LORNE LABORATORIES LTD.

GREAT BRITAIN

RAPID LATEX KIT

DIRECTIONS FOR USE

RF Latex kit: For Detection Of Rheumatoid Factor (RF).

SUMMARY

Rheumatoid factors are a group of antibodies directed to determinants in the Fc portion of the IgG molecule. Although rheumatoid factors are found in a number of rheumatoid disorders, such as systemic lupus erythematosis (sLE) and Sjögren's syndrome, as well as in non-rheumatoid conditions, it's central role lies in aiding in the diagnosis of rheumatoid arthritis.

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 the reagent will agglutinate (clump) in presence of rheumatoid factor (RF). No agglutination (no clumping) generally indicates absence of RF (see **Limitations**).

KIT DESCRIPTION

Lorne RF Latex Kit is for the detection of rheumatoid factor. The latex reagent is a suspension of polystyrene latex particles coated with human gamma globulins, which agglutinate in the presence of Rheumatoid Factor (RF). 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 latex 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.

SPECIMEN COLLECTION

Specimens should be drawn without anticoagulant using an aseptic phlebotomy technique. If testing is delayed, fresh serum can be stored at 2-8ºC for 7 days or for up to 3 months at or below –20ºC. Specimens must be free from bacterial contamination, fibrin, gross lipeamia and gross 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. All the reagents must be allowed to reach 18-25ºC before use.
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 HIV 1+2 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 the RF Positive and Negative Controls are 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. Use of kit and interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of country where kit is in use. The user must determine the suitability of the kit for use in other techniques.
6. Results obtained with a latex method do not compare with those obtained with the Rose Waaler test. Differences in the results between methods do not reflect differences in the ability to detect rheumatoid factors.

KIT COMPONENTS SUPPLIED

1) RF Latex Reagent (5 mL): Latex particles coated with human γ-globulin, pH, 8.2, and a preservative.
2) RF Positive Control (Red cap, 1 mL): Human serum with a RF concentration > 30 IU/mL and a preservative.
3) RF Negative Control (Blue cap, 1 mL): Animal serum and a preservative.
4) Pipette-Stirrers.
5) Reusable Agglutination Slide (18 each).

MATERIALS AND EQUIPMENT REQUIRED BUT NOT SUPPLIED

1) Glass Test Tubes (10 x 75 mm or 12 x 75 mm).
2) Pasteur and Graduated Pipettes.
3) Vortex mixer.
4) Mechanical rotator with adjustable speed of 80-100 rpm.

RECOMMENDED QUALITATIVE TECHNIQUE

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Shake the RF-latex reagent vigorously or use a vortex mixer before use and add one drop (50 µL) next to the sample to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on a rotary shaker at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read after more than two minutes.

INTERPRETATION OF QUALITATIVE RESULTS

1. **Positive:** Visible agglutination of latex particles constitutes a positive result and within the accepted limitations of the test procedure, indicates a level of RF in the specimen > 8 IU/ml.
2. **Negative:** No visible agglutination of latex particles in a milky liquid constitutes negative result and within accepted limitations of test procedure, indicates level of < 8 IU/ml RF in specimen.

RECOMMENDED SEMI-QUANTITATIVE TECHNIQUE

1. The semi-quantitative test can be performed in the same way as the qualitative test using dilutions of the serum.
2. Make doubling dilutions of serum specimen in 9 g/L saline as follows:

Dilution	Serum	Saline
1/2	100 µl undiluted serum	100 µl
1/4	100 µl 1/2 diluted serum	100 µl
1/8	100 µl 1/4 diluted serum	100 µl
1/16	100 µl 1/8 diluted serum	100 µl

3. Test the specimen dilutions in the same way as for the quantitative technique above.
4. Agglutination of the sera indicates:

Dilution	RF Levels (I.U/mL)
1/2	16 (8 x 2)
1/4	32 (8 x 4)
1/8	64 (8 x 8)
1/16	128 (8 x 16)

5. Normal levels of RF in adults is < 8 IU/mlL

RESULTS

The titre is expressed as the reciprocal of the highest dilution showing macroscopic agglutination: e.g. if this occurs in dilution 1/8, the titre is (8 x 8 IU/mL) = 64 IU/mL.

STABILITY OF THE REACTIONS

Slide tests should be interpreted straight 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. Using a latex test system, positive results are not always found with every case of clinically defined rheumatoid arthritis, the number of positives reported using various types of latex reagent range from 70% to over 90%.
2. The incidence of false positive results is about 3-5 %. Individuals suffering from infectious mononucleosis, hepatitis, syphilis as well as elderly people may give positive results.
3. Diagnosis should not be solely based on the results of latex method but also should be complemented with a Rose Waaler test along with the clinical examination.
4. Haemoglobin (≤ 10 g/L), bilirubin (≤ 20 mg/dL) and lipaemia (≤ 10 g/L) do not interfere. Other substances may interfere[6].
5. 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. The RF latex sensitivity is calibrated against the RF International Calibrator from the WHO (WHO 64/2 Rheumatoid Arthritis Serum).
3. Analytical sensitivity: 8 (6-16) IU/mL, under the described assay conditions.
4. Prozone effect: No prozone effect was detected up to 1500 IU/mL.
5. Diagnostic sensitivity: 100 %.
6. Diagnostic specificity: 100 %.
   The diagnostic sensitivity and specificity have been obtained using 139 samples compared with the same method of a competitor.

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
100 Tests Per Kit	830100A

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