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Lipoprotein (a) [Lp(a)]

REF: K-9520M

MONOREAGENT PROCEDURE

In vitro diagnostic reagents for the quantitative determination of Lipoprotein (a) [Lp(a)] in serum by means of particle-enhanced turbidimetric immunoassay.

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

This Lp(a) test is based upon the reactions between Lp(a) in the sample and latex-covalently bound rabbit antihuman Lp(a) antibodies. Lp(a) values are determined photometrically.

Reagents

Each Lp(a) kit contains:

A.- Buffer – 45.5 mL of Glycine buffer, pH: 8,0, containing protein stabilizers and 0,09 % sodium azide as preservative.

B.- Latex reagent – 6.5 mL of a suspension of latex microparticles covalently bound antibodies against human Lp(a) in a glycine buffer (0,1 M, pH: 8,2), containing NaCL (0,15M) and bovine serum albumin (0,5%). Preservative: Sodium azide 0,075%..

C.- Calibrator – lyophilised for 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 7 parts of Buffer Reagent. Prepare a fresh WR based on its workload. Shake gently the reagents before pipetting.

It is recommended that each Laboratory prepares a fresh Working Reagent based on its workload.

Calibration Curve and Controls

Analytical Range up to 800 mg/L.

Calibrator 1	100 µl of Biolatex Lp(a) 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 Calibrator 4 + 100 µl of Saline Solution
Calibrator 6	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

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

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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.

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

Spectrophotometric analyser. Saline solution. Controls.

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

Wavelength			600 nm
Temperature			37ºC
Cuvette			1cm light path
Measurement against distilled water blank.			
Bring the reagents at 37ºC and pipette:			
	Calibrator	Sample	Blank
Calibrator	4 µl	---	---
Sample	---	4 µl	---
Distilled Water	---	---	4 µl
Work. Reagent	500 µl	500 µl	500 µl
Mix and measure absorbance immediately (A1) incubate 4 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

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.

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

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.

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

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

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

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