LORNE LABORATORIES LTD.

GREAT BRITAIN

RAPID LATEX KIT

DIRECTIONS FOR USE

ASO Latex Kit: For Detection Of Anti-Streptolysin O (ASO) In Serum

SUMMARY

In acute streptococcal infections, the toxic immunogenic exoenzyme streptolysin O (ASO) is produced in response to streptolysin O antigens liberated by haemolytic streptococci of groups A, C and G. Information on extent and degree of infection can be obtained by measuring serum ASO levels. Elevated ASO levels have also been found in patients suffering from scarlet fever, acute rheumatoid arthritis, tonsillitis, and other streptococcal infections as well as in healthy carriers.

INTENDED PURPOSE

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

PRINCIPLE

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

KIT DESCRIPTION

Lorne ASO Latex Kit is a serologic test for the detection of ASO antibodies. 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.

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 3 months at or below –20ºC. Specimens must be free from bacterial contamination, fibrin, gross lipemia 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. 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.
5. 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. ASO Positive and Negative Controls must 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. 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.
6. The user must determine the suitability of the kit for use in other techniques.

KIT COMPONENTS SUPPLIED

1) ASO Latex Reagent (White cap, 5.0 mL): Latex particles coated with streptolysin O, pH, 8.2 containing a preservative.
2) ASO Positive Control (Red cap, 1.0 mL Red cap): Human serum with an ASO concentration > 200 IU/mL containing a preservative.
3) ASO Negative Control (Blue cap, 1.0 mL): Animal serum containing a preservative.
4) Pipette-Stirrers.
5) Disposable agglutination Slides.

REAGENTS AND MATERIALS REQUIRED BUT NOT SUPPLIED

a) Small glass / plastic test tubes.
b) Serological pipettes.
c) Graduated container.
d) 9 g/L saline solution.

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. Swirl the ASO-latex reagent gently before using 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. Swirl the slide gently and after 2 minutes read the results macroscopically. False positive results could appear if the test is read after more than two minutes.

INTERPRETATION OF QUALITATIVE RESULTS

1. **Positive:** Agglutination of latex particles constitutes a positive result and within the accepted limitations of the test procedure, indicates a level of ASO in the specimen > 200 I.U/ml.
2. **Negative:** No visible agglutination of latex particles constitutes a negative result and within the accepted limitations of the test procedure, indicates a level of ASO in specimen < 200 I.U/ml.

RECOMMEDED SEMI-QUANTITATIVE TECHNIQUE

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

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

Dilution	ASO Levels (I.U. / ml)
1/2	400 (200 x 2)
1/4	800 (200 x 4)
1/8	1600 (200 x 8)

5. Normal levels of ASO in adults is < 200 I.U/ml.

RESULTS

The titre is expressed as the reciprocal of the highest dilution showing macroscopic agglutination, e.g. if this occurs in the 1/8 dilution, the titre is 1600.

INTERPRETATION OF SEMI-QUANITATIVE RESULTS

Positive results may indicate an acute streptococcal infection. In which case the test should be repeated at weekly intervals to determine the progression of infection.

STABILITY OF THE REACTIONS

Slide tests should be interpreted immediately after the 2-minute period to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of the reagent.

LIMITATIONS

1. False positive results may be obtained in conditions such as scarlet fever, acute rheumatoid arthritis, tonsillitis and other streptococcal infections as well as in healthy carriers.
2. Hemoglobin (≤ 10 g/L), bilirubin (≤ 20 mg/dL), lipemia (≤ 10 g/L), rheumatoid factors (≤ 300 IU/mL) do not interfere. Other substances may interfere[7].
3. Early infections in children from 6 months to 5 years may cause false negative results.
4. A single ASO determination does not produce much information about the actual state of the disease. Titrations at biweekly intervals during 4 or 6 weeks are advisable to follow the disease evolution.
5. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.
6. 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 ASO Latex Kit is tested by **Recommended Techniques** to ensure suitable reactivity.
3. The ASO-latex sensitivity is calibrated against the WHO 1st International Standard for ASO available from NIBSC.
4. Analytical sensitivity: 200 (± 50) IU/mL, under the described assay conditions.
5. Prozone effect: No prozone effect was detected up to 1500 IU/mL.
6. Diagnostic sensitivity: 98 %.
7. Diagnostic specificity: 97 %.

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	031100A

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