# ASO LATEX TEST KIT

| Catalogue Number | Product Description |
|---|---|
| ASO/010 | Test Kit 50 |
| ASO/012 | Test Kit 100 |

**INTENDED USE**
The Plasmatec ASO Latex test kit is for the qualitative and semi-quantitative estimation of anti-streptolysin O (ASO) antibodies in human serum samples.

**WARNINGS AND PRECAUTIONS**
For *in vitro* diagnostic use only
For professional use only
**Health and Safety warnings:**
All patient samples and reagents should be treated as potentially infectious and the user must wear protective gloves, eye protection and laboratory coats when performing the test.
Non disposable apparatus must be sterilised after use by an appropriate method. Disposable apparatus must be treated as biohazardous waste and autoclaved or incinerated.
Spillages of potentially infectious material should be absorbed and disposed of as above. The site of spillage must be sterilised with disinfectant or 70% alcohol.
Do not pipette by mouth.
Control reagents contain human serum. The human serum used has been tested and found to be negative for HIV, HCV and HbsAg. Nonetheless the reagent must be treated as potentially infectious and appropriate precautions should be taken when handling and on disposal. The product also contains aqueous buffer salts including sodium azide as preservative - see material safety data sheet

**Analytical precautions:**
Do not modify the test procedure.
Do not dilute or modify the reagents in any way.
Allow all reagents and samples to reach room temperature (18 to 30ºC) before use.
Resuspend test and control cells gently but thoroughly.
Do not interchange reagents from different kit batches.

**COMPOSITION**
**Kit contents:**
**Latex reagent** sufficient for 50/100 slide tests (Yellow label). The latex reagent should be well shaken to ensure homogeneity.
**Positive Control** (Red label). This serum is human positive ASO serum. This reagent is ready for use and will give positive results when tested with the Plasmatec ASO latex test.
**Negative Control** (Blue label). This control is a negative ASO control serum. This reagent is ready for use and will give a negative result when tested with the Plasmatec ASO latex reagent.
**10x Concentrate Glycine Diluent Buffer** (Green label). Add one part to nine parts distilled water before use. On dilution the diluent has a pH between 8.0 and 8.2.
**Pipette/ Stirrers/ Reusable agglutination slide.**
**Pack insert.**

**STORAGE AND SHELF LIFE**
Store reagents, upright at 2-8ºC.
DO NOT FREEZE THE LATEX REAGENT
Do not use reagents after the stated expiry date.
Discard reagents if they become contaminated or do not demonstrate the correct activity with controls.

**MATERIALS AND EQUIPMENT REQUIRED BUT NOT PROVIDED.**
Small glass or plastic test tubes / Serological pipettes

**SPECIMEN AND SAMPLE PREPARATION**
Use fresh serum obtained by centrifugation of clotted blood. The sample may be stored at 2-8? C for 48 hours before performing the test. For longer periods of time the serum must be frozen. Haematic, lipaemic or contaminated serum must be discarded.

**PROCEDURE**
**Principle:**
Latex particles coated with streptolysin O are agglutinated when mixed with samples containing ASO. In those infections promoted by acute streptococcal infection, anti-streptolysin O antibodies are produced due to the presence of the streptolysin O antigen liberated by the bacteria. Information on the extent and degree of infection can be obtained from the measurement of serum ASO levels however increased ASO levels are also associated with rheumatic fever and glomerulonephritis.

**QUALITATIVE METHOD**
1. Allow each component to reach room temperature.
2. Gently shake the latex reagent to disperse the particles.
3. Place a drop of undiluted serum onto the circle of the test slide using the disposable pipettes provided.
4. Add one drop of the latex reagent next to the drop of serum.
5. Using the other end of the pipette (broad end) spread the reagent and serum sample over the entire area of the test circle.
6. Gently tilt the test slide backwards and forwards approximately once every two seconds for two minutes. Positive and negative controls should be included at regular intervals. Both are ready for use and do not require further dilution. At the end of the test rinse the test slide with distilled water and dry. Normal laboratory precautions should be maintained while handling patients samples.

**INTERPRETATION OF RESULTS**
Presence of agglutination indicates a level of ASO in the sample equal or > 200 I.U/ml.
The lack of agglutination indicates a level of ASO in the sample of < 200 I.U/ml.

**SEMI-QUANTITATIVE DETERMINATION**
The semi-quantitative test can be performed in the same way as the quantitative test using dilutions of the serum in saline, phosphate buffered saline or glycine saline as follows:-

| **Dilutions** | 1/2 | 1/4 | 1/8 |
|---|---|---|---|
| **Sample serum** | 100? l | - | - |
| **Saline** | 100? l | 100? l | 100? l |
| | ? | 100? l ? | 100? l ? |
| **Volume of sample** | 50? l | 50? l | 50? l |
| **200x Nº of dilution** | 200x2 | 200x4 | 200x8 |
| **I.U./ml** | 400 | 800 | 1600 |

Normal Levels :- Adults < 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 dilution 3, the titre is 1600.

**INTERPRETATION OF 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.

**PERFORMANCE CHARACTERISTICS**
Analytical sensitivity: 200 (? 50) IU/mL.
Prozone effect: No prozone effect was detected up to 1500 IU/mL.
Diagnostic sensitivity: 98 %.
Diagnostic specificity: 97 %.

**LIMITATIONS OF THE METHOD**
False positive results may be obtained in conditions such as, rheumatoid arthritis, scarlet fever, tonsillitis, several streptococcal infections and healthy carriers.
Early infections and children from 6 months to 2 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.

**INTERNAL QUALITY CONTROL**
Positive and negative control sera are provided and should be used to verify the test

**REFERENCES**

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2. Bach, G.L./ Cadotte, R, Wiatr, R.A., Bhorade, M. and Anderson, T.O., Amer, Clin. Path. 57 : 209(1972)
3. Spann, I., Bentzan, M.W., Larson, S.O. *at al.*,Bull., WHO.24 :271(1961).