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 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 beta-haemolytic streptococci of the Landfield Group A. Antistreptolysin O (ASO) testing is thus used for the diagnosis of non supplicative 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).

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:

<table>
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<tr>
<th>Standard</th>
<th>Sample</th>
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<tbody>
<tr>
<td>Reagent (R1)</td>
<td>400 µl</td>
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<tr>
<td>Standard</td>
<td>5µl</td>
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<tr>
<td>Sample</td>
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5 - Mix and incubate for 2 minutes, read absorbance (A1)

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.

Sensitivity
10.0 IU/mL.

Linearity
400 IU/mL.
Quality Control

Control serum 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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<thead>
<tr>
<th>CATALOG NO.</th>
<th>QUANTITY</th>
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<tbody>
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<td>100 test</td>
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