Please use the reagent after reading this package insert

Lp(a)

Quantitative turbidimetric latex assay for the measurement of Lp(a)

【General attention】

1. This reagent is for in vitro diagnostic use, and do not use for other purpose.
2. The doctor in charge along with clinical conditions and other laboratory results, etc. must judge the clinical diagnosis based on the result of a measurement overall.
3. Please use it according to use and the dosage regimen described in the package insert. The reliability of the result of a measurement cannot be guaranteed when use excluding described use and dosage regimen.

【Reagent Composition】

1. Buffer (R1) …… Liquid
2. Latex reagent (R2) …… Liquid

(Anti-human Lp(a) (goat) antibody sensitized latex)

【Intended use】

Measurement of Lp(a) in serum or plasma.

【Principle】

1. Principle of measurement

Antibody adsorbed latex particles and Lp(a) in the sample react immunologically, and causing the latex particles to agglutinate. This agglutination results in a change of turbidity, and the change in absorbance is a measure of the amount of Lp(a) in the sample.

2. Feature

1. Measurement principle is latex immuno turbidimetric assay.
2. It is possible to adjust to various general-purpose automatic analyzers.
3. unnecessary for preparation of reagent
4. The preprocessing of the sample (dilution of the sample) is unnecessary.

【Handling Precautions】

1. Measurement sample

Please use the fresh serum or plasma as a specimen for measurement. Please measure promptly after collecting serum, and if it is not possible to measure, preserve freezing. However, please do not repeat the freezing and thawing.

2. Interfering substance etc.

The following components hardly interfered with the test result: chyle (up to 5% of Intrafat), bilirubin F ≤50mg/dL, Hemoglobin 500mg/dL, and normal usage on blood collection of Heparin, Sodium citrate and EDTA.

3. Others

a. Storage reagents at (2-10℃), and the freezing preservation must be avoid

b. Please request material separately about the adaptation example to various automated analyzers.

【Procedure】

1. Preparation of the reagents

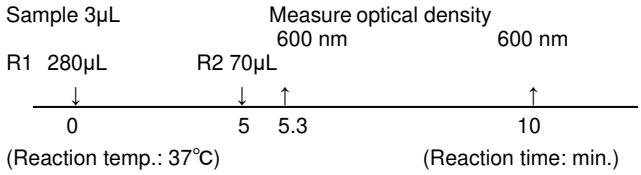
Buffer solution (R1) and Latex reagent (R2) are used as it is.

2. Stability

The reagents will remain stable until the expiration date printed on the label, when stored tightly closed at 2-10℃ and contaminations are prevented during their use.

3. Procedure

[Standard procedure]



4. Calibration

Using optional Lp(a) calibrator and measure them as sample based on the above-mentioned procedure, and made the calibration line.

【Judgment method of result】

(1) Normal reference values[4)]

<33mg/dL

(2)The nonspecific reaction can happen in various infectious diseases and autoimmune disease patients' serums. Please judge the diagnosis based on the result of a measurement overall in consideration of other inspections and clinical conditions.

【CLINICAL SIGNIFICANCE】

Lipoprotein (a) 「Lp(a)」 was discovered by K. Berg in 1963. Lp(a) is similar to low-density lipoprotein (LDL) in lipid composition but differs in protein profile. Lipid composition is similar to LDL (in the glycoprotein rich in sialic acid, a similar substance of plasminogen), and protein portion has the SS bound structure of apo B-100 with apo (a).Blood levels of Lp (a) is determined by the genetic, and is considered as an independent factor of arteriosclerosis. Lp(a) is structurally similar to plasminogen, and has been suggested to be involved deeply in the hardening of the arteries directly or via a coagulation and fibrinolysis as mediator of the fibrinolytic system.

【PERFORMANCE】

1. ANALYTICAL PERFORMANCE

1. Sensitivity

(a) When measured saline liquid as the sample, absorbance change (⊿OD) is below 0.002/min.

(b) When measure known concentration sample, absorbance change of Lp(a) concentration 20ng /dL is between 0.015 to 0.040/min, and between 0.100 to 0.250/min for Lp(a) concentration 100ng/dL

2. Accuracy

When measured the control serum of known concentration is measured, measurement value is within ±10% of the known value.

3. Reproducibility

When measure the same sample five times at the same time, the C.V of the absorbance value is 10% or less.

4. Measurement range

Measurement range of the Lp(a) in the sample is 0.5-100mg/dL.

2. Correlation

(1)Correlation performance study were conducted with commercially available EIA kit (x), resulted in a good correlation: n=58, y=1.016x - 0.212, and r=0.993.

(2)Comparing serum, plasma sample of the same patient, resulted in following correlation.
Serum (x), plasma (y): n=51, y=1.003x + 0.187, and r=0.999.

【Attention in handling for use】

1. Attention in handling (dangerous prevention)

(1) An infectious microorganism such as hepatitis B viruses might exist in the sample, please handle it assuming that there is a risk for infection.

(2) Sodium azide of 0.09w/v% is contained in the reagents as preservative. When entering eyes and mouths or adhering to the skin by mistake, flushing enough them with water as a stop-gap measure. If there is a necessity receive the doctor's treatment.

2. Directions

(1) Do not use the reagents after the expiration date.

(2) After open the reagents, use them as early as possible. When preserve them, please close the lid and preserve on a specified condition.

(3) Please do not use the bottle and the accessory in this kit for other purposes.

(4) Please set the buffer and the latex reagent at the position correctly after gently mixing by invert the bottle before measure. Please remove the bubble when bubbling.

(5) When the measurement value exceeds the measure range, please dilute with saline liquid, and measure the specimen material. Those obtained by multiplying the dilution factor in value is the measured value.

(6) Please do not use the reagent with different lot.

(7) Please make the working curve at each measurement. Moreover, please measure the calibration sample for two times or more respectively.

(8) Please use the calibrator sold separately, and refers to the manual of the goods before use.

(9) Preserve the reagent at refrigerated condition (2-10℃)and avoid the freezing.

3. Attention for Disposal

(1) Sodium azide of 0.09w/v% is contained is contained in the reagents as preservative. The sodium azide might generate the metallic azide that it reacts with the lead pipe and the copper pipe and explosiveness is strong, and flush it in volumes of water, please when you abandon it.

(2) An infectious microorganism such as hepatitis B viruses might exist in the sample, and process a used sample, the reagent container, and apparatus, etc. by sterilization, disinfection (0.5% solution of sodium hypochlorite), and incineration, etc.

(3) Please process it according to regulations of Wastes Disposal and Public Cleaning Law and Water Pollution Control Law, etc. when you abandon and apparatus, etc.

【Storage and validity period】

1. Storage ： 2～10℃
2. Validity period： 1 year after production
Expiration date is displayed on the outer box and bottle labels.

【Package】

Product Name	Contents
Lp(a) reagent	
Buffer (R1)	60mL ×1
Latex reagent (R2)	15mL ×1

〔Optional goods〕
(Product Name) (Contents)
Lp(a) Calibrator 5 conc. x 1mL each (lyophilized)
The indicated value is displayed on the label

【References】

1) Berg. K.：Acta Pathl. Microbiol. Scand., 59,369(1963).
2) McLean, J.W. et al.: Nature, 300, 132 (1987)
3) Yamashita Sumiko et al. : Rinsyokensakiki • Shiyaku, 15, 787 (1992)
4) Kuzuya Fumioet al. : Kiso to rinsyo, 26, 5411 (1992)
5) Fujita Seiichi et al. : Rinsyokensakiki • Shiyaku, 16, 39 (1993)
6) Fujino akihisa et al. : Kiso to rinsyo, 27, 563 (1993)
7) Takahashi Osamu et al. : Rinshokagaku, 22, 273 (1993)
8) Sakurabayashi Ikunosuke et al. : JJCLA, 20 : 712, (1995)

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【Manufacturing and distribution】

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