Biopanda Reagents

Product Insert: RAPG-DD-002

CE

D-dimer Rapid Test

Catalogue Number: RAPG-DD-002

TEST KIT DESCRIPTION

The Biopanda D-dimer Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of human D-dimer in whole blood and plasma samples. This test is a tool to assist in the diagnosis of Disseminated Intravascular Coagulopathy (DIC), deep venous thrombosis (DVT) and pulmonary embolism (PE).

SUMMARY

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. It is so named because it contains two crosslinked D fragments of the fibrin protein. D-dimer concentration may be determined by a blood test to help diagnose thrombosis. Since its introduction in the 1990s, it has become an important test performed in patients with suspected thrombotic disorders. While a negative result practically rules out thrombosis, a positive result can indicate thrombosis but does not rule out other potential causes. Its main use, therefore, is to exclude thromboembolic disease where the probability is low. In addition, it is used in the diagnosis of the disorder Disseminated Intravascular Coagulopathy.

The Biopanda D-dimer Rapid Test is a simple test that utilizes a combination of anti-D-dimer antibody coated particles and capture reagents to qualitatively detect D-dimer in whole blood or plasma. The minimum detection level is 500ng/ml.

PRINCIPLE

The Biopanda D-dimer Rapid Test is a qualitative, membrane based immunoassay for the detection of D-dimer in whole blood or plasma. The membrane is pre-coated with specific capture antibodies in the test line regions of the test. During testing, the whole blood or plasma specimen reacts with the particle coated with specific antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with specific capture antibodies on the membrane and generate a coloured line. The presence of this coloured line in the specific test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

KIT CONTENTS

- 20 x Foil wrapped cassettes containing dropper and desiccant.
- 1 x Buffer Tube
- 1 x Product insert

STORAGE AND STABILITY

Store the kit between 2-30°C and ensure the kits are not frozen or stored in direct sunlight. The test is valid until the expiration date printed on the foil wrapping. Keep tests inside the foil pouch until use.

PRECAUTIONS

Follow these instructions for the best results:

- This kit is for *in vitro* diagnostic use only and should only be used by trained health professionals.
- Blood samples may be potentially infectious and should be handled with standard biosafety procedures.
- Protective clothing such as laboratory coats, disposable gloves, and eye protection should be worn when working with assays.
- Ensure the test kit is at room temperature before running the test.
- Keep the test inside the foil wrapper until it is needed.
- Ensure each test is used only once.
- Test kits that have reached their expiry date should not be used.
- Only use reagents from this kit when performing the test to ensure quality controlled testing.
- Used tests and unused samples should be discarded according to local standard biosafety procedures.

SAMPLE COLLECTION AND PREPARATION

The Biopanda D-dimer rapid test can be performed using whole blood (from venipuncture or fingerstick) or plasma.

To collect Fingerstick Whole Blood specimens:

Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.

Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.

Puncture the skin with a sterile lancet. Wipe away the first sign of blood.

Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.

Add the Fingerstick Whole Blood specimen to the test by using a capillary tube:

- Touch the end of the capillary tube to the blood until filled to approximately 25 µl. Avoid air bubbles.
- Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.

Add the Fingerstick Whole Blood specimen to the test by using hanging drops:

- Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
- Allow 1 hanging drop of fingerstick whole blood to fall into the center of the specimen area on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.

To collect Whole Blood from venipuncture:

- Collect blood from venipuncture with or without anticoagulants (EDTA, Heparin, Citrate) and use it directly for the test.

Separate plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.

Testing should be performed immediately after the specimens have been collected. Do not leave the 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 run within 1 day of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.

Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

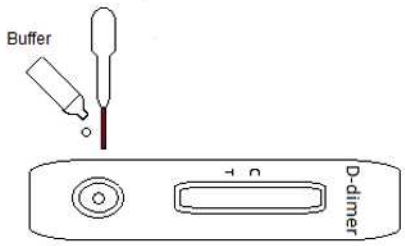
If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

1. Ensure specimen and test kits are brought to room temperature before testing. Ensure the blood specimen is

mixed well.

2. Open the foil wrapped pouch and remove the cassette, placing it on a flat, clean surface. Use the test as soon as possible or within one hour of opening.
3. For Plasma samples:
   Hold the dropper vertically and transfer 1 drop of plasma (approximately 25 µl) to the specimen area, then add 2 drops of buffer (approximately 80 µl), and start the timer.
4. For Venipuncture Whole Blood specimens:
   Hold the dropper vertically and transfer 1 drop of whole blood (approximately 25 µl) to the specimen area, then add 2 drops of buffer (approximately 80 µl), and start the timer.
5. For Fingerstick Whole Blood specimens:
   To use a capillary tube: Fill the capillary tube and transfer approximately 25 µl of fingerstick whole blood specimen to the specimen area of the test cassette, then add 2 drops of buffer (approximately 80 µl) and start the timer.
   To use hanging drops: Allow 1 hanging drop of fingerstick whole blood specimen (approximately 25 µl) to fall into the specimen area of the test cassette, then add 2 drops of buffer (approximately 80 µl) and start the timer.
6. Wait for the coloured line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.



TEST RESULTS

Positive Results: Two distinct coloured lines appear. One coloured line should appear in the control line region (C) and another coloured line should be in the test line region (T).

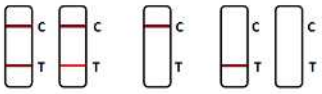
NOTE: The intensity of the colour in the test line region (T) will vary depending on the concentration of D-dimer present in the specimen. Therefore, any shade of colour in the test line region should be considered positive.

Negative Results:

If only the Control band appears without the presence of any band in the test region this indicates D-dimer levels are below the minimum detection levels.

Invalid Results:

If no Control band appears in any test, despite the presence of test bands or none, this indicates an invalid result and a new test should be performed.



LIMITATIONS OF THE PROCEDURE

1. The Biopanda D-dimer Rapid Test is for *in vitro diagnostic use* only. This test should be used for the detection of D-dimer in whole blood or plasma specimens only. Neither the quantitative value nor the rate of increase in D-dimer can be determined by this qualitative test.
2. The Biopanda D-dimer Rapid Test will only indicate the qualitative level of D-dimer in the specimen and should not be used as the sole criteria for the diagnosis of Disseminated Intravascular Coagulopathy (DIC), Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).
3. The sensitivity of immunological rapid tests is lower (negative predictive value=85,7 %) for patients with moderate or high pretest probability for thromboembolic infarction (high Wells score) as for patients with low pretest probability (low Wells score, negative predictive value=99,5 %). Hence, for moderate and high pretest probability an ultrasound examination is recommended irrespective the result of the rapid test.
4. The Biopanda D-dimer Rapid Test cannot detect less than 500 ng/ml of D-dimer in specimens. A negative result at any time does not preclude the possibility of Disseminated Intravascular Coagulopathy (DIC), Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).
5. False negative readings can occur if the sample is taken either too early after thrombus formation, if testing is delayed for several days or if the sample was take too later after the occurrence of thromboembolic infarction, because the D-dimer concentration may decrease to normal values after one week already. Additionally, a treatment with anti-coagulants prior sample collection can render the test negative because it prevents thrombus extension.
6. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.E.g. use "Wells score" for DVT resp. PE, Ultrasound, quantitative laboratory D-Dimer results etc.
7. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.
8. There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than 2 days may not run properly on the test cassette. Repeat the test with a plasma specimen from the same patient using a new test cassette.

SENSITIVITY AND SPECIFICITY

The Biopanda D-dimer Rapid Test has been evaluated with a leading commercial D-dimer ELISA test using clinical specimens. The results show that relative to leading ELISA tests, the Biopanda D-dimer Rapid Test shows >99.9% sensitivity, 98.2% specificity and an overall accuracy of 98.4%.

REFERENCES

1. Adam SS, Key NS, Greenberg CS (March 2009). "D-dimer antigen: current concepts and future prospects". Blood 113 (13): 2878–2887. doi:10.1182/blood-2008-06-165845. PMID 19008457
2. Fritscher, Claudia (2007): Bedeutung der D-dimer Untersuchung in der Diagnostik der tiefen Beinvenenthrombose,Labor Aktuell Nr.7/2007, 1-8.

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

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