JAN 8 2002

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: K013956

Applicant Information:

Date Prepared:	December 20, 2001
Name:	Diamedix Corporation
Address:	2140 N. Miami Avenue Miami, FL 33127
Contact Person:	Dr. Lynne Stirling
Phone Number:	305-324-2354
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Device Information:

Trade Name:	Is anti-β_2Glycoprotein I Screen Test System
Common Name:	Anti-β_2Glycoprotein I ELISA test
Classification Name:	Anti-β_2Glycoprotein I immunological test system

Equivalent Device:
Inova QUANTA Lite β_2GPI Screen

Device Description: The Is anti β_2Glycoprotein I Screen Test System is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative measurement of IgG, IgM and IgA antibodies to $\beta_2$glycoprotein I in human serum

Intended Use: The assay is intended for the semi-quantitative measurement of IgG, IgM and IgA antibodies to $\beta_2$glycoprotein I in human serum. The results of the assay can be used as an aid in the diagnosis of certain autoimmune thrombotic disorders in patients with SLE or SLE-like disorders.

Principle of the Procedure:

The Is anti β_2Glycoprotein I Screen Test System is an indirect solid-phase enzyme immunoassay. Highly purified β2 glycoprotein I is coated onto plastic microwells. Controls and diluted patient samples are added to the wells. Any patient IgG, IgM or IgA antibodies in the sample bind to the well. Anti-human horseradish peroxidase conjugate is then added After incubation and washing, a substrate solution is then added to each well. In the presence of bound enzyme, the substrate is converted to a blue colored product. After acid addition to stop the reaction, a yellow end product is formed that is read spectrophotometrically at 450 nm (reference 600-630 nm) and is directly proportional to the concentration of β2 glycoprotein I IgG, IgM and IgA antibodies in the sample.

SUMMARY OF SAFETY AND EFFECTIVENESS

Performance Characteristics

All non-clinical performance studies were performed using the manual method unless otherwise indicated.

A. Relative Sensitivity and Specificity

One hundred and eighty-seven frozen, retrospective sera were tested for IgG/IgM/IgA $\beta_2$glycoprotein I antibodies using the Is anti-β_2Glycoprotein I Screen Test Kit and a commercially available ELISA kit for detecting $\beta_2$glycoprotein I IgG/IgM/IgA antibodies. Based on the results of this testing the relative sensitivity, relative specificity and overall agreement were calculated. The results obtained are shown in TABLE 1. Further resolution of the discordant samples showed that three samples that were negative in the Is anti-β_2Glycoprotein I Screen and positive by the other EIA were negative by a referee EIA method. The remaining twenty-two discordant samples were positive in the referee test. Note that 17 of the 25 discordant samples were from normal blood donors with no history of disease.

TABLE 1

Is-anti-β_2Glycoprotein I Screen

		Positive	Negative	*Equivocal
Other EIA	Positive	63	25	4
	Negative	0	95	0
	*Equivocal	0	0	0

			**95% CI
Relative Sensitivity	63/88	= 71.6 %	61.0-80.7%
Relative Specificity	95/95	= 100.0%	96.2-100.0%
Overall Agreement	158/183	= 86.3%	81.4-91.3%

* Equivocal results were excluded from calculations. ** 95% Confidence Intervals (CI) calculated by the Exact Method.

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 judgement can be made on the comparison's accuracy to predict disease.

B. Clinical Sensitivity and Specificity

A total of three hundred and eighty-seven frozen retrospective, clinically characterized sera were assayed using the Is anti-β_2Glycoprotein I Screen Test Kit in order to assess both the clinical sensitivity and clinical specificity of the test system. These samples consisted of 248 normal sera, 57 sera from patients with diagnosed anti-phospholipid syndrome (APS), 33 sera from patients with systemic lupus erythematosus (SLE), 34 sera from patients with other autoimmune diseases such as Sjogren's Syndrome, scleroderma, polymyositis/dermatomyositis and rheumatoid arthritis and 15 samples from patients with positive RPR titers. Results are summarized in TABLE 2.

TABLE 2

Patient Group	Total	# Positive	# Negative	Equivocal
Normals	248	6	240	2
APS	57	48	7	2
SLE	33	10	21	2
Other Autoimmune Diseases	34	4	30	0
RPR Positive	15	1	13	1

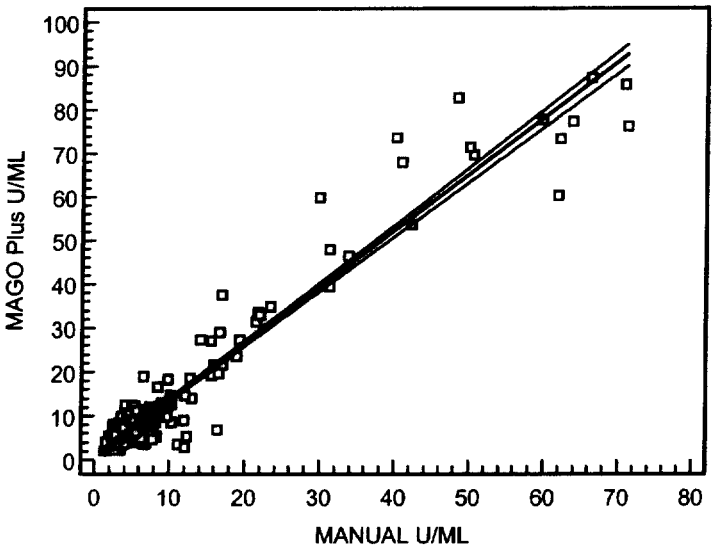
Clinical Specificity:	**# Neg/Total #**	
Normals	240 / 248	= 96.8%
RPR Positive	13 /15	= 86.7%
Other Autoimmune Diseases	30 / 34	= 88.2%

Clinical Sensitivity:	**# Pos/Total #**	
APS	48 / 57	= 84.2%
SLE	10/33	= 30.3%

C. Correlation of Manual and MAGO Plus results

The Is anti-β_2Glycoprotein I Screen Test Kit has been developed for automated as well as manual use. To demonstrate the equivalence of the manual and MAGO Plus procedures, the results of 305 serum samples tested for anti-glycoprotein I IgG/IgM/IgA antibodies by both the manual and automated methods, and whose values were within the reportable range of the assay, were plotted. Scattergrams and regression lines of the results obtained with 95% confidence intervals are shown in FIGURE 1. The data indicate good correlation with a Correlation Coefficient (r) of 0.9667.

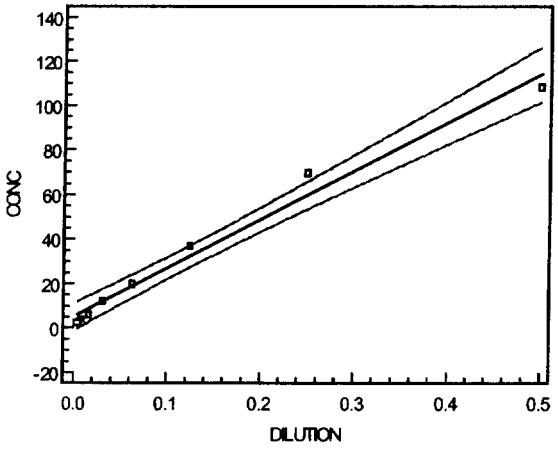
FIGURE 1: Is anti-β_2Glycoprotein I Screen Manual vs MAGO Plus Correlation



D. Linearity

To assess the linearityof the Is anti-β_2Glycoprotein I Screen Test Kit, several highly positive samples were serially diluted using Sample Diluent and each dilution was then tested in the assay system. A representative linear regeression graph and scattergram with 95% confidence intervals is shown in FIGURE 2.

FIGURE 2: Is anti-β_2Glycoprotein I Screen Linearity



Regression Equation
Y = 5.1789 + 217.8194 X

Intercept 5.17893 Slope 217.81940
Coefficient of Determination = 0.9808
Correlation Coefficient r = 0.9904
95% CI for r 0.9456 to 0.9983

E. Precision

To assess the precision of the Is anti-b_2Glycoprotein I Screen Test Kit six serum samples of varying reactivity (two negative and four positive) were tested in triplicate in three separate runs. Precision was assessed both manually and using the MAGO Plus Automated EIA Processor. The results obtained are shown in TABLES 3 and 4.

TABLE 3: Manual Intra-Assay and Interassay Precision for Is-anti-β_2Glycoprotein I Screen

SERUM	INTRA-ASSAY RUN 1			INTRA-ASSAY RUN 2			INTRA-ASSAY RUN 3			INTERASSAY (n=9)		
	MEAN U/ml	SD	CV%	MEAN U/ml	SD	CV%	MEAN U/ml	SD	CV%	MEAN U/ml	SD	CV%
A	3.8	0.200	5.26	3.6	0.115	3.24	3.9	0.252	6.51	3.7	0.219	5.84
B	3.5	0.153	4.41	3.0	0.153	5.15	3.8	0.173	4.56	3.4	0.389	11.40
C	20.0	0.723	3.62	17.7	1.137	6.41	19.2	1.153	6.01	19.0	1.324	6.98
D	30.8	1.172	3.81	26.7	0.764	2.86	27.1	0.361	1.33	28.2	2.062	7.31
E	49.7	2.818	5.67	44.4	0.755	1.70	45.1	1.159	2.57	46.4	2.927	6.31
F	92.4	1.044	1.13	89.3	1.150	1.29	90.3	0.624	0.69	90.7	1.616	1.78

TABLE 4: MAGO Plus Intra-Assay and Interassay Precision for Is-anti-β_2Glycoprotein I Screen

SERUM	INTRA-ASSAY RUN 1			INTRA-ASSAY RUN 2			INTRA-ASSAY RUN 3			INTERASSAY (n=9)		
	MEAN U/ml	SD	CV%	MEAN U/ml	SD	CV%	MEAN U/ml	SD	CV%	MEAN U/ml	SD	CV%
A	7.6	0.781	10.28	5.1	0.557	10.92	6.4	0.874	13.58	6.4	1.263	19.80
B	5.7	0.874	15.24	4.8	0.379	7.94	5.4	0.100	1.85	5.3	0.640	12.08
C	24.9	2.955	11.87	19.0	1.976	10.38	27.1	1.200	4.43	23.7	4.069	17.19
D	35.7	2.307	6.47	38.6	4.452	11.52	47.3	0.917	1.94	40.5	5.823	14.36
E	71.1	4.319	6.07	69.3	7.238	10.44	59.0	3.630	6.15	66.5	7.277	10.94
F	139.7	11.920	8.53	154.1	19.248	12.49	146.2	10.336	7.07	146.7	13.910	9.48

Expected Values

The prevalence of anti-b$_2$glycoprotein I antibodies may vary depending on a number of factors such as age, gender, geographical location, race, type of test used and clinical history of individual patients. Antibodies to anti-$\beta_2$glycoprotein I are generally absent, or have a very low incidence, in the normal healthy population.

In the present study, the expected values for a normal, healthy population were assessed by testing sera from one hundred and forty-eight S. Florida blood donors (ninety-eight males and fifty females) in the Is anti-β_2Glycoprotein I Screen Test Kit. One hundred and forty-one sera (95.3%) were negative for antibodies, five sera (3.4%) were positive and two (1.3%) were equivocal. The age distribution and antibody prevalence for this population are shown in TABLE 5.

The expected values for a clinical population were assessed by testing fifty-seven sera from patients with a diagnosis of anti-phospholipid syndrome (APS) in the Is anti-β_2Glycoprotein I Screen Test Kit. Forty-eight (84.2%) were positive, seven (12.3%) were negative and two (3.5%) were equivocal for IgG/IgM/IgA antibodies.

Histograms showing the distribution of values for these normal and clinical populations are shown in FIGURES 3 and 4.

TABLE 5 : Age Distribution and Prevalence of anti-β_2Glycoprotein I IgG/IgM/IgA in a Normal S. Florida Population

	Number of Donors	Prevalence
Total Number	148	
Geographic Location:	South Florida : 148	3.4%
Age		
10-19	7	14.3%
20-29	36	2.8%
30-39	73	1.4%
40-49	22	9.1%
50-59	8	0.0%
60-69	2	0.0%

FIGURE 3

Distribution of anti-β2glycoprotein I IgG/IgM/IgA Values in a Normal Population

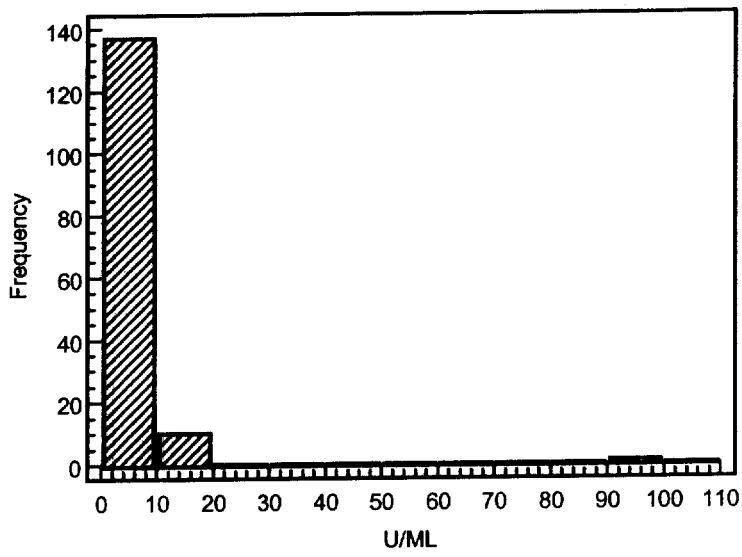
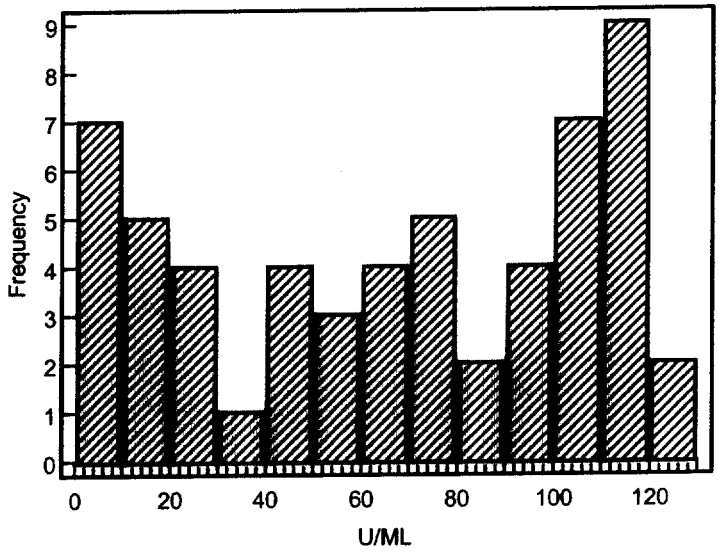


FIGURE 4

Distribution of anti-$\beta_2$glycoprotein I IgG/IgM/ IgA Values in a Clinical Population



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 8 2002

Lynne Stirling, Ph.D.
Vice President, Regulatory Affairs
Diamedix Corporation
2140 N. Miami Avenue
Miami, FL 33127

Re: k013956
Trade/Device Name: Is anti-β_2 Glycoprotein I Screen Test System
Regulation Number: 21 CFR 866.5660
Regulation Name: Multiple autoantibodies immunological test system
Regulatory Class: Class II
Product Code: MSV
Dated: November 28, 2001
Received: November 30, 2001

Dear Dr. Stirling:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

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

INDICATIONS FOR USE STATEMENT

510(K) NUMBER : K013956

DEVICE NAME : Is anti-β_2Glycoprotein I Screen Test System

Indications for Use : The Diamedix Is anti-β_2Glycoprotein I Screen Test Kit is an indirect enzyme immunoassay (EIA) for the semi-quantitative measurement of IgG, IgM and IgA antibodies to β_2-glycoprotein I in human serum as an aid in the diagnosis of certain autoimmune thrombotic disorders in patients with SLE or SLE-like disorders. These reagents can be used either manually or in conjunction with the MAGO® Plus Automated EIA Processor.

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 (OTC) Use

(Per 21CFR 801.109) (Optional Format 1-2-96).

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013956