D-dimer FIA Rapid Test

(Whole Blood/Plasma)

FIA-DDM-001

A rapid test for the detection of D-dimer in whole blood or plasma with the use of the Biopanda Fluorescence Immunoassay Analyser.
For professional in vitro diagnostic use only.

INTENDED USE

The D-dimer FIA Rapid Test is based on Fluorescence Immunoassay for the quantitative determination of human D-dimer in whole blood or plasma as an aid in the diagnosis of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).

SUMMARY

D-dimer (or D dimer) is a fibrin degradation product (or FDP), a small protein fragment present in the blood after a blood clot is degraded by fibrinolysis. Its formation or increase reflects the activation of coagulation and fibrinolysis system, and its plasma level can represent the production of thrombin active agent fibrin in vivo. It can be used as an indicator of thrombosis in the body. The D-dimer content in patients with thrombosis is significantly elevated.[1]
In addition, studies have shown that low levels of D-dimer (0.1-0.5 mg/L) are closely related to the occurrence of cardiovascular diseases, and high levels of D-dimer may be early exclusion diagnostic indicators for DVT and PE.[2]

PRINCIPLE

The D-dimer FIA Rapid Test Cassette detects D-dimer based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains D-dimer, it attaches to the fluorescent microspheres-conjugated anti-D-dimer antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of D-dimer in the sample correlates with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and standard curve, the concentration of D-dimer in the sample can be calculated by the Biopanda Fluorescence Immunoassay Analyser to show D-dimer concentration in specimen.

REAGENTS

The test includes anti-D-dimer antibody conjugated fluorophores and anti-D-dimer antibody coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Biopanda D-dimer FIA Rapid Test should only be used with the Biopanda Fluorescence Immunoassay Analyser by approved medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

KIT COMPONENTS

- 10 x foil wrapped D-dimer test cassettes
- 10 x Specimen collection tubes with extraction buffer
- 1 x ID card (D-dimer)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Analyser

SPECIMEN COLLECTION AND PREPARATION

PREPARATION

1. Before performing the test, please make sure that all components are brought to room temperature (15-30°C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a tube with buffer solution out of the kit. Document patients name or ID on it. Open the screw cap.

BLOOD SAMPLE TAKING

1. Collect the specimen according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Plasma specimens may be stored at 2-8°C for up to 3 days, for long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be used within a half-day of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
4. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

SAMPLE DILUTION / SAMPLE STABILITY

1. The specimen **(7.5 ul of whole blood or 5 ul of plasma)** can be added directly with a micro pipette into the buffer tube.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer.
3. Let the diluted sample homogenize for approximately **1 minute**.
4. It is best to place the diluted sample on an ice pack and leave the sample at room temperature for no more than 8 hours.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Analyser Operation Manual for the complete instructions on use of the Test. The test should be conducted at room temperature.
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyser. Then according to the user requirement, select “Standard test” or “Quick test” mode.
2. Take out the ID card and insert it into the Analyser port.
3. **Plasma:** Transfer **5 µl of plasma** into the buffer tube, mix the specimen and the buffer well.
4. **Whole Blood:** Transfer **7.5 µl of whole blood** into the buffer tube, mix the specimen and the buffer well.
5. **Add diluted specimen with a Pipette**: Pipette **85 µl** of diluted specimen into the sample well of the test cassette. Start the timer at the same time.
6. There are two test modes for the Biopanda Fluorescence Immunoassay Analyser; Standard Test mode and Quick Test mode. Please refer to the user manual of the Biopanda Fluorescence Immunoassay Analyser for details.

“Quick test” mode: Insert the test cassette into the Analyser at 15 minutes after sample application and click "New Test", the Analyser will automatically give the test result after a few seconds.
“Standard test” mode: Insert the test cassette into the Analyser immediately after sample application, click "New test" at the same time, the Analyser will automatically count down the 15 minutes. After the countdown, the Analyser will give the result at once.

INTERPRETATION OF RESULTS

The result of tests for D-dimer is calculated by the Biopanda Fluorescence Immunoassay Analyser and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Analyser.

Linearity range of the Biopanda D-dimer FIA Rapid Test is 0.1~10 mg/L.
Reference range: <0.5 mg/L.

QUALITY CONTROL

Each Biopanda D-dimer FIA Rapid Test Cassette contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by the Biopanda Fluorescence Immunoassay Analyser. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Analyser indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on the Biopanda Fluorescence Immunoassay Analyser. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The Biopanda D-dimer FIA Rapid Test Cassette is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of D-dimer.
2. The Biopanda D-dimer FIA Rapid Test Cassette will only indicate the presence of D-dimer in the specimen and should not be used as the sole criterion for evaluating DVT and PE.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. High concentrations of D-dimer may produce a dose hook effect, resulting in incorrect interpretation of D-dimer levels. High dose hook effect has not been observed with this test up to 10 mg/L of D-dimer.
5. The haematocrit level of the whole blood should be between 25% and 65%.
6. The results of the Biopanda D-dimer FIA Rapid Tests are based on measuring the levels of D-dimer in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED RESULTS

Concentrations	Clinical Reference
<0.5 mg/L	Healthy
0.5~1.5 mg/L	Low DVT and PE risk
1.5~3 mg/L	Moderate DVT and PE risk
3~5 mg/L	High DVT and PE risk
>5 mg/L	High DVT and PE risk (Increased mortality)

PERFORMANCE CHARACTERISTICS

1. **ACCURACY**: The test deviation is ≤±15%.
2. **SENSITIVITY**: The Biopanda D-dimer FIA Rapid Test Cassette can detect levels of D-dimer as low as 0.1 mg/L in whole blood or plasma.
3. **DETECTION RANGE**: 0.1~10mg/L
4. **LINEARITY RANGE**: 0.1~10mg/L, R≥0.990
5. **PRECISION**

INTRA-LOT PRECISION

Within-run precision has been determined by using 10 replicates of 2 specimens containing 0.1 mg/L and 0.5 mg/L of D-dimer. C.V. is ≤ 15%.

INTER-LOT PRECISION

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 0.1 mg/L and 0.5 mg/L of D-dimer. C.V. is ≤15%.

6**. CROSS-REACTIVITY**

Cross-reactivity studies were carried out with following analytes.
HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-syphilis IgG, anti-HIV IgG, anti-H.pylori IgG, anti-MONO IgM , anti-Rubella IgG, anti-Rubella IgM, anti-CMV IgG, anti-CMV IgM, anti-Toxo IgG and anti-Toxo IgM positive specimens.
The results showed no cross-reactivity.

7. **INTERFERING SUBSTANCES**

The following potentially interfering substances were added to D-dimer negative and positive specimens, respectively.

Acetaminophen: 20 mg/dL	Caffeine:20 mg/dL
Acetylsalicylic Acid:20 mg/dL	Gentisic Acid:20 mg/dL
Ascorbic Acid:20mg/dL	Albumin:10,500mg/dL
Creatin:200 mg/dL	Hemoglobin:1,000 mg/dL
Bilirubin:1,000mg/dL	Oxalic Acid:600mg/dL
Cholesterol:800mg/dL	Triglycerides:1,600mg/dL

None of the substances at the concentration tested interfered in the assay.

8. **METHOD COMPARISON**

The D-Dimer FIA Rapid Test was compared with the results obtained with ADVIA2400 for 90 samples. The correlation coefficient(r) is 0.983.

REFERENCES

1. Adam S S, Key N S, Greenberg C S. D-dimer antigen: current concepts and future prospects [J]. Blood, 2009, 113(13):2878.
2. General Practice Notebook > D-dimer. Retrieved September 2011.

Index of Symbols

	Attention, see instructions for use		Tests per kit		Do not reuse
IVD	For in vitro diagnostic use only		Use by	REF	Catalogue #
	Store between 4-30ºC	LOT	Lot Number		Consult instructions
	Do not use if package is damaged		Manufacturer		

Thank you for purchasing Biopanda's D-dimer FIA Rapid Test. Please read this manual carefully before operating to ensure proper use.

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