Antistreptolysin O (ASO)  
Immuno-Turbidimetry

**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 carbohydrates 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 beta-haemolytic streptococci of the Lancefield 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 antistreptolysin 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.

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

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

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

2- **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 pluming. 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 °C).

**ASO Standard:**  
The Standard is stable to the expiration date on the vial label when capped and stored at (2 - 8 °C).

Once opened the standard is stable for 6 weeks if stored tightly closed at 2 - 8 °C after use.

**SYMBOLS IN PRODUCT LABELLING**

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<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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<tbody>
<tr>
<td>EC REP</td>
<td>Authorised Representative</td>
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<tr>
<td>IVT</td>
<td>For in-vitro diagnostic use</td>
</tr>
<tr>
<td>LOT</td>
<td>Batch Code/Lot number</td>
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<tr>
<td>CAT</td>
<td>Catalogue Number</td>
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<tr>
<td>CI</td>
<td>Consult instructions for use</td>
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<td>FAB</td>
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For further storage at - 30 °C divide standard into aliquots. Stability 3 months , once thawed never freeze again.

**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 °C) 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. 15,000 rpm).

**Procedure**

1 - Bring the reagents and the photometer to 37°C

2 - **Assay conditions:**

| Wavelength | 580 nm |
| Temperature | 37°C |
| Cuvette | 1cm light path |

3 - Adjust the instrument to zero with distilled water.

4 - Pipette into a cuvette:

| Standard | 400 µl |
| Sample | 5µl |

5. Mix and incubate for 2 minutes, read absorbance (A1)

| Reagent (R2) | 60 µl |

After addition of R2, incubate and after 5 minutes record 2nd reading (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.

**Sensitivity**

10.0 IU/mL

**Linearity**

400 IU/mL

**Quality Control**

Control sera are recommended to monitor the performance 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.
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


ORDERING INFORMATION

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