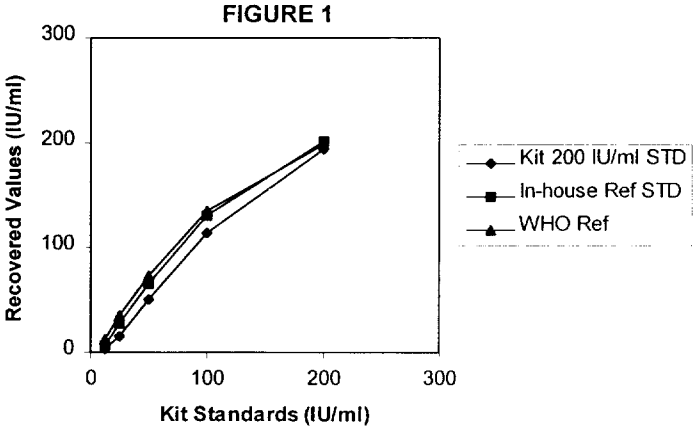
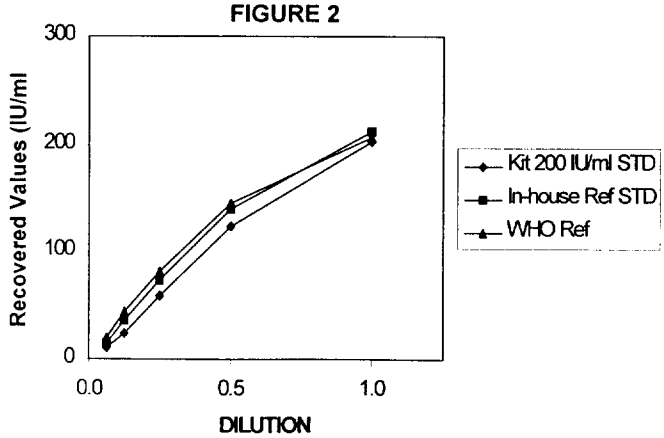


FIGURE 2



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 1 8 2000

Lynne Stirling, Ph.D.
Vice President, Regulatory Affairs
Diamedix® Corporation
2140 North Miami Avenue
Miami, Florida 33127

Re: K994424
Trade Name: Is-anti-dsDNA Test System
Regulatory Class: II
Product Code: LRM
Dated: December 29, 1999
Received: December 30, 1999

Dear Dr. Stirling:

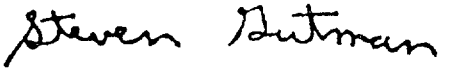
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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.

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" (21CFR 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,



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 : K994424

DEVICE NAME : Is-anti-dsDNA Test System

Indications for Use :*The Diamedix Is-anti-dsDNA an Enzyme Immunoassay (EIA) for the quantitative detection of IgG antibodies to double-stranded (ds) DNA in human serum as an aid in the diagnosis of systemic lupus erythematosus (SLE). These reagents can be used either manually or in conjunction with the MAGO® Plus Automated EIA Processor.*

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K994424

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR **Over-The-Counter Use**___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)