ASO Latex Kit Assay

Anti-Streptolysin O

REF IVD +2°C +8°C

CATALOGUE NUMBERS

RL-ASO50 RL-ASO50NA
RL-ASO100 RL-ASO100NA

INTENDED USE

The ASO-latex is a slide agglutination test for the qualitative and semiquantitative detection of anti-streptolysin O (ASO) in human serum. Latex particles coated with streptolysin O (SLO) are agglutinated when mixed with samples containing ASO.

SUMMARY

Streptolysin O is a toxic immunogenic exoenzyme produced by - heamolitic Streptococci of groups A, C and G. Measuring the ASO antibodies are useful for the diagnostic of rheumatoid fever, acute glomerulonephritis and streptococcal infections. Rheumatic fever is an inflammatory disease affecting connective tissue from several parts of human body as (skin, heart, joints, etc…) and acute glomerulonephritis is a renal infection that affects mainly to renal glommerulus.

MATERIALS

Materials provided

Latex	Polystyrene Latex particles coated with Streptolysin O. Sodium Azide: 0.9%
Control + (red cap)	Human Serum based, ASO concentration >250 IU/ML
Control – (green cap)	Human/Animal serum based, ASO negative control Sodium azide <1%

Following materials are available with RL-ASO50 & RL-ASO100

RL-ASO50
- 5 slide cards
- 50 plastic stirrers

RL-ASO100
- 10 slide cards
- 100 plastic stirrers

Materials required but not provided
- Mechanical rotor (100 r.p.m
- Micropipette and tips (50µl)
- Isotonic saline

PRECAUTIONS

- Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.
- Reagents must be stored between 2-8^{0}C
- Do not freeze
- Store vials upright
- Reagents are provided ready to use.
- Ensure that the reagents are mixed thoroughly before use
- If reagents have particulate matter and aggregates, discard vial and contact Rapid Labs

SAMPLE COLLECTION AND PREPARATION

- Use fresh serum
- Serum used must not be haemolysed or contaminated or lipemic as it may affect test results.
- Storage and usage after time serum must be stored at 2-8^{0}C.
- Use serum within 7 days
- For longer storage store at -20^{0}C for 3 months.
- Samples with fibrin should be centrifuged

CALIBRATION AND TRACEABILITY

Rapid Labs ASO Visual Latex has been calibrated against NIBSC 64/002.

LIMITIATIONS

- False positive results may be obtained in conditions such as, rheumatoid arthritis, scarlet fever, tonsilitis, several streptococcal infections and healthy carriers.
- Early infections and children from 6 months to 5 years may cause false negative results.
- 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.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

DIRECTIONS FOR USE

Qualitative method

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. Mix the ASO-latex reagent vigorously or on a vortex mixer 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. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

Semi-quantitative method

1. Make serial two fold dilutions of the sample in 9 g/L saline solution.

2. Proceed for each dilution as in the qualitative method.

INTERPRETATION OF RESULTS

- Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator.
- The presence of agglutination indicates an ASO concentration equal or greater than 200 IU/mL.
- The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.
- The approximate ASO concentration in the patient sample is calculated as follows:

200 x ASO Titer = IU/mL

QUALITY CONTROL

- Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.
- All result different from the negative control result, will be considered as a positive.

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EXPECTED VALUES
Up to 200 IU/mL(adults) and 100 IU/mL (children < 5 years old). Each laboratory should establish its own reference range.

PERFORMANCE CHARATERISTICS
- Analytical sensitivity: 200 (± 50) IU/mL, under the described assay conditions
- Prozone effect: No prozone effect was detected up to 1500 IU/mL.
- Diagnostic sensitivity: 98 %.
- Diagnostic specificity: 97 %.

INTERFERING SUBSTANCES
No interference from:
Bilirubin up to 20mg/dl
Haemoglobin up to 10g/l
Lipids up to 10g/l
RF up to 300IU/ml

BIBLIOGRAPHY

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Index of Symbols

	Consult instructions for use	IVD	For *in vitro* diagnostic use only
REF	Catalogue Number	LOT	Lot Number
+2°C +8°C	Store between 2-8°C		Use by
	Manufacturer		Date of manufacture

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