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-Sm Test System
Common Name:	Anti-Sm EIA Test
Classification Name:	Extractable Antinuclear Antibody

Equivalent Device:
Helix Diagnostics Enzyme Immunoassay Anti-Sm Antibody Test Kit

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

Intended use: *The assay is intended for use in detecting antibodies to Sm 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-Sm Test System is an enzyme-linked immunosorbent assay to detect IgG to Sm antigen in human serum. Purified Sm antigen is attached to a solid phase microtiter well. Diluted test sera are added to each well. If antibodies which recognize the Sm 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-Sm Test Kit was evaluated relative to another commercially available anti-Sm ELISA test kit using 100 sera from normal blood donors and 50 sera from autoimmune patients. The results are summarized in Table 1 below.

Table 1	Manual			MAGO		
	Number of Sera	%	95% Confidence	Number of Sera	%	95% Confidence
Relative Sensitivity	34/39	87	73-96	35/41	85	71-94
Relative Specificity	107/107	100	97-100	107/107	100	97-100
Agreement	141/146*	97	92-99	142/148**	96	92-99

* Two equivocal and two borderline samples were excluded from the calculations.
** Two borderline samples were excluded from the calculations.

Five sera negative by Is-anti-Sm (manual) and positive by the comparative method were negative when tested by a third method. Six sera negative by Is-anti-Sm (MAGO) and positive by the comparative method were negative when tested by a third method. All discordant sera were from patient samples.

B. Linearity

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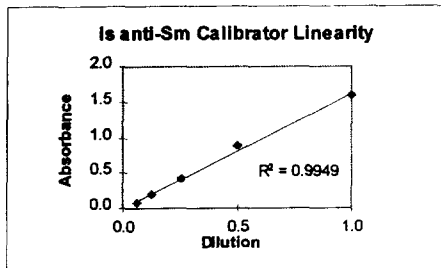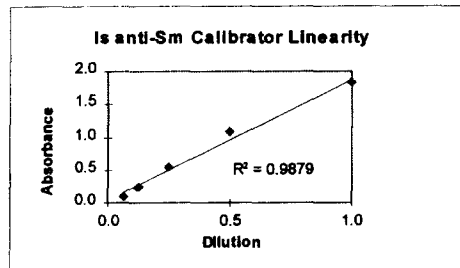

Figure 1 Manual Linearity

Figure 2 MAGO Linearity

C. Precision Testing

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

Table 2	_Z_ anti-Sm PRECISION				
SERUM	Overall MEAN EU/ml	MANUAL		MAGO	
		INTRA-CV%	INTER-CV%	INTRA-CV %	INTER-CV %
1 (NEG)	1.6	8.2	7.1	19.7	23.5
2 (NEG)	1.6	9.2	25.0	10.2	13.3
3 (POS)	56.0	3.2	3.5	3.9	4.5
4 (POS)	38.4	5.5	5.7	3.4	7.9
5 (POS)	80.7	3.9	4.6	2.1	3.4
6 (POS)	93.9	2.8	3.6	2.7	5.3
CAL	104.3	2.8	4.2	3.7	6.7
POS CTRL	52.6	3.1	4.2	5.2	7.6
NEG CTRL	0.8	12.1	25.0	47.2	50.0

D. Crossreactivity

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

Table 3 Crossreactivity

Sample	_Is_ anti-Sm	Interp	Specificity
1	2.2	NEG	SSA
2	2.6	NEG	SSA
3	1.4	NEG	SSA
4	1.3	NEG	SSA
5	2.0	NEG	SSB
6	2.2	NEG	SSB
7	2.1	NEG	SSB
8	1.5	NEG	SSB
9	78.2	POS	Sm
10	66.4	POS	Sm
11	103.6	POS	Sm
12	103.1	POS	Sm
13	7.1	NEG	RNP
14	3.8	NEG	RNP
15	10.2	NEG	RNP
16	2.1	NEG	RNP
17	2.8	NEG	Jo-1
18	4.0	NEG	Jo-1
19	3.4	NEG	Jo-1
20	2.6	NEG	Jo-1
21	1.6	NEG	Scl-70
22	2.0	NEG	Scl-70
23	2.3	NEG	Scl-70
24	1.9	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 Sm results in the normal population performed manually and on MAGO respectively.

The distribution of EU/ml values for 50 clinically characterized sera along with the 100 normal donor sera are shown in Figures 4 and 6 performed manually and on MAGO respectively.
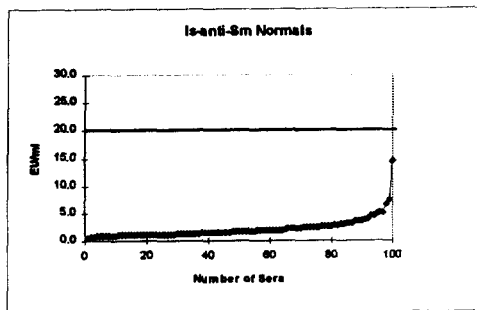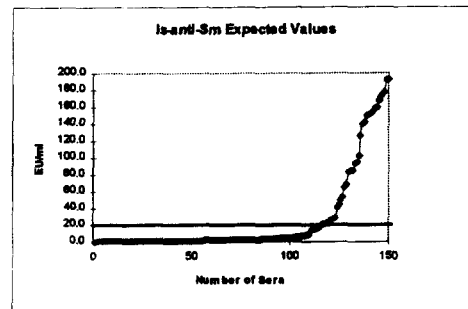

Figure 3 Manual Normals
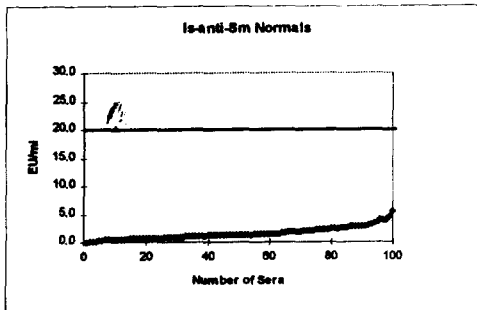

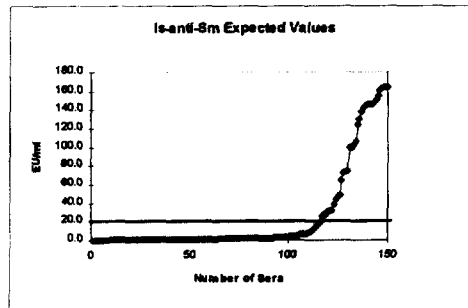**Figure 4 Manual Expected Values**

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 150 samples in the Is-anti-Sm Test Kit showed a correlation of 0.99 (Pearson).