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CORTEZ DIAGNOSTICS, INC.

21250 Califa Street, Suite 102 and 116, Woodland Hills, CA 91367
Tel: (818) 591-3030 Fax: (818) 591-8383
onestep@rapidtest.com
technicalsupport@rapidtest.com
www.rapidtest.com

IVD	See external label	2°C-8°C	Σ=50	REF 351-50

SYSTEMIC LUPUS ERYTHEMATOSUS

(SLE)

LATEX TEST

REF 351-50

INTENDED USE

The SLE Latex Test Kit is for use in the detection and quantitation of serum antinucleoprotein factors associated with systemic lupus erythematosus.

SUMMARY AND PRINCIPLES

The demonstration of antinuclear antibodies by laboratory methods include fluorescence, LE cell test, and aggultination of coated particles.1-5 The antibodies that are believed to be most characteristic of SLE are the ones directed against deoxyribonucleoprotein (DNP). These are the ones that are believed to cause the formation of the LE cell in vitro; this unusual happening occurs in 75-80% of those patients diagnosed as having SLE.4,6 It is not necessary to have a positive LE cell test for the diagnosis of SLE as this test has been found negative in certain individuals having symptoms suggestive of SLE.7 In these individuals, antinuclear antibodies may be demonstrated by methods other than the LE cell test.
The principle of the SLE latex agglutination test is that when latex particles coated with DNP are brought into contact with a serum which contains anti-nuclear antibodies, there occurs agglutination, which indicates a positive reaction. The reaction time for this occurrence is within one minute.

MATERIALS AND REAGENTS PROVIDED

One dropper vial containing SLE Latex-DNP 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.

One squeeze vial containing SLE positive human control serum that has been diluted and stabilized with buffers and contains sodium azide (0.1%) as a preservative. One squeeze vial containing SLE negative human control serum that has been diluted and stabilized with buffers and contains sodium azide (0.1%) as a preservative. Disposable pipettes and glass/disposable slide(s) are also provided.
Each kit contains enough reagents and ancillary materials for the test kit number supplied.

MATERIALS REQUIRED BUT NOT PROVIDED

- Materials required, but not provided:
- Serological test tubes, 12 x 75 mm
- Physiological saline (0.9% NaCI)
- Serological pipettes, 1.0 ml delivery
- Lab rotator
- Lab timer

STORAGE AND STABILITY

When not in use, store reagent and controls at 2-8˚C (35-46˚F).
Do not freeze. Prior to use, allow reagents and controls to warm to room temperature.
Expiration date is specified on the kit label. Biological indication of product instability is evidenced by inappropriate reaction of the latex reagent with the corresponding positive and negative control serums.

SPECIMEN COLLECTION

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

WARNINGS AND PRECAUTIONS

This product is for in vitro diagnostic use. Even though the control sera supplied in the SLE Kit was tested and found negative to HIV 1/2 and HCV and non-reactive for Hepatitis B Surface Antigen by FDA approved procedures, all human serum products and patient specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
The reagents in each kit are matched. Reagents from different kits must not be interchanged or pooled. If the kit does not yield expected results when controls are tested, the kit should be discarded. Mix the reagents well before use. Use clean equipment. Traces of detergent or dried reactants on the test slide may adversely affect test performance and results.
WARNING: The components of the test kit contain sodium azide. Sodium azide may react with lead and copper plumbing to form explosive metal azides. Upon disposal, flush lines with a large volume of water to prevent azide build up. Dropper Bulb(s) in this kit contain natural rubber.

PROCEDURE I (Screening)

1. Bring all reagents and serum samples to room temperature.
2. It is recommended that a positive and a negative control be tested for each new test kit and as often as the needs of the lab dictate.
3. The disposable pipettes supplied with the kit will dispense 0.030 ml.
4. Use a clean dry slide washed in a mild detergent and rinsed with distilled water.
5. With the dispensing pipette provided, place one drop (0.030 ml) of test serum in oval on glass slide. Use separate dispensing pipette for each test serum.
6. Important: The SLE Latex Reagent must be shaken vigorously for 30 seconds prior to using on each day's testing, this is to insure there is no aggregation of latex particles which may occur upon standing. Do not use a vortex mixer.
7. Expel contents of dropper and refill, then place one drop of SLE Latex Reagent to each oval to be tested and spread mixture by using paddle end of the pipette used in step 5.

8. Continue to mix for 1 minute with rotator or by hand and observe for macroscopic clumping using the indirect oblique light source.
9. The reaction of the test serum is compared to the SLE positive and negative control sera.
10. Observe for agglutination no longer than 1 minute.

QUALITY CONTROL PROCEDURE

A positive control will produce, usually within 1-minute, coarse agglutinated flocs against a clear background, as demonstrated by the positive control.
A negative control will produce, usually no agglutination. It should be used as a basis for comparison. The relative degree of smoothness of the SLE reagent itself, should be considered and incorporated in reading the results.
If the indicated results are not obtained by using the positive and negative controls, SLE Kit should not be used.

INTERPRETATION RESULTS

An agglutination of the latex particle suspension is a positive result. (Visible clumping within 30 seconds and complete agglutination within 1 minute.)
A weakly-reactive serum provides a very fine granulation or a partial clumping. The results should be read within 1 minute because non-specific reactions may occur after this time period.
Sera that are positive in the screening test should be retested in the titration test to provide verification for borderline interpretations.

PROCEDURE II (Semi Quantitative)

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. Proceed with step 5 as in screening Method 1.

QUALITY CONTROL PROCEDURE

Same as described in screening test.

RESULTS

Same as described in screening test.

LIMITATIONS

Those patients with scleroderma, rheumatoid arthritis, dermatomyositis, and a variety of connective tissue diseases may show reactivity when their serum is used in the SLE Latex Test Set.
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 systemic lupus erythematosus (SLE) syndrome.

PERFORMANCE CHARACTERISTICS

Utilizing the SLE Latex Test Kit, a study was conducted on 155 subjects which included 29 patients with active SLE, 23 with clinically inactive SLE, 8 having connective tissue diseases, and the remainder (95) were controls.8
The SLE Latex Test was compared with a standard LE cell preparation test and a fluorescent ANA test. On the serum from the 29 active SLE patients, the SLE Latex showed 82% positive, the LE cell prep showed 86% positive, and the ANA test showed 82% positive. On the serum from the 23 clinically

inactive SLE patients, the SLE gave 19% positive results, the LE cell prep gave 19%, and the ANA test 71%. Those patients having connective tissue disease showed no positive reactions with the SLE Latex Test, but the LE cell prep 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 Latex Test and the LE cell prep, while the ANA gave 6% positive results.

Since the initial comparisons were done, additional studies have confirmed both the specificity and sensitivity of the SLE Latex Test Set.

REFERENCES

1. Christian, C.L., R. Mendez-Bryan, and DL. Larson, 1958. Proc. Soc. Expit. Biol. Med. 98:820-823.
2. Friou, G.J., S.C. Finch, and K.D. Detre, 1958. J. Detectorl 80:324-329.
3. Hargraves, M.M., H. Richmond, and R. Morton, 1948. Proc. Mayo clin. 32:25-28.
4. Holman, HR., 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.
7. Rothfield, and A. Meischer, 1966. Lupus Erythematosus E L. Dubois, Ed., Blakis-ton Co., New York. Rothfield, N.E., J.J. Phythyon, c. McEwen, and P. Miescher, 1961. Arthritis Rheum. 4:223-229.
8. Data on file.
9. Bennett, R.M., B. Langer, and E. Molina, 1976. Am. J. clin. Path. 66:743-745.
10. Chapman, J.C., 1976. Am J. Med. Tech. 42:154-157.
11. Tuffanelli, DL. 1972. Arch Derm. 106:553-566.

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