



SUMMARY

β -hemolytic streptococcus group A produces several toxins that can act as antigens. One of these toxins is the streptolysin O that produces specific antibodies on the affected organism. The antibody level is directly related to the disease and remains high in chronic patients. Quantitative determination allows to monitoring the disease and differentiates chronic patients from those who are in a remission phase.

PRINCIPLE

The anti-streptolysin antibodies present in the sample, are capable of agglutinating latex particles coated with streptolysin O. The turbidity produced by the latex particles agglutination is proportional to the anti-streptolysin O (ASO) concentration in the sample and can be measured spectrophotometrically.

PROVIDED REAGENTS

A. Reagent A: glycine buffer solution, pH 8.0.

B. Reagent B: suspension of evenly sized latex particles, coated with streptolysin O.

NON-PROVIDED REAGENTS

- Wiener lab.'s **ASO Calibrador Turbitest AA**.
- Saline solution
- Distilled water

INSTRUCTIONS FOR USE

Provided Reagents: ready to use.

The Reagent B must be homogenized by gentle inversion several times before use.

WARNINGS

Reagents are for "in vitro" diagnostic use.

All samples from patients should be handled as capable of transmitting infection.

Use the reagents according to the working procedures for clinical laboratories.

The reagents and samples should be discarded according to the local regulations in force.

STABILITY AND STORAGE INSTRUCTIONS

Provided Reagents: stable in refrigerator (2-10°C) until the expiration date shown on the box. Do not freeze.

SAMPLE

Serum

- a) Collection:** obtain in the usual way.
- b) Additives:** not required.

c) Known interfering substances: do not use hemolyzed, lipemic or contaminated sera.

d) Stability and storage instructions: the sample should be preferably fresh. In case it cannot be processed immediately, the sample can be kept for 2 or 3 days refrigerated (2-10°C) or up to 3 months frozen (-20°C). Avoid repeated freezing and thawing.

REQUIRED MATERIAL (non-provided)

- Spectrophotometer.
- Spectrophotometric cuvettes.
- Micropipettes and pipettes for measuring stated volumes.
- Kahn or hemolysis tubes.
- Stopwatch.

ASSAY CONDITIONS

- Wavelength: 600 nm
- Reaction temperature: room temperature (25°C), it can range between 22 and 30°C.
- Reaction time: 20 minutes

PROCEDURE

The samples and the Calibrador are processed without a previous dilution.

In Kahn tubes labeled B (Blank), C (ASO Calibrador) and U (Unknown), place:

	B	C	U
Sample	-	-	10 ul
ASO Calibrador	-	10 ul	-
Distilled water	10 ul	-	-
Reagent A	300 ul	300 ul	300 ul
Reagent B	500 ul	500 ul	500 ul

Homogenize and incubate 20 minutes at room temperature. Read the Blank (A_B), ASO Calibrador (A_C) and Sample (A_U) absorbances at 600 nm, setting the instrument to zero with distilled water.

CALCULATIONS

$$\text{ASO (IU/ml)} = \frac{A_U - A_B}{A_C - A_B} \times \text{Calibrador concentration}$$

Samples with concentrations above 1,000 IU/ml must be diluted 1:2 with saline solution and processed again. Multiply the obtained result by 2.

QUALITY CONTROL METHOD

Wiener lab.'s **Control Inmunológico nivel 1** or **Control Inmunológico nivel 2 Turbitest AA**.

The Control should be processed in the same manner as the samples.

REFERENCE VALUES

0-200 IU/ml

Each laboratory should set its own reference values.

Two or more periodic determinations should be performed to monitor the development of the disease.

SI SYSTEM UNITS CONVERSION

ASO (IU/ml) x 1 = ASO (UTodd/ml)

PROCEDURE LIMITATIONS

Turbidity and particles in the sample may interfere with the test. Therefore, the particles that may be the result of an incomplete coagulation or protein denaturalization must be removed by centrifugation before testing the sample.

PERFORMANCE

a) Reproducibility: simultaneously processing 10 replicates of one sample, the following results were obtained:

Level	S.D.	C.V.
119 IU/ml	± 1.21 IU/ml	1.02 %
279.4 IU/ml	± 1.87 IU/ml	0.67 %

b) Sensitivity: 20 IU/ml

c) Dynamic range: 20 - 1,000 IU/ml

PARAMETERS FOR AUTOANALYZERS

Refer to the specific applications of each autoanalyzer.

WIENER LAB. PROVIDES

- 1 x 12 ml Reagent A
1 x 15 ml Reagent B
(Cat. 1073261)

- 1 x 12 ml Reagent A
1 x 15 ml Reagent B
(Cat. 1009349)

- 1 x 12 ml Reagent A
1 x 15 ml Reagent B
(Cat. 1009221)

- 1 x 12 ml Reagent A
1 x 15 ml Reagent B
(Cat. 1009641)

REFERENCES

- Otsuji, S. - J. Clin. Lab. Anal. 4:241, 1990.
- Henkel, E. - J. Clin. Chem. Clin. Biochem. 22:919, 1984.
- Curtis, G. - J. Clin. Pathol. 41:1331, 1988.

SYMBOLS

The following symbols are used in packaging for Wiener lab. diagnostic reagents kits.



This product fulfills the requirements of the European Directive 98/79 EC for "in vitro" diagnostic medical devices

	Authorized representative in the European Community
	"In vitro" diagnostic medical device
	Contains sufficient for <n> tests
	Use by
	Temperature limitation (store at)
	Do not freeze
	Biological risks
	Volume after reconstitution
	Contents
	Batch code
	Manufactured by:
	Harmful
	Corrosive / Caustic
	Irritant
	Consult instructions for use
	Calibrator
	Control
	Positive Control
	Negative Control
	Catalog number

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