



# CORTEZ DIAGNOSTICS, INC.

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## SLE

IVD	See external label	2°C-8°C	Σ= 50 tests	REF	Cat. #351-50
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### Cat. No. 351-50

#### INTENDED USE

The SLE Test is to be used as an aid in the diagnosis of Systemic Lupus Erythematosus (SLE) through the detection and quantitation of serum antinucleoprotein factors associated with SLE.

#### SUMMARY AND PRINCIPLES

The detection of antinuclear antibodies by laboratory methods includes immunofluorescence, LE cell test, and agglutination of coated particles<sup>1-5</sup>. The antibodies that are believed to be most characteristic of SLE are those that are directed against deoxyribonucleoprotein (DNP). These antibodies are believed to cause the formation of the LE cell *in vitro*, with this unusual event occurring in 75-80% of those patients diagnosed as having SLE<sup>4, 6</sup>. It is not necessary to have a positive LE cell test for the diagnosis of SLE as this test had been found negative in certain individual having symptoms suggestive for SLE<sup>7</sup>. In these individuals, antinuclear antibodies may be demonstrated by methods other than the LE cell test.

The principle of the SLE Test is based on the agglutination reaction between latex particles coated with DNP being brought into contact with a serum, which contains antinuclear antibodies. A visible agglutination indicates a positive reaction. The reaction time for this occurrence is within one minute.

#### MATERIALS AND REAGENTS PROVIDED

- SLE Latex Reagent:**  
Polystyrene latex particles coated with DNP extracted from fetal calf thymus. Sodium azide (0.1%) is used as preservative. Shake well prior to use.
- SLE Positive Control:**  
Human serum that has been diluted and stabilized with buffers and contains sodium azide (0.1%) as a preservative.
- SLE Negative Control:**  
Human serum that has been diluted and stabilized with buffers and contains sodium azide (0.1%) as a preservative.
- Dropper stirrers.
- Glass slide

#### MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Physiological saline
- Test tubes

#### STORAGE AND STABILITY

When not in use, store reagent and controls at 2-8°C. DO NOT FREEZE. Prior to use, allow reagents and controls to warm up to room temperature. Expiration date is specified on the kit label and on each vial. Biological indication of product instability is positive and negative controls.

#### SPECIMEN COLLECTION

The test should be performed on serum. The test sera and controls should not be heat inactivated. Fresh specimens (less than 24 hours old) should be used in performing the test. If testing is delayed, specimens should be refrigerated (or frozen where applicable). Bacterial contamination may cause false positive agglutination.

#### WARNINGS AND PRECAUTIONS

This product is for *in vitro* diagnostic use only. Even though the control sera supplied in the SLE Test Kit have been tested by an FDA approved method for the presence of Hepatitis B Surface Antigen (HBsAg) and HTLV-III antibodies and found to be non-reactive, all human serum products and patient specimens should be considered potentially hazardous and handled in the same manner as an infectious agent. The preservative sodium azide may react with metal plumbing to form explosive metal oxides. While disposing of samples, flush with a large volume of water to prevent metal azide build up.

#### PROCEDURE

##### Qualitative Test:

- Bring all reagents and serum samples to room temperature.
- Positive and Negative Control should be tested with each series of test sera.
- The disposable pipettes supplied with the kit will dispense 0.045 ml.
- Use a clean dry slide washed in a mild detergent and rinsed with distilled water.
- Using the disposable pipette provided, place one drop (0.045) of test serum onto a circle on the slide. Use separate disposable pipette for each test serum.
- Important: The SLE Latex Reagent must be shaken vigorously for 30 seconds prior to using on each day's testing. This is to insure that there is no aggregation of the latex particles, which may occur upon standing. Do not use a vortex mixer.
- Deliver one drop of SLE Latex to each circle that contains specimens on the slide. Spread the resulting mixture by using the paddle end of the pipette. Do not use the same paddle end to

mix each test serum or control as this will cause cross-contamination.

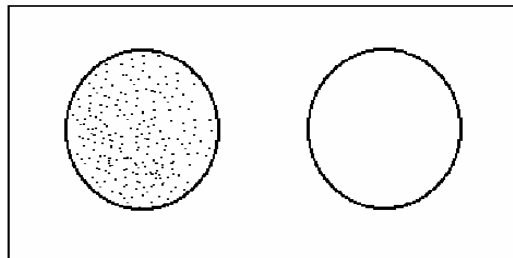
8. Gently tilt and rotate slide by hand for one minute.
9. Observe for macroscopic clumping using the indirect oblique light source and the reaction of the test serum is compared to the SLE positive and negative control sera.
10. Observe for agglutination no longer than one minute.

#### Semi-Quantitative Test:

1. For each test serum to be titrated, label 6 test tubes (12 x 75 mm).
2. To each tube add 0.2 ml physiological saline.
3. To Tube No.1 add 0.2 ml of undiluted test serum.
4. Serially make two-fold dilutions by mixing contents of tube No.1 with a pipette and transferring 0.2 ml to tube No.2. Repeat serial transfers for each tube. For the 6 tubes, the dilutions range from 1:2 to 1:64. If required, additional serum dilutions can be added.
5. Repeat Steps 5 to 10 as given in the Qualitative procedure.

#### **INTERPRETATION OF RESULTS**

1. Positive Result: Agglutination.
2. Negative Result: Smooth milky suspension.



Positive

Negative

Figure 1.

#### **LIMITATIONS**

Those patients with scleroderma, rheumatoid arthritis, dermatomyositis, and a variety of connective tissue diseases may show reactivity when their serum is tested with the SLE TEST latex. In recent studies, it has been reported that many widely used drugs such as hydralazine, isoniazid, procainamide and a number of anticonvulsant drugs can induce a SLE syndrome.

#### **PERFORMANCE CHARACTERISTICS**

Utilizing the kit, a study was conducted on 155 subjects, who included 29 patients with active SLE, 23 with clinically inactive SLE, 8 having connective tissue diseases, and the remainder (95) were controls<sup>8</sup>. The SLE TEST Kit was compared with a standard LE cell test and a fluorescent ANA test.

On the serum from the 29 active SLE patients, the SLE TEST Latex showed 82% positive, the LE cell test showed 86% positive and the ANA test showed 82% positive.

On the serum from the 23 clinically inactive SLE patients, the SLE Latex gave 19% positive results, the LE cell test gave a 19%, and the ANA test 71%.

Those patients having connective tissue disease showed no positive reactions with the SLE TEST Latex but the LE cell test gave a 17% positive reaction while the ANA procedure gave a 50% positive reaction.

The remaining controls which were made up from normal people and from patients who had diseases which included anemia, infectious

mononucleosis and rheumatic heart disease, showed a 1% positive result with both the SLE TEST Latex and the LE cell test, while the ANA gave 6% positive results.

#### **REFERENCES**

1. Christian C.L., R. Mendez-Bryan, and D.L. Larson, 1958. *Proc. Soc. Exptl. Biol. Med.* 98, 820-823.
2. Friou, G.J., S.C. Finch, and K.D. Detre, 1958. *J. Immunol.* 80, 324-329.
3. Hargraves, M.M., H. Richmond, and R. Morton, 1948. *Proc. Mayo Clin.* 23, 25-28.
4. Holman, H.R., and H.G. Kunkel, 1957. *Science* 126, 163.
5. Miescher, P.A., and R. Strassel, 1957. *Vox. Sang.* 2, 283-287.
6. Miescher, P.A., N. Rothfield, and A. Miescher, 1966. *Lupus Erythematosus*, E.L. Dubois, Ed., Blakiston Co., N.Y.
7. Rothfield, N.F., J.J. Phythyon, C. McEwen, and P. Miescher, 1961. *Arthritis Rheum.* 4, 223-229.
8. Data.



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