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ANTISTREPTOLYSIN O (ASO)

REF: L-9550T
B-9450T

Product for In Vitro Diagnostic use. The product should be used for the quantitative determination of antistreptolysin O (ASO) in human serum by the immunoturbidimetric procedure.

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 turbidimetrically using fixed-time measurement with sample blank correction. The relationship between absorbance and concentration permits a multipoint calibration with a measuring range between 0 and 900 IU/ml. The measuring temperature is 37ºC. The assay can be performed on different analytical instruments allowing turbidimetric measurements at 500 to 600 nm.

Reagents

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

B.- Latex reagent – 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%.

Precautions

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.

Materials required

Automatic analyzer. Saline solution. Calibrator. Controls.

Storage and Stability

Reagents are ready to use. Shake the latex reagent gently before dispensing its content into the appropriate plastic vials. Reagents in the original bottle are stable to the expiration date indicated on the label when capped and stored at +2…+8ºC. Do not freeze.

The ASO buffer reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarted.

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

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

The reagents are ready to use as supplied. Latex reagent should be gently shaken (invert the recipient 3-4 times) before each use.

Volume R1/working reagent:	Volume R2/start reagent:	Volume sample:
225 µl	40 µl	3 µl
Step 1: mix R1 and R2, add sample and read 1st reading immediately after mixing.		
Step 2: 6 min after read 2nd reading.		
Wavelength: 600 nm	Incubation Time at 37º C:6 min	

** Volume, time and wavelength are recommended. Adjust them depending of analyser features.*

This reagent is intended to be used in clinical chemistry analysers. Adaptations for some of them are available.

Calibration. Quality Control

Standardization: use Biolatex Calibrator or other suitable calibrator material. The method was standardized against WHO (1st International Standard for Antistreptolysin O).

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.

Calculation

The turbidimetric analysers automatically calculate the ASO concentration of each sample.

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.

Automatic Analyzer

This product is performed for use it in turbidimetric automatic analysers or in manual procedures.

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, this data must be calculated by each instrument.

(*) Analytical characteristics obtained in a single experiment in a Cobas-Mira plus analyser could be provided under demand.

Literature

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May 2004

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.

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