

Use

The reagent ASO are intended for the quantitative determination of antistreptolysin-O in serum, plasma. Turbidimetric method.

Summary

The ASO measurements are used in the diagnosis and treatments of infection by streptococci. The group A β -hemolytic streptococci produces various toxins that can act as antigens. One of these exotoxins, among which concentration of antistreptolysin-O in the patient's serum will enable to establish the degree of infection due to the β -hemolytic streptococcus.

Principle

The ASO reagents is a suspension of polystyrene latex particles of uniform size coated with streptolysin-O. When a sample containing antistreptolysin-O is mixed with the reagent, a clear agglutination occurs, which can be measured by turbidimetry.

Reagents

ASO R1 TRIS buffer pH 8.2 20.0 mmol/l
Sodium azide < 0.1%

ASO R2 Suspension of polystyrene latex particles coated with streptolysin-O, Ph 10.0.
Sodium azide < 0.1%

ASO CAL Calibrator. Human serum. ASO concentration is stated on the vial label.

Reagent Preparation

Working reagent: swirl the latex vial gently before use. Prepare the necessary amount as follow:
1 ml Latex Reagent + 9 ml Diluent

ASO Calibrator: Reconstitute with 1.0 ml of distilled water. Mix gently and incubate at room temperature for 10 minutes before use.

Storage And Stability

- Store the kit at 2-8°C. Do not freeze the reagents.
- After opening, the vials R1 and R2 are stable until the expiration date if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.
- Working reagent: stable for 30 days at 2-8 °C
- ASO Calibrator: stable for 1 month at 2-8°C or 3 months at -20°C.

Precaution In Use

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). However the reagent should be handled with care, according to good laboratory practice.
Caution: the reagents contain Sodium Azide (0.095%) as preservative. Avoid swallowing and contacting with skin, eyes and mucous membranes.

Waste Management

Please refer to the local legal requirements.

Sample

- Fresh Serum.
 - ASO is stable in the samples up to 7 days at 2-8°C or 3 months at -20°C
- Sample with presence of fibrin should be centrifuged before testing.
Do not use highly hemolized or lipemic samples.

Note

- The kit, according to this method, must be used in manual procedures. About automatic using follow specific applications.
- Avoid direct light, contamination and evaporation.
- The volumes in the procedure can be changed proportionally.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the singles vials.

Procedure

Wavelength λ : 540 nm
Working Temperature 37°C
Optical Path 1 cm
Reaction "end point"
Bring the reagents at 15-25°C before use them.

	STD	Sample
Working reagent	1000 μ l	1000 μ l
Sample	-	10 μ l
Standard	10 μ l	-

Mix and read the absorbance immediately (A_1) and after 2 minutes (A_2) of the sample addition

Calculations

ASO [UI/ml] =
 $\Delta A_{\text{sample}} / \Delta A_{\text{standard}} \times \text{Conc. STD}$

The reagent performances are related to 37°C, 1 cm and 540 nm

Reference Values

Serum - plasma 100-200 UI/ml

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

ANALYTICAL PERFORMANCES

Linearity

Reaction is linear up to a concentration of 850 UI/ml. Samples with values exceeding 850 UI/ml must be diluted with saline solution. Multiply, then, the result for diluting factor.

Precision

Determined on 20 samples for each control (N-H) (Normal-High). Results:
MEAN [mg/dl] N = 182.6 H = 334.7
C.V.% N = 5.3 H = 5.2

Analytical sensitivity

The test sensitivity in terms of detection limit is 50 UI/ml

Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor
 $r = 0.98$

Interferences

No interference was observed by the presence of
Bilirubin ≤ 20 mg/dl
Triglycerides ≤ 1282 mg/dl
Haemoglobin ≤ 10 mg/dl
Rheumatoid factor ≤ 600 UI/l
For a comprehensive review of interfering substances, refer to the publication by Young et al.








Quality Controls

It's necessary, each time the kit is used, to make the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Bibliography

Kaplan, L.A., Pesce, A.J.: "Clinical Chemistry", Mosby Ed. (1996).
Clinical Chemistry publication "Effects of Disease on Clinical Laboratory Tests"
Young D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Washington, DC 5th ed.2000.

Symbols

	CE Mark (98/79 CE regulation)
	in vitro medical device
	Batch Code
	Use by
	Storage temperature limits
	Read instruction for use
	Product by Spain