LORNE LABORATORIES LTD.

GREAT BRITAIN

RAPID LATEX KIT

DIRECTIONS FOR USE

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

SUMMARY

In LE (Lupus Erythmatosis), autoantibodies directed against native deoxyribonucleic acid (DNA) 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. 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 LE between monozygous twins (70-80%) and of close relatives (5-10%) indicates that LE may be a hereditary disease.

INTENDED PURPOSE

The reagent is a latex test reagent intended to be used to qualitatively and semi-quantitatively determine the presence or absence of antibodies against native DNA and other nuclear constituents in the serum or plasma of patients when tested in accordance with the recommended techniques stated in this IFU.

PRINCIPLE

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

KIT DESCRIPTION

Lorne LE Rapid Latex Kit is for the identification of Anti-DNA. The test reagent consists of latex particles coated with DNA extracted from foetal calf thymus. The reagents do not contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the user. 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 - 8ºC 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 30ºC.

SPECIMEN COLLECTION

Specimens should be drawn without anticoagulant, using an aseptic phlebotomy technique. If testing is delayed, store specimens at 2-8ºC for up to 48 hours. For longer storage, remove serum from clot by centrifugation and freeze at or below –20ºC. 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. The reagents in this kit have been processed to reduce the bio-burden, but are not supplied sterile. Once a vial has been opened the contents should remain viable up until the expiry date.
6. Materials used to produce the kit were tested at source and found to be negative for HTLV-1 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 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 18-25ºC 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

- LE Latex Reagent (Yellow label).
- LE Positive Control (Red label/cap).
- 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 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-DNA, 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-DNA, 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 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 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

1. Freezing the LE Latex Reagent will cause it to agglutinate.
2. Intensity of agglutination is not necessarily indicative of relative LE titres; therefore screening reactions should not be graded.
3. Anti-DNA may be found in diseases other than LE. Low titres have been detected in rheumatoid arthritis, chronic hepatitis, periarteritis nodosa, dermatomyositis, scleroderma, atypical pneumonia, tuberculosis and lymphoma.
4. 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

1. The kit has been characterised by procedures mentioned in the **Recommended Techniques**.
2. Prior to release, each lot of Lorne LE Latex Test Kit is tested by **Recommended Techniques** to ensure suitable reactivity.
3. The LE latex test has been 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 LE patients: LE latex 82% positive, LE cell prep 86% positive, ANA test 82% positive. Serum from clinically inactive LE patients: positive reactions, were LE latex 19%, ANA test 71%. Patients with connective tissue disease showed no positive reactions with the LE latex tests, but 17% and 50% positive reactions with the LE cell prep and ANA test, respectively.
4. Additional published studies have confirmed the sensitivity and specificity of the LE latex test.

DISCLAIMER

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

BIBLIOGRAPHY

1. David S.Jacobs et al. Laboratory Test Handbook, 3rd edition, Lexi-Comp Inc, 1994.

AVAILABLE KIT SIZES

Kit Size	Catalogue Number
50 Tests Per Kit	840050

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