D-Dimer Rapid Quantitative Test

For in vitro diagnostic use only. For professional use only.

INTENDED USE

The D-Dimer Rapid Quantitative Test along with Anbio FIA Meter is intended for vitro quantitative determination of D-Dimer in human whole blood or plasma.

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).
Normal Reference Value: < 0.5mg/L

AND PRINCIPLE OF THE PROCEDURE

The Anbio D-Dimer Rapid Quantitative Test is based on fluorescence immunoassay technology. The Anbio D-Dimer Rapid Quantitative Test uses a sandwich immunodetection method, when sample is added to the sample well of the Test Cartridge, the fluorescence-labeled detector D-Dimer antibody binds to D-Dimer antigen in blood 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 D-Dimer antibody that has been immobilized on test strip. Thus the more D-Dimer antigen is in blood 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 concentrations in blood specimen.

STORAGE AND STABILITY

1. Store the detector buffer at 2～30℃. The buffer is stable up to 18 months.
2. Store Anbio CRP Rapid Quantitative Test Cartridge at 4～30℃, shelf life is up to 18 months.
3. Test Cartridge should be used within 1 hour after opening the pack.

Materials Supplied

- Test Cartridge
- Test Cartridge ID Card
- whole blood buffer

MATERIALS REQUIRED BUT NOT PROVIDED

- Transfer Pipette Set (10μL, 100μL size)
- Specimen Collection Containers
- Sterile Lancets(for Fingerstick Whole Blood only)
- Alcohol Pads
- Centrifuge (for Plasma/Serum only)
- Timer

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 ID Chip # that is inserted onto the equipment.
5. The Anbio D-Dimer Rapid Quantitative 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. TheTest 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 buffer vials for different specimens.
9. Blood specimens, used Test Cartridges, pipette tips and detector buffer vials 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 serum or plasma or whole blood.

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 (EDTA recommended)
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 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℃.

TEST PROCEDURE

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

Step1: Preparation

Check/ swipe the ID Card information to the equipment.

Step2: Loading

plasma: take 100μL of serum or plasma samples, load it onto the sample well of the Test Cartridge;

Whole blood: take 120 μL of whole blood sample, load it onto the sample well of the Test Cartridge, immediately add a drop of whole blood buffer to the sample well;

Step3: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, serum and plasma specimen.
2. The results of Anbio D-Dimer Rapid Quantitative Test 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. The false positive results may come from cross-reactions with some similar antibodies in blood; and similar epitopes from non-specific components in blood capturing fluorescent labeled antibodies.
4. EDTA other than anticoagulants (e.g. heparin or citrate) is suggested to use for plasma.
5. Other factors may interfere with Anbio D-Dimer Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

PERFORMANCE CHARACTERISTICS

Detection Limit : 0.1mg/L ;
Linear Range: 0.1～10 mg/L;
Linear correlation coefficient R ≥ 0.990;
Precision: within batch C.V. is ≤ 15%; between batches C.V. is ≤ 20%;
Accuracy: the relative deviation of the measurement results shall not exceed ± 15% when the standardized accuracy calibrator is tested.

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.

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