TurbiMAX LP(a)

Turbilatex / Immunoturbidometric)

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVLPAT-50	50 ml	Two Liquid Reagents with Calibrator

INTENDED USE:

TurbiMAX LP(a) is an in-vitro diagnostic kit for the Quantitative determination of Lipoprotein (a) (Lp(a) in human serum or plasma.

PRODUCT FEATURES

1. Quantitative Immunoturbido metric Assay
2. Two liquid stable reagents(Turbilatex and Diluent).
3. Linearity range 90 mg/dL
4. Calibrator provided.
5. No Prozone effect was detected upon 75 mg/dL

CLINICAL SIGNIFICANCE

Lp(a) is a low density lipoprotein-like particle containing apolipoprotein B-100 disulphide-linked to one large glycoprotein called apolipoprotein (a). Many investigators have confirmed that a high Lp(a) concentration represents an indicator of risk for cardiovascular disease, especially when serum LDL-cholesterol or Apo B are elevated. The quantification of Lp(a) in serum or plasma is important for identification of individuals at risk for developing atherosclerosis.

PRINCIPLE

The Lp(a)-turbilatex is a quantitative turbidimetric test for the measurement of Lp(a) in human serum or plasma. Latex particles coated with antibodies anti-Lp(a) are agglutinated when mixed with samples containing Lp(a). The agglutination causes an absorbance change, dependent upon the Lp(a) contents of sample that can be quantified by comparison from a calibrator of known Lp(a) concentration.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the labels when stored at 2-8ºC and the contamination is prevented during their use. Do not freeze the latex and diluent.

KIT COMPONENTS

1. Buffer Reagent R1
2. LP (a) Latex Reagent R2
3. LP (a) Calibrators : Concentration as stated on the label

COMPOSITION

Diluent (R1)	Glycine buffer 50 mmol/L, pH 9.0.Sodium azide 0.95 g/L.
Latex (R2)	Latex particles coated with mouse monoclonal anti-human Lp(a), pH 8.2. Sodium azide 0.95 g/L
LP(a)-CAL	Calibrator. Human serum. (90 mg/dl) (Lot Specific).

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

1. When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

- Discard any turbid reagent if blank reagent absorbance exceeds 1.2 at 578 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN

Fresh serum or plasma.
Stable for 7 days at 2-8ºC or 3 months at –20ºC.
The samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolized or lipemic samples.

SYSTEM PARAMETERS : One Point Calibration

Reaction Type	:	Fixed Time / Initial Rate / Two Point Kinetic
Reaction Direction	:	Increasing
Sample Volume	:	20 µl
Working Reagent Volume	:	1000 µl
Wave Length	:	570 nm (540-600 nm)
Diluted Calibrator Conc.	:	27
Flow Cell Temp.	:	37^0C
Linearity	:	90 (One Point Calibration)/ (Calibration Curve)
Zero setting with	:	Distilled Water
Units	:	IU/mL
Delay	:	5 sec.
Interval	:	120 sec

PROCEDURE:Fixed Time (One Point Calibration)

Pipette into test tubes labeled Calibrator (C) and Test (T).

Reagent	(C)	(T)
Working Reagent	1.0 ml	1.0 ml
Diluted LP(a) Calibrator	20 µl	-
Sample	-	20 µl

Mix well and read absorbances of Calibrator (C) and Test (T) against distilled water at 570 nm (540-600 nm) as follows:

Initial absorbance A1 -exactly after 5 sec.
Final absorbance A2 - exactly 120 sec. after A1
Determine ∆A for Calibrator (C) and Test (T)

CALCULATIONS :

$$\text{Lp(a) Conc.: (mg/dL)} = \frac{\text{(A2-A1) Sample}}{\text{(A2-A1) Calibrator}} \times 27 \text{ (Diluted Calibrator Concentration)}$$

Calibration Curve Prepare the following Lp(a) calibrator dilutions in NaCl 9 g/L. Multiply the concentration of the Lp(a) calibrator by the corresponding factor stated in table bellow to obtain the Lp(a) concentration of each dilution.

Calibrator dilution	1	2	3	4	5
Lp(a) Calibrator (µL)	--	25	30	75	100
NaCl 9 g/L (µL)	100	75	50	25	--
Factor	0	0.25	0.5	0.75	1.0

Calibration curve (Note 1): Calculate the absorbance difference ∆Abs **(A2-A1)** of each point of the calibration curve and plot the values obtained against the LP(a) concentration of each Calibrator dilution. LP(a) concentration in the sample is calculated by interpolation of its **(A2- A1)** in the calibration curve.

EXPECTED VALUES

Normal values up to 30 mg/dL. Each laboratory should establish its own reference range.

QUALITY CONTROL & CALIBRATION

Control Sera are recommended to monitor the performance of manual and automated assay procedures.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

PERFORMANCE CHARACTERESTICS:

1. Linearity
Linearity : 90 mg/dL

2. Sensitivity/ Limit of Detection (LOD)
The lower limit of detection is 1.5 mg/dL

3.Interferences:
Hemoglobin (5 g/L), bilirrubin (20 mg/dL), plasminogen (680 mg/dL), ascorbic ac. (200 mg/dL), rheumatoid factors (100 IU/mL) and lipemia (20 g/L), do not interfere. Other substances may interfere[5].

4. Precision:
Intra-Assay

N=20	Mean (mg/dl)	SD (mg/dl)	CV%
Control serum 1	4.62	0.22	4.74
Control serum 2	12.35	0.29	2.33
Control serum 3	24.33	0.25	1.05

Inter-Assay

N=20	Mean (mg/dl)	SD (mg/dl)	CV%
Control serum 1	4.63	0.25	5.39
Control serum 2	12.45	0.31	2.48
Control serum 3	24.1	0.26	1.07

5. Method Comparison:
Results obtained using this reagent (y) were compared to those obtained using a commercial ELISA reagent (x). 50 samples were assayed. The correlation coefficient (r) was 0.997 and the regression equation y = 1.062x + 2.021
The results of the performance characteristics depend on the analyzer used.

LIMITATIONS
1.5-90 mg/dL, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in NaCl 9 g/L and retested again. The linearity limit and measurement range depends on the sample to reagent ratio. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

WASTE DISPOSAL
Reagents must be disposed off in accordance with local regulations.

NOTES
1. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

REFERENCE

1. Gaubatz JW et al. J Biol. Chem 1983; 258: 4582 – 4589.
2. Berg KA et al. Acta Pathol Microbiol Scand 1963; 59: 369-382.
3. Scanu AM et al. J Clin Invest 1990; 85: 1709-1715.
4. Frank S et al. Eur J Clin Invest 1996; 26: 109-114.
5. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		

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