s-LE LATEX TEST KIT

Catalogue number	Product Description
s-LE/010	50 Test Kit
s-LE/012	100 Test Kit

INTENDED USE
The Plasmatec s-LE Latex Agglutination Slide Test kit is for the Qualitative and Semi-Quantitative Determination of Anti-DNP Associated with Systemic Lupus Erythematosis in Human Serum

In s-LE, autoantibodies directed against native deoxyribonucleic acid and other nuclear constituents are produced. It is classed as the prototype of severe autoimmune diseases, involving a variety of tissues and associated with a wide range of antibodies in the circulation. Characteristics of the disease are antibodies against native DNA, nucleoprotein, denatured DNA and other extractable nuclear antigens. S-LE also affects a wide range of tissue. Organs affected are, in decreasing incidence, joints, skin, kidney, central nervous system, heart and lungs. One other important feature is the high frequency of the disease in women, approximately 3 to 4 times more frequent than in men. The high incidence of s-LE between monozygous twins (70-80%) and of close relatives (5-10%) indicates that s-LE may be a hereditary disease.

WARNINGS AND PRECAUTIONS
For *in vitro* diagnostic use only
For professional use only

Health and Safety warnings:
All patient samples and reagents should be treated as potentially infectious and the user must wear protective gloves, eye protection and laboratory coats when performing the test.
Non disposable apparatus must be sterilised after use by an appropriate method.
Disposable apparatus must be treated as biohazardous waste and autoclaved or incinerated.
Spillages of potentially infectious material should be absorbed and disposed of as above. The site of spillage must be sterilised with disinfectant or 70% alcohol.
Do not pipette by mouth.
The Reagents contain less than 0.1% sodium azide as a preservative. This agent is known to react with copper and lead in sink drains to form explosive azides. Disposed materials should be flushed with large quantities of water to prevent azide accumulation.void ingestion and contact with skin or mucus membrane.
SLE control sera have been tested and found non-reactive for Hepatitis B Surface Antigen (HbsAg) and HTLV-111; however, all human serum products and patient specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

Analytical precautions:
Do not modify the test procedure.
Do not dilute or modify the reagents in any way.
Allow all reagents and samples to reach room temperature (18 to 30ºC) before use.
Do not interchange reagents from different kit batches.

COMPOSITION
Kit contents:
- ??Latex reagent sufficient for 50/100 tests (Yellow label). Suspension of polysytrene latex particles coated with DNP extract in a saline buffer.
  The latex reagent should be well shaken to ensure homogeneity.
- ??Positive control. (Red label) Stabilized s-LE positive human serum.
- ??Negative control. (Blue label) Stabilized human serum, negative for s-LE.
- ??Pipette/ Stirrers/ re-usable agglutination slide.
- ??Pack insert.

STORAGE AND SHELF LIFE
Store reagents, upright at 2-8ºC. The components of the kit, when stored at 2 – 8 ?C, will remain stable until the expiration date stated on the label. DO NOT FREEZE THE LATEX REAGENT
Do not use reagents after the stated expiry date.
Discard reagents if they become contaminated or do not demonstrate the correct activity with controls.

MATERIALS AND EQUIPMENT REQUIRED BUT NOT PROVIDED.
Timer
Test tubes (Titration only)
Serological Pipettes (Titration only)
Physiological saline (0.9% NaCl) (Titration only)

SPECIMEN AND SAMPLE PREPARATION
It is recommended that serum only be used. Do not heat inactivate test sera or controls. Avoid repeated freeze-thawing of specimens. Do not use visibly haemolyzed specimens, as these have been known to produce false-positive results.

Sample Stability: Serum is stable for 48 hours when stored at 2-8?C
Interfering Substances: Use only a clean, dry slide washed in mild detergent and rinsed with distilled water.

PROCEDURE
Principle:
Anti-DNP antibodies are demonstrated by a number of laboratory procedures which include the LE cell test, immunofluorescence, and agglutination of coated latex particles. In the Plasmatec s-LE, latex particles are bound with native deoxyribonucleic protein (DNP) by means of an intermediary albumin matrix. These coated latex particles combine with anti-DNP antibodies in serum to give a visible agglutination.

Method:
1. Bring all reagents to room temperature and mix gently prior to use.
2. Place in separate divisions (cells) of the same slide:
   Serum 1 drop

Positive Control (red label) 1 drop
Negative Control (blue label) 1 drop

3. Add one drop of sLE latex reagent to each cell.
4. Mix with flat end of pipette/mixer and spread fluid evenly over each cell.
5. Tilt the slide back and forth slowly for 3 minutes while observing for agglutination.

SEMI-QUANTITATIVE DETERMINATION

Prepare dilutions of the specimens as shown below

Dilution
1:2 (1 part serum + 1 part saline)
1:4 (1 part serum + 3 parts saline)
1:8 (1 part serum + 7 parts saline)
1:16 (1 part serum + 15 parts saline)
1:32 (1 part serum + 31 parts saline)
1:64 (1 part serum + 63 parts saline)

Proceed as in screening test.

The serum s-LE antibody titre is the highest dilution of serum showing agglutination of the latex reagent with 3 minutes after mixing.

RESULTS

Any degree of agglutination visible within 3 minutes is to be interpreted as positive. Test is considered s-LE negative when no difference in agglutination is observed between specimen and negative control.

PERFORMANCE CHARACTERISTICS

The s-LE latex test was compared with a standard LE cell preparation test as well as a fluorescent ANA test. The three tests showed excellent agreement on serum from clinically active s-LE patients: s-LE latex 82% positive, LE cell prep 86% positive, ANA test 82% positive. Serum from clinically inactive s-LE patients: positive reactions were s-LE latex 19%, ANA test 71%. Patients with connective tissue disease showed no positive reactions with the S-LE latex test, but 17% and 50% positive reactions with the LE cell prep and ANA test, respectively.

Additional published studies have confirmed the sensitivity and specificity of the s-LE latex test.

LIMITATIONS OF THE METHOD

Patients with Rheumatoid Arthritis, Sjogren Syndrome, Mixed Connective Tissue Disease, Progressive Systemic Sclerosis and Discoid L.E. may show reactivity when using this test. Many widely used drugs may, in fact induce a systemic lupus erythematosis syndrome. Hydralazine, isoniazid, procainomide and a number of anti-convulsant drugs fall into this category.

REFERENCES

1. Christian, C.L.,R Mendez-Bryan, and D.L. Larson, 1958. Proc. Soc. Exptl. Biol. Med 98:820-823.
2. Friou, G.J., S.C. Finch, and K.D. Detre, 1958. J. Immunol 80: 324-329.
3. Hargraves, M.M., H.Richmond, and R.Morton. 1948, Proc. Mayo Clin 23: 25-28
4. Holman, H.R.,and H.G. Kinkel, 1957. Science 126:163
5. Miescher, P.A., and R. Strassle, 1957. Vox. Sang. 2:283-287.
6. Miescher, P.A., N. Rothfield and A.Miescher, 1966. Lupus Crythematosus, E.L. Dubois, E., Blakiston Co., New York.
7. Rothfield, N.F., J.M. Phythyon. C. McEwen, and P. Miescher, 1961. Arthritis Rheum. 4:223-229.
8. Data on file, Fisher Diagnostics.
9. Bennett,R.M., B. Langer, and E. Molina, 1976 Am J. Clin. Path. 66:743-745.
10. Chapman, J.C. 1976, Am. J. Med. Tech 42:1540157
11. Tuffanelli, D.L., 1972. Arch. Derm: 106-553-566.

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