SLE LATEX TEST
(A rapid latex slide test for Systemic Lupus Erythematosus (SLE) by the latex method)

INTENDED USE
This Latex Test kit is for use in the detection and quantitation of serum antinucleoprotein factors associated with systemic lupus erythematosus.

PRINCIPLE OF THE TEST
The demonstration of antinuclear antibodies by laboratory methods include immunofluorescence, LE cell test, and agglutination of coated particles. 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. 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. In these individuals, antinuclear antibodies may be demonstrated by methods other than the LE cell test.

The principle of this latex agglutination test is that when latex particles coated with DNP are brought into contact with a serum containing antinuclear antibodies, they are agglutinated, which indicates a positive reaction. The reaction time for this occurrence is within one minute.

REAGENTS AND MATERIALS PROVIDED
One dropper vial containing the 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 negative 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 positive human control serum that has been diluted and stabilized with buffers and contains sodium azide (0.1%) as a preservative.

Disposable pipettes and a glass slide are also provided.

Each kit contains enough reagents and ancillary materials for the test kit number supplied.

STORAGE AND STABILITY
When not in use, store reagents and controls at 2°C-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 itself, should be considered and incorporated in performance and results.

QUALITY CONTROL PROCEDURE
5. Proceed with step 5 as in screening Procedure A.

QUALITY CONTROL PROCEDURE
Same as described in screening test.

RESULTS
Same as described in screening test.

LIMITATIONS OF THE PROCEDURE
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 Kit. In recent studies, it has been reported that many widely used drugs such as hydralazine, isoniazid, procainamide, and a number of anti-convulsant drugs can induce a systemic lupus erythematosus (SLE) syndrome.

SPECIFIC PERFORMANCE CHARACTERISTIC
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. 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 latex 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 71% positive reaction while the ANA procedure gave 50% positive reaction. The remaining controls which were made up from normal people and from patients who had diseases 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.

BIBLIOGRAPHY

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