

**OneStep  
D-dimer  
(Whole Blood/Plasma)  
RapiCard™ InstaTest**

**175770-10-44**



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

**INTENDED USE**

The Cortez Diagnostics D-dimer RapiCard™ (Whole Blood/ Plasma) is a rapid chromatographic immunoassay for the qualitative detection of human D-dimer in whole blood or plasma as an aid in the diagnosis of Disseminated Intravascular Coagulopathy (DIC), deep venous thrombosis (DVT) and pulmonary embolism (PE).

**SUMMARY AND EXPLANATION**

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. 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.<sup>1</sup>

The D-dimer RapiCard™ (Whole Blood/ Plasma) 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.

**TEST PRINCIPLE**

The Cortez Diagnostics D-dimer RapiCard™ InstaTest (Whole Blood/ Plasma) 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 colored line. The presence of this colored 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 colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

**SPECIMEN COLLECTION AND PREPARATION**

- The D-dimer RapiCard™ (Whole Blood/ Plasma) 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 25µL. 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.
- To collect Whole Blood from venipuncture:
  - Collect blood from venipuncture with or without anticoagulants (EDTA, Heparin, Citrate and Oxalate) 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 halfday. 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 half 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.

**REAGENTS**

The test contains anti- D-dimer antibody conjugated colloid gold particles and capture antibodies coated on the membrane.

**MATERIALS AND COMPONENTS**

**Materials provided with the test kits**

- Test Cassettes
- Buffer
- Droppers

**Materials required but not provided**

- Specimen collection container
- Centrifuge
- Timer

*For fingerstick whole blood*

- Lancets
- Heparinized capillary tubes and dispensing bulb

**ASSAY PROCEDURE**

**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 **Plasma** specimen:

- Hold the dropper vertically and transfer **1 drop of plasma** (approximately **25µL**) to the specimen area, then **add 2 drops of buffer** (approximately **80µL**), and start the timer. See illustration below.

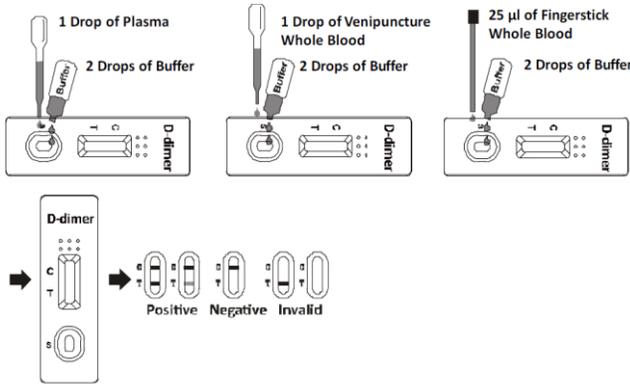
For **Venipuncture Whole Blood** specimen:

- 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. See illustration below.

For **Fingerstick Whole Blood** specimen:

- To use a capillary tube: Fill the capillary tube and transfer **approximately 25 µL of fingerstick whole blood specimen** to the specimen area of test cassette, then **add 2 drops of buffer** (approximately **80 µL**) and start the timer. See illustration below.
- To use hanging drops: Allow **1 hanging drop of fingerstick whole blood specimen** (approximately **25 µL**) to fall into the specimen area of test cassette, then **add 2 drops of buffer** (approximately **80 µL**) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.



**RESULTS**

**POSITIVE:** \* A colored line in the control line region (C) and the presence of one colored line in the test line regions indicates a positive result. This indicates that the concentration of D-dimer is above the minimum detection level.

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

**NEGATIVE:** One colored line appears in the control line region (C). No line appears in the test line region (T). This indicates that the concentration of D-dimer are below the minimum detection levels.

**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.

**PERFORMANCE CHARACTERISTICS**

**Sensitivity and Specificity**

The D-dimer RapiCard™ (Whole Blood/Plasma) has been evaluated with a leading commercial D-dimer ITM test using clinical specimens. The results show that relative to leading immunoturbidimetry (ITM) tests, the D-dimer RapiCard™ (Whole Blood/Plasma) shows 96.5% sensitivity, 98.3% specificity and an overall accuracy of 97.4%.

**D-dimer RapiCard vs. ITM**

Method	EIA		Total Result	
	Results	Positive		Negative
D-dimer RapiCard (Whole Blood/Plasma)	Positive	275	5	280
	Negative	10	295	305
Total Result		285	300	585

Relative sensitivity: 96.5% (95%CI\*: 93.6%~98.3%);  
 Relative specificity: 98.3% (95%CI\*: 96.2%~99.5%);  
 Accuracy: 97.4% (95%CI\*: 95.8~98.6%).

\*Confidence Intervals

**Precision Intra-Assay**

Within-run precision has been determined by using 10 replicates of below five specimens: D-dimer specimen levels at 0 ng/mL, 500

ng/mL, 1,000 ng/mL, 1,500 ng/mL and 3,000 ng/mL. The specimens were correctly identified at the prescribed reading time.

**Inter-Assay**

Between-run precision has been determined by 3 independent assays on the same five specimens: 0 ng/mL, 500 ng/mL, 1,000 ng/mL, 1,500 ng/mL and 3,000 ng/mL of D-dimer. Three different lots of the D-dimer RapiCard™ (Whole Blood/Plasma) have been tested using these specimens. The specimens were correctly identified at the prescribed reading time.

**Cross-reactivity**

The D-dimer RapiCard™ (Whole Blood/Plasma) has been tested with HBsAg, HBsAb, HBeAg, HBeAb, HbCAb, anti-syphilis, anti-HIV, anti-H.pylori, IM heterophile antibodies, anti-CMV, anti-Rubella and anti-Toxoplasma 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  
 Acetylsalicylic Acid: 20 mg/dL      Gentisic Acid: 20 mg/dL  
 Ascorbic Acid: 20 mg/dL      Albumin: 10,500 mg/dL  
 Creatin: 200 mg/dL      Hemoglobin: 1,000 mg/dL  
 Bilirubin: 1,000 mg/dL      Oxalic Acid: 600 mg/dL  
 Cholesterol: 800 mg/dL      Triglycerides: 1,600 mg/dL  
 None of the substances at the concentration tested interfered in the assay.

**QUALITY CONTROL**

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; 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.

**LIMITATION OF PROCEDURE**

1. The D-dimer RapiCard™ (Whole Blood/ Plasma) 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 D-dimer RapiCard™ (Whole Blood/ Plasma) 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.<sup>2</sup>
4. The D-dimer RapiCard™ (Whole Blood/Plasma) cannot detect less than 500ng/mL 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 taken 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.<sup>3,4</sup>
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.<sup>2</sup>
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.

### EXPECTED VALUES

Increased D-dimer concentration above the widely accepted cut-off value of 500 ng/ml FEU (Fibrinogen Equivalent Unit) is a sign of an active fibrinolysis and has been verified at patients with DIC, DVT and PE. Such increased concentrations after surgery and injury and during sickle cell anaemia, liver disease, heavy infections, sepsis, inflammation, malignant disease or in older people too. The concentration of D-dimer rises also during a normal pregnancy.

### PRECAUTION

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- 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 test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

### STORAGE

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. **DO NOT FREEZE**. Do not use after the expiration date.

### REFERENCE

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

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3. Dempfle, Carl-Erik (2005): Bestimmung des D-dimer-Antigens in der klinischen Routine, Deutsches Ärzteblatt Jg. 102, Heft 7, 18. Februar 2005: A428-A432.
4. Blackwell Publishing Ltd. (2004): The diagnosis of deep vein thrombosis in symptomatic outpatients and the potential for clinical assessment and D-dimer assays to reduce the need for diagnostic imaging, British Journal of Haematology, 124, 15–25.

<p><b>ISO 13485</b> <b>ISO 9001</b></p>  <p><b>Diagnostic Automation/</b> <b>Cortez Diagnostics, Inc.</b> 21250 Califa St, Suite 102 and 116, Woodland Hills, California 91367 USA</p>	
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