D-Dimer Rapid Test Cassette (whole blood/plasma/serum) Package Insert

REF CDIM-C41	English

A rapid test for the qualitative detection of D-Dimer in human whole blood, plasma or serum.
For professional in vitro diagnostic use only.

【INTENDED USE】

The D-Dimer Rapid Test Cassette (whole blood/plasma/serum) is a rapid chromatographic immunoassay for the qualitative detection of D-Dimer to aid in the diagnosis of deep vein thrombosis(DVT), pulmonary embolism(PE) and disseminated intravascular coagulation(DIC) .

【SUMMARY】

D-dimer is a biomarker that globally indicates the activation of hemostasis and fibrinolysis. It is a degradation product of fibrin, which is produced when cross-linked fibrin is degraded by plasmin-induced fibrinolytic activity. Fibrin D-dimer, a marker of on-going fibrin formation and degradation, is the most commonly used clinical assay for the detection of activation of the coagulation system. As D-dimer plasma levels are elevated after clot formation, the measurement of D-dimer is routinely used in conjunction with clinical parameters in the initial assessment of suspected acute VTE. Elevated D-dimer levels measurement provides prognostic indications for a variety of conditions, including venous thromboembolism, disseminated intravascular coagulation, cardiovascular disease, infectious diseases, and cancer. The D-Dimer Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of D-Dimer in whole blood, serum or plasma specimen. The test utilizes monoclonal antibodies to selectively detect elevated levels of D-Dimer in whole blood, serum or plasma. The minimum detection level is 500 ng/mL.

【PRINCIPLE】

The D-Dimer Rapid Test Cassette (whole blood/plasma/serum) is chromatographic immunoassay including anti-D-Dimer antibody conjugated to colloidal gold particles, anti-D-Dimer antibody on test line and IgG antibody on the control line. During testing, the whole blood, serum or plasma specimen reacts with anti-D-Dimer antibody coated particles in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with anti-D-Dimer antibody on the membrane in the test line region. If the specimen contains D-Dimer, one purple line will appear in the test line region. Presence of this purple line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a purple line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The D-Dimer Rapid Test Cassette contains anti-D-Dimer antibodies coated particles and anti-D-Dimer antibodies coated on the membrane.

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used tests, specimens and potentially contaminated materials should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- Do not mix the components from different lot to lot.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. The uncovered buffer could be stored at room temperature or refrigerated (2-30°C) for 1.5 months at least. **DO NOT FREEZE**. Do not use after the expiration date.

【SPECIMEN COLLECTION AND HANDLING】

The D-Dimer Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum 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 50 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.
- Separate serum or 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. Serum and 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 2 days 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.

【MATERIALS】

Materials Provided

- Test Cassettes
- Droppers
- Package insert
- Buffer (0.02%NaN_3+0.025%Kanamycin Sulfate)

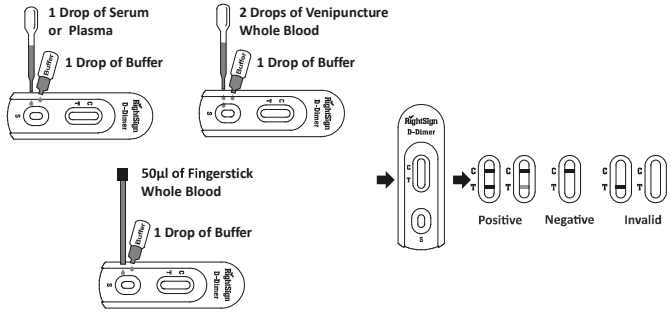
Materials Required But Not Provided

- Specimen collection containers
- Centrifuge
- Timer
- Lancets (for fingerstick whole blood only)
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

【DIRECTIONS FOR USE】

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the cassette on a clean and level surface.
   For **Serum or Plasma** specimen: Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25 μL) to the specimen area, then **add 1 drop of buffer** (approximately 40 μL), and start the timer. See illustration below.
   For **Venipuncture Whole Blood** specimen: Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 μL) to the specimen area, then **add 1 drops of buffer** (approximately 40 μL), and start the timer. See illustration below.
   For **Fingerstick Whole Blood** specimen:
   To use a capillary tube: Fill the capillary tube **and transfer approximately 50 μL of fingerstick whole blood specimen** to the specimen area of test cassette, then **add 1 drops of buffer** (approximately 40 μL) and start the timer. See illustration below.
3. Wait for the purple line(s) to appear. **Read results at 15 minutes.** Do not interpret the result after 20 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two lines appear. One purple line should be in the control line region (C) and another apparent purple line should be in the test line region (T).

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

NEGATIVE: One purple line appears in the control line region (C). No line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line 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.

【QUALITY CONTROL】

A procedural control is included in the test. A purple line appearing in the control line region (C) is considered an internal procedural control. It confirms adequate membrane wicking.

Control standards are not supplied with this test cassette; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The D-Dimer Rapid Test Cassette (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of D-Dimer in whole blood, serum 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 D-Dimer Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of D-Dimer in the specimen and should not be used as the sole criteria for the diagnosis of eep vein thrombosis(DVT), pulmonary embolism(PE) and disseminated intravascular coagulation(DIC).
3. For confirmation, further analysis of the specimens should be performed according to local health authorities' guidelines, such as ELISA.
4. As with all rapid test cassettes, all results must be interpreted together with other clinical information available to the physician.
5. This test is intended for screening purposes only.
6. A negative result does not exclude the possibility of thrombosis. Therefore, the result obtained with D-Dimer Rapid Test Cassette should be used in conjunction with clinical finding to make an accurate diagnosis.

Warning

This device will not give correct result if the instructions for use are not strictly followed.

【EXPECTED VALUES】

The D-Dimer Rapid Test Cassette has been compared with a leading commercial Rapid Test(Market advantage products), demonstrating an overall accuracy of 97%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The D-Dimer Rapid Test Cassette has been evaluated with specimens obtained from apparently healthy blood donor and patients specimen. The result shows that the sensitivity of the D-Dimer Rapid Test Cassette is 97.4% and the specificity is 98.1% relative to other Rapid Test.

Method		Other Rapid Test		Total Result
D-Dimer Rapid Test Cassette	Results	Positive	Negative	
	Positive	76	2	78
	Negative	2	101	103
Total Result		78	103	181

Relative sensitivity: 76/78=97.4% (95%CI*: 91.0%~99.7%);
Relative specificity: 101/103=98.1% (95%CI*: 93.2%~99.8%);
Accuracy: (76+101)/(78+103) =97.8% (95%CI*: 94.4%~99.4%).
*Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of below three specimens: D-Dimer specimen levels at 0μg/mL, 0.5μg/mL and 5μg/mL. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same three specimens: 0μg/mL, 0.5μg/mL and 5μg/mL of D-Dimer. Three different lots of the D-Dimer Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The D-Dimer Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by Fibrinogen, Fibrin monomer, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, anti-HCV, anti-HIV, anti-H.pylori positive specimens. The results showed no cross-reactivity.

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

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

【BIBLIOGRAPHY】

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Index of Symbols

	Consult Instructionfor use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

Manufacturer
Hangzhou Biotest Biotech Co., Ltd.
17#, Futai Road, Zhongtai Street,
Yuhang District, Hangzhou, P. R. China

EC REP
Shanghai International
Holding Corp. GmbH (Europe)
Eiffestrasse 80,
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