

LIPOPROTEIN (a) [Lp(a)]

REF: 550 001 50 test

R1 Buffer 1X 22 ml
R2 Latex 1 X 3.2 ml

Intended Use

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

Background

Lipoprotein (a) [Lp(a)] was initially thought 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.

Test 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

Buffer R1

Glycine buffer, pH: 8.0, containing protein stabilizers and 0.09 % sodium azide as preservative.

Latex reagent R2

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%..

Calibrator

Human - based reference fluid. Preservative: sodium azide, 0.075%. reconstitute the lyophilized calibrator vial with the amount of distilled water stated on the vial.

Stability 2 weeks after reconstitution when stored at 2-8 °C.

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

Precautions and Warnings

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.

SYMBOLS IN PRODUCT LABELLING

	Authorised Representative		Temperature Limitation
	For in-vitro diagnostic use		Use by/Expiration Date
	Batch Code/Lot number		CAUTION. Consult instructions for use
	Catalogue Number		Manufactured by
	Consult instructions for use		

As with other diagnostic tests, results should be interpreted considering all other test results and the clinical situation of the patient.

Material Required not provided

Spectrophotometric analyzer.
Saline solution.
Controls.

Storage and Stability

The Lp(a) reagents should be stored tightly capped at (2 - 8 °C) 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 - 8 °C). 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 - 8 °C) after use. The Lp(a) buffer reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarded. 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 discarded.

Specimen Collection and Preparation

Serum specimens should be collected by venipuncture following good laboratory practices. Lp(a) remain stable for 14 days at (2 - 8 °C). 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).

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.
e.g: 60 µl of latex reagent & 420 µl of buffer reagent.

Calibration curve

Calibrator 1	100 µl of Spectrum 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 Saline Solution

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

For quality control use Spectrum 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.

Procedure

Wavelength 600 nm
Temperature 37°C
Cuvette 1cm light path
Measurement against distilled water blank.
Bring the reagents at 37°C and pipette:

	Blank	Calibrator	Sample
Work. Reagent	480 µl	480 µl	480 µl
Distilled Water	4 µl	---	---
Calibrator	---	4 µl	---
Sample	---	---	4 µl

Mix and measure absorbance immediately (A1) incubate 4 min (37°C), after incubation read absorbance (A2).

Calculation

Determine Δ absorbance of the sample and each calibrator as following:

Δ absorbance of sample = $(A_2 - A_1)$ sample

Δ absorbance of each calibrator = $(A_2 - A_1)$ for each calibrator

Plot the calibration curve and obtain the result.

If is an one point calibration

$$\frac{(A_2 - A_1)_{\text{sample}} - (A_2 - A_1)_{\text{blank}}}{(A_2 - A_1)_{\text{calibrator}} - (A_2 - A_1)_{\text{blank}}} \times \text{Calibrator concentration}$$

Sensetivity

< 15 mg/L

Linearity

Up to 1000 mg/L.

Expected Values

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

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

References

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ORDERING INFORMATION	
CATALOG NO.	QUANTITY
550 001	50 test



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IFUFTI11

Rev.(2), 22/03/2014