SPINREACT

CE

Lp(a) -TURBI

Lp(a)-turbilatex

Latex turbidimetry

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

Store 2 - 8ºC.

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

Diluent (R1)	Glycine buffer 50 mmol/L. Preservative.
Latex (R2)	Latex particles coated with rabbit polyclonal anti-human Lp(a). Preservative.
Optional	Ref.: 1107022 Lp(a) Calibrator. Ref.: 1107024 Lp(a) Control.

CALIBRATION
The sensitivity of the assay and the target value of the calibrator have been standardized against an Internal Reference Material. It is not recommended the use of other commercially available Lp(a) calibrators.

PREPARATION
Ready for use
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 below to obtain the Lp(a) concentration of each dilution.

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

STORAGE AND STABILITY
All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Reagents should not be left inside the analyzer after use, they must be stored refrigerated at 2-8ºC. Latex may sediment. Mix reagents gently before use. Do not use reagents over the expiration date.
Do not freeze; frozen latex and diluent could change the functionality of the test.
Reagent deterioration: Presence of particles (R1, R2) and turbidity (R1).

ADDITIONAL EQUIPMENT
- MINDRAY BS-120 / BS-200E autoanalyzer.
- Laboratory equipment.

SAMPLES
Fresh serum or plasma. Stable 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.

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

QUALITY CONTROL
Control Sera are recommended to monitor the performance of manual and automated assay procedures. It should be used the SPINREACT Lp(a) Control Ref.: 1107024.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

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

MINDRAY BS-120 / BS-200E APPLICATION

PARAMETERS

Test	Lp (a) / Lp (a)	R1	240 / 240
Nº	**	R2	60 / 60
Full Name	Lp (a) / Lp (a)	Sample volume	5 / 5
Standard Nº	5 / 6	R1 Blank	
Reac. Type	Fixed T / Fixed T	Mixed Rgt Blank	
Pri. Wavelength	578 / 570	Linearity Range	3 mg/dL 80 mg/dL
Sec. Wavelength		Linearity Limit	*
Direction	Increase / Increase	Substrate Limit	*
Reac. Time	1_13 / 0_14	Factor	*
Incuba. Time		Prozone check	*
Units	mg/dL / mg/dL	q1	q2
Precision	0.1 / 0.1	q3	q4
		PC	Abs

CALIBRATION (Cal + Rgt Blk)

BS120 (MANUAL) / BS200E (AUTODILUTION)

Rule	Spline / Spline
Sensitivity	1 / 1
Replicates	2 / 2
Interval (days)	0 / 0

BS200E CALIBRATION (DILUTION) →5 CAL LEVELS + 1 WATER LEVEL

Nº CAL DIL	CONCENTRATION	DIL SAMPLE	DIL VOL	SAMPLE VOL
1	CAL *0.1	13,0	115	5,0
2	CAL *0.25	38,0	115	5,0
3	CAL *0.5	38,0	115	10,0
4	CAL *0.75	38,0	115	15,0
5	CAL*1			5,0

*Blank parameter must be performed in order to get good results in CALIB screen from main menu. The blank calibration is stable until **8 days**. After this period the blank parameter must be performed again in order to validate the calibration.*

PERFORMANCE CHARACTERISTICS
1. **Linearity:** Up to 100 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. **Quantification Limit:** Values less than 3,17 mg/dL give non-reproducible results.
3. **Prozone effect:** No prozone effect was detected upon 650 mg/dL.
4. **Precision:**

	Level 1	Level 2	Level 3
Mean (mg/dL)	18,81	34,12	47,60
SD	0,59	0,48	0,33
CV	3,15	1,42	0,69

5. **Accuracy:** The Spinreact method was compared with another manufacturer. The study was performed with 35 serum samples. Both tests were performed on a Spintech240. Both tests were calibrated with their respective calibrators. The correlation coefficient (r) was 0,9815 and the regression equation y= 1, 5734x + 1,5873.
The results of the performance characteristics depend on the analyzer used.

BIBLIOGRAPHY

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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.
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PACKAGING

Ref.: MI1107020	Cont.	R1. Diluent:1 x 20 mL R2. Latex:1 x 4 mL

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