Diamedix®
A Subsidiary of ERBA Diagnostics, Inc.

# ENA-6 Screen

*Enzyme Immunoassay Test Kit*
**For *In Vitro* Diagnostic Use**
**Catalog No. 720-230 – 96 Tests**

## SUMMARY OF PROCEDURE

1. Prepare a 1:101 dilution of samples in Sample Diluent. Mix well.
2. Add 100 µl of diluted samples into the antigen wells. Reserve one well for reagent blank (100 µl of Sample Diluent).
3. Incubate at room temperature (18 - 30° C) for 30 ± 5 min.
4. Discard contents of the wells. Wash the wells 3 times with Wash Solution.
5. Add 100 µl of Conjugate to each well.
6. Incubate at room temperature (18 - 30° C) for 30 ± 5 min.
7. Wash the wells as in #4 above.
8. Add 100 µl Substrate Solution to each well.
9. Incubate at room temperature (18 - 30° C) for 30 ± 5 min.
10. Add 100 µl Stop Solution to each well.
11. Read the absorbance at 405 nm (reference at 600 - 630 nm) against the reagent blank.

## INTENDED USE

For the qualitative screening of human IgG antibodies to extractable nuclear antigens (ENA) in human serum by indirect enzyme immunoassay as an aid in the diagnosis of certain autoimmune disorders. This test system screens for antibodies to Sm, Sm/RNP, SSA, SSB, Scl-70 and Jo-1 in one well. Positive samples should be evaluated further using tests designed for each ENA antibody.

## SUMMARY AND EXPLANATION

Systemic rheumatic disease is characterized by the presence of circulating autoantibodies that are widely reactive with both nuclear and cytoplasmic antigens. Antibodies to Sm (Smith) antigen are present in 25-40% of patients with systemic lupus erythematosus (SLE) and are considered to be highly specific markers for this disease.[1] Antibodies to Sm/RNP are detected in up to 40% of patients with SLE.[1,2] High titers of anti-RNP, in the absence of other autoantibodies, are correlated with mixed connective tissue disease (MCTD).[3] Antibodies to SSA (Ro) are present in approximately 60 to 70% of patients with Sjogren's Syndrome and 30 to 40% of patients with SLE.[4] Antibody to SSA occurs in about 60% of patients with "ANA negative" SLE, 63% of patients with subacute cutaneous erythematosus and in 75% of the homozygous C2-deficient patients with an SLE-like presentation.[5,6] Antibodies to SSB (La) are found in 11-24% of patients with SLE. They are also considered a serologic marker for Sjogren's Syndrome and are detected in up to 60% of these patients.[4,7] Antibodies to Scl-70 are present in approximately 20-33% of patients with scleroderma, but are rarely seen in patients with other connective tissue disorders.[1,8] Antibodies to Jo-1 are present in up to 35% of patients with polymyositis and much less commonly found in dermatomyositis. Anti-Jo-1 antibodies are rare in other rheumatic diseases.[1,9]

Until recently, laboratories have detected ENAs by immunodiffusion or counter-immunoelectrophoresis. These methods are time consuming and insensitive relative to newer methods. Enzyme immunoassay (EIA) has advantages over these methods in terms of sensitivity, specificity, ease of automation and testing turnaround time.

The Diamedix Immunosimplicity® *Is*-ENA-6 Screen Test Kit is an EIA procedure intended for the detection of IgG antibodies to six ENAs. Positive samples can be further evaluated using specific ENA test kits.

## PRINCIPLE OF THE PROCEDURE

Diluted samples are incubated with ENA antigens (SSA, SSB, Sm/RNP, Scl-70 and Jo-1) bound to the solid surface of a microtiter well. If IgG antibodies against any of these antigens are present in the samples they will bind to the respective antigen forming antigen-antibody complexes. Residual sample is eliminated by aspirating and washing. Conjugate (alkaline phosphatase-labeled anti-human IgG) is added and will bind to these complexes. Unbound conjugate is removed by aspiration and washing. Substrate is then added and incubated. In the presence of bound enzyme the substrate is converted to a colored end product. The absorbance of this end product can be read spectrophotometrically at 405 nm (reference 600-630 nm).

## REAGENTS

**Each *Is*-ENA-6 Screen Test Kit contains reagents for 96 tests.**

| | |
|---|---|
| Antigen Wells | Twelve, 8-well microwell breakapart strips, color-coded gold, coated with purified extractable nuclear antigens (SSA, SSB, Sm/RNP, Scl-70 and Jo-1). |
| Cut-Off Calibrator | One vial with blue cap containing 0.25 ml human serum, weakly reactive for ENA IgG antibodies, 0.1% sodium azide. |
| Low Positive Control | One vial with white cap containing 0.25 ml human serum reactive for ENA IgG antibodies, 0.1% sodium azide. |
| Negative Control | One vial with black cap containing human serum, non-reactive for ENA IgG antibodies, 0.1% sodium azide. |
| Sample Diluent | One bottle with blue cap containing 60 ml Phosphate buffer with protein stabilizers. Contains 0.1% sodium azide and Proclin® 300, 90 ppm active ingredient. Color-coded blue. |
| Wash Concentrate (20X) | Two bottles with clear caps containing 50 ml of Phosphate buffered saline with detergent and Proclin® 300, 15 ppm active ingredient. Each bottle is sufficient to make 1050 ml of wash solution. |
| Conjugate | One bottle with red cap containing 25 ml goat anti-human immunoglobulin G labeled with alkaline phosphatase. Also includes protein stabilizers and Proclin® 300, 30 ppm active ingredient. Color-coded pink. |
| Substrate | One amber bottle with brown cap containing 25 ml buffered p-Nitrophenyl phosphate solution. *Substrate solution may develop a slight yellow color upon storage.* |
| Stop Solution | One bottle with white cap containing 30 ml of Sodium phosphate, tribasic. Solution is caustic. Avoid contact with skin or eyes. If contact is made, flush area with copious amounts of water. |

**Store these reagents at 2 to 8° C.**

## OTHER MATERIALS REQUIRED

**Manual Users:**

Wash bottle or automated microplate washer

Pipettors capable of dispensing appropriate volumes

Timer

One liter graduated cylinder

One liter wash solution reservoir

Deionized or distilled water

Absorbent toweling

Tubes or microwell plate for serum dilution

Reader capable of reading absorbance at 405 nm, reference at 600 - 630 nm.

**Automated EIA Processor Users:**

One liter graduated cylinder

Deionized or distilled water

Pre-dilution cups, strips or plates.

ProbeClean™ Concentrate, or tip washing detergent solution, if applicable.

## PRECAUTIONS

REAGENT: For *in vitro* Diagnostic Use.

1. Handle samples, Calibrator, controls and the materials that contact them as potential biohazards. Each donor unit in the Calibrator and controls has been found negative for Hepatitis B surface antigen and HIV-I antibodies by FDA-approved third generation tests. However, because no method can offer complete assurance that HIV-1, Hepatitis B virus, or other infectious agents are absent, these materials should be handled at the Biosafety Level 2 as recommended for any potentially infectious serum or blood specimen in the Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbio-logical and Biomedical Laboratories", 1993.
2. Never pipette by mouth.
3. Avoid contact with open skin and mucous membranes.

Certain of the test reagents contain Proclin® 300 as a preservative. When disposing of reagents containing Proclin® 300, flush drains with copious amounts of water to dilute the active components below active levels.

5. Reagents containing Sodium Azide:

   (a) **CAUTION:** Some reagents in this kit contain Sodium Azide as preservative. Sodium Azide may react with lead or copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up. For further information, refer to "Decontamination of Laboratory Sink Drains to Remove Azide Salts", in the Manual Guide – Safety Management No. CDC-22, issued by the Centers for Disease Control and Prevention, Atlanta, GA, 1976.

   **European Communities Hazardous Substance Risk Phrases (Regulation (EC) No 1272/2008)**

   H300 –Fatal if swallowed.
   H310 – Fatal if contact with skin.
   EUH032 – Contact with acids liberates very toxic gas.
   H410 – Very toxic to aquatic life with long lasting effect.
   P264 – Wash all exposed external body areas thoroughly after handling.
   P302+P352 – IF ON SKIN: Wash with plenty of water and soap.
   P301+P310/P330 – IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth.
   P270 – Do not eat, drink or smoke when using this product.
   P501 – Dispose of contents/container as hazardous waste.
   P391 – Collect spillage.
   P273 – Avoid release to the environment. Refer to special instructions/ Safety Data Sheet.

   (b) Sodium Azide inhibits horseradish peroxidase activity. Care must be taken to ensure that azide is not carried over from other reagents into conjugate and substrate steps.

**ADDITIONAL PRECAUTIONS**

1. Do not interchange reagents from different reagent lots except for Sample Diluent, Wash Concentrate, Substrate and Stop Solution.
2. Do not use reagents beyond their expiration date. Expiration dates are printed on the reagent labels.
3. Store unused reagents at 2 to 8°C.
4. Incubations above or below the recommended temperatures or times may give erroneous results.
5. The EIA method is a very sensitive technique. Maintain consistent pipetting technique, incubation times, and temperature conditions throughout the test procedure. Cross contamination between reagents can invalidate the test.
6. Antigen coated microwells should be stored with the desiccant in the resealable bag provided and returned to the refrigerator immediately after use.
7. *(Manual Procedure Only)* The washing procedure is very important and requires special attention. (Please refer to the Procedure section).

   ***NOTE:*** *Improperly washed wells may give erroneous results.*

## SPECIMEN COLLECTION

Whole blood should be collected by accepted medical techniques. The serum is separated from the clot and refrigerated at 2 to 8°C for short-term storage (up to 7 days), or stored frozen at -20°C for long term storage. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen sera to room temperature slowly and mix gently, avoinding foam formation. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Grossly contaminated, hemo-lyzed, lipemic, or icteric specimens should not be used.

***CAUTION:*** *Serum samples must not be heat-inactivated prior to use.*

## PROCEDURE

Allow all test components and patient samples to warm to room temperature before use. Invert reagent bottles gently several times before use. Return promptly to the refrigerator after use.

Prepare Wash Solution by adding 50 ml of Wash Concentrate (20X) to one liter of deionized or distilled $H_2O$.

**Manual Users:**

1. Prepare 1:101 dilutions of the Cut-Off Calibrator, controls and patient samples in Sample Diluent. (e.g., by addition of 2 µl sample to 200 µl Sample Diluent or 5 µl sample to 500 µl Sample Diluent).

   The Cut-Off Calibrator must be run in triplicate.
2. Mix sample dilutions gently by withdrawing and expelling in a pipette tip 2 or 3 times or by vortex mixing for 2 or 3 seconds. Transfer 100 µl of diluted Cut-Off Calibrator, controls and diluted patient samples, to the antigen wells. Avoid formation of bubbles when transferring diluted samples.

   *NOTE: Include one well, which contains 100 µl of Sample Diluent only as the reagent blank. This will ultimately be used to "zero" the photometer before reading the test results.*
3. Allow the wells to incubate uncovered at room temperature (18 to 30°C) for 30 ± 5 minutes.
4. Aspirate or discard the contents of the wells. Remove any excess moisture in the wells by inverting the plate and tapping firmly on paper toweling. Wash the wells by rinsing 3 times with ~300 µl Wash Solution. Remove excess moisture from the wells after each washing. When using an automated washer, follow the manufacturer's instructions.
5. Place 100 µl of Conjugate into each well, avoiding bubble formation.
6. Allow the wells to incubate uncovered at room temperature (18 to 30°C) for 30 ± 5 minutes.
7. Wash the wells as described in Step 4 above.
8. Place 100 µl of Substrate into each well, avoiding bubble formation.
9. Allow the wells to incubate uncovered at room temperature (18 to 30°C) for 30 ± 5 minutes.
10. Place 100 µl of Stop Solution into each well, avoiding bubble formation.
11. Read the absorbance of the wells at 405 nm using a reference wavelength of 600-630 nm. The plate should be read within 60 minutes of adding Stop Solution.

**Automated EIA Processor Users:**

If using an Automated EIA Processor, refer to the Operator's Manual for the test setup and procedures.

***NOTE:*** *Automated EIA Processor users must validate their equipment to demonstrate that the results obtained are equivalent to those obtained using manual assay.*

## CALCULATION RESULTS

Calculate the mean absorbance of the Cut-Off Calibrator. Note: When calculating the mean absorbance value for the Cut-Off Calibrator exclude any absorbance value that deviates by more than 15% from the MEAN absorbance value. Calculate the mean from the two remaining absorbance values. Exclusion of more than one of the three absorbance values invalidates the run.

$$\frac{\textbf{Absorbance of Sample}}{\textbf{Mean Absorbance of Cut-Off Calibrator}} = \textbf{Index Value of Sample}$$

*Example: Absorbance values obtained for the Cut-Off Calibrator: 0.289, 0.268. 0.275 (after subtraction of Blank)*

*Mean Absorbance of Cut-Off Calibrator = 0.277*

*Sample Absorbance = 1.570*

*Index Value 1.570/0.277 = 5.66*

Automated EIA Processors (e.g. MAGO® Plus Automated EIA Processor), will calculate and print results automatically.

## QUALITY CONTROL

1. Each time the assay is run, the Cut-Off Calibrator must be run in triplicate. The Low Positive and Negative Controls must be included in each test run.
2. The absorbance of the Blank must be < 0.2.
3. The Index Value of the Positive Control must be ≥ 1.1.
4. The Index Value of the Negative Control must be ≤ 0.8.
5. The absorbance of the Cut-Off Calibrator must be ≥ 0.10.

If any of these criteria are not met, the results are invalid and the test should be repeated.

**NOTE:** Each lot of Is-ENA-6 Screen reagents is validated during quality control testing using all six antibodies. All six antibodies are not represented in the Cut-Off Calibrator and Low Positive Control materials. Additional controls may be tested according to guidelines or requirements of local, state, or federal regulations or accrediting organizations. For guidance on appropriate quality control practices, please refer to CLSI, formerly NCCLS, document C24-A2, Statistical Quality Control for Quantitative Measurements: Principles and Definitions.

## INTERPRETATION OF RESULTS

| Index Value | Interpretation |
|---|---|
| < 0.9 | Negative for anti-ENA IgG antibodies. |
| 0.91 to 1.09 | Equivocal* |
| ≥ 1.10 | Positive for anti-ENA IgG antibodies. |

* When equivocal results are obtained samples can be reported as equivocal, retested, tested by another method or a new sample can be tested. Equivocal samples that give positive results upon retest should be reported as positive. Equivocal samples that give negative results upon retest should be reported as negative.

## LIMITATIONS

1. The results obtained with the *Is*-ENA-6 Screen Test Kit serve only as an aid to diagnosis and should not be interpreted as diagnostic in themselves. Test results should be interpreted in conjunction with the clinical evaluation and the results of other diagnostic procedures.
2. The test should be performed on serum. The use of whole blood or plasma has not been established.
3. Positive antibodies to ENAs may be found in apparently healthy individuals.
4. Screening tests are used for testing entire populations or subsets of such populations for the presence of a characteristic. A negative screening result should infer that the individual has a high probability of being free of the characteristic, whereas a positive test may reflect only the need for further testing.
5. The Diamedix *Is*-ENA-6 Screen Test Kit will not identify the specific type of anti-ENA present in a positive sample. Positive samples must be tested for individual antibodies using the individual ENA antibody tests.
6. The performance characteristics of the Diamedix *Is-ENA*-6 Screen Test Kit with automated equipment other than the MAGO® and MAGO® Plus Automated EIA Processors have not been established.

## EXPECTED VALUES

The expected value for a normal patient is a negative result. However, positive results for autoantibodies may be found in some apparently healthy individuals. Patient sera containing autoantibodies to those antigens represented in the *Is*-ENA-6 Screen test will give positive results which can be further evaluated in specific tests. The number of positive samples detected is dependent upon the populations being tested. The expected values in a normal S. Florida blood donor population were evaluated by assaying 150 sera both manually and using the MAGO® and MAGO® Plus Automated EIA Processors. Figures 1, 3 and 5 show the distribution of results in this normal population. For manual and MAGO® Plus testing 98.6% of the normals gave negative results; for MAGO® 98% gave negative results. Two normal samples positive in the *is*-ENA-6 Screen were subsequently shown to be strongly positive for SSA antibodies.

The frequency of these six autoantibodies in various autoimmune disorders is outlined under Summary and Explanation. In the present studies 88 sera obtained from patients with an autoimmune disease or with a known autoantibody reactivity were evaluated in the *Is*-ENA-6 Screen. Figures 2, 4 and 6 show the distribution of results for this population.

**FIGURE 1**
**Expected Values**
**Normal Samples - Manual**

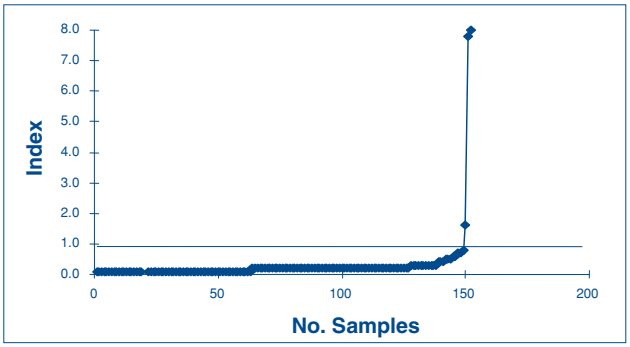



**FIGURE 2**
**Expected Values**
**Clinical Samples – Manual**

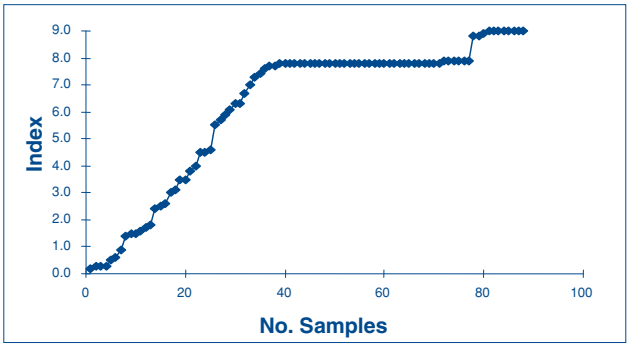



**FIGURE 3**
**Expected Values**
**Normal Samples - MAGO**

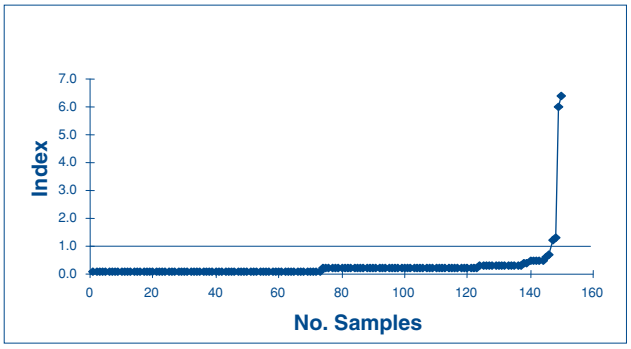



**FIGURE 4**
**Expected Values**
**Clinical Samples - MAGO**

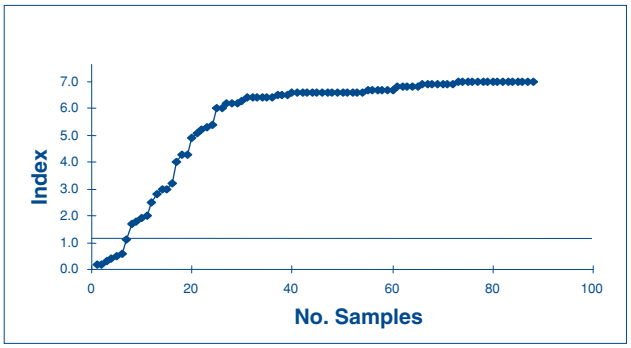


**FIGURE 5**
**Expected Values**
**Normal Samples - MAGO PLUS**

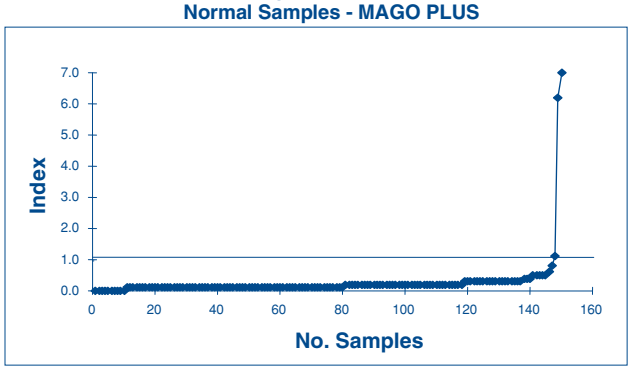
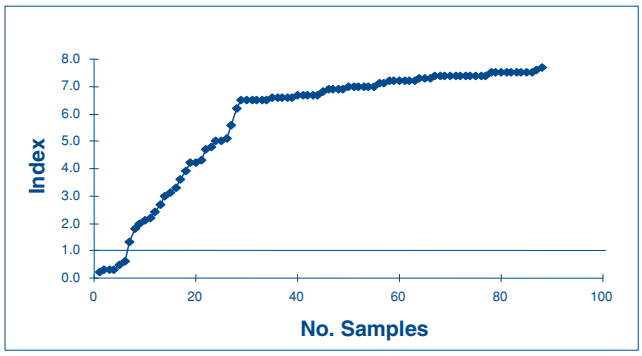



**FIGURE 6**
**Expected Values**
**Clinical Samples - MAGO PLUS**




## PERFORMANCE CHARACTERISTICS

### A. Comparison Testing

The Diamedix *Is*-ENA-6 Screen Test Kit was evaluated relative to another commercially available ENA Screen test kit. One hundred and fifty sera from normal blood donors and eighty-eight sera from clinical patients were tested by the *Is*-ENA-6 Screen Test Kit and the comparative method. Testing was performed manually and using the MAGO® and MAGO® Plus Automated EIA Processors. The results obtained are shown in Table 1.

**TABLE 1**

| | Manual | | | MAGO | | | MAGO Plus | | |
|---|---|---|---|---|---|---|---|---|---|
| | # of Sera | % | 95% CI | # of Sera | % | 95% CI | # of Sera | % | 95% CI |
| Relative Sensitivity | 81/88 | 92.0 | 84.3-96.7 | 82/89 | 92.1 | 84.5-96.8 | 82/89 | 92.1 | 84.5-96.8 |
| Relative Specificity | 143/146 | 97.9 | 94.1-99.6 | 142/146 | 97.2 | 93.1-99.2 | 143/146 | 97.9 | 94.1-99.6 |
| Overall Agreement | 224/234* | 95.7 | 92.3-97.9 | 224/235** | 95.3 | 91.8-97.6 | 225/235** | 95.7 | 92.3-97.9 |

* Four equivocal samples were excluded from calculations; ** Three equivocal samples were excluded from calculations. Ten sera were discordant in the manual and MAGO Plus testing; an additional sample was discordant in the MAGO testing. All discordant samples were tested in 6 specific commercially available ENA test kits for anti-SSA, -SSB, -Sm, -Sm/RNP, -Scl-70 and -Jo-1. The resolution of discordant samples is summarized in Table 2.

**TABLE 2**

| Sample # | *Is*-ENA-6 Screen Result | Other ENA Screen Result | Resolution |
|---|---|---|---|
| 82-normal | POS | NEG | NEG in all 6 specific ENA tests |
| 84-normal | NEG | POS | NEG in all 6 specific ENA tests |
| 90-normal* | POS | NEG | NEG in all 6 specific ENA tests |
| 91-normal | NEG | POS | NEG in all 6 specific ENA tests |
| 112-clinical | POS | NEG | POS for anti-SSA |
| 128-clinical | NEG | POS | NEG in all 6 specific ENA tests |
| 138-clinical | NEG | POS | POS for anti-Jo-1 |
| 140-clinical | NEG | POS | NEG in all 6 specific ENA tests |
| 173-clinical | POS | NEG | POS for anti-SSA |
| 205-normal | NEG | POS | NEG in all 6 specific ENA tests |
| 225-normal | NEG | POS | NEG in all 6 specific ENA tests |

* This sample was a weak positive (Index 1.2) during MAGO® testing only.

### B. Precision

The precision of the *Is*-ENA-6 Screen Test Kit was determined by testing six different sera (2 negative and 4 positive) and the kit calibrator and controls in triplicate in two different runs on three different days. Precision was evaluated manually and using the MAGO® and MAGO® PLUS Automated EIA Processors. The intra- and interassay precision is shown in Table 3.

**TABLE 3**

| | Overall | MANUAL | | MAGO | | MAGO PLUS | |
|---|---|---|---|---|---|---|---|
| SERUM | Mean Abs. | Intra-CV% | Inter-CV% | Intra-CV% | Inter-CV% | Intra-CV% | Inter-CV% |
| A (NEG) | 0.024 | 10.3 | 15.1 | 44.8 | 47.0 | 26.1 | 25.1 |
| B (NEG) | 0.044 | 4.7 | 9.3 | 10.1 | 28.6 | 5.8 | 15.3 |
| C (POS) | 0.600 | 7.0 | 8.4 | 7.3 | 12.0 | 5.9 | 11.6 |
| D (POS) | 0.927 | 4.0 | 10.4 | 7.1 | 11.0 | 6.3 | 8.3 |
| E (POS) | 1.004 | 3.0 | 9.3 | 6.6 | 9.9 | 6.7 | 9.9 |
| F (POS) | 1.488 | 4.9 | 8.5 | 6.7 | 10.4 | 4.9 | 7.9 |
| c/o CAL | 0.368 | 6.6 | 11.2 | 3.7 | 9.2 | 3.3 | 5.0 |
| POS | 0.487 | 3.1 | 7.7 | 5.6 | 9.1 | 3.6 | 7.0 |
| NEG | 0.060 | 9.0 | 12.9 | 18.1 | 23.0 | 10.7 | 13.7 |

### C. Correlation of Manual, MAGO and MAGO Plus Results

Correlation of manual, MAGO® and MAGO® PLUS Index Values for the 238 samples tested in the *Is*-ENA-6 Screen Test Kit is shown in Figures 7, 8 and 9.

**FIGURE 7**
**Manual vs. MAGO Correlation**

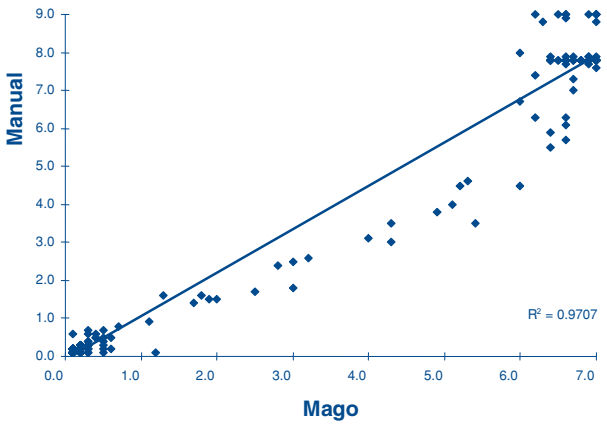


**FIGURE 8**
**Manual vs. MAGO Plus Correlation**

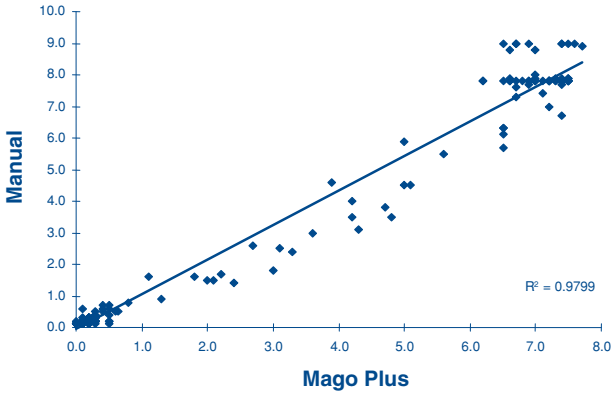
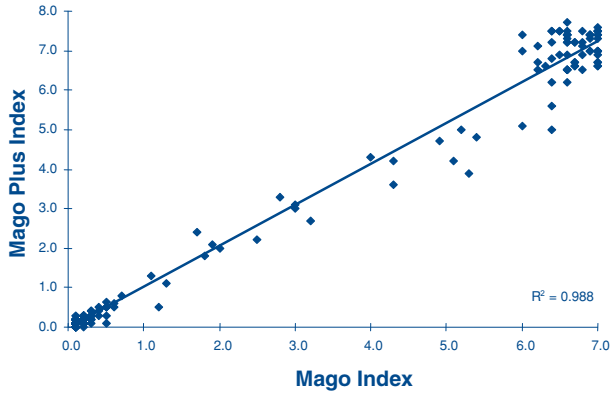



**FIGURE 9**
**MAGO vs. MAGO Plus Correlation**




## REFERENCES


1. Craft, J. and Hardin, J. A. 1993. Antinuclear Antibodies. In: Textbook of Rheumatology, Fourth Edition, W. B. Saunders Co., Philadelphia. p.164-187.
2. Mattioli, M. and Reichlin, M. 1971. Characterization of a Soluble Nuclear Ribonucleoprotein Antigen Reactive with SLE Sera. J. Immunol. 107: 1281-1290.
3. Sharp, G. C., Irvin, W. S., Tan, E. M. *et al.* 1972. Mixed Connective Tissue Disease - An Apparently Distinct Rheumatic Disease Syndrome Associated With a Specific Antibody to an Extractable Nuclear Antigen (ENA). Am. J. Med. 52: 148-159
4. Wilson, M. R. and Nitsche, J. F. 1986. Immunodiffusion Assays for Antibodies to Nonhistone Nuclear Antigens. In: Manual of Clinical Immunology, 3rd Ed., p.750-754, American Society for Microbiology, Washington, D.C.
5. Sontheimer, R. D., Maddison, P. J., Reichlin, M., Jordan, R. E., Stastny, P. and Gilliam, J. N. 1982. Serologic and HLA Associations in Subacute Cutaneous Lupus Erythematosus, a Clinical Subset of Lupus Erythematosus. Ann. Intern. Med. 97: 664-671.
6. Provost, T. T., Arnett, F. C. and Reichlin, M. 1983. Homozygous C2 Deficiency, Lupus Erythematosus and anti-Ro (SSA) Antibodies. Arthritis Rheum. 26: 1279-1282.
7. Maddison, P. J., Skinner, R. P., Vlachoyiannopoulos, P., Brennand, D. M. and Hough, D. 1985. Antibodies to nRNP, Sm, Ro(SSA) and La(SSB) detected by ELISA; Their Specificity and Interrelations in Connective Tissue Disease Sera. Clin. Exp. Immunol. 62: 337-345.
8. Steen, V. D., Powell, D. L. and Medsger, T. A. 1988. Clinical Correlations and Prognosis Based on Serum Autoantibodies in Patients with Systemic Sclerosis. Arthritis. Rheum. 31: (2) 196-203.
9. Yoshida, S., Akizuki, M., Mimori, T., Yamagata, H., *et al.* 1983. The Precipitating Antibody to an Acidic Nuclear Protein Antigen, the Jo-1, in Connective Tissue Diseases. Arthritis Rheum. 26, No. 5: 604-611.
10. Manual Guide – Safety Management No. CDC-22, “Decontamination of Laboratory Sink Drains to Remove Azide Salts”, Centers for Disease Control and Prevention, Atlanta, GA, April 30, 1976.





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