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ARLINGTON
SCIENTIFIC, INC.

(800) 654-0146 · (801) 489-8911 Springville, UT, USA
Fax (801) 489-5552 info@arlingtonscientific.com
www.arlingtonscientific.com

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ASI
SLE SLIDE TEST

For in vitro diagnostic use

Catalog Number	Kit Size
350025	25 Tests
350050	50 Tests
350100	100 Tests
3501000	1000 Tests

CPT Code: 86225

INTENDED USE

The **ASI SLE Slide Test** is a latex slide agglutination assay for the qualitative and semiquantitative detection of anti-deoxyribonucleoprotein (anti-DNP) in human serum. No initial dilution of patient samples is required for this test. These materials are intended to be acquired, possessed and used only by health professionals.

SUMMARY AND EXPLANATION

The detection of antinuclear antibodies, by such laboratory methods as immunofluorescence, LE cell test, and agglutination of coated particles, can aid in the diagnosis of such autoimmune diseases as systemic lupus erythematosus (SLE) [1,2,3,4,5]. The antibodies most associated with SLE are those directed against DNP. These antibodies are believed to cause the formation of the LE cell *in vitro*, occurring in 75-80% of patients diagnosed as having SLE [4,5,6]. Given that 20-25% of SLE patients do not exhibit the formation of LE cells[7], other methods can be used to detect antinuclear antibodies.

PRINCIPLE OF THE PROCEDURE

The **ASI SLE Slide Test** provides a means of detecting anti-DNP in human serum. SLE LATEX REAGENT is a stabilized buffered suspension of polystyrene latex particles that have been coated with DNP. When the LATEX REAGENT is mixed with the serum containing antibodies to DNP, agglutination occurs. Using dilutions of a reactive patient sample, the anti-DNP titer can be determined.

REAGENTS

LATEX REAGENT - Suspended inert latex particles coated with DNP, with 0.1% sodium azide as preservative.

CONTROLS (REACTIVE, NONREACTIVE) - Human serum or defibrinated plasma (liquid), with 0.1% sodium azide as preservative.

WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use

1. ASI SLE LATEX REAGENT and CONTROLS contain sodium azide. Azides in contact with lead and copper plumbing may react to form highly explosive metal azides. When disposing of reagents containing azide, flush down the drain with large quantities of water to prevent azide build-up.
2. ASI SLE CONTROLS contain human serum or plasma which has been tested at the donor level for HBsAg and for HIV-1, HIV-2 and HCV antibodies and found to be nonreactive. As no known test offers complete assurance that infectious agents are absent, the CONTROLS should be considered potentially infectious and universal precautions should be used. The CDC/NIH Health Manual “Biosafety in Microbiological and Biomedical Laboratories” describes how these materials should be handled in accordance with Good Laboratory Practice.
3. Do not pipet by mouth.
4. Do not smoke, eat, drink or apply cosmetics in areas where plasma/serum samples are handled.
5. Any cuts, abrasions or other skin lesions should be suitably protected.

Handling and Procedural Notes

1. In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed. Do not modify the handling and storage conditions for reagents or samples.
2. Do not use past the expiration date indicated on the kit.
3. Do not interchange components of one kit with those of another kit.

Storage Instructions

Store all reagents at 2-8°C in an upright position when not in use. Do not freeze reagents. Pipets and cards do not require refrigeration.

Indications of Deterioration

1. Turbidity or precipitation in controls is indicative of deterioration and the component should not be used.
2. Bacterial contamination of reagents or specimens may cause false positive results.

SPECIMEN COLLECTION AND STORAGE

1. Use only serum that is free from contamination. Test samples should not be heat-inactivated.
2. It is preferable to test samples on the day of their collection. If samples cannot be tested immediately, maintain them in their original tubes at 2-8°C and test within 48 hours.
3. Serum samples stored longer than 48 hours should be stored at -20°C or below until testing. Avoid repeated freezing and thawing of specimens.
4. If necessary before testing, centrifuge the specimens at a force sufficient to sediment cellular components.
5. Samples to be sent out for testing should be placed on ice packs and packaged like any other biohazardous material that could potentially transmit infection.

PERFORMANCE OF THE TEST

Materials Provided:

	25 Tests	50 Tests	100 Tests	1000 Tests
SLE LATEX REAGENT	1.0 ml	2.0 ml	2 x 2.0 ml	20 x 2.0 ml
REACTIVE CONTROL	0.5 ml	1.0 ml	1.0 ml	10 x 1.0 ml
NONREACTIVE CONTROL	0.5 ml	1.0 ml	1.0 ml	10 x 1.0 ml
0.03 ml Disposable Stirrer Pipets	25	50	100	1000
Disposable Test Cards (6-well)	5	9	17	170

Additional Materials Required

- Timing device
- 13 x 75 mm test tubes
- Volumetric pipet to deliver 0.25 ml
- Saline (0.9% NaCl solution)
- Mechanical rotator (optional)

TEST PROCEDURE

PREPARATION FOR THE ASSAY

1. Allow all reagents and samples to warm to room temperature (20-30°C) before use. Remove reagents from foam holders. Do not heat reagents in a water bath.
2. All reagents are ready for use as supplied. Gently mix the reagents before use; avoid foaming.
3. Gently mix the LATEX REAGENT before each use to ensure homogeneity.

ASSAY PROTOCOL - QUALITATIVE

1. Using the stirrer pipets, dispense one free-falling drop (0.03 ml) of each serum sample onto a separate circle on the test card. Use a fresh stirrer pipet for each sample. When using the stirrer pipet, keep it in a vertical position to ensure accurate delivery. Repeat by adding one free-falling drop of REACTIVE or NONREACTIVE CONTROL from the dropper vials supplied onto a separate circle on the test cards. Note the location of each sample by using the numbers located above and to the left of each circle.
2. Expel the contents of the LATEX REAGENT dropper and refill. Add one drop of the reagent to each serum specimen and to each control.
3. Using the flat end of the stirrer pipets, mix each specimen and control serum with the LATEX REAGENT, in a circular manner, over the entire area in the circles of the card.
4. Gently tilt and rotate the card for one (1) minute and observe for agglutination. All test results should be compared to both REACTIVE and NONREACTIVE CONTROLS.

ASSAY PROTOCOL - SEMIQUANTITATIVE

1. Prepare serial dilutions of patient serum, in saline, in test tubes as follows:

Tube	Dilution	Composition
1	1:2	0.25 ml of serum + 0.25 ml saline. Mix.
2	1:4	0.25 ml from tube 1 + 0.25 ml saline. Mix.
3	1:8	0.25 ml from tube 2 + 0.25 ml saline. Mix.
4	1:16	0.25 ml from tube 3 + 0.25 ml saline. Mix.
5	1:32	0.25 ml from tube 4 + 0.25 ml saline. Mix.
6	1:64	0.25 ml from tube 5 + 0.25 ml saline. Mix.

Testing on additional dilutions should be performed as needed.

2. Using each dilution as a separate test specimen, apply the samples to the card as described in Step 1 of the "Qualitative Assay Protocol" and proceed with Steps 2 through 4 of the "Qualitative Assay Protocol". Include undiluted sample if not tested previously on that day with the same lot of LATEX REAGENT.

QUALITY CONTROL

Quality Control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control Procedures. Controls with graded reactivity should be included. If control samples do not yield the expected response, the assay should be considered invalid and the assay repeated. If the repeat assay does not elicit the expected results for the control samples, discontinue use of the kit and contact ASI Technical Support at 800.654.0146.

INTERPRETATION OF RESULTS- QUALITATIVE

Agglutination indicates a reactive SLE sample. Sera that elicit a reactive result should be retested and titered using the "Semiquantitative Assay Protocol".

INTERPRETATION OF RESULTS- SEMIQUANTITATIVE

The highest dilution in which visible agglutination occurs is considered the endpoint titer.

LIMITATIONS OF THE PROCEDURE

1. Serum from patients with scleroderma, rheumatoid arthritis, dermatomyositis, and a variety of connective tissue diseases may elicit agglutination in the SLE slide test.
2. Because extremely high levels of antibodies might affect the degree of agglutination, positive samples should be reassayed using the semi quantitative procedure.
3. Contaminated, lipemic, or grossly hemolyzed sera should not be used because of the possibility of nonspecific results.
4. Plasma samples should not be used because of the possibility of nonspecific results.
5. Samples yielding indeterminate results may be resolved by repeating the test utilizing a two (2) minute slide rotation period. Reaction times longer than two minutes might cause false positive results due to a drying effect.
6. Drugs such as hydralazine, isoniazid, procainamide and a number of anticonvulsant drugs can induce an SLE syndrome.
7. In accord with all diagnostic methods, a final diagnosis should not be made on the result of a single test, but should be based on a correlation of test results with other clinical findings.

EXPECTED VALUES

Serum samples from 155 individuals were tested using the **ASI SLE Slide Test**. Of the 155 individuals, 29 had active SLE, 23 had clinically inactive SLE, 8 had connective tissue diseases and the remaining 95 were either clinically normal or had some nonrelated disease (including anemia, infectious mononucleosis and rheumatic heart disease) and were used as controls. Results from testing with the **ASI SLE Slide Test** were compared with the results from testing of the samples using a standard LE cell preparation assay and a fluorescent ANA assay.

Of the 29 active SLE patients, 82% were positive using the SLE Slide Test, 86% were positive by the LE cell prep, and 82% positive by the ANA test. For the 23 clinically inactive SLE patients, 19% were positive by both the SLE Slide Test and the LE cell prep; and 71% were positive by the ANA test. None of the 8 patients having connective tissue disease tested positive with the SLE Slide Test, whereas 17% and 50% tested positive by the LE cell prep and the ANA procedures, respectively. Of the controls, 1% tested positive by both the SLE Slide Test and the LE cell prep, while 6% tested positive by the ANA assay.

WARRANTY

This product is warranted to perform as described in its labeling and ARLINGTON SCIENTIFIC, INC. literature. ARLINGTON SCIENTIFIC, INC. disclaims any implied warranty of merchantability or fitness for a particular purpose and in no event shall ARLINGTON SCIENTIFIC, INC. be liable for consequential damages.