ASO TURBIDIMETRIC

En

REF 01R86-31 3385 Tests
REF 01R86-21 1795 Tests

FOR USE WITH
ARCHITECT

Test for the quantitative immunological determination of Antistreptolysin-O (ASO) in human serum. Liquid. Dual reagents. Store at 2°C - 8°C. Do not freeze. For in Vitro Diagnostic Use.

01R86-31 / 01R86-21 Ref Number Products are Produced Specifically for Abbott Architect Chemistry Analyzer Series.
Note: REF 01R86-21 is not available in Poland.

INTENDED USE

Test for the quantitative immunological determination of Antistreptolysin-O (ASO) in human serum.
The Archem Anti Streptolysin-O assay is applied for the quantitative immunological measurement of ASO (Anti Streptolysin-O fraction) in human sample (Serum) on auto analyzers in clinical laboratories.

Anti-streptolysin-O is 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.*[6]

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) are agglutinated when they react with samples that contain ASO specific antibodies. The latex particles agglutination is proportional to the concentration of the ASO in the sample and can be measured by turbidimetry. [7]

TEST PARAMETERS

Method	: Immunoturbidimetric, Increasing Reaction, Fixed Time
Wavelength	: 548 nm
Temperature	: 37 ºC.
Sample	: Serum
Linearity	: 20 IU/mL - 800 IU/mL

REAGENT COMPOSITION

Reagent 1:

Tris buffer	< 30 mmol/L,
Sodium chloride	< 190 mmol/L,
Sodium azide	< 0.1 g/L,
pH 8.2	

Reagent 2:
Suspension of latex particles coated with streptolysin O, sodium azide <0.1 g/L.

REAGENT PREPARATION

Reagents are ready to use, liquid.

REAGENT STABILITY AND STORAGE

Store at 2-8ºC.
Reagents are stable until the expiry date stated on the label when stored in closed vials and avoiding contamination during their usage.

Indications of deterioration:
Reagents: absorbance of the blank over 0.2 at 548 nm.
On board stability:
Once opened vials are stable 30 days at 2-8°C at optimum conditions. There is a strong relation between on board stability and auto analyzer's cooling specification and carry-over values.

SAMPLE

Serum:
Serum is collected by standard procedures.
ASO in serum is stable for 2 days at 2-8ºC, minimum 6 months at – 20°C. [8]
Use fresh serum samples. Clot formation must be completed prior to centrifugation. Also after centrifugation red blood cells must be separated from serum immediately.

PROCEDURE

Materials Provided

ASO Turbidimetric, REF 01R86-31 or
REF 01R86-21

Materials Required but not Provided

- Archem ASO Turbidimetric Calibrator
  REF**:** 01R90-01

Assay Procedure and Specimen Dilution Procedures:
For higher samples run the dilution within the ARCHITECT application.

REFERENCE INTERVALS (NORMAL VALUES) (37°C)

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

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.[2, 12]

QUALITY CONTROL

Commercially available control material with established values determined by this method may be used. We recommend:

Specific Protein Control Level I **REF: 04R42-01**
Specific Protein Control Level II **REF: 04R43-01**

Quality control is recommended every day.
Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

CALIBRATION

Calibrator. We recommend:
ASO Turbidimetric Calibrator (Standard)
REF: 01R90-01

Calibration Stability: Calibration stability is 30 days on ARCHITECT c Systems.

Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity (LOQ) (LOQ values are based on CV% values ≤ 20%): 20 IU/mL ASO.

High linearity: 800 IU/mL ASO.

Precision Studies (Based on CLSI EP05A3):

Repeatability (within run) (intra-assay)

Mean conc.		SD	CV	N
98.3	IU/mL	0.92	0.94 %	20
255.3	IU/mL	3.75	1.47 %	20

Reproducibility (day to day) (inter-assay)

Mean conc.		SD	CV	N
208.5	IU/mL	4.84	2.32 %	80
283.5	IU/mL	10.39	3.66 %	88

Correlation: Correlation with a comparative method is: r=0.996 (Range 54 IU/mL to 562 IU/mL)
According to Passing-Bablok Fit:
Slope: 1.022
Intercept: -0.37

Sensitivity (LOD): 10 IU/mL

Prozone effect: If ASO is present in the sample at a concentration higher than 2900 IU/mL, it will result in obtaining falsely low values.

Interferences: [9]
The acceptable interference limit is set 10% below the highest interferent concentration that is within ±10% recovery of the target.

Hemoglobin up to 6.3 g/L, bilirubin up to 58.5 mg/dL, lipemia (Triglycerides) up to 2250 mg/dL do not interfere. Other drugs and substances may interfere. Significant interference may be observed with hemolyzed samples. Reference observed results in the table below. [10, 11]

Interferent and Concentration	ASO Turbidimetric Target (IU/mL)	N	Observed Recovery %
Bilirubin Total 65 mg/dL	165	3	98
	315	3	101
Triglyceride 2500 mg/dL	137	3	100
	336	3	98
Hemoglobin 7 g/L	131	3	93
Hemoglobin 25 g/L	308	3	98

The effect of interfering substances has only been evaluated for those listed in this labeling.
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. Caps of the reagents bottles cannot 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.

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.
R32: Contact with acids liberates very toxic gas.
EUH032: Contact with acids liberates very toxic gas.
H300: Fatal if swallowed.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
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
mL : milliliter
QC : Quality Control
mg : milligram
L : liter
g : gram
IU : International unit
dL : deciliter

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SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot number
R1	Reagent 1
R2	Reagent 2
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practices
FOR USE WITH	Identifies products to be used together
PRODUCT OF TURKEY	Product of Turkey
	Manufacturer
	Expiration date
	Temperature limitation
	Consult instructions for use
	Caution
	Sufficient for

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