Reactivos GPL

Barcelona, España

CE

- Lp(a)-TURBI -

LIPOPROTEIN (a)
TURBILATEX

Store at: +2+8ºC.

Presentatión:
Cod. TL040 CONT: R1 37,5 ml / R2 5 ml. / CAL 1 ml.

Procedure

Diagnostic reagent for quantitative measurement of Lipoprotein (a) in human serum.

Only for *in vitro use in clinical laboratory* (IVD)

TEST SUMMARY
Latex particles coated with human anti-Lp(a) are mixed with a serum sample.
Agglutination is formed when a sample containing Lp(a) is combined with the reagent. The degree of agglutination is directly proportional to the concentration of Lp(a) in the sample.

REAGENTS COMPOSITION

Diluent (R1)	Glycine buffer , sodium azide 0.9 g/L. Stabilizers pH 8.2.
Latex (R2)	Suspension of latex particles coated with human Lp(a), sodium azide 0.75 g/L, pH 8.2
Calibrator	Human serum: Lp(a). Concentration is stated on the vial label.
Control (Optional)	Human serum: Lp(a). Concentration is stated on the vial label. Ref.: TL042

PRECAUTIONS
Components from human origin have been tested and found to be negative for the presence of HBsAg and HCV, and of antibody to HIV (1/2). However handle cautiously as potentially infectious.

Good laboratory safety practices should be followed when handling laboratory reagents or human samples.

REAGENT PREPARATION AND STABILITY
Working reagent: Shake the latex vial gently before use. Prepare the necessary amount as follow: 1 mL Latex Reagent + 7,5 mL Diluent.
Stable for 7 days at 2-8ºC.
Do not freeze; frozen reagents could change the functionality of the test.
Immediately following the completion of an assay run, the reagent vial should be capped until next use in order to maximize curve stability.
Signs of reagent deterioration**:**

- **Visible agglutination or precipitation may be sign of deterioration and the reagent should be discarded**.

All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Stored at tightly closed at 2-*8º C*. Do not use reagents over the expiration date.

CALIBRATION
The assay is calibrated against the highly purified material. The use of other commercially available Lp(a) calibrators is not recommended.

SPECIMEN
Fresh serum. Lp(a) remains stable for 14 days at 2-8ºC. or 3 months at –20ºC. Lipemic or turbid samples, must be clarified before the assay by high speed centrifugation (10 min at 15000 rpr).

Discard contaminated specimen

MATERIAL REQUIRED BUT NOT PROVIDED
- Thermostatic bath at 37ºC.
- Spectrophotometer or photometer thermostatable at 37º C with a 600 nm.
- Cuvettes with 1 cm light path.

General laboratory equipment

TEST PROCEDURE
1. Bring the working reagent and the photometer to 37ºC.
2. Set spectrophotometer wavelength to 600 nm and adjust to zero absorbance against saline solution.
3. Pipette into a Cuvette:

	Calibrator	Sample	Blank
Working reagent (µL)	850	850	850
Saline Sol. (µL)	-	-	8
Calibrator (µL)	8	-	-
Sample (µL)	-	8	-

4. Mix and incubate 5 min (37º C). After incubation read absorbance.

CALCULATIONS
Multipoint Calibration:
1- Prepare the following dilutions of the calibrator using saline solution 1, ½, ¼, 1/8, 1/16.
2- Follow procedure as a sample and read prepare calibration curve with absorbance.
3- Calculation of sample concentration is against interpolation of the absorbance in the calibration curve.
4- Calibration Curves are stable for 14 days, after wich a new curve must be generated. Additionally, recalibration must be performed whenever reagent lots are changed or QC so indicate.

One point calibration:

$$\frac{(A_{Sample}-A_{Blank})}{(A_{Calibrator}-A_{Blank})} \times \text{Calibrator concentration} = \text{mg/L Lp(a)}$$

QUALITY CONTROL
SERUM CONTROLS are recommended to monitor the performance.

Serum controls are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES
Up to 30 mg/dL (adults).
For the children, each laboratory should establish an expected range for the geographical area in which is located.

It is suggested that each laboratory establish its own reference range

CLINICAL SIGNIFICANCE
Lp(a) is a low density lipoprotein-like particle containing Apolipoprotein B-100 dissulphide-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 Lp(a) is that it is distinct from all other serum proteins and apolipoproteins. This protein is belived to be inherited as an autosomal dominant trait and appears to be insensitive to either diet, lifestyle or most hypolipidaemic drugs. Since its discovered by Berg in 1963, there has been a considerable rise in interest, not only specialized research centres but also in clinical routine laboratories, in the accurate measurement of Lp(a) in blood. This interest was stimulated by reports indicating that levels above 200-300 mg/L, present in aprox. 25% of the population are associated with an increased risk of coronary heart disease. Many investigators have confirmed that high Lp(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 quantification of Lp(a) in serum or plasma is important for identification of individual at risk fro developing atherosclerosis.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENT PERFORMANCE
1. *Linearity limit:* Up to 800 mg/L[(note1)] (under the described assay conditions)
2. *Prozone effect:* No prozone effect was detected up to 2250 mg/L.
3. *Detection limit:* Values less than 5 mg/L give non-reproducible results.
4. *Sensitivity:* Δ 0.65 mA. IU/mL.
5. *Precision:*

	Intra-assay n=20			Inter-assay n=20		
Mean (IU/mL)	160	479	715	165	464	720
CV (%)	4.7	4.5	3.4	5.1	3.9	3.5

6. *Accuracy:* Results obtained using these reagents (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 80 Lp(a) samples were assayed. The correlation coefficient (r) was 0.957 and the regression equation was y=1.133x+4.3.

The results of the performance characteristics depend on the used analyzer.

INTERFERING SUBSTANCES
Do not interfere:
- Proteins (albumin): < 160 g/L
- Bilirubin: < 20 □mol/L
- Hemoglobin: < 10 g/L
- Lipids: < 5 g/L.

Other substances may interfere[7]

NOTES
1- Samples with higher concentrations shoud be diluted 1/5 in NaCl 9 g/L. and retested again The linearity limit depends on the sample reagent ratio. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

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