CE

D-Dimer Rapid Test Kit

Instructions for use | IVD | For in vitro diagnostic use only.

REF | A02008002 | Σ | 25 Tests

【Product Name】

D-Dimer Rapid Test Kit

【Intended Use】

The Anbio D-Dimer Rapid Test Kit along with Anbio FIA Meter is a fluorescence immunoassay for quantitative measurement of D-Dimer in human whole blood or plasma. The test kit is used as an important basis to exclude the formation of pulmonary embolism (PE) and deep venous thrombosis (DVT) in clinical.

⚠ ***For professional use only.***

【Summary】

D-Dimer is a specific degradation product of fibrin monomer after cross-linking with activation factor XIII, which is produced by fibrinolytic enzyme hydrolysis. It can reflect the coagulation function and fibrinolytic activity in vivo, and it is an indicator of hypercoagulability, thrombosis and secondary hyperfibrinolysis. The level of D-dimer increased in deep vein thrombosis, pulmonary embolism, disseminated intravascular coagulation, severe hepatitis and other diseases, as well as after thrombolytic therapy, which can be used as an effective observation index of thrombolytic therapy. Because of its high sensitivity and negative predictive value, D-dimer negative has been used as an important basis to exclude the formation of pulmonary embolism (PE) and deep venous thrombosis (DVT).

【Test Principle】

The Anbio D-Dimer Rapid Test Kit is based on fluorescence immunoassay technology. The Anbio D-Dimer Rapid Test Kit uses a sandwich immuno detection method. When sample is added to the sample well of the test, the fluorescence-labeled detector D-Dimer antibody binds to D-Dimer antigen in the specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and D-Dimer are captured to anti-D-Dimer antibody that has been immobilized on test strip. Thus the more D-Dimer antigen is in the specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of D-Dimer captured and Anbio FIA Meter shows D-Dimer concentration in the specimen.

【Main Components】

The following components are included in the D-Dimer Rapid Test Kit:

Supplied materials:

Component	Main Ingredients
Test Cartridge	1) T line: Mouse anti-D-Dimer monoclonal antibody (coated) 2) C line: Goat anti-rabbit IgG polyclonal antibody 3) Binding pad: Fluorescent microsphere-labeled mouse anti-D-Dimer monoclonal antibody (labeled) and fluorescent microsphere-labeled rabbit IgG polyclonal antibody
IC Card	/
Sample Diluent	10mmol/L PBS
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Optional Materials:

1. Sterile lancets (for Fingerstick Whole Blood only)
2. Alcohol pads (for Fingerstick Whole Blood only)
3. Disposable pipettes (50μL)
4. D-Dimer Quality control

Materials Required but not Provided:

1. Transfer Pipette Set
2. Specimen Collection Containers
3. Timer
4. Centrifuge (for Plasma only)
5. Anbio FIA Meter (model number: AF-100, AF-100s, AF-1200, AF-100C)

【Storage Conditions and Shelf Life】

Component	Storage- Temperature Limitation	Stability
Test Cartridge		The shelf life is up to 24 months. Please refer to use-by date on the label. Test Cartridge should be used within 1 hour after opening the pack.
IC Card		/
Sample Diluent		The diluent is stable up to 24 months. Please refer to use-by date on the label.

⚠【Warnings and Precautions】

1.This kit is for in vitro diagnostic use only.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Do not use Test Cartridge if its lot # does not match with IC Card # that is inserted onto the equipment.
5. The Anbio D-Dimer Rapid Test Kit is only operational in the Anbio FIA Meter.
6. Do not use the Test Cartridge if the pouch is punctured or not well sealed.
7. The Test Cartridge and Meter should be used away from vibration and magnetic field. During normal usage, the Meter itself may cause vibration, which should be regarded as normal.
8. Use separate clean pipette tips and detector diluent tubes for different specimens.
9. Blood specimens, used Test Cartridges, pipette tips and detector diluent tubes should be handled and disposed in accordance with standard procedures and relevant regulations of microbiological hazard materials.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

【Specimen Collection and Preparation】

The test can be performed with plasma or whole blood. The plasma and whole blood samples are recommended to use EDTA, heparin or sodium citrate for anticoagulation. Other body fluids and samples may not get accurate results.

For Plasma:

1. Separate the plasma from blood as soon as possible to avoid hemolysis.
2. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2℃～8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

For Whole Blood Collected by Venipuncture:

1.Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant.
2.It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they may be stored at 2℃～8℃.
3.It's not suitable to test the whole blood samples storing at 2℃～8℃ for more than 2 days.

For Fingertip Whole Blood Samples:

1.Clean the puncture site with the alcohol pad.
2.After the alcohol is dried, the fingertips are punctured with safety lancet to form blood droplets.
3.Lay the disposable pipettes, do not squeeze, automatically collect fingertip whole blood for 50μL.
4. It is recommended that specimens should be tested immediately.

【Test Procedure】

Refer to Anbio FIA Meter Operation Manual (attached to Anbio FIA Meter) for the complete instructions on use of the Test. The test should be operated in room temperature.

Step1:Preparation

Check/ Swipe the IC Card information to the equipment.
Make sure the sample diluent is at the bottom of the tube by tapping or flicking before using.

Step2:Sampling

Draw 50 μL of plasma/whole blood with a transfer pipette and add it to the diluent tube.

Step3: Mixing

Close the lid of diluent tube and mix the specimen by shaking or tapping 6-8 times, until the specimen

completely mixed. Let it stand 1 minute.

Step4: Loading

Take 50μL of sample mixture with a transfer pipette and load it into the sample well of the Test Cartridge.

Step5:Testing

Standard test: Insert the Test Cartridge onto the Test Cartridge Holder and click “Timing Test”. 15 minutes later, the result will show in the display and print out when click “Print”.

Quick test: Put the Test Cartridge on the operation platform.15 minutes later, insert the Test Cartridge onto the Test Cartridge Holder and click “Quick Test”. The result will show in the display and print out when click “Print”.

【Limitations of Procedure】

1. This test has been developed for testing human whole blood and plasma specimen.
2. The results of Anbio D-Dimer Rapid Test Kit should be evaluated with all clinical and laboratory data available. If D-Dimer test results do not agree with the clinical evaluation, additional tests should be performed.
3. Incorrect results can be caused by interference from some similar substance in the sample.
4. Other factors may interfere with Anbio D-Dimer Rapid Test Kit and may cause erroneous results. These include technical or procedural errors, as well as additional substances in the specimens.

【Quality Control】

- Internal procedural controls are included in the test. When testing, the quality control line (C line) will show a certain luminescence intensity, which is an internal procedural control. It confirms that a sufficient volume of samples has been added and that the correct procedure has been performed.
- Anbio D-Dimer Control is recommended for Anbio D-Dimer Rapid Test Kit and can be used in the following cases: When a box of a new lot is opened; When the Anbio FIA Meter or Anbio D-Dimer Rapid Test Kit are not working properly; When the result and the symptoms are not consistent or if there are doubts about their accuracy.

Note: Please refer to the Instructions For Use of Anbio D-Dimer Control for detailed operation.

【Interpretation of Results】

The Anbio FIA Meter calculate the test result automatically and displays D-Dimer concentration of the test sample in terms of mg/L FEU.

1. Conversion Factor:

mg/L FEU = μg/mL FEU or mg/L FEU = 1000×μg/L FEU or mg/L FEU = 1000×ng/mL FEU

2. The Reference Value

< 0.5mg/L FEU

Note: Individual reference range is suggested to be established for each laboratory.

【Performance Characteristics】

Limits and Range

Limit of Detection:0.05mg/L FEU;
Limit of Quantitation:0.1mg/L FEU;
Measuring range: 0.1-10mg/L FEU

Precision

Precision was determined with Anbio test kits, samples, and controls according to the CLSI (clinical and Laboratory Standards Institute) protocol (EP05- A3):

(1) 3 batches of test kits, repeated 10 times per batch (n=30)

mg/L	Intra-batch						Inter-batch	
	Batch 1		Batch 2		Batch 3			
	SD	CV	SD	CV	SD	CV	SD	CV
0.498	0.0377	7.16%	0.0446	8.88%	0.0440	8.36%	0.0424	8.18%
5.003	0.4945	10.23%	0.3490	6.67%	0.4456	9.00%	0.4517	9.02%

(2) 3 laboratories with duplicate testing 5 times a day for 5 days (n = 75).

mg/L	Repeatability		Intra laboratory precision		Inter laboratory precision	
	SD	CV	SD	CV	SD	CV
0.498	0.0394	7.82%	0.0394	7.82%	0.0394	7.82%
5.003	0.4552	9.00%	0.4552	9.00%	0.4556	9.01%

Limitations-Interference

Detection of the effects of the following endogenous substances on assay performance. Interfering substances detected in the listed concentration range had no effect on the results.

Compound	Concentration
Bilirubin	350μmol/L
Triglycerides	40mmol/L
Hemoglobin	2g/L
RF	1500IU/mL
HAMA	1000ng/mL
Antinuclear antibody	1:640

Limitations-Cross-Reactivity

FDP at a concentration of 1000 mg/L does not interfere with D-Dimer test results.

【Bibliography of Suggested Reading】

1.Sakamoto K,Yamamoto Y,OKamatsu H,Okabe M.D-Dimer is helpful for differentiating acute aortic dissection and acute pulmonary embolism from acute myocardial infarction.Hellenic J Cardiol.2011 Mar-Apr;52(2):123-7

2.Yasuoka S,Kubota S.The value of blood D-Dimer test in the diagnosis of walk-in patients with venous thromboembolism.Vasc Health Risk Manag.2011;7;125-7.Epub 2011 Mar 1.

【Index of Symbols】

IVD	In vitro diagnostic medical device		Do not re-use
EC REP	Authorized representative in the European Community/ European Union		Consult instructions for use or consult electronic instructions for use
	Caution		Manufacturer
30°C 2°C	Temperature limit	LOT	Batch code
	Use-by date		Keep dry
	Keep away from sunlight	REF	Catalog number
	Date of manufacture	Σ	Contains sufficient for <n> tests
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		Do not use if package is damaged and consult instructions for use

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