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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. Sodium azide (0.1%) is used as a preservative. Shake well prior to use.

SLE Positive Control: Human serum that has been diluted and stabilized with buffers and contains 0.1% sodium azide as preservative.

SLE Negative Control: Human serum that has been diluted and stabilized with buffers and contains 0.1% sodium azide as preservative.

Disposable pipettes and test slides

Additional Items Required:

Physiological saline, Serological pipettes, 12 x 75 mm test tubes and timing device.

STORAGE & STABILITY

When not in use, store reagents and controls at 2 - 8 degrees Celsius. 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 evidenced by inappropriate reaction of the latex reagent with the corresponding positive and negative control sera.

PRECAUTIONS

This product is for In Vitro Diagnostic Use Only.
Even though the control sera supplied in the PULSE SLE TEST Kit have been tested by an FDA approved method for the presence of Hepatitis B Surface Antigen (HBsAg) and HIV-I and HIV-II 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. 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.
2. Positive and negative controls should be tested with each series of test sera.
3. The disposable pipettes supplied with the kit will dispense 0.03ml.
4. Using the disposable pipette provided, place one drop (0.03 ml) of test serum onto a circle on the slide. Use a separate disosable pipette for each test serum.
5. Important: The PULSE SLE TEST Latex Reagent must be agitated well for 10 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.
6. 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.
7. Gently tilt and rotate slide by hand for one minute.
8. Observe for macroscopic clumping using the indirect oblique light source. Compare the reaction of the test serum to the SLE positive and negative control sera.
9. Observe for agglutination no longer than one minute.

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. 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 Method I (Qualitative).

RESULTS

Positive Result: Agglutination
Negative Result: Smooth milky suspension

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 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 anitconvulsant 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 the 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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