ASO IMMUNOTURBIDIMETRY

ANTI STREPTOLYSIN-O (ASO)

Test for the quantitative immunological determination of Antistreptolysin-O (ASO) in human serum and plasma.

Liquid. Dual reagents. Store at 2°C - 8°C. Do not freeze. For in Vitro Diagnostic Use.

<table>
<thead>
<tr>
<th>Ref No</th>
<th>Pack</th>
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</thead>
<tbody>
<tr>
<td>TA111</td>
<td>5 x 100 mL</td>
<td>VAB110</td>
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<td>NAB110</td>
<td>667 Tests</td>
<td>SAB111</td>
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<td>333 Tests</td>
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<td>MAB110</td>
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<td>3385 Tests</td>
<td>MAB111</td>
<td>1671 Tests</td>
<td>KAB110</td>
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<td>1818 Tests</td>
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<td>2727 Tests</td>
<td>KAB111</td>
<td>1364 Tests</td>
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</table>

* 01R86-31 / 01R86-21 Ref Number Products are Produced Specifically for Abbott Architect Biochemistry Analyzer Series

INTENDED USE

The Archem Anti Streptolysin-O assay is applied for the quantitative immunological measurement of ASO (Anti Streptolysin-O fraction) in human sample (Serum/plasma) on auto analyzer in clinical laboratories.

Anti-streptolysin-O are extracellular enzymes, which are the specific antibodies to streptolysin O, produced by Lancefield group A, α-hemolytic streptococci (Streptococcus pyogenes). Antibodies against streptolysin-O can be detected from one week to one month after the onset of a streptococcal infection. A wide variety of upper respiratory infections such as acute pharyngitis are caused by Streptococcus pyogenes.

Glomerulonephritis, rheumatic fever, bacterial endocarditis and scarlet fever are other effects of streptococcus pyogenes infection.

Not only the findings of a single test result but also an integration of both clinical and laboratory data should be used in clinical diagnosis.

TEST PRINCIPLE

The latex particles coated with streptolysin O (SLO) is agglutinated when they react with samples that containing specific antibodies ASO. The latex particles agglutination is proportional to the concentration of the ASO in the sample and can be measured by turbidimetry.

TEST PARAMETERS

Method : Immunoturbidimetric, Incerasing Reaction, Fixed Time

Wavelength : 546 nm

Temperature : 2-8°C

Sample : Serum/Plasma

Linearity : 20 IU/mL - 800 IU/mL

REAGENT COMPOSITION

Reagent 1:
- Tris buffer < 30 mmol/L,
- Sodium chloride < 190 mmol/L,
- Sodium azide < 0.99 g/L,
- pH 8.2.

Reagent 2:
- Suspension of latex particles coated with streptolysin O, sodium azide <0.99 g/L.

Once opened vials, R1 and R2 are stable 30 days minimum at 2-8°C. There is a strong relation between on board stability and analyzers specifications.

ASO Calibrator (Standard): Human serum. ASO concentration is given on the label. Concentration value is traceable to the Biological Reference Material 97/662 (National Institute for Biological Standards and Control, United Kingdom).

Testing of human serum used in the preparation of the standard is resulted as negative for the presence of antibodies anti-HIV and anti-HCV, beside for HBs antigen. Because of the possibility of being infectious, standard should be used cautiously.

REAGENT PREPARATION

The reagent is ready for use.

Working Reagent:
Working reagents are stable at 2-8°C when they are stored in closed vials and avoiding contamination after preparation.

Reagent volumes can be prepared by mixing: 1 mL of Reagent 2 + 4 mL of Reagent 1. Gently mix the Reagent 2 vial before pipetting.

ASO Calibrar (Standard): Reconstitute with 1.00 mL of distilled water. It is stable for 3 days at 2-8°C.
After reconstitution; frozen samples are stable at least 1 month.

For manual working procedures; if working reagent will be used; first shake Reagent 2 vial gently then pouring its contents to reagent 1 vial. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

REAGENT STABILITY AND STORAGE
Store at 2-8ºC.
Reagents are stable till the expiry date stated on the label when they stored in closed vials and avoiding contamination during their usage.
Indications of deterioration:
Reagents: absorbance of the blank over 0.900 at 540 nm.
Calibrator: Presence of moisture.
Once opened vials are stable minimum 30 days at 2-8ºC at optimum conditions. There is a strong relation between on board stability and auto analysers cooling specification and carry-over values.

SAMPLE
Serum is collected by standard procedures.
ASO in serum is stable for 2 days at 2-8ºC, minimum 6 months at –20ºC.
For reagents which are related antigen antibody interaction, do not shake the sample, R2, control and calibrator; just gently mix.

TEST PROCEDURE
Sample Start
In case of request, ready application procedures dedicated to different kind of photometers and ready manual working procedures can be supplied.
In case of request, ready application procedures dedicated to different kind of biochemistry auto analysers can be supplied.

Substrate Start
In case of request, ready application procedures dedicated to different kind of biochemistry auto analysers can be supplied.

CALCULATIONS
The anti-streptolysin O concentration in the sample is calculated using the following general formula:

\[
\frac{A_2 - A_1}{A_2 - A_1} \times \frac{C \text{ Standard}}{C \text{ Sample}} = C \text{ Sample}
\]

REFERENCE INTERVALS (NORMAL VALUES) (37ºC)
Serum Adults: < 200 IU/mL
Children: < 150 IU/mL
*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION
Commercially available control material with established values determined by this method may be used. We recommend:
Rheumatoid Control Serum level I
Cat No: RCN01
Rheumatoid Control Serum level II
Cat No: RCN05
Liquid Rheumatoid Control Serum level I
Cat No: RCN06
Liquid Rheumatoid Control Serum level II
Cat No: RCN07
Calibrator. We recommend:
ASO Turbidimetric Calibrator (Standard)
Cat.No. TA111S (01R90-01)
*Calibration Stability: It is strongly depend on application to auto analyzers and auto analyzers specification. Calibration stability is 30 days in general.
*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.
Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS
Low linearity (LOQ): 20 IU/mL ASO. Considerable variation may be seen in linearity depending on the analyzer model and application method.

High linearity: 800 IU/mL ASO. For higher values dilute sample 1/5 with distilled water and repeat measurement. Considerable variation may be seen in linearity depending on the analyzer model and application method.

Precision Studies (Based on CLSI EP5 Doc.):

<table>
<thead>
<tr>
<th></th>
<th>Mean concentration</th>
<th>CV</th>
<th>n</th>
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<tbody>
<tr>
<td>Repeatibility (within run) (intra-assay)</td>
<td>200 IU/mL</td>
<td>3.4 %</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>366 IU/mL</td>
<td>3.4 %</td>
<td>25</td>
</tr>
<tr>
<td>Reproducibility (run to run) (inter-assay)</td>
<td>200 IU/mL</td>
<td>3.6 %</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>366 IU/mL</td>
<td>3.4 %</td>
<td>25</td>
</tr>
</tbody>
</table>
Sensitivity (LOD) (Based on CLSI EP17 document): Limit of detection of the test is 1.06 mA mL/IU.

Trueness: No systematic differences seen in results obtained with this reagent when compared with reference reagents. It's available to get details of comparison experiments in case of requirement.

Zone effect: If ASO is present in the sample at a concentration higher than 4000 IU/mL, it will be resulted in obtaining falsely low values.

Interferences: Hemoglobin (10 g/L), bilirubin (20 mg/dL), lipemia (triglycerides 10 g/L) and rheumatoid factors (2200 IU/mL) do not interfere. Other drugs and substances may interfere.

An analyzer has been used to obtain these performance characteristics. Usage of different analyzer or a manual procedure may cause the variance in results.

NOTES
1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators and controls must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should capped and kept at 2-8°C. Caps of the reagents bottles can not be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The reagents contain sodium azide (< 0.1%) as a preservative.
8. These reagents may be used in several automatic analyzers. Instructions for many of them are available on request.
9. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL
This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general GLP guidelines.
R36/38 Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28: After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45: In case of accident or if you feel unwell, seek medical advice immediately.
S56: Dispose of this material and its container at hazardous or special waste collection point.
S61: Avoid release in environment. Refer to special instructions/safety data sheets Please consult local regulations for a correct waste disposal.

ABBREVIATIONS
ASO : Anti Streptolysin-O
CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : milliliter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

REFERENCES


SYMBOLS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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<tbody>
<tr>
<td>IVD</td>
<td>Only for in vitro diagnostic use</td>
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<tr>
<td>LOT</td>
<td>Lot of manufacturing</td>
</tr>
<tr>
<td>R1</td>
<td>Reagent 1</td>
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<td>R2</td>
<td>Reagent 2</td>
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- Expiration date
- Storage temperature interval
- Read the directions
- Biological risk

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