

COD 31323 1 x 20 mL	COD 31923 1 x 50 mL	COD 31031 2 x 200 mL
STORE AT 2-8°C		
Reagents for measurement of ASO concentration Only for <i>in vitro</i> use in the clinical laboratory		

ANTI-STREPTOLYSIN O (ASO)



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 turbidimetry¹.

CONTENTS

	COD 31323	COD 31923	COD 31031
A. Reagent	1 x 16 mL	1 x 40 mL	2 x 160 mL
B. Reagent	1 x 4 mL	1 x 10 mL	2 x 40 mL

COMPOSITION

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

STORAGE

Store at 2-8°C.

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.

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 2-8°C.

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 2-8°C.

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.

ADDITIONAL EQUIPMENT

- Thermostatic water bath at 37°C.
- Analyzer, spectrophotometer or photometer able to read at 540 ± 20 nm.

SAMPLES

Serum collected by standard procedures.

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

PROCEDURE

- Bring the Working Reagent and the instrument to 37°C.
- Pipette into a cuvette (Notes 1, 2):

Working Reagent	1.0 mL
Standard (S) or Sample	10 µL

- Mix and insert cuvette into the instrument. Start stopwatch.
- Record the absorbance at 540 nm after 10 seconds (A_1) and after 2 minutes (A_2).

CALIBRATION

A calibration is recommended at least every 2 months, after reagent lot change or as required by quality control procedures.

CALCULATIONS

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

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

REFERENCE VALUES

Serum²

Adults: < 200 IU/mL

Children: < 150 IU/mL

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

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

- Detection limit: 3 IU/mL ASO.
- Linearity limit: 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..

- Repeatability (within run):

Mean concentration	CV	n
200 IU/mL	3.4 %	20
366 IU/mL	3.4 %	20

- Reproducibility (run to run):

Mean concentration	CV	n
200 IU/mL	3.6 %	25
366 IU/mL	3.4 %	25

- 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 interfere⁷.

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

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

- 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.
- These reagents may be used in several automatic analysers. Instructions for many of them are available on request.
- The linearity limit depends on the sample to reagent ratio. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

BIBLIOGRAPHY

- Borque L, Rus A, Dubois H. Automated determination of streptolysin O antibodies by turbidimetric latex immunoassay method. *J Clin Immunoassay* 1992; 15: 182-6.
- Klein GC, Baker CN, Jones WL. Upper limits of normal antistreptolysin O and antideoxyribonuclease B titers. *Appl Microbiol* 1971; 21: 758-60.
- Bisno AL. Group A streptococcal infections and acute rheumatic fever. *N Engl J Med* 1991; 325: 783-93.
- Stevens DL. Invasive group A streptococcal disease. *Clin Infect Dis* 1992; 14: 2-11.
- Immunology and Serology in Laboratory Medicine, 2nd edition. Turgeon mL. Mosby, 1996.
- Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.
- Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.