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Systemic Lupus Erythematosus (SLE) Test

INTENDED USE

The PULSE SLE TEST is intended 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 include immunofluorescence, LE cell test and agglutination of coated particles[1-5]. 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[4,6]. 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 individuals having symptoms suggestive for SLE[7]. In these individuals, antinuclear antibodies may be demonstrated by methods other than the LE cell test.

The principle of the PULSE 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. An agglutination indicates a positive reaction. The reaction time for this occurrence is within one minute.

MATERIALS SUPPLIED

SLE Latex Reagent: Polystyrene latex particles coated with DNP extracted from fetal calf thymus with < 0.1% sodium azide.
SLE Positive Control: Human serum that has been diluted and stabilized with buffer with < 0.1% sodium azide.
SLE Negative Control: Human serum with < 0.1% sodium azide.
Disposable pipettes and test slides.
Additional Items Required: Serological pipettes, 12 x 75 mm test tubes and timing device.

STORAGE & STABILITY

Store reagents and controls at 2 - 8 degree Celsius. DO NOT FREEZE. Prior to use, warm reagents and controls to room temperature. Product instability is shown by improper reaction between latex reagent with the positive and negative control sera.

PRECAUTIONS

This product is for In Vitro Diagnostic Use Only. Each donor unit used in this product has been tested by an FDA approved method and found to be non-reactive for the presence of HbsAg and antibody to HIV Virus. Because no known test method can offer complete assurance that hepatitis B virus, HIV Virus, or other infectious agents are absent, all human blood-based products should be handled in accordance with good laboratory practices. The preservative sodium azide may react with metal plumbing to form explosive metal oxides. In disposal, flush with a large volume of water to prevent metal azide build up.

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) 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

PROCEDURE

A. Method I (Qualitative)

1. Bring all test reagents and serum specimens to room temperature. Gently shake the SLE latex vial to suspend the latex particles.
2. Place one drop of test serum (with disposable pipette) onto a circle on the slide. Use new pipette for each test serum. Deliver one drop of SLE Latex to each circle that contains specimens or controls. Use paddle end of pipette to spread the mixture on each circle. Do not use the same paddle end to mix each mixture as this will cause cross-contamination.
3. Gently tilt and rotate slide by hand for one (1) minute. Observe for macroscopic clumping using the indirect oblique light source.

B. Method 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.
5. For the 6 tubes, the dilutions range from 1:2 to 1:64. If required, additional serum dilutions can be added.
6. Repeat steps 1 to 3 as given in Method I (Qualitative).

RESULTS

Qualitative
Positive Result: Agglutination **Negative Result:** Smooth milky suspension

QUALITY CONTROL PROCEDURE

Positive and Negative controls should be included in each test series. The Positive control should produce visible agglutination; and Negative control should produce no agglutination.

LIMITATIONS OF THE PROCEDURE

The results of this test SHOULD NOT be used as a single diagnostic tool to make a clinical diagnosis. Instead, other clinical findings must be evaluated with other observed symptoms to aid in the final diagnosis. This test is to be performed by hand rotation. The use of a mechanical rotator could yield false positive/negative results. Those patients with scleroderma, rheumatoid arthritis, dermatomyositis, and a variety of connective tissue diseases may show reactivity when their serum is tested with the PULSE 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 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 PULSE SLE TEST kit was compared with a standard LE cell test and a fluorescent ANA test on serum from the 29 active SLE patients, the PULSE SLE TEST 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 PULSE SLE TEST gave 19% positive results, the LE cell test gave 19% and the ANA test 71%.Those patients having connective tissue disease showed no positive reactions with the PULSE 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 with diseases including anemia, infectious mononucleosis and rheumatic heart disease, showed a 1% positive result with both the PULSE SLE TEST and the LE cell test, while the ANA gave 6% positive results.

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