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Lipoprotein a (LPa)

This kit is used to determine the amount of LPa in human serum.

REF: BS.1/APOA02.025.0050

CLINICAL SIGNIFICANCE

Higher than normal blood Lp(a) levels are closely associated with atherosclerosis, angina pectoris, myocardial infarction, and cerebral hemorrhage. Lp(a) is not affected by age, gender, or food, and is not correlated with other lipid changes and is not affected by most lipid-regulating drugs. In recent years, a large number of studies have concluded that serum Lp(a) levels are closely correlated with cardiovascular and cerebrovascular diseases, atherosclerosis and other diseases. In the 1988 International Lp(a) Conference, Lp(a) was identified as an independent risk factor for coronary heart disease.

METHOD PRINCIPLE

The combination of the antigen LPa and the specific antibody (sheep anti-human LPa antiserum) sensitizing particles forms an insoluble immune complex, resulting in a turbid reaction solution, the turbidity of which reflects the amount of LPa in the serum sample. The amount of LPa in the serum can be found by comparing it with the standard solution of the same treatment.

REAGENT COMPOSITION

R1: Tris(hydroxymethyl)aminomethane(Tris) 12 g/L **Preservatives the right amount**
R2: Tris(hydroxymethyl)aminomethane(Tris) 12 g/L **Preservative, BSA the right amount** **Lp(a) antibody sensitizing particles 25 ml/L**

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to the Lipoprotein a (LPa) material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien lipoprotein a (LPa) reagents are supplied ready-to-use.

All reagents are stable until expiration date stated on label when stored at 2-8°C contamination is avoided. Do not freeze and protect from light. The open-vial stability of the reagent is 18 months until expiry date.

Deterioration

The ***BioScien*** lipoprotein a (LPa) reagent is normally clear, do not use reagent if it is turbid.

SPECIMEN COLLECTION AND PRESERVATION

Serum or Plasma

Serum. 2 to 8°C stable for 3 days.

SYSTEM PARAMETERS

Wavelength	604 (540~610) nm
Optical path	1 cm
Assay type	Endpoint
Direction	Increase
Sample Reagent Ratio	4:1
Incubation Time	10 min. at 37 C
Temperature	37˚C
Zero adjustment	Reagent blank
Sensitivity	30 mg/dl
Linearity	240 mg/dL

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes, automatic pipet
- Centrifuge and spectrophotometer

ASSAY PROCEDURE

	Calibrator	*Specimen*
R1	240 µl	240 µl
Calibrator	4 µl	-
Specimen	-	4 µl
Mix well and incubator for 5 mins. at 37° C		
R2	60 µl	60 µl

Mix well & incubate for 5 min. at 37 C. Measure the absorbance of calibrator & sample.

CALCULATION

LP a concentration (mg/l) = $\frac{\text{Abs specimen}}{\text{Abs standard}}$ x Calibrator concentration.

QUALITY CONTROL

To ensure adequate quality control, it is recommended that normal and abnormal commercial control serum of known concentrations included in each run. If control values are found outside the defined range, check the instrument calibration, and reagent for problems. If control still out of range please contact ***BioScien*** technical support.

PERFORMANCE CHARACTERISTICS

Absorbance of reagent blank: wavelength 604 nm, optical diameter 1.0 cm, temperature 37°C, A0 ≤ 1.2. Analytical sensitivity: The kit tests 240mg/L of the analyte, the absorbance change value ΔA ≥ 0.05.
Linearity range: test serum samples, reagent linearity in the interval of 40-800 mg/L, the linear correlation coefficient |r| should not be less than 0.975; in the interval of 40-300 mg/L, the absolute deviation of linearity should not exceed 30 mg/L; in the interval of (300-800 mg/L, the relative deviation of linearity should not exceed ±10%.
Precision: repeatability CV ≤ 8%; relative extreme difference between batches ≤ 10%. Accuracy: Relative deviation ≤ 10%.

LIMITATIONS

1. The Kit is for in vitro diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.

INTERFERING SUBSTANCES

Bilirubin

≤ 40 mg/dL.

Hemoglobin

≤ 500 mg/dL.

Celiac

≤ 500 mg/dL did not interfere with the determination.

EXPECTED VALUES

0~300 mg/L.

REFERENCES

1. Lv Jinkai et al; Shanghai Journal of Medical Laboratory 4(2): 97.(1989)
2.Galivin, J. P. et al; Clin Lab. Assays 4:73-95.(1983)

SYMBOLS IN PRODUCT LABELLING			
IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number	⚠	Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		

EC REP

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