Nephchem D Dimer (D-D)
(Nephelometry method)

KIT NAME	KIT SIZE	CAT. NO
Nephchem - D Dimer	25 Tests	NDD001025T

GENUINE BIOSYSTEM

INTRODUCTION

D Dimer (D-D) is intended for Invitro quantitative determination of D-D in human serum. D-dimer is a fibrin degradation product, a small protein fragment present in blood after fibrinolysis degrades a blood clot. D-dimer is normally undetectable in the blood and is synthesized only after a clot has formed and is in the process of being broken down. D-dimer levels rise when a significant formation and breakdown of blood clots occurs. D-dimer is useful in diagnosis of deep vein thrombosis (DVT), pulmonary embolism (PE), and disseminated intravascular coagulation (DIC).

METHOD PRINCIPLE

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

KIT CONTENTS

Reagent kit - box	
R1 - D Dimer buffer	1 x 4.9 ml
R2 - D Dimer antibody	1 x 1.6 ml
Test Card	1 no
Accessories kit box	
Cuvettes	25 nos
Big tips	25 nos
small tips	50 nos

Working reagent preparation and stability

Reagent R1 and R2 are ready to use liquid stable at 2-8°C till the expiry date printed on the package.

Concentrations in the test

R1 - Tris buffer solution. Sodium azide < 0.1%

R2 - Latex suspension, anti-d-dimer antibodies, buffer solution, sodium azide < 0.1%

Warnings and notes

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. Reagents contain less than 0.1% sodium azide as preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

SPECIMEN

Follow standard laboratory procedures to collect serum or heparin plasma samples.

It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at 2- 8° C for up to 1 day or at -80° C for up to 6 months. Avoid repeated freezing and thawing.

PROCEDURE

It is very important for antigen-antibody reaction needs the pre-warm of both reagents and samples. Along with GB NEPHCHEM equipment, dry bath incubator will be provided, in that dedicated R1, R2 and sample positions were available. Please use the respective positions for desired pre-warm temperature of 37°C

Step 1: Insert Test Card to Card reader slot and display will show promptly add R1 + S (sample)

Step 2: Pipette out 180 µl of R1 into dedicated cuvette and add 5 µl of sample (serum) and place the cuvette in the reading chamber

Step 3: After the incubation, the display will show promptly add R2

Step 4: Pipette out 60 µl of R2 using sensor pipette connected with machine into the cuvette

Step 5: Once the reaction time got over, the result will show in the display and (if external printer connected then it will get print out)

REFERENCE VALUES

0 to 0.5 mg/L (0.5*1000=500 ng/ml) is the conversion factor

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

To ensure adequate quality control, each kit can be cross checked with commercially available third party Immunological quality control or use recommended GB Immunology Quality control.

PERFORMANCE CHARACTERISTICS

- **Linearity:** 0 to 20.0 mg/L
- **Precision:** within Run CV ≤ 8%
- **Specificity / Interferences**
  No interference detected for saturated bilirubin upto 19.6 mg/dL, free bilirubin 18.4 mg/dL, Rheumatoid factor 500 IU/L and hemoglobin 460 mg/dL

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Adam S.S., Key N.S., Greenbery C.S. D-dimer antigen: current concepts and future prospects. Blood 113 (13): 2878-87.
2. Gaffney, P.J. Distinction between Fibrinogen and Fibrin Degradation Products in Plasma. Clin. Chem. Acta. 65 (1): 109-115; 1975.
3. Rylatt, D.B., et al. An Immunoassay for Human D-DImer using Monoclonal Antibodies. Thromb. Res. 31(6): 767-778; 1986.
4. Smith, R.T.,e.tal.Fibrin Degradation Products in the Postoperative Period. Evaluation of a New Latex Agglutination Method. Am. J. Clin. Pathol. 60(5): 644-647; 1973

IVD CE

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