ANTISTREPTOLYSINO(ASO)

Product for InVitro Diagnostic use. The product should be used for the quantitative determination of antistreptolysinO (ASO) in human serum by the immunoturbidimetric procedure.

DiagnosticRelevance

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 streptolysinO, an enzyme secreted by beta-haemolytic streptococci of the Landfield GroupA. AntistreptolysinO (ASO)testing is thus used for the diagnosis of non suppurative complications of the infections caused by these pathogens :acute rheumatic fever or acute post streptococcalglomerulonephritis. In the determination of antibodies tovariousstreptococcalexoenzymespreferenceistob egiventoanti-streptolysinO, since this sensitive parameteris found to be elevate din about 80to85%ofcases.

Principle

The present ASO testis based upon the reactions between antibodies against streptolysinO (ASO) and latex particles bound streptolysinO.ASO values are determined turbidimetrically using fixed-time measurement with sample blank correction. The relationship between absorbance and concentration permits a multipoint calibrationwith ameasuringrangebetween0and 900IU/ml. The measuring temperatureis37℃.
The assay can be performed on different analytical instruments allowingturbidimetricmeasurementsat500to600n m.

Reagents

- Buffer-Phosphatebuffer,pH:7,0,containing proteinstabilizersand0,09 % sodium azideas preservative.
- Latex reagentñ polystyreneparticles bound Streptolysinin a glycinbuffer (0.1 M,pH: 8,2), containing NaCL(0,15M) and bovine serum albumin (0,5%).Preservative: Sodium azide 0,075%
- Calibrator

Precautions

For invitro diagnostic cuse 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 alwaysbe handled withprecaution usingestablished good laboratorypractices.

Disposalof allwaste material shouldbein accordancewithlocalguidelines.

Aswithotherdiagnostic tests,resultsshouldbe interpretedconsideringall othertestresultsand theclinicalsituationofthepatient.

Materialsrequired

Automaticanalyzer. Saline solution, Controls.

Storageand Stability

Reagents are readyto use. Shake the latexreagentgently beforedispensingitscontentinto the appropriate plastic vials.Reagents in the original bottlearestabletotheexpirationdate indicatedon thelabelwhencappedandstoredat +2°C+8°C.Donotfreeze.

TheASO bufferre agent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarted.

The ASOlatex reagent should have a lightly yellow, turbid appearance freeof granular particulate.Visible agglutinationor precipitation may bea signof deterioration, and there agent should be discarted.

Working reagent : shake Latex vial gently before use , prepare the necessary amount as follow : **1 ml Latex Reagent + 9 ml buffer reagent**

Specimens

Serumspecimensshouldbecollected by venipuncturefollowinggoodlaboratorypractices.
Suitable assayspecimensarehumanserum samples,asfreshaspossible(storedup to2days at +2°C+8°C) or deep-frozen. Any additional clottingor precipitationwhichoccursduetothe freeze/thawcycle shouldberemovedby centrifugationpriortoassay.

Heavilylipemicseramay 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(15minat approx.15.000 rpm).

Procedure

1- Bring the working reagent and the photometer to 37ºC.
2- Set spectrophotometer wavelength to 540 nm and adjust to zero absorbance against water.
3- Pipette into a Cuvette:

	Calibrator	Sample
Working reagent	500 µ	500 µ
Calibrator	5 µ	----
Sample		5 µ

4- Mix and read the absorbance immediately (A1) of Calibrator & sample. exactly 2 minutes later, read absorbance (A2) of Calibrator & sample.

Calibration.QualityControl

Standardization: use BIOMEDC calibrator or other suitable calibrator material. The method was standardized against WHO(1stInternational Standard for AntistreptolysinO).

For qualitycontroluseBIOMEDControlor other suitable control material. The control intervals and limits must be adapted to the individual laboratoryrequirements.Valuesobtained should fall within establishedlimits. Each laboratory shouldestablishcorrectivemeasurestobetaken if valuesfall outsidethelimits.Control mustbe assayedandevaluatedasfor patientsamples.

Calculation

(A2-A1) Sample

---------- × Calibrator Conc.

(A2-A1) Calibrator

ReferenceValues

Each laboratory shouldestablish an expected range for the geographicalarea in which it is located.

Values<200lU/mlarewithinthenormalrange. Childrencouldhavegreatervalues.

AutomaticAnalyzer

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

SpecificPerformanceCharacteristics*

Asiswellknown,theanalyticalcharacteristics ofa clinicalchemistryreagent depend on boththe reagentsandtheinstrumentused. Multicenter studies indicateimportant differences in analytical characteristics among similar instruments. Therefore, this data must be calculatedbyeachinstrument.

(*)Analyticalcharacteristicsobtainedin asingle experimentin a Cobas-Miraplus analysercould beprovidedunderdemand.

Literature

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