NEPHSTAR®
D-Dimer (DD) Kit

Code No. DK065

1. Intended Use
This product is used on NEPHSTAR® protein analysis system for quantitative determination of human D-Dimer (DD) in human citrated plasma.

2. Summary
D-Dimer is contained in the soluble derivatives formed upon plasmin degradation of Factor XIII a cross-linked fibrin plasmin, a serin protease, when free from inhibitors digests the insoluble cross-linked fibrin yielding a variety of soluble derivatives. These soluble fibrin degradation products contain a neoantigen(D-Dimer domain) which is not present on the original fibrinogen molecule or on soluble fibrin. The determination of D-Dimer is becoming a widespread tool for diagnosing thrombosis and monitoring thrombolytic therapy.
Elvated levels of D-Dimer are found in clinical conditions such as deep vein thrombosis(DVT), pulmonary embolism(PE) and disseminated intravascular coagulation(DIC),.
In additional, myocardial infarction(MI), cerebral infarctio(CI) , kidney disease, surgical operation, tumour, infection, tissue necrosis and organ transplant rejection reaction can also lead to high levels of D-Dimer .

3. Test Principle
Particle-enhanced immunonephelometry is applied. This method involves measuring the light scattered by insoluble complexes formed by reaction between specific protein in samples and its respective antibody covalently coupled to latex particles, and the amount of scattered light is directly proportional to the concentration of the protein under condition that antibody is in excess. The latex particles increase the size of complexes formed and thus the amount of light as well as the test sensitivity. Concentrations are automatically calculated by reference to a calibration curve stored in the instrument.

4. Kit Components

Code	Name	Volume/Quantity
DA065	DD Antiserum	2×0.63 ml
DB065	DD Reaction buffer	25mL
DC065	DD 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 Equipment for collection of samples
5.6 NEPHSTAR D-Dimer Control（Code: DM065，1×0.5mL）

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 kit at 2-8℃. Under these conditions the buffer is stable for 3 months, and antisera for 1 month.

7. Reagent preparation
7.1D-Dimer Control: Open the vial and accurately add 0.5mL distilled water into the vial to dissolve the contents. Gently mix for 10 minutes, or until all material has dissolved. The reconstituted control should be treated as citrated plasma sample. The reconstituted control is stable for one month if stored at 2-8℃.

8. Sample Collection And Preparation
Nine parts of freshly drawn venous blood are collected into one part of 3.13%trisodium citrate, use 3000r/min to centrifuge the sample and the centrifuge time should be at least 10min. the assay must be performed within 2 hours at room temperature. Citrated plasma may be stored at 2-8°C for 48 hours, otherwise freeze at –20°C or below; do not freeze and thaw citrated plasma more than once. Sample dilutions should be freshly prepared on the day of assay. Testing of the following types of sample may result in misleading values:
8.1 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.
8.2 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.

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

Reagent	Volume
Sample	10ul
DD Reaction Buffer	350ul
DD Antiserum	25ul

9.1 Switch NEPHSTAR on. Enter chemistry number. Enter chemistry number of DD kit (DD=65). If DD assay has never been performed on the instrument before, please swipe card when “please swipe card” is displayed.
9.2 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.
9.3 Prepare one cuvette for each sample to be assayed. Place a stirring bar to the cuvette using the forceps supplied with NEPHSTAR, then add 10uL of sample carefully to the bottom of the cuvette.
9.4 Enter sample ID. Press number keys to enter the sample ID; or press ENTER to accept the currently displayed sample ID.
9.5 Enter sample dilution: 1. Accept the sample dilution by pressing ENTER, otherwise press number keys to alter the dilution scheme.
9.6 Place cuvette in chamber. Place the cuevette containing a stirring bar and 10uL 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.
9.7 Add reagent. Add 350 uL DD reaction buffer and 25 uL DD 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.
9.8 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.

9.9 If NEPHSTAR indicates result is higher than measurement range, reassay the sample at a higher dilution of e.g. 1/5 （400μL sample diluent + 100μL sample）. Accordingly the sample dilution should be altered to 5 （press BACK and then the number keys to alter the sample dilution）。

9.10 On completion of all assays of the same chemistry press ESC and return to step 9.1. Enter new chemistry number and begin another assay.

10. 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.

11. Sensitivity and measuring range

The sensitivity limit is 0.1mg/L and the upper limit is 7.5 mg/L.

12. Reference Range

12.1 Normal range of DD concentration of healthy adult is: <0.5mg/L. We recommend local reference ranges are produced.

12.2 Diagnosis and treatment can not only depend on determination of DD. 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:

DD（mg/L）	CV（%）
2.15	3.59
0.99	3.22

14. Caution and Warning

14.1 The reagents are only for in vitro diagnostic use。

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

14.3 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.

14.4 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.

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

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