

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

Equivalent Device:

Helix Diagnostics Enzyme Immunoassay Anti-SS-A/Ro Antibody Test Kit

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

Intended use: *The assay is intended for use in detecting antibodies to SSA (Ro) 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-SSA Test System is an enzyme-linked immunosorbent assay to detect IgG to SSA (Ro) in human serum. Purified SSA (Ro) antigen is attached to a solid phase microtiter well. Diluted test sera are added to each well. If antibodies which recognize the SSA 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-SSA Test Kit was evaluated relative to another commercially available anti-SSA ELISA test kit using 100 sera from normal blood donors and 65 sera from autoimmune patients. The results are summarized in Table 1 below.

| | Manual | | | MAGO | | |
|----------------------|----------------|----|----------------|----------------|----|----------------|
| | Number of Sera | % | 95% Confidence | Number of Sera | % | 95% Confidence |
| Relative Sensitivity | 64/69 | 93 | 84-98 | 64/69 | 93 | 84-98 |
| Relative Specificity | 92/93 | 99 | 94-100 | 91/93 | 98 | 92-100 |
| Agreement | 156/162* | 96 | 92-99 | 155-162* | 96 | 91-98 |

* Three borderline samples were excluded from the calculation.

Five sera negative by Is-anti-SSA (manual and MAGO) and positive by the comparative method were negative when tested by a third method. For manual testing, one serum positive by Is-anti-SSA and negative by the comparative method was negative when tested by a referee method. For MAGO testing, two sera were positive by Is-anti-SSA and negative by the comparative method. When tested by a third method, one was negative and one was positive.

B. Linearity

Figures 1 and 2 show typical examples of Is-anti-SSA Test Kit linearity. The figures depict the results of the Calibrator tested by Is-anti-SSA 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 the Is-anti-SSA Test Kit throughout the testing range.

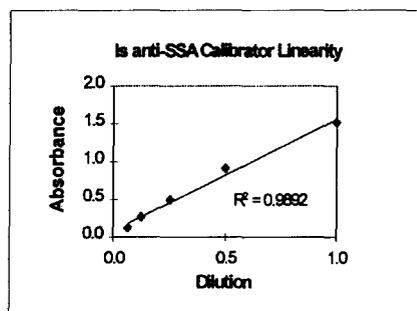


Figure 1 Manual Linearity

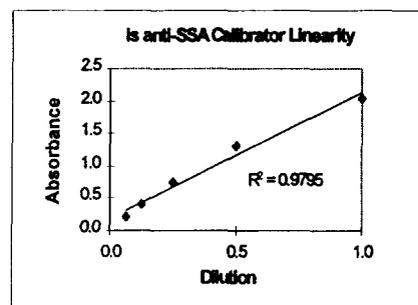


Figure 2 MAGO Linearity

C. Precision Testing

The precision of the Is-anti-SSA 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.

| SERUM | Overall MEAN EU/ml | MANUAL | | MAGO | |
|----------|--------------------------|-----------|-----------|---------------|---------------|
| | | INTRA-CV% | INTER-CV% | INTRA-CV % | INTER-CV % |
| 1 (NEG) | 2.0 | 14.5 | 22.2 | 16.3 | 13.0 |
| 2 (NEG) | 2.4 | 6.5 | 20.0 | 11.1 | 12.5 |
| 3 (POS) | 46.7 | 4.1 | 6.3 | 3.9 | 5.2 |
| 4 (POS) | 23.6 | 6.5 | 8.5 | 6.6 | 10.4 |
| 5 (POS) | 65.6 | 5.0 | 8.2 | 2.3 | 5.2 |
| 6 (POS) | 104.5 | 4.4 | 7.5 | 2.4 | 4.4 |
| CAL | 100.1 | 4.8 | 5.8 | 6.2 | 8.6 |
| POS CTRL | 42.6 | 3.1 | 5.0 | 5.0 | 7.4 |
| NEG CTRL | 1.5 | 9.1 | 21.4 | 24.9 | 25.0 |

D. Crossreactivity

Twenty-four sera positive for the six autoimmune specificities were tested in **Is-anti-SSA** Test Kit. The results are shown in Table 5. Since anti-SSB antibodies are nearly always accompanied by anti-SSA antibodies, samples 5-8 are positive in the **Is-anti-SSA** test due to the additional presence of anti-SSA antibodies.

Table 3 Crossreactivity

| Sample | Is-anti-SSA EU/ml | Interp | Specificity |
|--------|-------------------|--------|-------------|
| 1 | 154.8 | POS | SSA |
| 2 | 204.0 | POS | SSA |
| 3 | 54.8 | POS | SSA |
| 4 | 203.6 | POS | SSA |
| 5 | 203.7 | POS | SSB |
| 6 | 204.7 | POS | SSB |
| 7 | 203.9 | POS | SSB |
| 8 | 203.7 | POS | SSB |
| 9 | 31.8* | POS | Sm |
| 10 | 4.4 | NEG | Sm |
| 11 | 1.8 | NEG | Sm |
| 12 | 3.6 | NEG | Sm |
| 13 | 6.0 | NEG | RNP |
| 14 | 18.2** | EQ | RNP |
| 15 | 8.0 | NEG | RNP |
| 16 | 6.8 | NEG | RNP |
| 17 | 2.5 | NEG | Jo-1 |
| 18 | 5.1 | NEG | Jo-1 |
| 19 | 4.3 | NEG | Jo-1 |
| 20 | 2.6 | NEG | Jo-1 |
| 21 | 4.1 | NEG | Scl-70 |
| 22 | 6.4 | NEG | Scl-70 |
| 23 | 2.1 | NEG | Scl-70 |
| 24 | 6.5 | NEG | Scl-70 |

* Confirmed positive for anti-SSA by an alternative ELISA method.

** Repeated equivocal in Is-anti-SSA.

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 SSA 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.

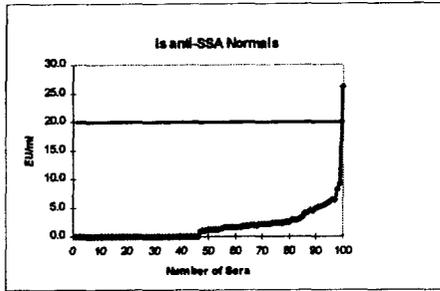


Figure 3. Manual Normals

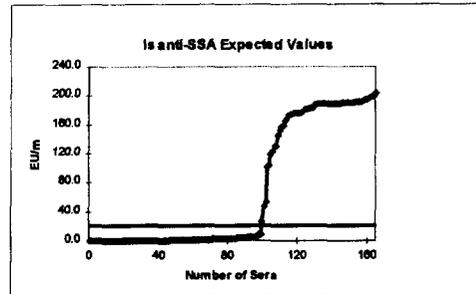


Figure 4. Manual Expected Values

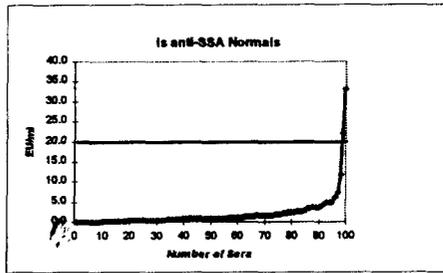


Figure 5. MAGO Normals

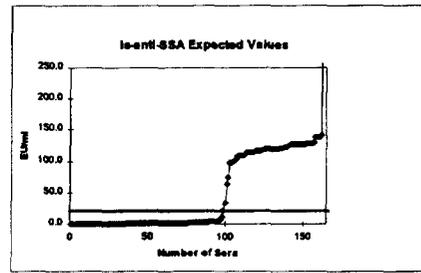


Figure 6. MAGO Expected Values

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-SSA Test Kit showed a correlation of 0.85 (Pearson).