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.

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
TA112	5X100 ML	RAB110	1923 Tests	NAB110	667 Tests	SAB111	1309 Tests
TA112	5X50 ML	RAB111	641 Tests	NAB111	333 Tests	BY111	7676 Tests
TA113	5X25 ML	DMT110	840 Tests	MAB110	2512 Tests	BY112	5114 Tests
LAB110	3409Tests	TAB110	3474 Tests	MAB111	1671 Tests	KAB110	2927 Tests
LAB111	1818 Tests	TAB111	1795 Tests	SAB110	2727 Tests	KAB111	1951 Tests

INTENDED USE

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

Anti-streptolysin O are the specific antibodies to streptolysin O, an extracellular enzyme 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. *Streptococcus pyogenes* causes a wide variety of upper respiratory infections such as acute pharyngitis. Other manifestations of Streptococcus pyogenes infection include glomerulonephritis, rheumatic fever, bacterial endocarditis and scarlet fever.
Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

TEST PRINCIPLE

The latex particles coated with streptolisyn 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 : 2-8ºC.
Sample : Serum/Plasma
Linearity (High) : 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, R1and R2 are stable 30 days minimum at 2-8ºC. On board stability is strongly related of 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).

Human serum used in the preparation of the standard has been tested and found to be negative for the presence of antibodies anti-HIV and anti-HCV, as well as for HBs antigen. However, the standard should be handled cautiously as potentially infectious.

REAGENT PREPARATION

The reagent is ready for use.
Working Reagent:
Working reagents are stable at 2-8ºC in case of 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 Calibrator (Standard): Reconstitute with 1.00 mL of distilled water. Stable for 3 days at 2-8ºC. After reconstitution; freezed samples are stable at least 1 month.
For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. 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 until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.
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 2-8°C at optimum conditions. On board stability is strongly related to auto analysers cooling specification and carry-over values.

SAMPLE

Serum is collected by standard procedures. ASO in serum is stable for 7 days at 2-8ºC, minimum 7 days at – 20°C.

TEST PROCEDURE

Sample Start
There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

Substrate Start
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATIONS

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

$$\frac{A2 - A1\ Sample}{A2 - A1\ Standard} \times C\ Standard = C\ Sample$$

REFERENCE INTERVALS (NORMAL VALUES) (Based on CLSI C28-P Document)* (37°C)

Serum Adults : < 200 IU/mL
Children : < 150 IU/mL

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

It is recommended to use the Rheumatoid Control Serum level I (Ref No: RCN01) and II (Ref No: RCN05) to verify the performance of the measurement procedure. Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.
Calibrator. We recommend:

ARCHEM Calibrator (Standard)
Ref.No. TA111S.

*Calibration Stability: It is strongly depend of 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.

PERFORMANCE CHARACTERISTICS

Low linearity: 20 IU/mL ASO

High linearity: 800 IU/mL ASO. For higher values dilute sample 1/5 with distilled water and repeat measurement. Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatibility (within run) (intra-assay)		
Mean concentration	CV	n
200 IU/mL	3.4 %	20
366 IU/mL	3.4 %	20

Reproducibility (run to run) (inter-assay)		
Mean concentration	CV	n
200 IU/mL	3.6 %	25
366 IU/mL	3.4 %	25

Sensitivity (LOD) (Based on CLSI EP17 document): 1.06 mA mL/IU

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Zone effect: Falsely low values are obtained when ASO is present in the sample at a concentration higher than 4000 IU/mL.

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. These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or manual procedures are used.

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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 “Good Laboratory Practice” (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.
S57: Use appropriate container to avoid environmental contamination.
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 : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
R2	Reagent 2
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog Number)
SN	Serial Number


Expiration date


Storage temperature interval


Read the directions


Biological risk

CE

Archem Diagnostics Industry LTD. ŞTİ.
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