LORNE LABORATORIES LTD.

GREAT BRITAIN

RAPID LATEX KIT

DIRECTIONS FOR USE

IM Latex Kit: For Detection Of Heterophile Antibody Associated With Infectious Mononucleosis

SUMMARY

Infectious mononucleosis (IM) involves the reticuloendothelial tissue and is thought to be caused by the Epstein Barr virus. It generally affects children and young adults. Infectious mononucleosis can be confused on a symptomatic basis with other diseases and for this reason an accurate diagnosis is necessary.

INTENDED PURPOSE

The reagent is a latex test reagent intended to be used to qualitatively and semi-quantitatively determine the presence or absence of Rheumatoid Factors 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 the presence of the heterophile antibody associated with IM. No agglutination generally indicates the absence of the heterophile antibody associated with IM (see **Limitations**).

KIT DESCRIPTION

Lorne IM Latex Test Kit is for detection of the heterophile antibody associated with Infectious Mononucleosis. The test reagent consists of latex particles coated with partially purified glycoprotein from bovine red cells. 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 reagents are supplied at optimal dilution for use with all recommended techniques without 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.

SPECIMEN COLLECTION

Specimens should be drawn with or without anticoagulant using an aseptic phlebotomy technique. If testing is delayed specimens can be stored at 2-8ºC for 7 days or for up to months at or below –20ºC. Specimens must be free from bacterial contamination and haemolysis.

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. The controls used in this kit have been tested by an FDA approved method and found non-reactive for the presence of HBsAg, HCV and antibodies to HIV(1+2).
7. No known tests can guarantee 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 the IM 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 use of kit and the 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.
6. The user must determine the suitability of the kit for use in other techniques.

KIT COMPONENTS SUPPLIED

1) IM Latex Reagent (White cap, 2.5 mL): Latex particles with antigenic extract of beef erythrocyte membranes, phosphate buffer pH 7.2, preservative.
2) IM Positive Control (Red cap, 1.0 mL): Human serum with anti-IM antibodies titre ≥1/4, preservative.
3) IM Negative Control (Blue cap, 1.0 mL): Animal serum, preservative.
4) Pipette-Stirrers.
5) Reusable agglutination slide.

MATERIALS AND EQUIPMENT REQUIRED BUT NOT SUPPLIED

a) Test Tubes.
b) Mechanical rotator with adjustable speed of 80-100 rpm.
c) Vortex mixer.

RECOMMENDED QUALITATIVE TECHNIQUE

1. Using the dispensing pipette provided, place on separate test circles of the agglutination slide: one drop of undiluted patient serum, one drop of Positive Control and one drop of Negative Control.
2. Shake the IM latex reagent vigorously by hand or on a vortex mixer and add one drop of the IM Latex reagent to each sample.
3. Mix the reagent and sample drops with a stirrer and spread over the entire area of each test circle.
4. Gently rotate the slide for two (2) minutes manually or on a mechanical rotator set at 80-100 rpm.
5. After 2 minutes, examine each test circle for agglutination and record the results.

INTERPRETATION OF QUALITATIVE RESULTS

1. **Positive:** Visible agglutination of latex particles constitutes a positive result and within accepted limitations of test procedure, indicates presence of heterophile antibody associated with IM.
2. **Negative:** No visible agglutination of latex particles in a milky liquid constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of the heterophile antibody associated with IM.
3. The presence of agglutination indicates a titre of ≥ 1/128 of the specific anti-IM antibodies by the Davidsohn method.

RECOMMENDED SEMI-QUANTITATIVE TECHNIQUE

1. Make doubling dilutions of the specimen in 9 g/L saline up to 1/16 as follows:

Dilution	Serum	9 g/L Saline
1/2	100 µl undiluted serum	100 µl
1/4	100 µl undiluted serum	300 µl
1/8	100 µl undiluted serum	700 µl
1/16	100 µl undiluted serum	1500 µl

2. Test each serum specimen dilution in exactly the same way as for the **Qualitative Technique** above.

INTERPRETATION OF SEMI-QUANTITATIVE RESULTS

The titre is expressed as reciprocal of the highest dilution showing macroscopic agglutination: e.g. if this occurs in dilution 1/8, the titre is 8. The actual titre of the antibody is not related to the stage or severity of the disease. However, an increase in the IM heterophile agglutination titre may be clinically significant in the early stages of the disease and may assist in the diagnosis of IM.

EXPECTED VALUES

Detectable levels of the IM heterophile antibody can be expected to occur between the 6th and 10th day following the onset of symptoms. The level usually increases thorough second or third week of illness and can be expected to persist with gradual decline over a 12-month period. Positive results should be seen in about 98% of all IM cases.

STABILITY OF THE REACTIONS

Slide tests should be interpreted immediately after the 2-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. A diagnosis of infectious mononucleosis should not be made on the basis of a positive test result without the support of patient history and haematological or other clinical evidence.
2. A false positive reaction may be obtained in some geographical area where “horse serum” is used as a prophylactic measure (vaccination).
3. Apparent false positive reactions have been associated with sera from patients with other diseases such as infections, leukaemia, Burkitt’s lymphoma, and viral hepatitis.
4. Although patients develop heterophile antibodies within 3 weeks of the onset of symptoms, some patients may take up to several months to develop detectable levels.
5. If the Lorne IM Test is negative in the presence of strong evidence suggesting a diagnosis of infectious mononucleosis, testing on specimens obtained at intervals of several days will reveal development of the heterophile agglutinin. Some patients with haematological and clinical evidence of IM remain persistently negative and so a negative result cannot completely rule out infectious mononucleosis.
6. A single heterophile antibody titre cannot be interpreted as an indication of the stage or severity of the disease. However, titrations on sequential specimens may be useful in following the course of the disease in an individual patient.
7. Haemoglobin (≤ 10 g/L), bilirubin (≤ 20 mg/dL), lipemia (≤ 10 g/L) and rheumatoid factors (≤ 300 IU/mL) do not interfere. Other substances may interfere[7].
8. False positive or false negative results may also occur due to:
   a) Contamination of test materials
   b) Improper storage of test materials or omission of reagents
   c) Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The kit has been characterised by all the procedures mentioned in the **Recommended Techniques**.
2. Prior to release, each lot of Lorne IM Latex Test Kit is tested by the **Recommended Techniques** to ensure suitable reactivity.
3. Analytical sensitivity: Titre equal to 1/128 by the Davidsohn method, under the described assay conditions.
4. Prozone effect: No prozone effect was detected up to titres of 1/256.
5. Diagnostic sensitivity: 100%.
6. Diagnostic specificity: 100%.

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	041050A

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