

LORNE LABORATORIES LTD.

GREAT BRITAIN

RAPID LATEX KIT DIRECTIONS FOR USE

s-LE Latex Test Kit: For Identification Of Anti-DNP.

SUMMARY

In s-LE, autoantibodies directed against native deoxyribonucleic acid (DNP) 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 tissues. 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.

PRINCIPLE

When used by recommended techniques, latex particles in reagent will agglutinate (clump) in presence of Anti-DNP. No agglutination generally indicates the absence of Anti-DNP (see **Limitations**).

KIT DESCRIPTION

Lorne s-LE Rapid Latex Kit is for the identification of Anti-DNP. The test reagent consists of latex particles coated with DNP extracted from foetal calf thymus. All the reagents are supplied at optimal dilution for use with all recommended techniques without the need for further dilution or addition. For lot reference number and expiry date see **Vial Labels**.

STORAGE

Do not freeze. Reagent vials should be stored at 2 - 8°C on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity. Reagent will remain stable for up to 7 days when subjected to temperatures not exceeding 30°C.

SPECIMEN COLLECTION

Specimens should be drawn without anticoagulant, using an aseptic phlebotomy technique. If testing is delayed, store specimens at 2-8°C for up to 48 hours. For longer storage, remove serum from clot by centrifugation and freeze at or below -20°C. Avoid repeated freeze thawing of specimens. Do not use visibly haemolysed serum as this may cause false-positive reactions.

PRECAUTIONS

1. The kit is for *in vitro* diagnostic use only.
2. Do not use kit past expiration date (see **Vial and Box Labels**).
3. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
4. The reagents contain less than 0.1% sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive metal azides. On disposal flush away with large volumes of water.
5. Materials used to produce the kit were tested at source and found to be negative for HTLV-111 and HBsAg using approved microbiological tests. However, no known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

DISPOSAL OF KIT REAGENT AND DEALING WITH SPILLAGES

For information on disposal of kit reagent and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

CONTROLS AND ADVICE

1. It is recommended that s-LE Positive and Negative Controls be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. All the reagents must be allowed to reach 18-25°C before use.
3. Shake the reagents well before use to ensure homogeneity.
4. Do not interchange components between different kits.
5. The reusable agglutination slide must be washed in a suitable mild disinfectant after use and then rinsed twice with deionised water to remove any residue.
6. The use of kit and interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the kit is in use.
7. The user must determine the suitability of the kit for use in other techniques.

KIT COMPONENTS SUPPLIED

- s-LE Latex Reagent (Yellow label).
- s-LE Positive Control (Red label/cap).
- s-LE Negative Control (Blue label/cap).
- Reusable agglutination slide.
- Pipette-Stirrers.

RECOMMENDED QUALITATIVE TECHNIQUE

1. Place in separate test circles of the same slide one drop of undiluted serum, one drop of positive control and one drop of negative control using the disposable pipettes provided.
2. Add one of s-LE Latex reagent next to each test circle.
3. Using the broad end of a pipette spread the latex reagent and specimen over entire area of the test circle.
4. Gently tilt agglutination slide backwards and forwards for 3 minutes whilst observing for agglutination.

INTERPRETATION OF QUALITATIVE RESULTS

1. **Positive:** Agglutination of latex reagent constitutes a positive result and within the accepted limitations of the test procedure, indicates the presence of Anti-DNP, s-LE positive.
2. **Negative:** No agglutination of latex reagent constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of Anti-DNP, s-LE negative.

RECOMMENDED SEMI-QUANTITATIVE TECHNIQUE

1. Using saline, dilute the specimen(s) 1:2, 1:4, 1:8, 1:16, 1:32 and 1:64.
2. Place one drop of each dilution on successive fields of the agglutination slide.
3. Add one drop of s-LE latex reagent to each test field and using stirrers spread the reaction mixture over the entire test field.
4. Rotate the slide for 3 minutes whilst observing for agglutination.

INTERPRETATION OF SEMI-QUANTITATIVE RESULTS

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

STABILITY OF THE REACTIONS

Slide tests should be interpreted immediately after the 3-minute rotation period to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of the reagent.

LIMITATIONS

- Freezing the s-LE Latex Reagent will cause it to agglutinate.
- Intensity of agglutination is not necessarily indicative of relative s-LE titres; therefore screening reactions should not be graded.
- Anti-DNP may be found in diseases other than s-LE. Low titres have been detected in rheumatoid arthritis, chronic hepatitis, periarteritis nodosa, dermatomyositis, scleroderma, atypical pneumonia, tuberculosis and lymphoma.
- False positive or false negative results may also occur due to:
 - Contamination of test materials
 - Improper incubation time or temperature
 - Improper storage of test materials or omission of reagents
 - Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS

- The kit has been characterised by procedures mentioned in the **Recommended Techniques**.
- Prior to release, each lot of Lorne s-LE Latex Test Kit is tested by **Recommended Techniques** to ensure suitable reactivity.
- The s-LE latex test has been compared with a standard s-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, s-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 tests, but 17% and 50% positive reactions with the s-LE cell prep and ANA test, respectively.
- Additional published studies have confirmed the sensitivity and specificity of the s-LE latex test.

DISCLAIMER

- The user is responsible for the performance of the kit by any method other than those mentioned in the **Recommended Techniques**.
- Any deviations should be validated prior to use using established laboratory procedures.

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

AVAILABLE KIT SIZES

Kit Size	Catalogue Number
50 Tests Per Kit	840050

For the availability of other sizes, please contact:

Lorne Laboratories Limited
 Unit 1 Danehill
 Cutbush Park Industrial Estate
 Lower Earley RG6 4UT
 England
 Tel: +44 (0) 118 921 2264
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TABLE OF SYMBOLS

	Batch Number		<i>in-vitro</i> Diagnostic
	Catalogue Reference		Store At
	Expiry Date		Manufacturer
	Read Pack Insert		