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patients with low levels of RNP antibodies, together with other autoantibodies, 
may be observed in the serum of patients with progressive systemic sclerosis, 
Sjögren’s Syndrome, and rheumatoid arthritis. The presence of RNP antibodies 
in the serum of SLE patients is usually associated with a lower incidence of 
renal involvement and a more benign disease course. To the contrary, patients 
with Sm antibodies experience a higher frequency of renal and central nervous 
system complications (4). Studies have observed autoantibodies directed 
against SSA and SSB in patients with SLE (5, 6), and Sjögren’s disease (7 - 9). 
SSA antibodies are frequently present in the serum of ANA negative SLE 
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recent onset of Raynaud’s phenomenon is highly significant (15). The following 
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disease association (16): 

<table>
<thead>
<tr>
<th>Antibody</th>
<th>Disease State</th>
<th>Relative Frequency of Antibody Detection</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-Jo-1</td>
<td>Myositis</td>
<td>25-44% (19)</td>
<td></td>
</tr>
<tr>
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<td>30*</td>
<td></td>
</tr>
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<td>MCTD, SLE</td>
<td>100**, &gt;40, respectively</td>
<td></td>
</tr>
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<tr>
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</tr>
<tr>
<td>Anti-Scl-70</td>
<td>Systemic sclerosis</td>
<td>20-28*</td>
<td></td>
</tr>
<tr>
<td>Anti-dsDNA</td>
<td>SLE</td>
<td>40-60*</td>
<td></td>
</tr>
</tbody>
</table>

* Highly Specific 
**Highly specific when present alone at high titer

Until recently, testing of autoantibodies occurred using indirect immuno-
fluorescence, outherlony gel diffusion, hemagglutination, radioimmunossay, 
or enzyme-linked immunosorbent assay (ELISA). Unlike several other systems, 
the ELISA methodology offers sensitive, objective, and rapid evaluation of 
specimens, and therefore is suitable for screening a large number of samples 
for total ANA.

The exact etiology of autoimmune diseases is unknown, and the specific role 
played by autoantibodies in the onset of various autoimmune connective tissue 
diseases is obscure. The DAI ANA Screen ELISA Test System offers an efficient 
test procedure for the laboratory workup of patients with suspected various 
connective tissue diseases using the association and frequency of detection of 
these antibodies.

The DAI ANA Screen ELISA test system is designed to detect IgG class 

<table>
<thead>
<tr>
<th>INTENDED USE</th>
</tr>
</thead>
</table>
| The Diagnostic Automation, Inc. (DAI) ANA Screen ELISA test system is a 
 qualitative screening assay designed to detect anti-nuclear antibodies (ANA) in 
 human sera. When performed according to the enclosed instructions, this test 
 system is capable of detecting all ANAs commonly tested for, such as those 
 against double stranded DNA (dsDNA), Jo-1, SM, Sm/RNP, SSA, SSB, and Scl-70. 
 The test is also capable of detecting ANA demonstrating centromere, nucleolar, 
 peripheral, and spindle indirect immunofluorescence antibody (IFA) patterns. 
 This device is for in Vitro diagnostic use. |

<table>
<thead>
<tr>
<th>SIGNIFICANCE AND SUMMARY</th>
</tr>
</thead>
</table>
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antibodies to a variety of common nuclear antigens in human sera. Wells of plastic microwell strips are sensitized by passive absorption with antigen. The test procedure involves three incubation steps:

1. Test sera (properly diluted) are incubated in antigen coated microwells. Any antigen specific antibody in the sample will bind to the immobilized antigen. The plate is washed to remove unbound antibody and other serum components.

2. Peroxidase Conjugated goat anti-human IgG is added to the wells and the plate is incubated. The Conjugate will react with the antibody immobilized on the solid phase in step 1. The wells are washed to remove unreacted Conjugate.

3. The microwells containing immobilized peroxidase Conjugate are incubated with peroxidase Substrate Solution. Hydrolysis of the Substrate by peroxidase produces a color change. After a period of time the reaction is stopped and the color intensity of the solution is measured photometrically. The color intensity of the solution depends upon the antibody concentration in the original test sample.

**SPECIMEN COLLECTION & PREPARATION**

1. It is recommended that specimen collection be carried out in accordance with CLSI document M49: Protection of Laboratory Workers from Infectious Disease (Current Edition).

2. No known test method can offer complete assurance that human blood samples will not transmit infection. Therefore, all blood derivatives should be considered potentially infectious.

3. Use only freshly drawn and properly refrigerated sera obtained by approved aseptic venipuncture procedures should be used in this assay (17, 18). No anticoagulants or preservatives should be added. Avoid using hemolyzed, lipemic, or bacterially contaminated sera.

4. Store sample at room temperature for no longer than 8 hours. If testing is not performed within 8 hours, sera may be stored between 2 and 8°C for no longer than 48 hours. If delay in testing is anticipated, store test sera at -20°C or lower. Avoid multiple freeze/thaw cycles that may cause loss of antibody activity and give erroneous results. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine stability criteria for its laboratory (21).

**MATERIALS AND COMPONENTS**

Materials provided with the test kit

Each kit contains the following components in sufficient quantities to perform the number of tests indicated on packaging label. Note: All reactive reagents contain sodium azide as a preservative at a concentration of < 0.1% (w/v):

- Controls and Calibrators and Sample Diluent

  1. Plate: 96 wells configured in twelve, 1x 8-well, strips coated with inactivated antigen. The strips are packaged in a strip holder and sealed in an envelope with desiccant.

  2. Conjugate: Conjugated (horseradish peroxidase) goat anti-human IgG (Fc chain specific). One, 15 mL, white- capped bottle. Ready to use.

  3. Positive Control (Human Serum): One, 0.35 mL, red-capped vial.

  4. Calibrator (Human Serum): One, 0.5 mL, blue-capped vial.

  5. Negative Control (Human Serum): One, 0.35 mL, green-capped vial.


  8. Stop Solution: One, 15 mL, red-capped, bottle containing 1M H₂SO₄ 0.7M HCl. Ready to use.

9. Wash Buffer Concentrate (10X): Dilute 1 part concentrate + 9 parts deionized or distilled water. One, 100 mL, clear-capped, bottle containing a 10X concentrated phosphate-buffered–saline and Tween-20 solution (Blue solution). Note: 1X solution will have a pH of 7.2 ± 0.2.

The following components are not kit lot number dependent and may be used interchangeably with the ELISA assays: TMB, Stop Solution, and Wash Buffer.

Note: Kit also contains

1. Component list containing lot specific information is inside the kit box.

2. Package insert providing instructions for use.

Materials required but not provided

1. ELISA microwell reader capable of reading at a wavelength of 450nm.

   Note: Use of a single (450nm), or dual (450/620 - 650nm), wavelength reader is acceptable. Dual wavelength is preferred, as the additional reference filter has been determined to reduce potential interference from anomalies that may absorb light.

2. Pipettes capable of accurately delivering 10 - 200µL.

3. Multichannel pipette capable of accurately delivering 50 - 200µL.

4. Reagent reservoirs for multichannel pipettes.

5. Wash bottle or microwell washing system.

6. Distilled or deionized water.

7. One liter graduated cylinder.

8. Serological pipettes.

9. Disposable pipette tips.


11. Laboratory timer to monitor incubation steps.

12. Disposal basin and disinfectant. (i.e.: 10% household bleach - 0.5% Sodium Hypochlorite).

**PRECAUTIONS**

1. For In Vitro Diagnostic Use.

2. Normal precautions exercised in handling laboratory reagents should be followed. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable protective clothing, gloves, and eye/face protection. Do not breathe vapor. Dispose of waste observing all local, state, and federal laws.

3. The wells of the ELISA plate do not contain viable organisms. However, the strips should be considered potentially biohazardous materials and handled accordingly.

4. The human serum controls are potentially biohazardous materials.

   Source materials from which these products were derived were found negative for HIV-1 antigen, HBsAg and for antibodies against HCV and HIV by approved test methods. However, since no test method can offer complete assurance that infectious agents are absent, these products should be handled at the Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories": current edition; and OSHA’s Standard for Bloodborne Pathogens (20).

5. Adherence to the specified time and temperature of incubations is essential for accurate results. All reagents must be allowed to reach room temperature (20-25°C) before starting the assay. Return unused reagents to refrigerated temperature immediately after use.

6. Improper washing could cause false positive or false negative results. Be sure to minimize the amount of any residual wash solution; (e.g., by blotting or aspiration) before adding Conjugate or Substrate. Do not allow the wells to dry out between incubations.

7. The Sample Diluent, Controls and Calibrator contain Sodium Azide at a concentration of <0.1% (w/v). Sodium azide has been reported to form lead or copper azides in laboratory plumbing which may cause explosions.
on hammering. To prevent, rinse sink thoroughly with water after disposing of solution containing sodium azide.
8. The Stop Solution is TOXIC. Causes burns. Toxic by inhalation, in contact with skin and if swallowed.
9. The TMB Solution is HARMFUL. It is irritating to eyes, respiratory system and skin.
10. The Wash Buffer concentrate is an IRRITANT. It is irritating to eyes, respiratory system and skin.
11. Wipe the bottom of the plate free of residual liquid and/or fingerprints that can alter optical density (OD) readings.
12. Dilution or adulteration of these reagents may generate erroneous results.
13. Do not use reagents from other sources or manufacturers.
14. TMB Solution should be colorless, very pale yellow, very pale green, or very pale blue when used. Contamination of the TMB with Conjugate or other oxidants will cause the solution to change color prematurely. Do not use the TMB if it is noticeably blue in color.
15. Never pipette by mouth. Avoid contact of reagents and patient specimens with skin and mucous membranes.
16. Avoid microbial contamination of reagents. Incorrect results may occur.
17. Cross contamination of reagents and/or samples could cause erroneous results.
18. Reusable glassware must be washed and thoroughly rinsed free of all detergents.
19. Avoid splashing or generation of aerosols.
20. Do not expose reagents to strong light during storage or incubation.
21. Allowing the microwell strips and holder to equilibrate to room temperature prior to opening the protective envelope will protect the wells from condensation.
22. Collect the wash solution in a disposal basin. Treat the waste solution with disinfectant (i.e.: 10% household bleach - 0.5% Sodium Hypochlorite). Avoid exposure of reagents to bleach fumes.
23. Caution: Neutralize any liquid waste at an acidic pH before adding to a bleach solution.
24. Do not use ELISA plate if the indicator strip on the desiccant pouch has turned from blue to pink.
25. Do not allow the Conjugate to come in contact with containers or instruments that may have previously contained a solution utilizing Sodium Azide as a preservative. Residual amounts of Sodium Azide may destroy the Conjugate’s enzymatic activity.
26. Do not expose any of the reactive reagents to bleach-containing solutions or to any strong odors from bleach-containing solutions. Trace amounts of bleach (sodium hypochlorite) may destroy the biological activity of many of the reactive reagents within this Test System.

ASSAY PROCEDURE

1. Remove the individual components from storage and allow them to warm to room temperature (20-25°C).
2. Determine the number of microwells needed. Allow six Control/Calibrator determinations (one Reagent Blank, one Negative Control, three Calibrators and one Positive Control) per run. A Reagent Blank should be run on each assay. Check software and reader requirements for the correct Controls/Calibrator configurations. Return unused strips to the resealable pouch with desiccant, seal, and return to storage between 2-8°C.

<table>
<thead>
<tr>
<th>EXAMPLE PLATE SET-UP</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

3. Prepare a 1:2 dilution (e.g.: 10µL of serum + 200µL of Sample Diluent) of the Negative Control, Calibrator, Positive Control, and each patient serum.
4. To individual wells, add 100µL of each diluted Control, Calibrator and patient specimen. Ensure that the samples are properly mixed. Use a different pipette tip for each sample.
5. Add 100µL of Sample Diluent to well A as a Reagent Blank. Check software and reader requirements for the correct Reagent Blank well configuration.
6. Incubate the plate at room temperature (20-25°C) for 60 to 65 minutes.
7. Wash the microwell strips 5 times.
   a. Manual Wash Procedure:
   1. Vigorously shake out the liquid from the wells.
   2. Fill each microwell with Wash Buffer. Make sure no air bubbles are trapped in the wells.
   3. Repeat steps a. and b. for a total of 5 washes.
   4. Shake out the wash solution from all the wells. Invert the plate over a paper towel and tap firmly to remove any residual wash solution from the wells. Visually inspect the plate to ensure that no residual wash solution remains. Collect wash solution in a disposable basin and treat with disinfectant at the end of the day’s run.
   b. Automated Wash Procedure:
   If using an automated microwell wash system, set the dispensing volume to 300-350µL/well. Set the wash cycle for 5 washes with no delay between washes. If necessary, the microwell plate may be removed from the washer, inverted over a paper towel and tapped firmly to remove any residual wash solution from the microwells.
8. Add 100µL of the Conjugate to each well, including reagent blank well, at the same rate and in the same order as the specimens were added.
9. Incubate the plate at room temperature (20-25°C) for 30 to 35 minutes.
10. Wash the microwells by following the procedure as described in step 7.
11. Add 100µL of TMB to each well, including reagent blank well, at the same rate and in the same order as the specimens.
12. Incubate the plate at room temperature (20-25°C) for 30 to 35 minutes.
13. Stop the reaction by adding 50µL of Stop Solution to each well, including Reagent Blank well, at the same rate and in the same order as the TMB was added. Positive samples will turn from blue to yellow. After adding the Stop Solution, tap the plate several times to ensure that the samples are thoroughly mixed.
14. Set the microwell reader to read at a wavelength of 450nm and measure the optical density (OD) of each well against the Reagent Blank. The plate should be read within 30 minutes after the addition of the Stop Solution.

ABBREVIATED TEST PROCEDURE

1. Dilute Serum 1:21.
2. Add diluted sample to microwell – 100µL/well.
3. Incubate 60 - 65 minutes.
4. Wash.
5. Add Conjugate – 100µL/well.
6. Incubate 30 - 35 minutes.
7. Wash.
8. Add TMB – 100µL/well.
RESULTS

1. Calculations:
   a. Correction Factor: A cutoff OD value for positive samples has been determined by the manufacturer and correlated to the Calibrator. The correction factor (CF) allows for the determination of the Cutoff Value for positive samples. It will also correct for slight day-to-day variations in test results. The Correction Factor is determined for each lot of components and is printed on the Component Label located in the Test System box.
   b. Cutoff OD Value: To obtain the cutoff OD value, multiply the CF by the mean OD of the Calibrator determined above.
   c. Index Values or OD Ratios: Calculate the Index Value or OD Ratio for each specimen by dividing its OD value by the Cutoff OD from step 2.

<table>
<thead>
<tr>
<th>Example</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean OD of Calibrator</td>
<td>= 0.793</td>
</tr>
<tr>
<td>Correction Factor (CF)</td>
<td>= 0.25</td>
</tr>
<tr>
<td>Cutoff OD</td>
<td>= 0.793 x 0.25 = 0.198</td>
</tr>
<tr>
<td>Unknown Specimen OD</td>
<td>= 0.432</td>
</tr>
<tr>
<td>Specimen Index Value or OD Ratio</td>
<td>= 0.432 / 0.198 = 2.18</td>
</tr>
</tbody>
</table>

2. Interpretations: Index Values or OD ratios are interpreted as follows:

<table>
<thead>
<tr>
<th>Index Value or OD Ratio</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Specimens</td>
<td>&lt; 0.90</td>
</tr>
<tr>
<td>Equivocal Specimens</td>
<td>0.91 to 1.09</td>
</tr>
<tr>
<td>Positive Specimens</td>
<td>≥ 1.10</td>
</tr>
</tbody>
</table>

   a. An OD ratio ≤ 0.90 indicates no significant amount of IgG antibodies to ANA detected.
   b. An OD ratio ≥ 1.10 indicates IgG antibodies specific to ANA were detected.
   c. Specimens with OD ratio values in the equivocal range (0.91 - 1.09) should be retested in duplicate. Report any two of the three results which agree. Evaluate repeatedly equivocal specimens using an alternate serological method and/or re-evaluate by drawing another sample one to three weeks later.

QUALITY CONTROL

1. Each time the assay is run the Calibrator must be run in triplicate. A Reagent Blank, Negative Control, and Positive Control must also be included.
2. Calculate the mean of the three Calibrator wells. If any of the three values differ by more than 15% from the mean, discard that value and calculate the mean using the remaining two wells.
3. The mean OD value for the Calibrator, Positive Control, and Negative Controls should fall within the following ranges:

<table>
<thead>
<tr>
<th>OD Range</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Control</td>
<td>≤ 0.250</td>
</tr>
<tr>
<td>Calibrator</td>
<td>≤ 0.300</td>
</tr>
</tbody>
</table>

Positive Control | ≥ 20.500

a. The OD of the Negative Control divided by the mean OD of the Calibrator should be ≤ 0.9.
b. The OD of the Positive Control divided by the mean OD of the Calibrator should be ≥ 1.25.
c. If the above conditions are not met the test should be considered invalid and should be repeated.

4. The Positive Control and Negative Control are intended to monitor for substantial reagent failure, however will not ensure precision at the assay cut-off.
5. Additional controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.

PERFORMANCE CHARACTERISTICS

1. Comparative Study
   In a clinical investigation conducted by Diagnostic Automation, Inc., 270 serum specimens were tested using the Diagnostic Automation Inc. ANA Screen ELISA test system, and a commercial ELISA test system. Specificity was evaluated using 72 asymptomatic normal specimens from southeastern United States, and Sensitivity was evaluated using 198 disease-state sera from northeastern United States. The results of the study are summarized in Table 1 below:

   Table 1: Evaluation of Specificity Performance

<table>
<thead>
<tr>
<th>Sample</th>
<th>Positive</th>
<th>Negative</th>
<th>Equivocal</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAI ELISA ANA Screen</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Commercial ELISA Kit</td>
<td>0</td>
<td>59</td>
<td>8</td>
<td>67</td>
</tr>
<tr>
<td>Equivocal</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>0</td>
<td>61</td>
<td>11</td>
<td>72</td>
</tr>
</tbody>
</table>

*Represents Discrepant Specimens. See Table 4 for Calculations of Relative Sensitivity.

Table 2: Evaluation of Sensitivity Performance

<table>
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<th>Negative</th>
<th>Equivocal</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAI ELISA ANA Screen</td>
<td>141</td>
<td>7*</td>
<td>8</td>
<td>156</td>
</tr>
<tr>
<td>Commercial ELISA Kit</td>
<td>16*</td>
<td>2</td>
<td>2</td>
<td>20</td>
</tr>
<tr>
<td>Equivocal</td>
<td>18</td>
<td>2</td>
<td>2</td>
<td>22</td>
</tr>
<tr>
<td>Total</td>
<td>175</td>
<td>11</td>
<td>12</td>
<td>198</td>
</tr>
</tbody>
</table>

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Table 3: Summary of Discrepant Specimens

<table>
<thead>
<tr>
<th>Sample Number</th>
<th>ELISA Results</th>
<th>Other ELISA</th>
<th>IFA Hep-2 Results*</th>
</tr>
</thead>
<tbody>
<tr>
<td>62</td>
<td>0.902/Equivocal</td>
<td>0.87/Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>64</td>
<td>0.926/Equivocal</td>
<td>0.65/Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>65</td>
<td>0.940/Equivocal</td>
<td>0.74/Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>66</td>
<td>0.950/Equivocal</td>
<td>0.53/Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>68</td>
<td>1.022/Equivocal</td>
<td>0.92/Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>69</td>
<td>1.026/Equivocal</td>
<td>0.74/Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>0</td>
<td>1.045/Equivocal</td>
<td>0.43/Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>71</td>
<td>1.089/Equivocal</td>
<td>0.46/Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>73</td>
<td>0.472/Negative</td>
<td>4.88/Positive</td>
<td>≥ 1:40,Speckled</td>
</tr>
<tr>
<td>74</td>
<td>0.482/Negative</td>
<td>4.98/Positive</td>
<td>≥ 1:40,Speckled</td>
</tr>
<tr>
<td>76</td>
<td>0.585/Negative</td>
<td>5.47/Positive</td>
<td>≥ 1:40,Speckled</td>
</tr>
<tr>
<td>77</td>
<td>0.634/Negative</td>
<td>6.64/Positive</td>
<td>≥ 1:40,Speckled</td>
</tr>
<tr>
<td>79</td>
<td>0.714/Negative</td>
<td>3.14/Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>81</td>
<td>0.798/Negative</td>
<td>2.67/Positive</td>
<td>≥ 1:40,Centromere</td>
</tr>
</tbody>
</table>
Replicability


Briefly, eight specimens were tested; two strong positive samples, two moderately positive specimens, two specimens near the cutoff, and two negative specimens. Each sample was tested in duplicate, two times per day (AM and PM), on each day. Table 5 summarizes the results.

Table 5: Summary of Reproducibility Testing

<table>
<thead>
<tr>
<th>ID</th>
<th>Mean Ratio</th>
<th>Swr *</th>
<th>St b</th>
<th>Days Tested</th>
<th>% CV</th>
<th>Total Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>9.86</td>
<td>0.81</td>
<td>1.28</td>
<td>19</td>
<td>12.95</td>
<td>76</td>
</tr>
<tr>
<td>2</td>
<td>11.22</td>
<td>1.25</td>
<td>1.63</td>
<td>20</td>
<td>14.60</td>
<td>80</td>
</tr>
<tr>
<td>3</td>
<td>4.20</td>
<td>0.43</td>
<td>0.53</td>
<td>18</td>
<td>12.92</td>
<td>72</td>
</tr>
<tr>
<td>4</td>
<td>3.77</td>
<td>0.49</td>
<td>0.56</td>
<td>19</td>
<td>14.96</td>
<td>76</td>
</tr>
<tr>
<td>B1</td>
<td>1.24</td>
<td>0.07</td>
<td>0.14</td>
<td>20</td>
<td>11.29</td>
<td>80</td>
</tr>
<tr>
<td>B2</td>
<td>0.94</td>
<td>0.07</td>
<td>0.13</td>
<td>20</td>
<td>14.16</td>
<td>80</td>
</tr>
<tr>
<td>5</td>
<td>0.40</td>
<td>0.09</td>
<td>0.14</td>
<td>19</td>
<td>N/A</td>
<td>76</td>
</tr>
<tr>
<td>6</td>
<td>0.20</td>
<td>0.05</td>
<td>0.07</td>
<td>18</td>
<td>N/A</td>
<td>72</td>
</tr>
</tbody>
</table>

*Point estimate of within run precision standard deviation.
*Point estimate of total precision standard deviation

Cross Reactivity

Specimens Negative for ANA by HEP-2 IFA and positive for IgG antibody to various antigens such as EBV-VCA, EBNA, HSV-1, HSV-2, CMV, Rubella, and/or Toxo, were tested for potential cross reactivity using the Diagnostic Automation, Inc. ANA Screen ELISA test system. All samples were negative on the ELISA, indicating that the potential for cross reactivity with such antibodies in minimal.

Table 4: Calculations of Relative Specificity and Relative Sensitivity:

Relative Specificity:
1. Calculations including equivocal specimens: 59/67 = 88%
2. Calculations excluding equivocal specimens: 59/59 = 100%

Relative Sensitivity:
1. Calculation including equivocal specimens; without resolution of discrepant specimens: 141/156 = 90.4%
2. Calculation excluding equivocal specimens; after resolution of discrepant specimens: 141/147 = 95.9%

Percent Agreement: 200/207 = 96.6%

LIMITATIONS OF THE ASSAY

1. The DAI ANA Screen ELISA test system is a diagnostic aid. Interpret test results in conjunction with the clinical evaluation and the results of other diagnostic procedures.

EXPECTED RANGES OF VALUES

The expected value for a normal patient is a negative result. The number of reactivities and the degree of reactivity is dependent upon parameters such as population type being tested, treatment, etc. Each laboratory should establish their own expected values based upon the specimens typically being tested. With respect to disease-state and percent reactivity, the Table in the Summary and Explanation section of this package insert shows the relative frequency of autoantibody activity for various rheumatic disorders.

REFERENCES