

## Quantitative determination of Lipoprotein (a) (Lp(a))

### IVD

Store 2 - 8°C.

### PRINCIPLE OF THE METHOD

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.

### 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.

### REAGENTS

<b>R1</b>	Glycine buffer 50 mmol/L, pH 9.0. Sodium azide 0.95 g/L.
<b>R2</b>	Latex particles coated with mouse monoclonal anti-human Lp(a), pH 8.2. Sodium azide 0.95 g/L.
<b>Saline Solution</b>	NaCl 9% (for samples predilution)
<b>Optional</b>	Ref.: ACC16-028 Lp(a) Control.

### CALIBRATION

The sensitivity of the assay and the target value of the calibrator have been standardized against an Internal Reference Material.

### PREPARATION

**Reagents:** Ready to use.

**Samples and Controls Pre-Dilution:** Before the use, samples and/or controls must be diluted in this way:

- 50 µL sample or control + 250 µL NaCl 9 g/L

### ADDITIONAL EQUIPMENT

- Pipette 100 - 1000 µL
- Pipette 10 - 100 µL
- Cuvettes and microstirrers (ref. code ACC16-037)

### STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C and contaminations are prevented during their use. Do not use reagents over the expiration date.

**Reagent deterioration:** Presence of particles and turbidity.

Do not freeze; frozen latex and diluent could change the functionality of the test.

### SAMPLES

Fresh serum or plasma. Stable 7 days at 2-8°C or 3 months at -20°C.

The samples with presence of fibrin should be centrifuged before testing.

Do not use highly hemolyzed or lipemic samples.

### TEST PARAMETER

Filter: set filter on position A

Reading time: 240 seconds

### PROCEDURE

1. Pipette into an appropriate number of cuvettes:

kind of reagent	µL
R1	400
R2	100

2. Incubate the cuvettes in positions 1-4 for at least 1 minute
3. Transfer each cuvette in the reading channel and, when requested on the display, add 50 µL of the diluted sample or control
4. Read the result which will appear automatically on the reader's display after 240 sec.

### QUALITY CONTROL

Control Sera are recommended to monitor the performance of the assay procedures. Vital Diagnostics Lp(a) Control Serum is available: ACC16-028.

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. Each laboratory should establish its own reference range.

### PERFORMANCE CHARACTERISTICS

1. **Linearity:** Up to 80 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.
2. **Limit detection:** Values less than 3 mg/dL give non-reproducible results.
3. **Prozone effect:** No prozone effect was detected upon 250 mg/dL.
4. **Sensitivity:** Δ 6 mA. mg/dL.
5. **Precision:**

	Mean	SD	CV%
Intra-assay (n=10)	12.35	0.29	2.33
Inter-assay (n=10)	39.10	0.66	1.70

1. **Accuracy:** 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  $y = 1.062x + 2.021$

### INTERFERENCES

Hemoglobin (5 g/L), bilirubin (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<sup>5</sup>.

### NOTES

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

### BIBLIOGRAPHY

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.

### PACKAGING

Ref.: ACC16-019	Cont.	:1 x 20 mL R1 :1 x 4 mL R2 :1 x 50 mL Saline Solution
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