SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) VISILATEX – SLIDE ASSAY

CAT NO	DESCRIPTION	PACK SIZE
LATSLE1	SLE Visilatex	50T

Intended Use:

SLE Visilatex is a latex agglutination for the qualitative determination of SLE in human serum. This reagent is for In vitro Diagnostic use only.

Summary and Principle:

A suspension of latex particles coated with Deoxyribonucleoprotein reacts with human serum containing antinuclear antibodies and produces agglutination, which is read visually. Systemic lupus erythematosus (SLE) is a chronic inflammatory disease of unknown cause that affects multiple organ systems (articulations, skin, kidneys, central nervous system, heart, lungs). Immunologic abnormalities, especially the production of a number of antinuclear antibodies (ANA), are another prominent feature of this disease. The clinical course is marked by spontaneous remissions and relapses. Its multisystemic manifestations and the complications from the use of immunosuppressive agents make the diagnosis and management of this entity challenging.

The detection of ANA antibodies by laboratory methods include immnunofluorescence, LE Cells test and agglutination of coated latex particles. These antibodies anti-DNP 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. Some patients having symptoms suggestive for SLE had been found negative with LE Cells Test. In these individuals, ANA antibodies may be demonstrated by methods other than the LE cell test, as latex agglutination or inmunofluorescence.

Reagent Composition:

SLE Latex Reagent (2ml)	**Polystyrene Latex particles coated with DNP antigen stabilized in a buffered saline**
	Sodium Azide 0.95 g/l
Positive Control (1ml)	**Serum Base with Antinuclear antibodies**
Negative Control (1ml)	**Serum base with no Antinuclear antibodies**

Warnings and Precautions:

- The reagent contains Sodium azide. Do not allow contact with skin or mucous membranes.
- Components of different human origin have been tested and found to be negative for the presence of antibodies to HIV 1+2 and HCV as well as for HBsAg. However, controls should be handled as potentially infectious.
- Mix the latex reagent before each use.

Reagent Preparation and Stability:

Unopened reagents are stable up to expiry when stored at 2-8°C.
Bacterial contamination of the reagent can cause false positive results. Store without contamination.
The reagents and controls are provided liquid stable. Once opened store at 2-8°C tightly capped. DO NOT FREEZE.

Materials required but not provided:

Pipettes, Saline solution (0.9% NaCl for Semi quantitation), Mechanical Rotor adjustable to 100 rpm.

Specimen Collection:

Fresh Clear Serum. Use immediately. Samples that cannot be tested immediately can be stored at 2-8°C for a period of 1 week. (for longer periods store serum samples at -20°C).
Before use, bring all samples to room temperature (+25°C)

Procedure:

Qualitative Assay:

1. Bring the test reagents and samples to room temperature.
2. Resuspend the Reagent vial gently. Aspirate dropper several times to obtain a thorough mixing.
3. Using an automatic pipette, place **1 drop (30 µL)** of the serum under test into one of the circles on the card. Dispense 1 drop of positive control and 1 drop of negative control into two additional circles.
4. Add 1 drop of SLE-Latex Reagent **(40 µL)** to each circle next to the sample to be tested.
5. Mix the contents of each circle with a disposable stirrer while spreading over the entire area enclosed by the ring. Use separate stirrers for each mixture.
6. Rotate the slide by means of a mechanical rotator (100 r.p.m.) for a period of **1 minute**.
7. Observe immediately under a suitable light source for any degree of agglutination.

Interpretation:

- Non Reactive: Smooth suspension with no visible agglutination as shown by negative control
- Reactive: Any degree of agglutination visible macroscopically.

Semi-Quantitative Assay:

1. For each specimen to be tested place with an automatic pipette 30 µL of Normal saline solution into each of the 6 circles of a card.
2. To circle one add 30 µL of specimen to the saline solution and, using the same tip, mix the saline solution with the sample by repeated aspiration and expulsion of the fluid and transfer 30 µL of the mixture to the saline solution in the second circle.
3. Continue with the 2-fold serial dilutions in a similar manner up to the sixth circle, and discard 30 µL from this circle. Final sample dilutions will be: 1:2, 1:4, 1:8, 1:16, 1:32, 1:64.
4. Test each dilution as described in steps 4-7 for the Qualitative Test.

Interpretation:

- Non Reactive: Smooth suspension with no visible agglutination as shown by negative control
- Reactive: Any degree of agglutination visible macroscopically. The titre of the sample is reported as the highest dilution that shows reactivity.

Expected Values:

A positive result indicates that anti DNP antibodies to the level seen in SLE is observed.
A number of drugs could interfere with the assay.

Quality Controls:

Positive and Negative controls should be run daily following the steps outlined in the qualitative assay. The positive control should produce clear agglutination. If it does not, discard the kit and use a fresh one for further assays.

Note:

- The sensitivity of the assay may be reduced at low temperatures. Ensure that the test is performed at 15-25°C.
- Samples giving indeterminate results may be retested using an increased rotation period to 2 minutes. Reaction times longer than 2 minutes may lead to false positive results.
- Serum from patients suffering from scleroma, Arthritis, dermatomyositis and a number of connective tissue disorders may lead to a positive SLE assay.
- Plasma samples should not be used because of the possibility of non-specific results.

References:

1. Chapman J.C., 1976. Am J Med Tech 42: 154-157
2. Holman H.R and Kunkel HG 1957. Science 126:163.

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		

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