Bioway Chemistry Reagent Series

The Serum Lipoprotein(a) Detection Kit

Detection of Lipoprotein(a) in Human Blood on Chemistry Analyzers

Cat. No. R044K11 ***Lipoprotein(a) Detection Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

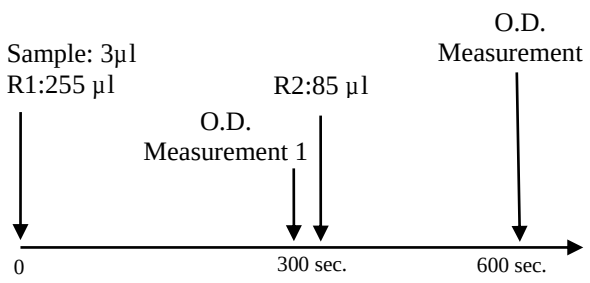

Table 1: Instrument Parameters*

Calibration method	5 point non-linear	Slope of reaction	increase
Wavelength	660nm	Sample volume	3 µl
Test method	2 point end	R1 volume	255 µl
Reaction temperature	37℃	R2 volume	85 µl

*Refer to Figure 1 and the package insert for detail

INTENDED USE

Bioway Chemistry Reagent Series **Lipoprotein(a) Reagent Kit** (the Kit) is a latex-enhanced immunoturbidimetric assay intended for *in vitro* quantitative detection of lipoprotein(a) in human blood on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Lp(a) is a subclass of lipoprotein discovered in 1963 by Kare Berg. It is similar to LDL in that it contains a single ApoB protein along with cholesterol and other lipids. The similarities in components of Lp(a) to that of LDL and plasminogen suggests that Lp(a) may be associated with atherosclerosis and thrombosis. Numerous studies suggested that Lp(a) level is an important risk factor that may contribute to coronary artery disease independently or cooperatively with other risk factor. Lp(a) values should be interpreted with clinical evaluation and other lipoprotein tests when assessing atherosclerotic cardiovascular disease.

TEST PRINCIPLES

The Kit utilizes latex-enhanced immunoturbidimetry to measure the Lp(a) level in human serum or plasma. During the test, Lp(a) in the sample binds with the specific anti-Lp(a) antibody that is coated on latex particles to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry analyzer. The change in absorbance is proportional to the level of Lp(a) in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

MATERIALS PROVIDED

Reagents:

R1	Glycine buffer solution.
R2	0.4% suspension with latex particles sensitized with anti-Lp(a) antibodies.

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer.
2. Lp(a) calibrator set (available for purchase) and control set (commercially available).

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8℃. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. R1 and R2 reagents are stable for 1 month at 2-8℃ after opening.

PRECAUTIONS

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.
5. Samples containing levels of Lp(a) above the assay range should be diluted with physiological saline and retested.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect samples.

1. For serum samples, after the collection of blood, centrifuge to separate from blood cells and fibrins.
2. For plasma samples, collect sample with Disodium EDTA, Dipotassium EDTA, Sodium Heparin, Lithium Heparin or Citric acid.
3. It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at - 20° C for up to 6 months. Avoid repeated freezing and thawing.

TEST PROCEDURE (see Figure 1)

No pretreatment required for reagents and samples.

Calibration: 5 level calibrator set available for purchase. Recommend using Bioway calibrators for optimal results. Use multi-point non-linear calibration method.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

4. Add 3 µl of sample and 255 µl of R1; mix well and incubate at 37℃ for 300 seconds.
5. Take optical density measurement OD 1 just before addition of R2.
6. Add 85 µl of R2, mix well and incubate at 37℃.
7. Take optical density measurement OD 2 at 600 seconds.
8. Calculate ΔOD = OD 2 – OD 1

RESULT

The Lp(a) value can be obtained by using the calculated ΔOD to find the corresponding value on a calibration curve prepared with known values.

EXPECTED VALUES

<300 mg/L, as determined by previous studies.

It is recommended for each laboratory to establish its own expected values. Lp(a) levels are largely influenced by hereditary factors and vary with ethnic population.

QUALITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. Hemolysis samples may cause inconsistent results.
3. The test result from the Kit should not be used as the only basis for definite diagnosis. Lp(a) value should be interpreted together with clinical evaluations and other lipoprotein tests for assessment of atherosclerotic cardiovascular disease in specific populations.

PERFORMANCE CHARACTERISTICS

Linearity: 2 – 800 mg/L (R≥0.990)

Precision: Within Run: CV≤4%;
Run-to-Run: CV≤7%

Interference: no interference detected for: Bilirubin (60 mg/dL), triglycerides (1000 mg/dL), and hemoglobin (10 g/L).

Reagent Blank Absorbance: at 660nm wavelength and 10 mm optical diameter, O.D. ≤ 0.20

REFERENCES

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5. Armstrong VW, Cremer P, Eberle E, Manke A, Schulze F, Wieland H, Kreuzer H, Seidel D. The association between serum Lp(a) concentrations and angiographically assessed coronary atherosclerosis. Atherosclerosis 1986; 62: 249-257.

Not Intended for Sale in the United States.

Pointe Biotech (Nanjing) Co., Ltd.

No.85,Xingmin South Road, Jiang Ning District, Nanjing,P.R.China 211100
Tel:86-25-52425019,
Fax:86-25-52424836
info@biowaydx.com