| COD 13923 1 x 50 mL |
|---|
| STORE AT 2-8ºC |
| Reagents for measurement of ASO concentration<br>Only for *in vitro* use in the clinical laboratory |

**ANTI-STREPTOLYSIN O (ASO)**

BioSystems

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**ANTI-STREPTOLYSIN O (ASO)**
LATEX

## PRINCIPLE OF THE METHOD

Serum anti-streptolysin O (ASO) causes agglutination of latex particles coated with streptolysin O. The agglutination of the latex particles is proportional to the streptolysin O concentration and can be measured by turbidimetry[1].

## COMPOSITION

A. Reagent: 1 x 40 mL. Tris buffer 20 mmol/L, sodium chloride 150 mmol/L, sodium azide 0.95 g/L, pH 8.2.
B. Reagent: 1 x 10 mL. Suspension of latex particles coated with streptolysin O, sodium azide 0.95 g/L.

## 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 the limit indicated in "Assay Parameters".

## AUXILIARY REAGENTS

S. ASO Standard: 1 x 1 mL (BioSystems Cod. 31119). Human serum. ASO concentration is given on the label. The concentration value is traceable to the Biological Reference Material WHO 97/662 (National Institute for Biological Standards and Control, NIBSC).

*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.*

Reconstitute with 1.00 mL of distilled water. Stable for 1 month at 2-8ºC.

## REAGENT PREPARATION

Working Reagent: Pour the contents of a Reagent B vial into a Reagent A bottle (Note 1). Mix thoroughly. Stable for 30 days at 2-8ºC.

Smaller Working Reagent volumes can be prepared by mixing: 1 mL of Reagent B + 4 mL of Reagent A. Shake the Reagent B vial before pipetting.

Reagent open and kept in the refrigerated compartment of the analyzer is stable 1 month.

## SAMPLES

Serum collected by standard procedures.

Anti-streptolysin O in serum is stable for 7 days at 2-8ºC.

## REFERENCE VALUES

Serum[2]

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

This range is given for orientation only; each laboratory should establish its own reference range.

## CALIBRATION

It is recommended to do a reagent blank every day and a calibration at least every 1 month, after reagent lot change or as required by quality control procedures.

## ASSAY PARAMETERS

| | | A25 | A15 |
|---|---|---|---|
| GENERAL | Test name | ASO | ASO |
| | Analysis mode | mono. end point | mono. end point |
| | Sample type | SER | SER |
| | Units | IU/mL | IU/mL |
| | Reaction type | increasing | increasing |
| | Turbidimetry test | yes | yes |
| | Decimals | 0 | 0 |
| | No. of replicates | 1 | 1 |
| | Test name in patient report | - | - |
| PROCEDURE | Reading | bichromatic | bichromatic |
| Volumes | Sample | 3 | 3 |
| | Reagent 1 | 300 | 300 |
| | Reagent 2 | - | - |
| | Washing | 1.2 | 1.2 |
| | Predilution factor | - | - |
| | Postdilution factor | 2 | 2 |
| Filters | Main | 535 | 535 |
| | Reference | 670 | 670 |
| Times | Reading 1 | 180 s | 192 s |
| | Reading 2 | - | - |
| | Reagent 2 | - | - |
| CALIBRATION | Calibration type | specific | specific |
| | No. of calibrators | 1 | 1 |
| | Calibrator replicates | 3 | 3 |
| | Blank replicates | 3 | 3 |
| | Calibration curve | - | - |
| OPTIONS | Blank absorbance limit | 0.900 | 0.900 |
| | Kinetic blank limit | - | - |
| | Linearity limit | 800 | 800 |

## QUALITY CONTROL

It is recommended to use the Rheumatoid Control Serum level I (Cod. 31213) and II (Cod. 31214) to verify the performance of the measurement procedure.

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

## METROLOGICAL CHARACTERISTICS

The following data were obtained using an A25 analyser. Results are similar with A15. Details on evaluation data are available on request.

– Detection limit: 14.3 IU/mL ASO
– Linearity limit: 800 IU/mL ASO. For higher values dilute sample 1/5 with distilled water and repeat measurement.
– Repeatibility (within run):

| Mean concentration | CV | n |
|---|---|---|
| 205 IU/mL | 4.5 % | 20 |
| 349 IU/mL | 3.4 % | 20 |

– Reproducibility (run to run):

| Mean concentration | CV | n |
|---|---|---|
| 205 IU/mL | 4.8 % | 25 |
| 349 IU/mL | 4.2 % | 25 |

– Trueness: Results obtained with this procedure did not show systematic differences when compared with a reference procedure. 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[7].

## DIAGNOSTIC CHARACTERISTICS

Anti-streptolysin O are the specific antibodies to streptolysin O, an extracellular enzyme produced by Lancefield group A, β-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 [3-6].

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

## NOTES

1. Shake the Reagent B vial gently before pouring its contents into the Reagent A bottle. It is advisable to wash the Reagent B vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

## BIBLIOGRAPHY


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