Hipro Biotechnology Co.,Ltd

EN
ENGLISH

D-Dimer

D-Dimer Test Kit
(Nephelometry Immunoassay Method)

Instructions for Use

Version: A/8

REF HP-D-Dimer-25

Manufacturer

Shijiazhuang Hipro Biotechnology Co.,Ltd.
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Product Name

General Name: D-Dimer Test Kit (Nephelometry Immunoassay Method)

Specification

Package Specification

25 Tests/ Kit.

Intended Use

This product is used to determine the content of D-Dimer (D-Dimer) in human blood, and specific reagent for the specific protein analyzer, applies only to the clinical in vitro assisted diagnosis.

D-Dimer is one of fibrin degradation product(FDP) decomposed by cross-linked fibrin and plasmin, due to the role of coagulation factor X III, in the blood coagulation - fibrinolysis system. D- Dimer in blood increased has proved that the body has thrombosis. The high values also shown in obstetric disorders, vascular disease, disseminated intravascular coagulation syndrome (DIC: Disseminated Intravascular Coagulation Syndrome) etc.

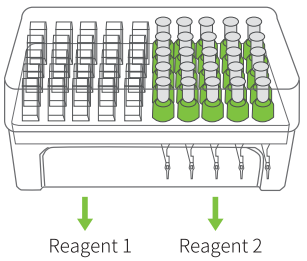
Test Principle

The D-Dimer units conjugated anti-human D-Dimer antibody in the latex surface. D-Dimer in the sample and the antibody become to immune complexes by Latex condensation reaction. The immune complexes will produce the phenomenon of light scattering, is proportional to the intensity of scattered light and samples of D-Dimer levels. Using specific protein analyzer to measure the intensity of scattered light, the concentration of D-Dimer is determined by comparing the turbidity of samples to the standard concentration.

Component

The D-Dimer test kit consists of two reagents R1 and R2, as shown on Figure 1.

Figure 1



Name	Content	Quantity
Reagent 1 (R1)	Tris (hydroxymethyl) aminomethane buffer	30mmol/L
Reagent 2 (R2)	Polystyrene particles, murine anti-human monoclonal	Appropriate
IC Card (optional)	/	1

Do not mix different batches of reagents.

Storage&stability

Store the test kit at 2°C-8°C until the expiration date indicated on the label. The test kit is stable for one year when unopened.

Use up the test kit within one month after opening the package.

Do not freeze the test kit.

Do not mix different lots of the test kit.

Special Instrument Requirements

HP-083/4-I POCT Immunoassay System,

HP-083/4-II POCT Immunoassay System,

HP-AFS/1 Automatic Immunoassay System,

HP-AFS/3 Automatic Immunoassay System.

Specimen type

Whole blood（Finger blood or Venous blood）. The sample store at 2-8°C for 48 hours.

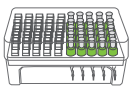
Procedures

HP-083/4-I&HP-083/4-II: POCT Immunoassay System

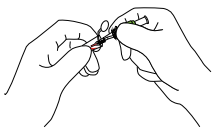
Note:

- Please read user manual of HP-083/4-I and HP-083/4-II before use;
- The analyzer will finish self check after start-up;
- Insert the IC card of D-Dimer test kit to let analyzer read the parameter;
- The analyzer calibration can be done with app. It is recommended that analyzer calibration should be done for each new lot of test kit.

Step 1 Sample Preparation



1a Allow the test kit back to room temperaturefor 30 minutes before use.



1b Use the R2 with quantitative capillary to collect sample.

1c Insert the R2 into R1.

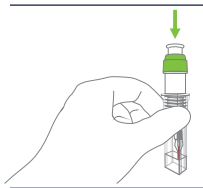
Note:

- The parameter is built in the IC card.
- Please insert the corresponding IC card into analyzer to let the analyzer read the parameter before each assay test.
- The capillary of the R2 should be fully filled.

Step 2 Testing

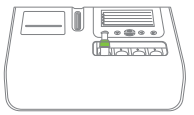
2a Hold the narrow side of R1 and shake from left to right for 12 times to let the sample completely mix with R1.

Note:Do not hold the wide sides of R1



2b Press the piston on R2.

2c Hold the narrow sides of R1 and shake for 3-5 seconds to let R1 and R2 mix well.



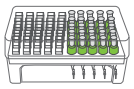
2d Insert the R1 into test channel of HP-083/4-II and the analyzer will finish the test and print out results automatically.

HP-AFS/1&HP-AFS/3 Automatic Immunoassay System

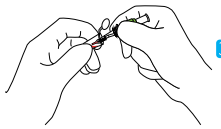
Note:

- Please read user manual of HP-AFS/1 and HP-AFS/3 before use;
- The analyzer will finish the self check after start-up;
- It is recommend to do analyzer calibration monthly and for each new lot of test kit.

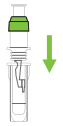
Step 1 Sample Preparation



3a Allow the test kit back to room temperature for 30 minutes before use.



3b Use the R2 with quantitative capillary to collect sample.

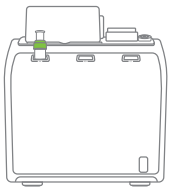


3c Insert the R2 into R1.

Note:

- Please update the standard curve with the barcode on the R1 cuvette if a new lot test kit is to be used.
- The capillary of the R2 should be fully filled.

Step 2 Testing



4a Insert the R1 into test channel of analyzer.

4b The analyzer will mix the sample from R2 capillary with R1 automatically.

4c The analyzer will mix the R2 and R1 automatically.

4d The analyzer will test and print the results automatically.

Calibration

The calibration values for the different lots of the kits are stored on the calibration IC card or the two-dimensional code on the cuvette. Before test the new lot of kits, read the calibration card parameters first. Or the instrument automatically scan the two-dimensional code on the cup to obtain the corresponding calibration curve during testing.

Quality control

3- level calibration system guarantee the results' reliability for each lot of test kits, including the instrument calibration, remote reagent calibration and the third party calibration.

The third party calibration applicable for:

1. The daily indoor quality control test.
2. New lots of reagent.
3. New operator training.
4. The results can not match the clinical symptoms.
5. The first use of the reagent.

If still can not be calibrated, contact the manufacture for further technical support.

Reference Value

Normal reference range is 0 ~ 0.5mg/L.
Recommended that each laboratory establish its own reference range.

Interpretation

1.The test result ⩾ 0.5 indicates that there may be thrombotic diseases caused by various reasons, and the fibrinolytic activity is enhanced.

2.The D-Dimer units is the test results depends on the ratio of the reaction components and make changes to the reagents or the sample volume will affect the precision of the result.

3.The D-Dimer units measure D-Dimer levels in the samples only, clinical judgment by doctor's combination of clinical symptoms and other indicators to judge.

Limitations

Bilirubin⩽359μmol/L,hemoglobin⩽0.5g/L,triglycerid⩽23mmol/L had no effect on the test result.

Performance Characteristics

1. Linearity range: 0.2mg/L ~ 20mg/L.

2. Detection limit: ⩽0.2mg/L

The limit of detection means the lowest detectable analyte level that can distinguish the concentration. Calculate based on the minimum standard above the two standard deviation of the data (Blank table, 1+2SD, within-run precision, n=20).

3. Precision

Test the control material by D-Dimer Test Kit 2 times per day for 20 days (n=80) according to EP5-A2 of CLSI.

The data as below:

a.

HP-083/4-II POCT Immunoassay System					
Sample	Mean mg/L	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	1.15	0.05	4.4	0.07	6.1
Control 2	2.48	0.13	5.2	0.15	6.0

b.

HP-AFS/3 Automatic Immunoassay System					
Sample	Mean mg/L	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	1.14	0.06	5.3	0.04	3.5
Control 2	2.46	0.14	5.7	0.16	6.5

c.

HP-AFS/1Automatic Immunoassay System					
Sample	Mean mg/L	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	1.18	0.06	5.1	0.05	4.2
Control 2	2.49	0.16	6.4	0.13	5.2

4. Methodology comparison
We used the same person's whole blood sample compared with the plasma sample in ACL TOP
the relative data as below:

HP-AFS/3 Automatic Immunoassay System				
Site No.	Sample Type	No.of Assays	Regression Line	Coefficient correlation
1	Whole blood	50	Y= 0.94X+0.35	0.95

The concentration of sample is about 0.2 mg/L -20mg/L

Precautions

⚠ Attention:

Only for in vitro diagnostic.

Only for professional use.

All samples and reactive wastes are treated as sources of infection.

Do not use the kits beyond shelf life.

Do not mix different batches of reagents.

⚠ Warning :

To avoid error, do not forced to take out the cuvette from the device. Follow the device operation manual strictly, If the problem cannot be solved, contact the manufacturer for further technical support.

SYMBOLS USED ON LABELS

Symbol	Usage	Symbol	Usage
	Use-By date		Do not freeze
LOT	Batch code		Biological risks
	Manufacturer		Do Not Reuse
2°C 8°C	Temperature Limit		
Σ	Contains sufficient for <n> tests		
	Do not use if package is damaged		
	Consult Instructions for use		
	Keep Away from Sunlight		
IVD	In Vitro Diagnostic Medical device		
EC REP	Authorized Representative in the European Community		

References

1.Demple,C.E.,Sybille Zips, Hanimsah Ergul,(2001)The Fibrin Assay Comparision Trial(FACT):Evaluation of 23 quantitative D-dimer assays as basis for the development of D-dimer calibrators. Thromb Haemost 85:671-678

2.Schutgens,R.E.G.,Haas,F.J.L.M.,Gerritsen,B.M.,(2003) The usefulness of five D-dimer assays in the exclusion of deep venous thrombosis. Journal of Thrombosis and Haemostasis,1:976-1

3.Chris Gardiner,Coralie Pennaneach,Claire Walford,(2005) An evaluation of rapid D-dimer assays for the exclusion of deep vein thrombosis. British Journal of Haematolgy,128:842-8

Approval Date&Revision Date

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Revision Date: Jan 10, 2020
Revision Date: May 10, 2020
Revision Date: Jan 1, 2021
Revision Date: Apr 1, 2021
Revision Date: Jan 1, 2023
Revision Date: Dec 22,2023

CE IVD

尺寸:24*25cm展开尺寸,横向三折页再垂直方向两次对折