

Antistreptolysin O (ASO) Turbi Latex

REF: 559 001 100 test
R1 Buffer 2 X 20 ml
R2 Latex 1 X 10 ml

Intended Use

In vitro diagnostic reagents for the quantitative determination of Antistreptolysin O (ASO) in human serum by means of particle-enhanced turbidimetric immunoassay.

Background

Immunological testing for specific antibodies to streptococcal metabolites provides important information regarding a prior streptococcal infection. Antibodies are formed against both the pathogen itself and its metabolic products. An example for the latter is the antibody against streptolysin O, an enzyme secreted by beta-haemolytic streptococci of the Landfield Group A. Antistreptolysin O (ASO) testing is thus used for the diagnosis of non-suppurative complications of the infections caused by these pathogens: acute rheumatic fever or acute poststreptococcal glomerulonephritis. In the determination of antibodies to various streptococcal exoenzymes preference is to be given to anti-streptolysin O, since this sensitive parameter is found to be elevated in about 80 to 85% of cases.

Test Principle

The present ASO test is based upon the reactions between antibodies against streptolysin O (ASO) and latex particles bound streptolysin O. ASO values are determined photometrically.

Reagents

R1 Diluent

Trisbuffer 20mmol/L, pH 8.2. Sodium azide 0.95 g/L.

R2 Latex reagent

Latex particles coated with streptolysin O, pH 10.0
Sodium azide 0.95 g/L.

Calibrator

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

All raw materials of human origin used in the manufacture of this product showed no reactivity when tested for HBsAg, anti-HIV-1/2 and HCV with commercially available test methods. However, this product should be handled as though capable of transmitting infectious diseases.

Precautions and Warnings

For in vitro diagnostic use only. Do not pipette by mouth. Reagents containing sodium azide must be handled with precaution. Sodium azide can form explosive azides with lead and copper plumbing. Since absence of infectious agents cannot be proven, all specimens and reagents obtained from human blood should always be handled with precaution using established good laboratory practices.

Disposal of all waste material should be in accordance with local guidelines.










As with other diagnostic tests, results should be interpreted considering all other test results and the clinical situation of the patient.

Storage and Stability

Reagents in the original vial is stable to the expiration date on the vial label when capped and stored at (2 - 8 °C). Immediately following the completion of an assay run, the reagent vial should be capped until next use in order to maximize curve stability. Do not freeze reagents.

The ASO latex reagent should have a white, turbid appearance free

SYMBOLS IN PRODUCT LABELLING

	Authorised Representative		Temperature Limitation
	For in-vitro diagnostic use		Use by/Expiration Date
	Batch Code/Lot number		CAUTION. Consult instructions for use
	Catalogue Number		Manufactured by
	Consult instructions for use		

of granular particulate. Visible agglutination or precipitation may be a sign of deterioration, and the reagent should be discarded.

The ASO diluent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarded.

Specimen Collection and Preparation

Serum specimens should be collected by venipuncture following good laboratory practices. Suitable assay specimens are human serum samples, as fresh as possible (stored up to 2 days at 2 - 8 °C) or deep-frozen. Any additional clotting or precipitation which occurs due to the freeze/thaw cycle should be removed by centrifugation prior to assay.

Heavily lipemic sera may lead to a non-specific reaction due to chylomicrons. Lipemic specimens, or turbid frozen specimens after thawing, must be clarified before the assay by high-speed centrifugation (15 min at approx. 15.000 rpm).

Reagent Preparation and Stability

Working Reagent is prepared with 1 part of Latex Reagent and 4 parts of Diluent. Prepare a fresh WR based on its workload. Shake gently the reagents before pipetting.
e.g. 400 µl Diluent + 100 µl Latex Reagent.

stability : 1 month at at 2 - 8 °C.

ASO Calibrator: Reconstitute with 1 ml distilled water. mix gently and incubate at room temperature for 10 minutes before use.

Stability: 1 month at at 2 - 8 °C or 3 months at at -20 °C

Quality Control

Control sera are recommended to monitor the performance of manual and automated assay procedures. Each laboratory should establish its own Quality Control Scheme and corrective actions if controls do not meet the acceptable tolerances.

Procedure

1 - Bring the reagents and the photometer to 37°C

2 - Assay conditions:

Wavelength 540 nm (530 -550 nm)
Temperature 37°C
Cuvette 1cm light path

3 - Adjust the instrument to zero with distilled water .

4 - Pipette into a cuvette :

Working Reagent	500 µl
Calibrator or Sample	5 µl

5. Mix and read absorbance immediately (A1) and after 2 min (A2) of the sample addition.

Calculation

$$\frac{(A_2 - A_1)_{\text{sample}}}{(A_2 - A_1)_{\text{calibrator}}} \times \text{Calibrator concentration} = \text{IU/ml ASO}$$

Sensitivity

Up to 20 IU/mL.

Linearity

Up to 800 IU/mL.

specimens showing higher concentration should be diluted 1+2 using physiological saline and repeat the assay (result×3).

Expected Values

Normal values < 200 IU/ml (adults) and 100 IU/ml (children<5 years old).

Each laboratory should establish an expected range for the geographical area in which it is located.

interferences

Hemoglobin (10 g/L) , bilirubin (20 mg/dL) and lipemia (10 g/L) ,and rheumatoid factors (600 IU/ml) do not interfere.Other substances may interfere6.

References

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ORDERING INFORMATION	
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559 001	100 test



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