ANTISTREPTOLYSIN O (ASO)

OSR6194  
4 x 51 mL  R1
4 x  7 mL   R2

**Intended Use**
System reagent for the quantitative determination of Anti-Streptolysin O antibodies in human serum on the Beckman Coulter AU analyzers.

**Summary**
Streptolysin O is a hemolysin produced by group A streptococci. In an infected individual Streptolysin O acts as a protein antigen to which the patient mounts an antibody response. A rise in titer begins about 1 week after infection and peaks 2 – 4 weeks later. In the absence of complications or re-infection, the ASO titer will usually fall to preinfection levels within 6 – 12 months. Both clinical and laboratory findings should be correlated in reaching a diagnosis.

**Methodology**
Immune complexes formed in solution scatter light in proportion to their size, shape, and concentration. Turbidimeters measure the reduction of incidence light due to reflection, absorption or scatter.
In this procedure, the rate of decrease in light intensity transmitted (increase in absorbance) through particles suspended in solution is the result of complexes formed during the antigen-antibody reaction.

**System Information**
AU400/400/480, AU600/640/640 and AU2700/5400/AU5800 Beckman Coulter Analyzers.

**Reagents**
Final Concentration of Reactive Ingredients:
- Phosphate Buffer (pH 7.0)  40 mmol/L
- Latex particles coated with Streptolysin O Antigen
Also contains preservatives.

**Precautions**
1. For *in vitro* diagnostic use.
2. Do not ingest. Harmful if swallowed.
3. Contains sodium azide as a preservative, which may react with lead joints in copper plumbing to form explosive compounds. Even though the reagent contains minute quantities of sodium azide, drains should be well flushed with water when discarding the reagent.

**Preparation of Reagents**
The ASO reagent is ready for use. No preparation is required. The R2 latex solution should be mixed by gentle inversion 5 – 10 times before placing on the instrument.

**Storage and Stability**
1. The unopened reagents are stable until the expiration date printed on the label when stored at 2 - 8°C.
2. Opened bottles of reagent are stable for 60 days when stored in the refrigerated compartment of the analyzer.

**Indications of Deterioration**
Visible signs of microbial growth, gross turbidity, precipitate, or change in color in the ASO reagents may indicate degradation and warrant discontinuance of use.

**Specimen Collection And Preparation**
Serum, free from hemolysis, is the recommended specimen.

**Sample Storage and Stability**
Anti-Streptolysin O specimens are stable for several weeks stored at 2 - 8°C. For longer storage, freeze serum to ≤ -20°C or lower.

**Interfering Substances**
Results of studies show that the following substances may interfere with this Anti-Streptolysin O procedure.
The criteria for no significant interference is recovery within 10% of the initial value.
- Ascorbic acid: No significant interference up to 20 mg/dL Ascorbate
- Bilirubin: No significant interference up to 40 mg/dL Bilirubin
- Hemolysis: No significant interference up to 500 mg/dL Hemolysate
- Lipemia: No significant interference up to 1000 mg/dL Intralipid*

* Intralipid, manufactured by Kabivitrium Inc., is a 20% IV fat emulsion used to emulate extremely turbid samples.
The information presented is based on results from Beckman Coulter studies and is current at the date of publication. Beckman Coulter Inc. makes no representation about the completeness or accuracy of results generated by future studies. For further information on interfering substances, refer to Young for a compilation of reported interferences with this test.

**Procedure**
A complete list of test parameters and operational procedure can be found in the User’s Guide appropriate to the analyzer.

**Materials Provided**
Anti-Streptolysin O Reagent
Anti-Streptolysin O (ASO)

Materials required but not provided
Serum Protein Multi-Calibrator (Cat # ODR3021)
MC Cal A (Cat # ODR30037) for Mastercurve enabled systems

Stability of Final Reaction Mixture
The Beckman Coulter AU analyzer automatically computes every determination at the same interval.

Calibration
The frequency of calibration for the Anti-Streptolysin O procedure is every 7 days. Calibration of this Anti-Streptolysin O procedure is accomplished by use of the Serum Protein Multi-Calibrator (Cat # ODR3021), which is traceable to WHO International reference materials for Anti-Streptolysin O. The Serum Protein Multi-Calibrator is a 5-level calibrator for serum proteins including ASO.

Use MC Cal A Cat. No. ODR30037 for Mastercurve enabled systems only. Please refer to User Guide for further instructions.

Recalibration of this test is required when any of these conditions exist:
1. A reagent lot number has changed or there is an observed shift in control values.
2. Major preventative maintenance was performed on the analyzer.
3. A critical part was replaced.

Quality Control
During operation of the Beckman Coulter AU analyzer at least two levels of immunology control material should be tested a minimum of once a day. In addition, controls should be performed after calibration, with each new lot of reagent, and after specific maintenance or troubleshooting steps described in the appropriate User’s Guide. Quality control testing should be performed in accordance with regulatory requirements and each laboratory’s standard procedure.

Results
Results are automatically printed out for each sample in IU/mL.

Dynamic Range
The Anti-Streptolysin O method is linear from 100 to 1000 IU/mL. Samples exceeding the upper limit of linearity should be diluted with physiological saline and repeated. The sample may be diluted, repeated, and multiplied by the dilution factor automatically utilizing the AUTO REPEAT RUN.

Expected Values

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Expected Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 2 years</td>
<td>&lt; 50 IU/mL</td>
</tr>
<tr>
<td>2 – 5 years</td>
<td>&lt; 100 IU/mL</td>
</tr>
<tr>
<td>5 – 10 years</td>
<td>&lt; 166 IU/mL</td>
</tr>
<tr>
<td>Adults</td>
<td>≤ 250 IU/mL</td>
</tr>
</tbody>
</table>

Determined Reference Range

0 – 250 IU/mL

A single serum determination is not as valuable as the study of sequential specimens obtained during the acute stage of the infection and then timed at intervals after the acute stage and into convalescence. A rise in titer of four or more dilution increments between acute and convalescent samples is considered to be significant regardless of the magnitude of the titer. For a single specimen, ASO titers ≤ 250 IU/mL are considered normal; but higher titers may be normal in demographic groups or may be associated with chronic pharyngeal carriage.

Specific Performance Characteristics
The following data was obtained using the ASO reagent on Beckman Coulter AU analyzers according to established procedures. Results obtained in individual laboratories may differ.

Precision
Estimates of precision, based on CLSI recommendations, are consistent with typical performance. The within run precision is less than 5% CV and the total precision is less than 10% CV. The assays of serum pools and control sera were performed using Serum Protein Multi-Calibrator ODR3021 and the data reduced following CLSI guidelines above.

<table>
<thead>
<tr>
<th>N=80</th>
<th>Mean, IU/mL</th>
<th>SD</th>
<th>CV%</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Within run</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>145.9</td>
<td>2.52</td>
<td>1.7</td>
<td>2.74</td>
<td>1.9</td>
</tr>
<tr>
<td>291.5</td>
<td>3.43</td>
<td>1.2</td>
<td>4.11</td>
<td>1.4</td>
</tr>
<tr>
<td>499.6</td>
<td>5.54</td>
<td>1.1</td>
<td>9.34</td>
<td>1.9</td>
</tr>
</tbody>
</table>

Method Comparison:
Patient samples were used to compare this Anti Streptolysin O Reagent. The table below demonstrates performance on AU analyzers.

<table>
<thead>
<tr>
<th>Y Method</th>
<th>AU640</th>
</tr>
</thead>
<tbody>
<tr>
<td>X Method</td>
<td>Method 2</td>
</tr>
<tr>
<td>Slope</td>
<td>1.18</td>
</tr>
<tr>
<td>Intercept</td>
<td>2.0</td>
</tr>
<tr>
<td>Correlation Coeff. (r)</td>
<td>0.992</td>
</tr>
<tr>
<td>No. of Samples (n)</td>
<td>198</td>
</tr>
<tr>
<td>Range (IU/mL)</td>
<td>5.4 – 796.5</td>
</tr>
</tbody>
</table>

References
3. In-house data; available upon request.
7. Beckman Coulter Inc. data on samples collected from 200 blood donors in Texas.
8. CLSI/NCCLS Evaluation Protoc EP5-T.
9. Data is on file for specific AU analyzers.

Manufactured by: Beckman Coulter, Inc., 250 S. Kraemer Blvd. Brea, CA 92821, USA