SPECTRUM

The Creative Approach to Bioscience

Antistreptolysin O (ASO)
Turbi Latex

REF: 559 001 **100 test**
R1 Buffer reagent 2 X 20 ml
R2 Latex reagent 1 X10 ml
C Calibator 1 X 1 ml

REF: 559 002 100 test
Without Calibrator

REF: 559 003 **50 test**
R1 Buffer reagent 1 X 20 ml
R2 Latex reagent 1 X 5 ml
C Calibator 1 X 1 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 betahaemolytic 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 Buffer reagent
Trisbuffer 20mmol/L, pH8.2.
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

Reagent in the original vial is stable to the expiration date stated on the vial label when capped and stored at (2 - 8 ºC). Do not freeze reagents.Open vial is stable for 3 months when stored at (2 - 8 ºC).

SYMBOLS IN PRODUCT LABELLING

EC REP Authorised Representative	Use by/Expiration Date
IVD For in-vitro diagnostic use	CAUTION. Consult instructions for use
LOT Batch Code/Lot number	Manufactured by
REF Catalogue Number	(Xi) - Irritant
Consult instructions for use	
Temperature Limitation	

Deterioration

The ASO latex reagent should have a white, turbid appearance free of granular particulate. Visible agglutination or precipitation may be a sign of deterioration and the reagent should be discarded.

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

Reagent Preparation and Stability

Working Reagent(WR) is prepared with 1 part of Latex Reagent and 4 parts of Buffer reagent. Prepare a fresh WR based on the workload. Shake gently the reagents before pipetting. e.g.400µl Buffer reagent + 100 µl Latex Reagent.
Stability : 1 month at 2 - 8 ºC.

ASO Calibrator: Reconstitute with 1 ml distillid water. Mix gently and incubate at room temperature for 10 minutes before use.
Stability: 1 month at 2 - 8 ºC or 3 months at -20 ºC

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 ºC) 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).

Procedure

1. Bring the reagents and the photometer to 37ºC

2. Assay conditions:
Wavelength 540 nm (530 -550 nm)
Temperature 37ºC
Cuvette 1cm light path
Zero adjustmnet distilled water .

3. Pipette into a cuvette :

Working Reagent	500 µl
Calibrator or Sample	5 µl

4. Mix and read absorbance immediately (A_1) and after 2 minutes read (A2).

Calculation

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

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.

Quality Control

Control sera are recommended to monitor the perfomance 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.

Performance characteristics

Detection limit

Values less than 20 IU/mL give non-reproducible results.

Prozone effect

No prozone effect was detected up to 1000 IU/mL.

Precision

The reagent has been tested for 20 days, using three different ASO concentrations in a EP5-based study.

EP5	CV (%)		
	+/- 100 IU/mL	+/- 200 IU/mL	+/- 400 IU/mL
Total	6.4%	5.7%	5.1%
Within Run	2.4%	1.7%	1.4%
Between Run	3.6%	4.2%	4.9%
Between Day	4.7%	3.5%	0.7%

Accuracy

Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 60 samples of different concentrations of ASO were assayed. The correlation coefficient (r) was 0.99 and the regression equation y = 0.915x –4.844.

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).

Interferences

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

Waste Disposal

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

References

1- Tadzynsky LA, Ryan ME. Diagnostic of rheumatoid fever. A guide to criterial and manifestations. Postgrad Med 1986;79:295.
2- Bach GL, Cadotte R, Wiatr RA, et al. Latex antiestreptolysin O test as a tube dilution procedure. Am J Clin Pathol 1972; 57:209.
3- Rantz LA, Randall E. A modification of the technic for determination of the antiestreptolysin titer. Proc Soc Exp Biol Med 1945; 59:22.
4- Curtis GDW, Kraak WAG, Mitchell RG. Comparison of latex and hemolysis tests for determination of antiestreptolysin O (ASO) antibodies. J Clin Pathol 1988; 41: 1331.
5- Passing H, Bablok W. A new biometrical procedure for testing the equality of measurements from two analytical methods.
6- Application of linear regression procedures for method comparison studies. Part I. J Clin Chem Clin Biochem 1983;21:709-20.

ORDERING INFORMATION	
CATALOG NO.	QUANTITY
559 001	100 test
559 002	100 test Without Calibrator
559 003	50 test

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CE

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