NEPHSTAR®
Lipoprotein(a) (Lp(a)) Kit

Catalog No. **DK043**

1. Intended Use
This product is used on NEPHSTAR® protein analysis system for quantitative determination of human Lipoprotein(a) (Lp(a)) in serum.

2. Summary
Lipoprotein (a) (Lp (a)) is a particle composed of lipids and proteins; a portion of this particle consists of phospholipids, cholesterol and a specific apolipoprotein, apolipoprotein B100, identical to LDL (low-density lipoprotein), which transports cholesterol. The other part is an apolipoprotein (a) linked to apolipoprotein B100 by disulphide bridges. Apolipoprotein (a) (not to be confused with apo A1) is specific to Lp (a) and is synonymous with increased cardiovascular risk. There is no known specific function for Lp (a). It is possible that Lp (a) acts as an acute phase protein. It is therefore preferable to determine the level in the absence of an inflammatory reaction. The concentration of Lp (a) seems, for a very large part, genetically determined; the indication for determining the Lp (a) level occurs when screening for cardiovascular risk (coronary artery atherosclerosis). It appears that Lp (a) increases the risk of heart disease either by competing with plasminogen for binding sites on blood clots or by causing atheroma formation.

3. Test Principle
Immunonephelometry is applied. This method involves measuring the light scattered by insoluble complexes formed by reaction between specific protein in samples and its respective antiserum, and the amount of scattered light is directly proportional to the concentration of the protein under condition that antiserum is in excess. Concentrations are automatically calculated by reference to a calibration curve stored in the instrument.

4. Kit Components

Code	Name	Volume/Quantity
DA043	Lp(a) Antiserum	1.5 ml
DB043	Lp(a) Reaction buffer	20 mL
DM043	Lp(a) Control	0.3 ml
DC043	Lp(a) Magnetic card	1
	Manual	1

5. Materials required but not supplied
5.1 NEPHSTAR Protein analysis system（NS100）
5.2 NEPHSTAR Accessory pack（DK110）
5.3 Electronic pipette（YB201）
5.4 Pipette 5-50uL (YB301)
5.5 Pipette 200-1000uL(YB302)
5.6 Equipment for collection of Samples

6. Storage and Stability
The unopened reagent kit should be stored under 2-8℃ and can be used until the expiry date labeled on the kit. Do not freeze! The buffer should be equilibrated to room temperature before use. Once opened store the antisera and control at 2-8℃ and the buffer at **18-25℃ and be sure to screw on the cap tightly.** Under these conditions the buffer is stable for 3 months, antisera and control for 1 month.

7. Sample Collection And Preparation
7.1 Use fresh serum sample. Sera may be stored at 2-8°C for 48 hours, otherwise freeze at –20°C or below; do not freeze and thaw sera more than once. Sample dilutions should be freshly prepared on the day of assay.

7.2 Highly lipemic, turbid and haemolysed samples are not suitable for nephelometric assays and should not be used unless centrifuged or prepared using other methods. If the background is too turbid and can not be removed, please think of other measuring method.

7.3 Testing of samples containing rheumatoid factors, paraproteins or circulating immunocomplexes can result in misleading values due to non-specific scattering light possibly generated by these articles.

8. Test Procedure
Summary: Reagent volumes added to the cuvette

Reagent	Volume
Sample（1/30）	30ul
Lp(a) Reaction Buffer	400ul
Lp(a) Antiserum	30ul

8.1 Switch NEPHSTAR on.

8.2 Enter chemistry number. Enter chemistry number of Lp(a) kit (Lp(a)=43). If Lp(a) assay has never been performed on the instrument before, please swipe card when “please swipe card” is displayed.

8.3 The assay name and lot of reagent are displayed. Check carefully, press ENTER if the lot number is identical to that printed on the card or kit label, otherwise swipe card to update the curve data stored in NEPHSTAR.

8.4 Dilute serum samples or controls using NEPHSTAR Sample Diluent supplied in NEPHSTAR Accessory pack (Cat. No: DK110）. The default dilution scheme for Lp(a) assay is 1/30 (e.g. 580uL sample diluent + 20uL sample）。

8.5 Prepare one cuvette for each sample to be assayed. Place a stirring bar to the cuvette using the forceps supplied with NEPHSTAR, then add 30uL of diluted sample carefully to the bottom of the cuvette.

8.6 Enter sample ID. Press number keys to enter the sample ID; or press ENTER to accept the currently displayed sample ID.

8.7 Enter sample dilution: 30. Accept the default sample dilution by pressing ENTER, otherwise press number keys to alter the dilution scheme.

8.8 Place cuvette in chamber. Place the cuvette containing a stirring bar and 30uL of diluted sample in the chamber and press it down slightly until it reaches the bottom of the chamber. The cuvette will be detected automatically.

8.9 Add reagent. Add 400 uL Lp(a) reaction buffer and 30 uL Lp(a) antiserum simultaneously into the cuvette using the electronic pipette （Cat. No.: YB201）supplied with NEPHSTAR. NEPHSTAR will sense the addition of reagents. With movement of the stirring bar, the assay begins after blanking and result will be printed automatically at the end of the assay.

8.10 On completion of the assay remove the cuvette, press ENTER to perform the next assay. Sample ID will increase sequentially. For alteration of the ID press BACK twice and tip in the right number.

8.11 On completion of all assays of the same chemistry press ESC and return to step 8.2. Enter new chemistry number and begin another assay.

9. Quality Control

In accord with good laboratory practice, users should run control with every batch of samples. Results of control should fall in the validity range labeled on the control vial.

10. Sensitivity and measuring range

The sensitivity limit is60mg/L and the upper limit is 1200mg/L when the default dilution scheme is applied.

11. Limitation

When the sample concentration is higher than reportable range 7560mg/L, it's not suggested to increase dilution for further testt. Sample concentration of less than 15000mg/L will not result in antigen excess. If the concentration is higher than 15000mg/L, the results will be misleadingly low.

12. Reference Range

12.1 Normal range of Lp(a) concentration is：<300mg/L. We recommend local reference ranges are produced.

12.2 Diagnosis and treatment can not only depend on determination of Lp(a). The clinical symptoms and other laboratory findings of respective patients should be taken into consideration。

13. Precision

Two analyte concentrations are assayed within several days using this kit of the same lot on NEPHSTAR. 20 repeat assays are performed for each concentration. The average coefficient variations (CV) for each concentration are displayed in the following table:

Lp(a)（mg/L）	CV（%）
665	5.95
980	6.47

14. Correlation Study

A correlation study is performed on 20 clinical serum samples using Lp(a) reagent kit on NEPHSTAR and Beckmancoulter IMMAGE800. The linear regression equation and correlation equation got as showed below demonstrate a good correlation between the two methods:

Y=0.992X+1.85

(Y= NEPHSTAR® Lp(a)，X= IMMAGE800 Lp(a))

Correlation coefficient r=0.982

15. Caution And Warning

15.1 The reagents are only for in vitro diagnostic use。

15.2 The reagents can be used only by trained personnel and good laboratory practice (GLP) and the stated procedure should be abided strictly.

15.3 All sera have been tested to be HIV(1&2) antibody negative, HBsAg negative. However, the performed testing method can not assure the absolute absence of infectious agents in blood products, so please be sure to handle the blood products such as controls and antisera as potentially infectious sources.

15.4 All reagents of the kit contain sodium azide as preservative. Take caution when handling them. Ingest or contact of the reagents with skin or mucous membranes is forbidden. Wash with large amount of water and seek medical advice if contact does occur. In addition, explosive metal azides may be formed with lead or copper plumbings; when disposing the reagents be sure to flush with large amount of water to avoid buildup of azide.

15.5 All components of kit are NEPHSTAR® specific. Reagents of different lots are not interchangeable, otherwise the results can be misleading.

16. Referrences

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