todylaboratories®

**Latex Reagents**

REF C23LX1001

# Anti Streptolysin O (ASO)
# Instructions for use

For *in-vitro* diagnostic use only.
Store at 2-8°C.

## PRINCIPLE

The ASO-Latex test is a rapid slide agglutination test for the direct detection and semi-quantitation of anti-streptolysin O (ASO). The antigen, a particulate latex suspension coated with streptolysin O, agglutinates in the presence of specific antibodies present in the sera of patients with Streptococcal ß-haemolytic infection (group A and C).

## PRESENTATION

| Contents | 100 Tests |
|---|---|
| ASO Latex | 1 x 4,0 ml |
| Positive Control | 1 x 1,0 ml |
| Negative Control | 1 x 1,0 ml |
| Test Cards Reusable | 2 |
| Pipette / Stirrers | 100 |

## COMPOSITION

**ASO Latex**:
• Suspension of white latex particles coated with streptolysin O
• Sodium azide 0.95g/L
**Positive Control**:
• Stabilized Serum
• Sodium Azide 0.95g/L
**Negative Control**:
• Stabilized Serum
• Sodium Azide 0.95g/L
Although the controls which have been derived from human origin have been tested and found to be negative for the presence of anti- HIV, anti-HCV as well as HbsAg, it is recommended that they be handled cautiously and treated potentially infectious.

## STORAGE

Store components at 2-8°C. Cards and Pipettes may be kept at Room Temperature.

## SAMPLES

• Serum stable for 48 hours at 2-8°C
• Samples should be free from contamination, haemolysis and Lipaemia.

## MATERIALS REQUIRED BUT NOT SUPPLIED

• Mechanical Rotator set at 100 r.p.m. or Vortex Mixer
• Diluent: Normal Saline for dilution of samples (9 g/L)

## QUALITATIVE TEST PROCEDURE

1. Bring the reagents and samples to room temperature.
2. Mix the ASO-latex vigorously or on a vortex mixer before use.
3. Place 50µl of the sample and 1 drop of each control into separate circles on the card.
4. Add one drop of the latex reagent to each circle next to the sample which is to be tested.
5. Mix with the disposable pipette / stirrer and spread over the entire area enclosed by the ring. Use a new stirrer for each sample.
6. Rotate the cards at 100 r.p.m. for 2 minutes.

## QUANTITATIVE TEST

**Quantitative estimation of ASO can be carried out by using 2 different procedures. Both procedures yield identical results. Procedure II should be used for higher dilution series.**

**PROCEDURE**

1. Mix the ASO-latex reagent vigorously or on a vortex mixer before using.
2. Using a semi-automatic pipette, add 50µl of 9g/L saline to circles 2, 3, 4 and 5. Do not spread the saline.
3. Add 50µl of patient sample to circles 1 & 2.
4. Mix the saline and sample in circle 2 by drawing the mixture up and down being careful to avoid the formation of any bubbles. Use different stirrers for each sample.
5. Transfer 50µl from circle 2 to the saline in circle 3.
6. Perform serial dilutions in the same manner until the last circle, discarding 50µl at the end.
7. Using the pipette / stirrer, spread the diluted samples over the entire area of each circle starting at circle 5 and working backwards to the neat sample in circle 1.
8. Proceed as a qualitative test from step 3.

| DILUTION | ASO IU/ML |
|---|---|
| Neat | 200 |
| 1:2 | 400 |
| 1:4 | 800 |
| 1:8 | 1600 |

**PROCEDURE II**

| DILUTION | Sample undiluted | Diluent | Latex Reagent | ASO IN IU/ML (UNDILUTED SAMPLE CONC) |
|---|---|---|---|---|
| NEAT | 50ul | | 50ul | 200 |
| 1 + 1 | 50ul | 50ul | 50ul | 400 |
| 1 + 2 | 50ul | 100ul | 50ul | 600 |
| 1 + 3 | 50ul | 150ul | 50ul | 800 |
| 1 + 4 | 50ul | 200ul | 50ul | 1000 |
| 1 + 5 | 50ul | 250ul | 50ul | 1200 |
| 1 + 6 | 50ul | 300ul | 50ul | 1400 |
| 1 + 7 | 50ul | 350ul | 50ul | 1600 |

## QUALITY CONTROL

Each run of tests should be validated with a positive and negative control.

## READING AND INTERPRETATION

• Examine macroscopically for the presence or absence of clumps or agglutination within 1 minute of removing the card from the rotator.
• The presence of visible agglutination indicates a content of anti- streptolysin ≥200 iu/ml.
• Positive sera may be titred. To titrate make serial two-fold dilutions in 9g/L saline as indicated in the Quantitative Test procedure. The serum titre is defined as the highest dilution showing positive agglutination. The approximate ASO level (iu/ml) present in the sample may be obtained multiplying the titer by the limit of sensitivity (200iu/ml). For example:
ASO (IU/ml) = Highest dilution with Positive Reaction x 200
(200 IU/ml is the sensitivity of the reagent).
• ASO titers ≤200iu/ml are found in 95% of the healthy adult population, being that value higher (up to 300iu/ml) among school going children.

## LIMITATION OF THE PROCEDURE

• Positive results may be obtained in conditions other than rheumatic fever and glomerulonephritis such as scarlet fever, amigdalitis, various streptococcal infections and even in healthy carriers.
• False negative reactions may occur in early primary infections and children aged between 6 months and 2 years of age.
• A single ASO determination does not yield much information on the contemporary significance of the disease. Therefore it is advisable that titrations on questionable cases are carried out at bi-weekly intervals for 4 to 6 weeks in order to ascertain the evolution of the disease.

## NOTES

1. The sensitivity of the test may be reduced at low temperatures. The best results are obtained over 10°C.
2. Delay in reading the results may result in over-estimation of the ASO level.

## REFERENCE


1. Ingram GBP et al. Am J Clin Pathology 1972; 25: 543 – 544
2. Halbert SP. Ann N and Acad Sci 1963; 103 – 111
3. Bach G et al. Am J Clin Pathology 1969; 52 – 57
4. Schimdt et al. Rheumatol 1970; 29: 29 – 32
5. Alouf et al. Biochemie 1973; 56 – 61
6. Klein et al. Applied Microbiology 1970; 19: 60 – 61


## SYMBOL INDEX

IVD For In Vitro Diagnostics Use Only
LOT Lot Number
REF Catalogue Number
Storage Temperature
Expiry Date (Year/Month)
Warning, Read Enclosed Documents
Instructions For Use
Manufactured By

*Rev: 1.2020*


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CE IVD 2°C 8°C