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LIPOPROTEIN (a) [Lp(a)]

REF: L-9520T
B-9420T

Product for In Vitro Diagnostic use. The product should be used for the quantitative determination of lipoprotein (a) [Lp(a)] in human serum by the immunoturbidimetric procedure.

Diagnostic Relevance

Lipoprotein (a) [Lp(a)] was initially though to be a genetic variant of low density lipoprotein (LDL). Lp(a) is a low density lipoprotein-like particle containing apolipoprotein B-100 disulphide-linked to one large glycoprotein called apolipoprotein (a). Apolipoprotein (a) has been shown to have a considerable degree of homology with human plasminogen. The characteristic feature of lipoprotein (a) is that it is distinct from all other serum proteins and apolipoproteins. This protein is believed to be inherited as an autosomal dominant trait and appears to be insensitive to either diet, lifestyle or most hypolipidaemic drugs.

Since its discovery by Berg in 1963, there has been a considerable rise in interest, not only in specialized research centres but also in clinical routine laboratories, in the accurate measurement of lipoprotein (a) in blood. This interest was stimulated by reports indicating that levels above 0,2 – 0,3 g/l, present in approximately 25 % of the population, are associated with an increased risk of coronary heart disease. Many investigators have confirmed that a high lipoprotein(a) concentration represents an indicator of risk for cardiovascular disease, especially when the serum LDL-cholesterol or apo B are elevated. Therefore a convenient and reliable method for the quantitation of Lp(a) in serum or plasma is important for identification of individuals at risk for developing atherosclerosis.

Principle

The Lp(a) test is based upon the reactions between Lp(a) in the sample and latex-covalently bound antibodies against human Lp(a). Lp(a) 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 800 mg/L. The measuring temperature is 37ºC. The assay can be performed on different instruments allowing turbidimetric measurements at 500 to 600 nm.

Reagents

A.- Buffer - Glycine buffer, pH 8.0. Containing protein stabilizers and < 0.1% sodium azide as preservative.

B.- Latex reagent – suspension of latex microparticles covalently bound antibodies against human Lp(a) in a glycine buffer, containing NaCL and bovine serum albumin. Preservative: Sodium azide < 0.1%.

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

The Lp(a) reagents should be stored tightly capped at +2..+8ºC when not in use. Do not freeze. Reagents in the original vials are 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 vials 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. The Lp(a) buffer reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarted. The Lp(a) 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 discarted.

Specimens

Serum specimens should be collected by venipuncture following good laboratory practices. Lp(a) remain stable for 14 days at +2...+8ºC. if the test should be performed later, it is recommended to freeze the serum. Lipemic specimens, or turbid specimens, must be clarified before the assay by high-speed centrifugation (10 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: 5 min after read 2nd reading.		
Wavelength: 600 nm	Incubation Time at 37º C: 5 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 the highly purified material. 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 Lp(a) concentration of each sample.

Reference Values

Values < 300 mg/L are within the normal range. This data must be interpreted as a guide.

Each laboratory should establish its own reference intervals.

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

Berg K. A new serum type system in man: The Lp-system. Acta Pathol. Microbiol. Scand. 1963;59:369-82.

Gaubatz JW, Heideman C, Gotto A MJr., Morriset JD, Dahlen G.H. Human plasma lipoprotein (a): Structure and properties. J.Biol. Chem.1983;258: 4582-89.

Scanu A M, Fless G M. Lipoprotein (a). J. Clin. Invest.1990; 85:1709-15.

Sandkamp M, FunkeH, Schulte H, Kohler E, Assmann G. Lipoprotein (a) is an independent risk factor for myocardial infarction at a young age. Clin Chem.1990;36: 20-3.

Rosengren A, Wilhelmsen L, Eriksson E, Risberg B, Wedel H.Lipoprotein (a) and coronary heart disease: A prospective case-control study in a general population sample of middle age men. Br. Med. J.1990; 301: 1248-51.

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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'etichets. Significado dos símbolos indicados nas etiquetas. Erläuterung der symbole auf den etiketten.

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