

INTENDED USE

SLE Latex Kit is intended to be used to detect the presence of antinuclear antibodies in serum samples as an aid in the diagnosis of the Systemic Lupus Erythematosus (SLE). The detection can be qualitative or semi-quantitative.

INTRODUCTION

The detection of antinuclear antibodies is attainable through several methods including immunofluorescence, LE cell test and agglutination of coated particles. The antibodies that are directed against deoxyribonucleoprotein (DNP) are believed to be most characteristic of SLE. These antibodies may cause the formation of the LE cell in-vitro, this unusual event is occurring in 75-80% of those patients diagnosed as having SLE. A positive result of LE cell test is not necessarily verification for diagnosis of SLE as some individuals having symptoms indicative for SLE were tested negative in this test. In this case, other methods such as immunofluorescence and agglutination of coated particles are advisable for antinuclear antibodies detection.

PRINCIPLE OF THE TEST

SLE Latex Kit is an agglutination test to detect a reaction between latex particles coated with DNP being brought into contact with a serum, which contains antinuclear antibodies. Agglutination indicates a positive reaction.

REAGENT PREPARATION & STABILITY

- The reagents are stable when stored refrigerated at 2-8°C.
- DO NOT FREEZE.** Frozen reagents could change the functionality of the test.
- Prior to use, allow reagents and controls to warm up to room temperature.
- These reagents are stable until the expiry date stated on the product label.
- Presence of particles and turbidity will result in reagents deterioration. Bacterial contamination of reagents or specimens may cause false positive results.

SPECIMEN COLLECTION & HANDLING

- The test should be performed using serum sample.
- After the clear serum has been separated it may be stored at 2-8°C for up to one week or longer periods at -20°C.
- Contaminated, lipemic, or hemolyzed samples should not be used.

MATERIALS

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- SLE Latex Reagent: Suspension of polystyrene latex particles coated with DNP (calf thymus) in a buffered solution. Contains 0.95 g/L of sodium azide.
- SLE Positive Control Human serum with anti-DNP activity. Contains 0.95 g/L of sodium azide.
- SLE Negative Control: Animal serum with negative anti-DNP activity. Contains 0.95 g/L of sodium azide
- Glass Reaction Slide
- Stirring sticks.

MATERIALS NEEDED BUT NOT PROVIDED

- Automatic pipettes.
- Saline solution (9 g/L NaCl, only for semi-quantitation procedure).
- Mechanical rotator, adjustable at 100 r.p.m.
- Laboratory alarm clock.

PROCEDURES

A. QUALITATIVE TEST

- Bring the reagents, controls and serum samples to reach room temperature.
- Re-suspend the reagent vial gently. Aspirate dropper several times to obtain a thorough mixing.
- Place 40 µL of the serum under test into one of the circles on the slide.
- Dispense 1 drop of positive control and 1 drop of negative control into two additional circles.
- Place 1 drop of SLE-Latex Reagent (40 µL) to each circle next to the sample/control to be tested.
- Mix the contents of each circle using a stirring stick spreading

the mixture over the entire area enclosed by the ring. Use separate stirrer for each mixture.

- Rotate the slide by means of a mechanical rotator (100 r.p.m.) for 1 minute.
- Observe immediately under a suitable light source for any degree of agglutination

B. SEMI-QUANTITATIVE TEST

- For each specimen to be tested, place **40 µL** of 9/L NaCl solution into each of the 6 circles of a slide.
- Add **40 µL** of specimen to the saline solution in circle one and mix the saline solution with the sample using the same tip by repeated aspiration and expulsion of the fluid and transfer 40 µL of the mixture to the saline solution in the second circle.
- Continue with the **2-fold serial dilutions** in a similar manner up to the sixth circle, and discard **40µL** from this circle. Final sample dilutions will be: 1:2, 1:4, 1:8, 1:16, 1:32, 1:64.
- Test each dilution as described in steps 4-7 for the Qualitative Test.

READING AND INTERPRETATION OF RESULTS

Positive Result:

Presence of any visible agglutination macroscopically. A positive result indicates the level of anti-deoxyribonucleoprotein antibodies (DNP) is in the range commonly found in systemic lupus erythematosus.

Negative Result:

Smooth milky suspension with no visible agglutination, similar to the reaction with the negative control

For Semi-Quantitative method, the titer of the specimen is reported as the highest dilution that shows reactivity. The next higher dilution should be negative.

STABILITY OF THE REACTION

The results should be read immediately after removing the slide from the rotator. Delay may cause the possibility of misinterpreting the result as positive or falsely negative due to drying of reagents.

PROCEDURES LIMITATION

- Those patients with scleroma, rheumatoid arthritis, dermatomyositis, and a variety of connective tissue diseases may show reactivity when their serum is tested with the SLE Latex Kit.
- Make sure to re-assay the positive samples using semi-quantitative procedure because high levels of antibodies might affect the degree of agglutination.
- Avoid using plasma samples due to the possibility of non-specific results.
- Drugs such as hydralazine, isoniazid, procainamide and a number of anticonvulsant drugs can induce an SLE syndrome.

QUALITY CONTROL

- Positive and negative controls should be run daily following the steps outlined in the Qualitative Test, in order to check the optimal reactivity of the latex reagent.
- The positive control should produce clear agglutination. If the expected result is not obtained, do not use the kit.

PERFORMANCE CHARACTERISTIC

Analytical Performance

155 Serum samples were tested with SLE-Latex: 29 had active SLE, 23 had clinically inactive SLE, 8 had connective tissue diseases and the remaining 95 were clinically normal or had some nonrelated diseases (anemia, infectious mononucleosis and rheumatic diseases). Results were compared with a standard LE Cell preparation assay and a fluorescent ANA method.

Samples from	VeroTest SLE Latex	LE Cell preparation	F-ANA test	Total
Active SLE	24 (83%)	25 (86%)	24 (83%)	29
Inactive SLE	4 (17.4%)	4 (17.4%)	16 (70%)	23
Connective tissue diseases	0(0%)	1 (12.5%)	4(50%)	8

Clinically normal / non related diseases	1(1%)	1 (95%)	6(6%)	95
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PRECAUTIONS & WARNINGS

















- For In Vitro Diagnostic Use Only.
- Components of human origin have been tested and found to be negative for the presence of anti-HIV 1+2 and anti-HCV, as well as for HBsAg. However, the controls should be handled cautiously as potentially infectious source.
- The reagents contain sodium azide which if combined with copper and lead plumbing might form highly explosive metal azide. When drained, flush with a large volume of water to prevent azide build up. Do not allow to contact with skin or mucous membranes
- The sensitivity of the test may be reduced at low temperatures. The best results are achieved at 15-25°C.
- Samples giving indeterminate results may be retested increasing the rotation period to 2 minutes. Reaction times longer than 2 minutes might cause false positive results.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data
- Bacterial contamination of controls and specimens as well as freezing and thawing of the reagent may lead to false positive results.
- Traces of detergent on the reaction slide may give false positive results. Make sure to wash used cards first using tap water until all reactants are removed and then with distilled water. Allow to air dry and avoid using the organic solvents as they may impair the special finish on the slide.
- Do not use the SLE-Latex reagent beyond its expiry date as this can affect the sensitivity of the reagent.
- Make sure to wear protective clothing when handling the reagents, such as disposable gloves and a laboratory coat.
- When the testing is completed, wash hands and clean the test table top with water and soap.
- Discard properly the test materials and samples in a biohazard container.

REFERENCES

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 Catalogue Number	 Temperature limit	 Manufacturer fax number	 Fragile, handle with care
 <i>In Vitro</i> diagnostic medical device	 Caution	 Manufacturer telephone number	 Use-by date
 Contains sufficient for <n> tests and Relative size	 Consult instructions for use (IFU)	 Keep away from sunlight	 Date of Manufacture
 Batch code	 Manufacturer	 Do not use if package is damaged	 Keep dry