



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

REF 175770

PIC CM175770VV86

IVD See External Label 2°C 30°C 25 Tests

D-dimer RapiCard™ InstaTest	
Principle	Immunochromatographic Assay
Detection	Qualitative
Sensitivity	97.2%
Specificity	94.0%

PRODUCT FEATURES

- High Sensitivity and Specificity**
- Built in Internal Controls**
- Simplified Workflow, Non-invasive, and Safe**
- Rapid and Faster Results**

INTENDED USE

The OneStep 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).

SIGNIFICANCE AND 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. It is so named because it contains two crosslinked D fragments of the fibrin protein.¹D-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.¹

The OneStep 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.

ASSAY PRINCIPLE

The OneStep 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 OneStep 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 half day. 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.
- EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

REAGENTS

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

Materials provided with the kit

- Test cassettes
- Buffer
- Droppers
- Package inserts

Materials required but not provided

- Specimen collection container
- Centrifuge (for plasma only)
- Timer
- Lancets (For fingerstick Whole Blood Only)
- Heparinized Capillary Tubes and Dispensing Bulb (For fingerstick Whole Blood Only)

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.

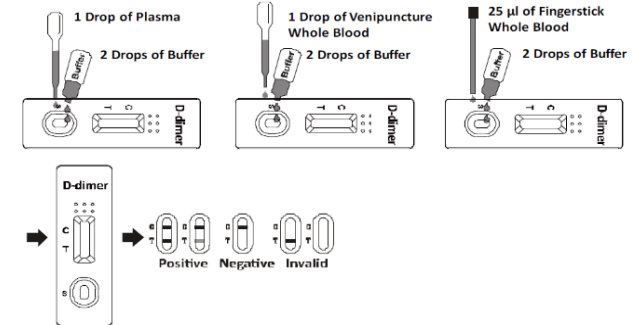
For **Venipuncture Whole Blood** specimen:

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

Note: It is suggested not to use the buffer, beyond 30 days after opening the vial.



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.

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.

LIMITATIONS OF THE ASSAY

1. The OneStep 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 OneStep 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 OneStep 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).
4. 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.^{3,4}

5. 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.²
6. 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.
7. The hematocrit of the whole blood should be between 25% and 65%.

EXPECTED RANGE OF 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.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

421 clinical specimens with known status of D-dimer above or below cut-off value of 500ng/ml collected from local hospitals were tested with the OneStep D-dimer RapiCard™ InstaTest (Whole Blood/Plasma) in house. Results indicated

relative sensitivity was 97.2%, relative specificity was 94.0%, and the overall accuracy was 96.4% compared with ITM (Immunoturbidimetry Tests)

Clinical Study Result (In-house)

Method	ITM			Total Result
	Results	Positive	Negative	
OneStep D-dimer RapiCard™ (Whole Blood/Plasma)	Positive	312	6	318
	Negative	9	94	103
Total Result		321	100	421

Relative sensitivity: 97.2% (95%CI*: 94.7%~98.7%);
Relative specificity: 94.0% (95%CI*: 87.4%~97.8%);
Accuracy: 96.4% (95%CI*: 94.2%~98.0%).

*Confidence Intervals

396 clinical specimens were evaluated with the OneStep D-dimer RapiCard™ InstaTest (Whole Blood/Plasma) at a German site, results indicated relative sensitivity was 92.0%, relative specificity was 89.9%, and the overall accuracy was 90.2% compared with ITM.

Clinical Study Result (At German site)

Method	Results	ITM			
		0-250 ng/ml	250-500 ng/ml	500-2500 ng/ml	>2500 ng/ml
OneStep D-dimer RapiCard™ InstaTest (Whole Blood/Plasma)	Positive	5	30	35	11
	Negative	9	207	4	0
Total Result		109	237	39	11
Accuracy		95.4%	87.3%	89.7%	100%

Relative sensitivity: 92.0% (95%CI*: 80.8%~97.8%);
Relative specificity: 89.9% (95%CI*: 86.2%~92.9%);
Accuracy: 90.2% (95%CI*: 86.8%~92.9%).

*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 OneStep 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 OneStep D-dimer RapiCard™ InstaTest (Whole Blood/Plasma) has been tested with HBsAg, anti-syphilis, RF, anti-HIV, anti-HCV, anti-H. pylori, anti-Rubella IgG, anti-CMV IgG and anti-Toxo IgG 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
Cholesterol: 800 mg/dL	Triglycerides: 1,600 mg/dL

PRECAUTIONS

- 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 CONDITIONS

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.

REFERENCES

- 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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- Dempfl e, Carl-Erik (2005): Bestimmung des D-dimer-Antigens in der klinischen Routine, Deutsches Ärzteblatt Jg. 102, Heft 7, 18. Februar 2005: A428-A432.
- 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.

MANUFACTURER AND BRAND DETAILS

 <p>ISO 13485:2016 Quality Management for Medical Devices CERTIFIED</p>	
 <p>Diagnostic Automation/Cortez Diagnostics, Inc. 21250 Califa Street, Suite 102 and 116, Woodland Hills, California 91367 USA</p>	
Date Adopted	2025-05-27
Brand Name	RapiCard™ InstaTest
REF 175770	OneStep D-dimer RapiCard™ InstaTest (Whole Blood/Plasma)
PIC	CM175770VV86
EU REP	AR Experts BV, Boeingavenue 201-219 1119 PD Schiphol-Rijk, The Netherlands info@ar-experts.eu
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