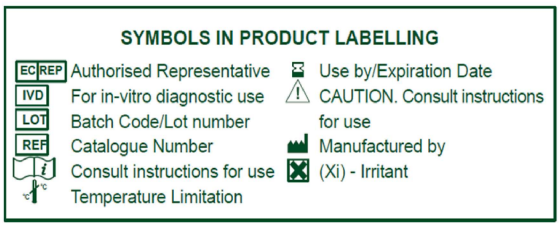
SPECTRUM

The Creative Approach to Bioscience

# Antistreptolysin O (ASO) Immuno-Turbidimetry

**REF**: 596 001 100 test
R1 Buffer 2 x 20 ml
R2 Latex 1 x 6 ml
Standard 1 x 0.2 ml




## Intended Use

In vitro diagnostic reagents for the quantitative determination of Antistreptolysin O (ASO) in human serum by means of particle-enhanced turbidimetric immunoassay.

## Background

Immunological testing for specific antibodies to streptococcal metabolites provides important information regarding a prior streptococcal infection. Antibodies are formed against both the pathogen itself and its metabolic products. An example for the latter is the antibody against streptolysin O, an enzyme secreted by betahaemolytic streptococci of the Landfield Group A.
Antistreptolysin O (ASO) testing is thus used for the diagnosis of non suppurative complications of the infections caused by these pathogens: acute rheumatic fever or acute poststreptococcal glomerulonephritis. In the determination of antibodies to various streptococcal exoenzymes preference is to be given to anti-streptolysin O, since this sensitive parameter is found to be elevated in about 80 to 85% of cases.

## Test Principle

This ASO test is based upon the ASO antigen-antibody reaction.

## Reagents

***R1* Buffer**
Phosphate buffered saline (pH 7.43)
Enhancer.
Sodium azide (0.095 g/L)

**R2 Latex reagent**
Glycine Buffer (pH8.2)
ASO sensitized Latex (0.17 %)
Sodium azide 0.95 g/L.

**Standard**
ASO concentration is stated on the vial label.

**Materials required but not provided with the kit**
***Controls***

## Precautions and Warnings

For in vitro diagnostic use only. Do not pipette by mouth. Reagents containing sodium azide must be handled with precaution. Sodium azide can form explosive azides with lead and copper plumbing. Since absence of infectious agents cannot be proven, all specimens and reagents obtained from human blood should always be handled with precaution using established good laboratory practices. Disposal of all waste material should be in accordance with local guidelines.
As with other diagnostic tests, results should be interpreted considering all other test results and the clinical situation of the patient.

## Reagent Preparation,Storage and Stability

All reagents are supplied ready to use.
Reagents in the original vial are stable to the expiration date on the vial label when capped and stored at (2 - 8 ºC).

**ASO Standard:**
The Standard is stable to the expiration date on the vial label when capped and stored at (2 - 8 ºC).
Once opened the standard is stable for 6 weeks if stored tightly closed at 2 - 8 ºC after use.

## Specimen Collection and Preparation

Serum specimens should be collected by venipuncture following good laboratory practices. Suitable assay specimens are human serum samples, as fresh as possible (stored up to 2 days at 2 - 8 ºC) or deep-frozen. Any additional clotting or precipitation which occurs due to the freeze/thaw cycle should be removed by centrifugation prior to assay.
Heavily lipemic sera may lead to a non-specific reaction due to chylomicrons. Lipemic specimens, or turbid frozen specimens after thawing, must be clarified before the assay by high-speed centrifugation (15 min at approx. 15000 rpm).

## Procedure

1 - Bring the reagents and the photometer to 37ºC.
2 - Assay conditions:

| | |
|---|---|
| Wavelength | 580 nm |
| Temperature | 37ºC |
| Cuvette | 1cm light path |

3 - Adjust the instrument to zero with distilled water .
4 - Pipette into a cuvette :

| | Standard | Sample |
|---|---|---|
| Reagent (R1) | 400 µl | 400 µl |
| Standard | 5µl | --- |
| Sample | --- | 5µl |

5- Mix and incubate for 2 minutes,read absorbance ($A_1$)

| | | |
|---|---|---|
| Reagent (R2) | 60 µl | 60µl |

After addition of **R2,** incubate and record 2nd reading after 5 minutes (A2)

## Calculation

Generate a reference curve by successive 1 : 2 dilutions of standard in saline (At Least 4 points are recommended). Use Saline as zero point. Determine Δ absorbance of the sample and each standard as following:
Δ absorbance of sample = (A2 - A1) sample
Δ absorbance of each standard = (A2 - A1) for each standard
Plot the calibration curve and obtain the result.

## Quality Control

Control serum are recommended to monitor the perfomance of manual and automated assay procedures. Each laboratory should establish its own Quality Control Scheme and corrective actions if controls do not meet the acceptable tolerances.

## Performance characteristics

### Detection limit

12.5 IU/mL

### Precision

| | CV (%) | |
|---|---|---|
| | **Intra-Run** | **Inter-Run** |
| **Low** | 4.33 | 4.44 |
| **Medium** | 2.29 | 3.35 |
| **High** | 2.41 | 2.25 |

### Interferences

No interference for :
Hemoglobin (1000 mg/dL)
Na-citrate (1000 mg/dL)
Heparin (50 mg/dL)
Bilirubin (60 mg/dL)
Triglyceride (2500 mg/dL)
EDTA (5 mg/dl)

### Sensitivity

10.0 IU/mL.

### Linearity

400 IU/mL.

Specimens showing higher concentration should be diluted 1+4 using physiological saline and repeat the assay (result×5).

### Expected Values

Normal values 0 - 200 IU/ml

Each laboratory should establish an expected range for the geographical area in which it is located.

### References

1.Tadzynsky LA, Ryan ME. Diagnostic of rheumatoid fever. A guide to criterial and manifestations. Postgrad Med 1986; 79:295.
2.Dillon,H.C.jr,Reeves M.A,aM.J.Med,56,333-346(1974).
3.Bach GL, Cadotte R, Wiatr RA, et al. Latex antiestreptolysin O test as a tube dilution procedure. Am J Clin Pathol 1972; 57: 209.
4.Klein,G.C.Baker,C.N,Jones,W.L,21,999-1001(1971).
5-Curtis GDW, Kraak WAG, Mitchell RG. Comparison of latex and hemolysis tests for determination of antiestreptolysin O (ASO) antibodies. J Clin Pathol 1988; 41: 1331.

| ORDERING INFORMATION | |
|---|---|
| **CATALOG NO.** | **QUANTITY** |
| 596 001 | 100 test |

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