Antistreptolysin O FS*
Diagnostic reagent for quantitative in vitro determination of antistreptolysin O (ASO) in serum on photometric systems

Order Information
Cat. No. Kit size
1 7012 99 10 021 R1 5 x 25 mL + R2 1 x 25 mL
1 7012 99 10 930 R1 4 x 20 mL + R2 2 x 8 mL
1 7012 99 10 935 R1 2 x 20 mL + R2 1 x 8 mL
1 7010 99 10 059 5 x 1 mL TruCal ASO: Calibrator set with 5 different levels

Summary [1-3]
Antistreptolysins (ASL) are specific antibodies to extracellular products of Streptococcus pyogenes (Group A streptococcus: GAS), among which antistreptolysin O (ASO) is the one most used for clinical laboratory evaluation. Antistreptolysin O determination provides useful information for diagnosis and monitoring of human streptococcal infections such as in tonsillitis, otitis, erysipela, scarlet fever as well as connected diseases like rheumatic fever or glomerulonephritis. Antibodies against streptolysin O can be detected 1 – 3 weeks after infection with maximum levels reached at 3 – 6 weeks. Pathological ASO values always indicate the presence of a streptococcal infection whereas a negative result cannot exclude an existing or preceding GAS infection.

Method
Particle enhanced immunoturbidimetric test

Principle
Determination of the concentration of ASO via photometric measurement of the antigen-antibody-reaction of latex particles coated with streptolysin O and antibodies to streptolysin O present in the sample.

Reagents
Components and Concentrations
R1: Phosphate buffer pH 7.0 100 mmol/L
NaCl 150 mmol/L
R2: Latex particles coated with streptolysin O
Glycine buffer pH 8.0 100 mmol/L
NaCl 150 mmol/L

Storage Instructions and Reagent Stability
The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8 °C and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions
1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. In very rare cases, samples of patients with gammopathy might give falsified results [7].
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patients’ medical history, clinical examinations and other findings.
4. For professional use only!

Waste Management
Please refer to local legal requirements.

Reagent Preparation
The reagents are ready to use. The latex reagent (R2) must be carefully mixed before use.

Materials required but not provided
NaCl solution 9 g/L
General laboratory equipment

Specimen
Serum
Stability: 2 days at 20 – 25 °C
2 days at 4 – 8 °C
6 months at −20 °C

Only freeze once!
Discard contaminated specimens!

Assay Procedure for Analyzers
Application sheets for automated systems are available on request.

Wavelength 500 – 600 nm
Optical path 1 cm
Temperature 37 °C
Measurement Against reagent blank

Sample or calibrator
Blank
Dist. water 3 µL
Reagent 1 250 µL 250 µL
Mix, incubate for 3 - 5 min., then add:
Reagent 2 50 µL 50 µL
Mix, and read absorbance (A1). Incubate for a further 5 min. and read absorbance again (A2).

△A= (A2 – A1) sample or calibrator

Calculation
The concentration of antistreptolysin O in unknown samples is derived from a calibration curve using an appropriate mathematical model such as spline. The calibration curve is obtained with five calibrators at different levels and NaCl solution (9 g/L) for determination of the zero value.

Stability of calibration: 4 weeks.

Calibrators and Controls
For the calibration of automated photometric systems the DiaSys TruCal ASO calibrator set is recommended. The assigned values of TruCal ASO have been made traceable to a commercially available standard material, traceable to the First International Standard as ASL reference standard. For internal quality control a DiaSys TruLab Protein control should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
</tr>
</thead>
<tbody>
<tr>
<td>TruLab Protein Level 1</td>
<td>5 9500 99 10 046</td>
</tr>
<tr>
<td>TruLab Protein Level 2</td>
<td>5 9510 99 10 046</td>
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</tbody>
</table>
Performance Characteristics

Measuring Range
The test is developed to determine ASO concentrations within a measuring range from 7 – 800 IU/mL, at least up to the concentration of the highest calibrator. When values exceed this range the samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Prozone Limit
No prozone effect was observed up to an ASO concentration of 1500 IU/mL.

Specificity/Interferences
Due to its antibodies, DiaSys Antistreptolysin O FS is a specific immunoassay for Antistreptolysin O. No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL, hemoglobin up to 500 mg/dL and lipemia up to 2000 mg/dL triglycerides. For further information on interfering substances refer to Young DS [5].

Sensitivity/Limit of Detection
The lower limit of detection is 7 IU/mL.

Precision (n = 20)

<table>
<thead>
<tr>
<th>Intra-assay precision</th>
<th>Mean [IU/mL]</th>
<th>SD [IU/mL]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>168</td>
<td>3.43</td>
<td>2.04</td>
</tr>
<tr>
<td>Sample 2</td>
<td>284</td>
<td>5.90</td>
<td>2.08</td>
</tr>
<tr>
<td>Sample 3</td>
<td>479</td>
<td>11.1</td>
<td>2.32</td>
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</table>

<table>
<thead>
<tr>
<th>Inter-assay precision (daily calibration)</th>
<th>Mean [IU/mL]</th>
<th>SD [IU/mL]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>170</td>
<td>5.06</td>
<td>2.98</td>
</tr>
<tr>
<td>Sample 2</td>
<td>267</td>
<td>8.21</td>
<td>3.08</td>
</tr>
<tr>
<td>Sample 3</td>
<td>481</td>
<td>12.8</td>
<td>2.65</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inter-assay precision (single calibration)</th>
<th>Mean [IU/mL]</th>
<th>SD [IU/mL]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>165</td>
<td>5.84</td>
<td>3.54</td>
</tr>
<tr>
<td>Sample 2</td>
<td>275</td>
<td>8.82</td>
<td>3.20</td>
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<tr>
<td>Sample 3</td>
<td>472</td>
<td>15.8</td>
<td>3.34</td>
</tr>
</tbody>
</table>

Method Comparison
A comparison of DiaSys Antistreptolysin O FS (y) with a commercially available test (x) using 77 samples gave the following result: \( y = 0.89 \times \) x + 1.80 IU/mL; \( r = 0.987 \)

Reference Range [6]

- Adults ≤ 200 IU/mL
- Children ≤ 150 IU/mL

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9   65558 Holzheim   Germany