



ANTI-O-STREPTOLYSIN (ASO-ASL)

Qualitative and semiquantitative determination of anti-o-streptolysin by agglutination to latex

TEST SUMMARY

Anti-O-Streptolysin antibodies contained in the serum, produce agglutination of latex particles coated with O-Streptolysin.

SAMPLES

Fresh serum. Stability 7 days at 2-8°C. For longer periods of time it is recommended to freeze samples at -20°C. Frozen samples must be totally unfrozen and brought to room temperature before using. Samples in which turbidity is observed must be cleared by centrifugation before being analysed.

REAGENTS

Latex

Latex particles coated with O-Streptolysin; conservative and stabilizer.

Positive control

Human base stabilized solution of anti-O-streptolysin antibodies with a titre that gives a clear agglutination.

Negative control

Proteic solution not reactive with latex.

All reagents contain 0.095% of sodium azide.

REAGENTS PREPARATION AND STORAGE

Reagents are ready for the use.

The latex suspension must be resuspended with much care. When the suspension becomes homogeneous by sweet inversion, it is necessary to fill and to empty the dosage's pipette many times.

Stability: the components of this kit will remain stable until the expiration date stated on the label, when stored at 2-8°C. Do not freeze.

MATERIAL REQUIRED BUT NOT SUPPLIED

Physiologic solution.

COD. AK00310 Slide and disposable stirrers.

PRECAUTIONS

Reagent may contain not reactive and conservative components. It is opportune to avoid contacts with the skin and do not swallow.

Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

QUALITATIVE PROCEDURE

Reagents	Sample	Positive control	Negative control
Sample	50 µl (1 gt)	--	--
Control +	--	50 µl (1 gt)	--
Control -	--	--	50 µl (1 gt)
Latex	50 µl (1 gt)	50 µl (1 gt)	50 µl (1 gt)

Mix using disposable stirrers and spreading homogeneously the mixture on the slide, then, shake slide for 2 minutes by a sweet rotating motion or by a stirrer at 100 r.p.m., and observe eventual agglutination using artificial light.

RESULTS INTERPRETATION

POSITIVE: A clear agglutination within 2 minutes.
NEGATIVE: No agglutination within 2 minutes.

In case of positivity it is opportune to titre semiquantitatively the serum.

SEMIQUANTITATIVE PROCEDURE

Prearrange serial dilution of the serum, pipetting in five slide areas, 50 µl of physiologic solution and 50 µl of sample in the first area. Using the pipette (inspiring and discharging many times) mix carefully contents of first area and transfer 50 µl in the following area etc. Discharge 50 µl from last area. Dispense latex suspension, shake, and after 2 minutes observe agglutination. The titre is given by last clear agglutination. Procedure is summarized in the scheme below same.

Reagents	Area 1	Area 2	Area 3	Area 4	Area 5
Physiologic	50 µl	50 µl	50 µl	50 µl	50 µl
Sample	50 µl	25 µl	50 µl from 1	50 µl from 2	50 µl from 3
Reject 50 µl from last area					
Latex	50 µl	50 µl	50 µl	50 µl	50 µl
Titre	400 UI/ml	600 UI/ml	800 UI/ml	1200 UI/ml	1600 UI/ml

EXPECTED VALUES

95% of healthy adults have ASO titres of 200 IU/ml or less, the highest titres been found in school children with titres up to 250 IU/ml. Since a single ASO determination does not provide much information unless is high, titrations at bi-weekly intervals for 4 to 6 weeks of the doubtful cases are advisable to follow the evolution of the disease. The ASO titres resulting from ordinary streptococcal infections and acute rheumatic fever differ in that the titre of the alter condition is usually much higher and persists for a longer period of time.

CLINICAL SIGNIFICANCE

Elevated ASO serum titres occur in response to infection with hemolytic streptococci of group A, C and G, producers of streptolysin O, an extracellular protein of enzymatic character with strong antigenic properties. Immunochemical assay of these specific antibodies to streptococcal metabolites provide valuable information to establish a diagnosis of streptococcal infections (acute rheumatic fever, glomerulonephritis).

NOTE

- If reaction's times are bigger than 2 minutes, they may cause a supervaluation of samples concentrations.
- Human sera used in controls have been found negative in the reaction with HIV and HBsAg. However, they should be handled with care.
- If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.

CALIBRATION

Positive and Negative control sera should be always used to distinguish an eventual background's agglutination of reactive.

TEST PERFORMANCE

Sensitivity

Test gives positive results as from concentrations of 200 UI/ml.

Not happened phenomenon of prozone in ASO concentrations studied until 1500 UI/ml.

Specificity

A comparison with an available commercial method gave following results on 118 samples compared, giving a specificity = 98%:

		LTA srl		TOT.
		+	-	
COMPETITORS	+	48	1	49
	-	2	67	69
	TOT.	50	68	118

Interferences

Any interferences are produced with :

Haemoglobin	≤ 1000 mg/dl
Bilirubin	≤ 20 mg/dl
Lipids	≤ 1000 mg/dl
RF	≤ 300 UI/ml

Lipemic or turbid samples may give false positivity.

WASTE DISPOSAL

Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

PACKAGING

CODE AK00310 (100 TESTS)
Latex 1 x 5 ml

CODE AK00311 (100 TESTS)
Latex 1 x 5 ml
Positive control 1 x 0.5 ml
Negative control 1 x 0.5 ml
Slide black spot 3
Stirrers 50

CODE AK00305 (ASO Controls)
Positive control 1 x 0.5 ml
Negative control 1 x 0.5 ml

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SYMBOLS

- IVD** Only for IVD use
LOT Lot of manufacturing
REF Code number
 Storage temperature interval
 Expiration date
 Warning, read enclosed documents
 Read the directions
 Biological risk

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