Lp(a)-F

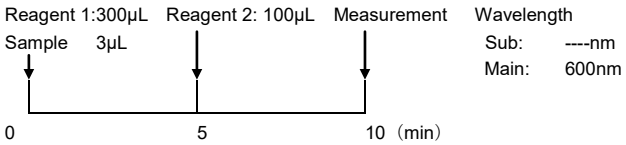
[Intended Use]
The Lp(a)-F is an in vitro assay for the quantitative determination of Lipoprotein(a) a in serum or plasma.

[Summary and explanation of the test]
Lipoprotein(a) [Lp(a)] was dicovered in 1963 by Kåre Berg. Lipoprotein(a) consists of an LDL-like particle and the specific apolipoprotein(a) [apo(a)], which is covalently bound to the apoB of the LDL like particle. High Lp(a) in blood is a risk factor for coronary heart disease (CHD), cerebrovascular disease (CVD), atherosclerosis, thrombosis, and stroke.

[Principle of method]
When a latex reagent is made to react with a specimen, the Lp(a) in the specimen and anti-human Lp(a) goat antibody-sensitized latex in the latex reagent produce a specific antigen-antibody reaction, resulting in turbidity.
As the degree of turbidity is in proportion to the concentration of Lp(a) in a specimen, the turbidity is measured optically to determine the concentration of Lp(a) in a specimen.

[Reagent preparation]
Reagent 1 : Use Reagent 1 as supplied.
Reagent 2 : Use Reagent 2 as supplied.

[Procedure]



Temperature: 37 degree C

This is the standard procedure. Instrument applications are available upon request.

[Precautions on procedure]
(1) Specimen
  (a) Use serum or plasma as a specimen. It is recommended to measure Lp(a) immediately after collection.
  (b) Ascorbic acid, bilirubin and hemoglobin do not have a significant effect on the measurement.
(2) Interfering substances
  The anticoagulants used (heparin, citrate, EDTA, and sodium fluoride) hardly affect the measured values under normal use.

[Expected values]
Serum : less than 30 mg/dL

[Performance characteristics]
(1) Sensitivity
  Absorbance change of a sterile saline sample is 0.02 or less.
  Absorbance change of a 40mg/dL Lp(a) sample is 0.2 or more.
(2) Specificity
  Obtained values of control serum samples with known amount of Lp(a) fall within plus minus 10%.

(3) Precision
Within-run CV of 5 repeated assays is 10% or less.
(4) Measurable range
1.0～100mg/dL Lp(a) (In the case of using the standard procedure) .
(5) Correlation
Correlation coefficient: r=0.9981 (n=90)
Regression equation: y= 1.042x +0.045
y= Lp(a)-F, x= Company A

[Primary Standard]
In-house standard material.

[Warning and precautions]
(1) Be careful about the handling of serum, etc., which involve the risk of infection with HBV, HCV, HIV, etc.
(2) After opening the reagent, it is not recommended to store it for a long period of time. When the opened reagent is stored, cap the bottle and keep it at the specified temperature.
(3) Before determining, reagents should be mixed thoroughly.
(4) Do not use the reagents described above for any purpose other than described herein.
(5) When concentration of a sample exceeds measurement range, dilute the sample with a saline solution.
(6) Do not use mixed reagent from different lots.
(7) Some specimens may not allow correct measurement because of unspecific turbidity that occurred during measurement. If measurement results are questionable, presence or absence of unspecific turbidity should be confirmed by the time course for the reaction or by a dilution test.
(8) Use an optional Lp(a) Calibrator for the calibration. It should be used according to the manufacturer's instructions.
(9) Avoid contact with eyes and skin. If contacted, flush eyes or rinse skin with a large amount of water. If irritation, persists, consult a physician.
(10) Sodium azide, which is contained in the reagent as an antiseptic, combines with heavy metals, such as copper and lead, and forms an azide. Heavy metal azides easily explode when given a shock in dryness. After drainage, they should be flushed with a sufficient amount of water so that they are cleared away from the water pipe.
(11) Clinical diagnosis should be made synthetically based on clinical symptoms and examination results, etc.

[Reference]
References
1) Berg K. : Acta Pathol. : Microbiol. Scand **59** 369 (1963).
2) Eaton D.L. et al. : Proc. Natl. Acad. Sci. USA **84** 3224 (1995).
3) Mclearn J. W. et al. : Nature **300** 132 (1987)

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