BIOLATEX, S.L.
POL. INDUSTRIAL LA PORTALADA
CALAHORRA, 4 · PAB. 6
26006 LOGROÑO (SPAIN)
TEL.: (34) 941 270 047
FAX: (34) 941 271 077
INFO@BIOLATEX.COM

ANTISTREPTOLYSIN O

REF: K-9550M

MONOREAGENT PROCEDURE

Product for In Vitro Diagnostic use. For the quantitative determination of Antistreptolysin O (ASO) in serum by means of particle-enhanced turbidimetric immunoassay.

Diagnostic Relevance

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.

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

Each kit of ASO Monoreagent contains:

A.- Buffer – 45 mL Phosphate buffer, pH: 7,0, containing protein stabilizers and 0,09 % sodium azide as preservative.

B.- Latex reagent – 5 mL polystyrene particles bound Streptolysin in a glycin buffer (0.1 M, pH: 8,2), containing NaCL (0,15M) and bovine serum albumin (0,5%). Preservative: Sodium azide 0,075%.

C.- Calibrator – 1 mL. Human - based reference fluid. Preservative: sodium azide, 0.075 %. 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

Reagent Preparation

Working Reagent is prepared with 1 part of Latex Reagent and 9 parts of Buffer Reagent. Prepare a fresh WR based on its workload. Shake gently the reagents before pipetting.

Calibration Curve and Controls

Analytical Range up to 940 IU/mL.

Calibrator 1	100 µl of Biolatex ASO Calibrator*
Calibrator 2	100 µl of Calibrator 1 + 100 µl of Saline Solution
Calibrator 3	100 µl of Calibrator 2 + 100 µl of Saline Solution
Calibrator 4	100 µl of Calibrator 3 + 100 µl of Saline Solution
Calibrator 5	100 µl of Saline Solution

(*) See values on the label or on the insert. Multiply by the appropriate factor.

For quality control use Biolatex Control or other suitable control material. The control intervals and limits must be adapted to the individual laboratory requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits. Control must be assayed and evaluated as for patient samples.

Storage and Stability

Reagents in the original vial is stable to the expiration date on the vial label when capped and stored at +2 - +8ºC. Immediately following the completion of an assay run, the reagent vial should be capped until next use in order to maximize curve stability. Once opened the reagent can be used within 1 month if stored tightly closed at +2 - +8ºC after use. Do not freeze reagents.

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 sign of deterioration and reagent should be discarded.

WR is stable for up to one month at 4ºC. **It is recommended that each Laboratory prepares a fresh Working Reagent based on its workload.**

Precautions

For in vitro diagnostic use only. Do not pipette by mouth. Reagents containing sodium azide must be handled with precaution. Sodium azide can

BIOLATEX, S.L.
POL. INDUSTRIAL LA PORTALADA
CALAHORRA, 4 · PAB. 6
26006 LOGROÑO (SPAIN)
TEL.: (34) 941 270 047
FAX: (34) 941 271 077
INFO@BIOLATEX.COM

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.

Materials required

Spectrophotometric analyser. Saline solution. Controls.

Specimens

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...+8ºC) 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

Wavelength		550 nm	
Temperature		37ºC	
Cuvette		1cm light path	
Measurement against distilled water blank.			
Bring the reagents at 37ºC and pipette:			
	Calibrator	Sample	Blank
Calibrator	5 µl	---	---
Sample	---	5 µl	---
Distilled Water	---	---	5 µl
Work. Reagent	500 µl	500 µl	500 µl
Mix and measure absorbance immediately (A1) incubate 2 min (37ºC), after incubation read absorbance (A2).			

Calculation

Plot the calibration curve and the sample concentration is obtained by interpolation the sample absorbance (A2-A1) in the calibration curve.

If is an one point calibration:

$$\frac{(A2-A1)_{sample} - (A2-A1)_{blank}}{(A2-A1)_{calibrator} - (A2-A1)_{blank}} x Calibrator Concentration$$

Reference Values

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

Values < 250 IU/ml are within the normal range. Children could have greater values.

Specific Performance Characteristics

As is well known, the analytical characteristics of a clinical chemistry reagent depend on both the reagents and the instrument used. Multicenter studies indicate important differences in analytical characteristics among similar instruments. Therefore, the data must be calculated by each instrument.

Literature

Tadzynsky LA, Ryan ME. Diagnostic of rheumatoid fever. A guide to criterial and manifestations. Postgrad Med 1986; 79:295.

Bach GL, Cadotte R, Wiatr RA, et al. Latex antiestreptolysin O test as a tube dilution procedure. Am J Clin Pathol 1972; 57: 209.

Rantz LA, Randall E. A modification of the technic for determination of the antiestreptolysin titer. Proc Soc Exp Biol Med 1945; 59:22.

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.

Passing H, Bablok W. A new biometrical procedure for testing the equality of measurements from two analytical methods.

Young DS. Effects of Drugs on Clinical Laboratory Test. 5th Edition, AACC Press, 2000.

Application of linear regression procedures for method comparison studies. Part I. J Clin Chem Clin Biochem 1983; 21:709-20.

Sonderdruck aus DG Klinische Chemie Mitteilungen 1995; 26: 207 – 224

BL, SL. C/Calahorra 4 – 6.26006 LO-Spain

December 07

Significados de los símbolos indicados en las etiquetas. Explanation of symbols used on labelling. Explication des symbols figurant sur les etiquettes. Spiegazione dei simboli utilizzati sull'eticheta. Significado dos símbolos indicados nas etiquetas. Erläuterung der symbole auf den etiketten.

Fecha de Caducidad Expirate Date Date de Péremption Data di Scadenza Data Expiração Verwendbar bis	Temperatura de almacén Storage Temperature Temperature de Conservation Temperatura de Conservazione Temperatura de Conservação Lagertemperatur	Número de Lote Lot Number Número de Lot Numero di Lotto Número de Lote Chargen-Nr	Para Diagnóstico In Vitro For In Vitro Diagnostic Usage In Vitro Per Uso Diagnostico In Vitro Utilizar em Diagnostico In Vitro In Vitro Diagnosticum	Número de catálogo Catalog Number Numéro de catalogue Numero di catalogo Número de catálogo Katalognummer	Conformidad Europea European Conformity Conformité aux normes européennes Conformità europea Comformidade com as normas europeias CE-Konformitätskennzeichnung	Fabricado por Manufactured by Fabriqué par Fabbricato da Fabricado por Hergestellt	REAG Reactivo Reagent Réactif Reagenti Reagente Reagenz	CAL Calibrador Calibrator Calibrateur Calibratore Calibrador Kalibrator	Buffer Tampón Buffer Tampon Tampone Buffer Puffer	LYOPH Liofilizado Lyophilised Lyophilisé Liofilo Liofilizado Lyophilisiert	Conc. Concentración Concentration Concentration Concentrazione Concentraçao Koncentration	Control H / Control L Control Alto / Control Bajo Control High / Control Low Contrôle élevé / Contrôle Bas Controllo Alto / Controllo Basso Controlo Alto / Controlo Baixo Kontrolle Hoch / Kontrolle Niegrid

CE