Atlas Medical CE

ATLAS SLE LATEX TEST

A latex agglutination slide test for the qualitative and semi-quantitative detection of DNP antibodies associated with Systemic Lupus Erythematosus (SLE) in human serum

IVD *For In-Vitro diagnostic and professional use only*

Store at 2°-8°C

INTENDED USE

The 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.

INTRODUCTION AND PRINCIPLE

The detection 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 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. 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. In these individuals, antinuclear antibodies may be demonstrated by methods other than the LE cell test.

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

MATERIALS

MATERIALS PROVIDED

- SLE Latex 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.
- SLE Positive Control: Human serum that has been diluted and stabilized with buffers and contains sodium azide (0.1%) as a preservative.
- SLE Negative Control: Human serum that has been diluted and stabilized with buffers and contains sodium azide (0.1%) as a preservative.
- Disposable stirring sticks.
- Glass slide.

MATERIALS NEEDED BUT NOT PROVIDED

- Timer.
- Micropipette.
- Physiological saline (0.9%NaCl).
- Test tubes 12x75mm.
- Serological pipettes (1ml delivery).
- Lab rotator (optional).

PRECAUTIONS

- For In Vitro Diagnostic Use Only.
- Even though the control sera supplied in the SLE TEST Kit have been tested by an FDA approved method for the presence of Hepatitis B Surface Antigen (HBsAg) and HTLV-III 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.

STORAGE & STABILITY

- When not in use, store reagent and controls at 2-8°C.
- 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 positive and negative controls.

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.

PROCEDURES

A. Method I (Qualitative)

1. Bring all reagents and serum samples to room temperature.
2. Positive and Negative Controls should be tested with each series of test sera. Using micropipette, place 0.040ml of test serum on one circle of the test slide. Use separate pipette tip for each test serum.
3. Important: The SLE Latex Reagent must be shaken vigorously for 30 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.
4. Deliver one drop of SLE Latex to each circle that contains specimen on the slide. Spread the resulting mixture by using the plastic stick provided. Do not use the same plastic stick to mix each test serum or control as this will cause cross-contamination.
5. Gently tilt and rotate slide by hand for one minute (rotator can be used).
6. Observe for macroscopic clumping using the indirect oblique light source. The reaction of the test serum is compared to the SLE positive and negative control sera.
7. Observe for agglutination no longer than one minute.

* Sera that are positive in the screening test should be retested in the titration test (semi-quantitative test) to provide verification for borderline interpretations.

B. Method II (Semi-Quantitative)

1. For each test serum to be titrated, label 6 test tubes (12x75 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 3 to 7 as given in Method I (Qualitative).

RESULTS:

1. Positive Result:
Presence of agglutination within 1 minute.

2. Negative Result:
Smooth milky suspension within 1 minute.

LIMITATION

Those patients with scleroderma, rheumatoid arthritis, dermatomyositis, and a variety of connective tissue diseases may show reactivity when their serum is tested with the 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 systemic lupus erythmatosis (SLE) syndrome.

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
LATEX	Contains or presence of natural rubber latex	CONTROL-	Negative control
CONTROL+	Positive control		