K970237

APR - 8 1997

510(k) Summary of Safety and Effectiveness

This summary of 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: _____

Applicant Information:

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Device Information:

Trade Name:	Is-(immunosimplicity)-anti-SSB Test System
Common Name:	Anti-SSB EIA Test
Classification Name:	Extractable Antinuclear Antibody

Equivalent Device:
Helix Diagnostics Enzyme Immunoassay Anti-SS-B/La Antibody Test Kit

Device Description: *The Is-anti-SSB Test Kit System is an enzyme-linked immunosorbent assay (ELISA) for the detection and semi-quantitation of IgG to SSB (La) antigen in human serum.*

Intended use: *The assay is intended for use in detecting antibodies to SSB (La) antigen in a single human serum sample. The results of the assay are to be used as an aid in the diagnosis of autoimmune disorders.*

Comparison to Predicate Device:

The Is-anti-SSB Test System is an enzyme-linked immunosorbent assay to detect IgG to SSB (La) in human serum. Purified SSB (La) antigen is attached to a solid phase microtiter well. Diluted test sera are added to each well. If antibodies which recognize the SSB 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 the prior step, the substrate will be converted to produce a colored product. The reaction is stopped and the color intensity is measured photometrically providing an indirect measure of the specific antibody present in the patient sample.

Summary of Safety and Effectiveness

Performance Characteristics

A. Comparison Testing

The Diamedix Is-anti-SSB Test Kit was evaluated relative to another commercially available anti-SSB ELISA test kit using clinically characterized sera. One hundred sera from normal blood donors and 65 sera from autoimmune patients were tested by Is-anti-SSB and a commercially obtained anti-SSB ELISA test kit. The results are summarized in Table 1. below.

Table 1	Manual			MAGO		
	Number of Sera	%	95% Confidence	Number of Sera	%	95% Confidence
Relative Sensitivity	38/40	95	83-99	38/40	95	83-99
Relative Specificity	124/124	100	97-100	124/124	100	97-100
Agreement	162/164*	99	96-100	162/164*	99	96-100

* One borderline sample was excluded from the calculation.

Two sera were negative in Is-anti-SSB and positive in the comparative method (manual and MAGO). Upon retest by a referee method, one of the sera was positive, the other was negative.

B. Linearity

Figures 1 and 2 show typical examples of Is-anti-SSB Test Kit linearity. The figures depict the results of the Calibrator tested by Is-anti-SSB after a serial two-fold manual dilution in Sample Diluent. Separate dilutions were tested both manually and with MAGO. The results demonstrate a high degree of linearity for the Is-anti-SSA Test Kit throughout the testing range.

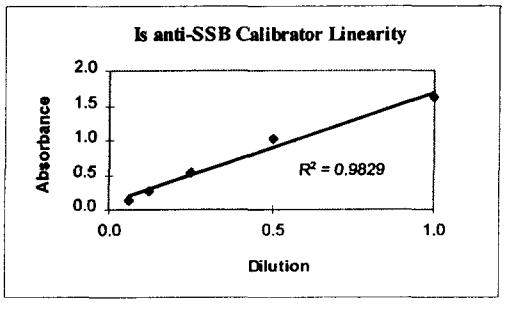

Figure1. Manual Linearity

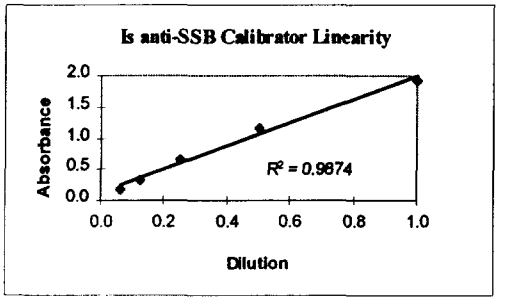

Figure 2. MAGO Linearity

C. Precision

The precision of the Is-anti-SSB Test Kit was determined by testing six different sera and kit Calibrator and controls in two runs on three different days. The intra- and inter assay precision is shown in Table 2.

Table 2

SERUM	OVERALL MEAN EU/ml	MANUAL		MAGO	
		INTRA-CV%	INTER-CV%	INTRA-CV %	INTER-CV %
1 (NEG)	1.4	10.1	21.4	27.3	30.8
2 (NEG)	1.4	4.3	6.3	13.9	16.7
3 (POS)	37.5	4.5	11.2	8.2	11.2
4 (POS)	29.7	4.1	10.4	4.1	9.2
5 (POS)	55.4	4.0	8.0	4.0	8.3
6 (POS)	96.9	3.5	5.3	3.0	8.7
CAL	100.8	4.2	6.5	5.6	10.1
POS CTRL	39.8	2.5	8.5	4.5	11.3
NEG CTRL	0.9	10.3	30.0	53.0	50.0

i anti-SSB PRECISION

D. Crossreactivity

Twenty-four sera positive for the six autoimmune specificities were tested in Is-anti-SSB Test Kit. The results are shown in Table 3

Table 3 Crossreactivity

Sample	Is-anti-SSB EU/ml	Interp	Specificity
1	5.5	Neg	SSA
2	3.7	Neg	SSA
3	0.9	Neg	SSA
4	1.6	Neg	SSA
5	236.2	Pos	SSB
6	48.3	Pos	SSB
7	148.3	Pos	SSB
8	128.4	Pos	SSB
9	6.3	Neg	Sm
10	1.4	Neg	Sm
11	1.1	Neg	Sm
12	1.6	Neg	Sm
13	3.7	Neg	RNP
14	2.1	Neg	RNP
15	2.3	Neg	RNP
16	3.3	Neg	RNP
17	1.4	Neg	Jo-1
18	4.5	Neg	Jo-1
19	1.5	Neg	Jo-1
20	1.7	Neg	Jo-1
21	2.1	Neg	Scl-70
22	2.5	Neg	Scl-70
23	2.3	Neg	Scl-70
24	1.8	Neg	Scl-70

E. Expected Values

The expected values in the normal population were determined by assaying 100 normal donor sera collected in South Florida. Figures 3 and 5 show the distribution of SSB results in the normal population performed manually and on MAGO respectively.

The distribution of EU/ml values for 65 clinically characterized sera along with the 100 normal donor sera are shown in Figures 4 and 6 performed manually and on MAGO respectively.

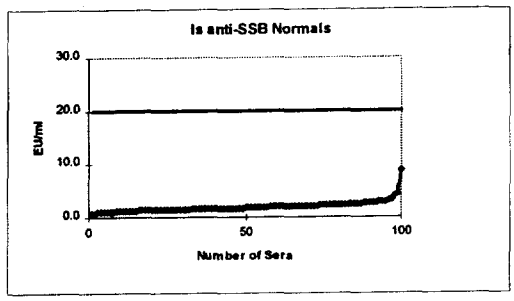

Figure 3. Manual Normals

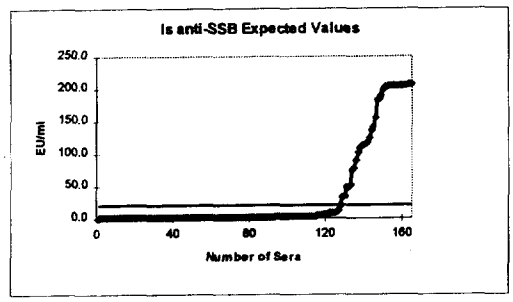

Figure 4. Manual Expected Values

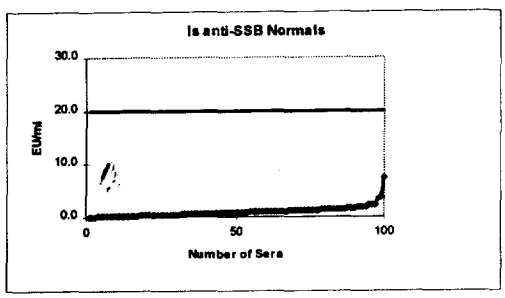

Figure 5 MAGO Normals

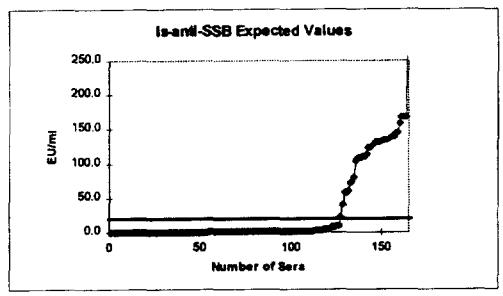

Figure 6. MAGO Expected Values

F. Correlation of Manual and MAGO Results

Numerical comparison of EU/ml values, between manual and MAGO results for 165 samples in the Is-anti-SSB Test Kit showed a correlation of 0.91 (Pearson).