



One Step Test for D-Dimer (Colloidal Gold)

Instructions for Use

REF CG1006 for FIA8000
CG3006 for FIA8600

INTENDED USE

One Step Test for D-Dimer (Colloidal Gold) is intended for *in vitro* quantitative determination of D-Dimer in plasma or whole blood. The test is used as an aid in the assessment and evaluation of patients suspected of deep-vein thrombosis or pulmonary embolism.

SUMMARY

Deep-vein thrombosis is a common condition, with a lifetime cumulative incidence of 2 to 5 percent. Untreated deep-vein thrombosis can result in pulmonary embolism, a potentially fatal outcome. Anticoagulant therapy reduces both morbidity and mortality from venous thromboembolism, and early diagnosis is therefore important. Accurate diagnosis of deep-vein thrombosis minimizes the risk of thromboembolic complications and averts the exposure of patients without thrombosis to the risks of anticoagulant therapy.

D-Dimer is a marker of endogenous fibrinolysis and should therefore be detectable in patients with deep-vein thrombosis. In recent years, an increasing number of studies have shown the D-Dimer assay has a high negative predictive value and D-Dimer is a sensitive but nonspecific marker of deep-vein thrombosis. Negative D-Dimer can exclude deep-vein thrombosis and pulmonary embolism.

PRINCIPLE

The test uses an anti-human D-Dimer monoclonal antibody conjugated with colloidal gold and another anti-human D-Dimer monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the gold-labelled anti-human D-Dimer monoclonal antibody binds with the D-Dimer in sample and forms a marked antigen-antibody

complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human D-Dimer monoclonal antibody resulting in a purplish red streak appears on the test line. The color intensity of the test line increases in proportion to the amount of D-Dimer in sample.

Then insert test card into FIA8000/FIA8600 Quantitative Immunoassay Analyzer (hereinafter referred to as FIA8000 and FIA8600), the concentration of D-Dimer in sample will be measured and displayed on the screen. The value will be stored in FIA8000/FIA8600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for FIA8000/FIA8600 contains:

Package specifications: 25 tests/box, 10 tests/box

- 1) Getein D-Dimer test card in a sealed pouch with desiccant
- 2) Disposable pipet
- 3) Sample diluent
- 4) Instructions for use: 1 piece/box
- 5) SD card: 1 piece/box

2. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, a colloidal gold pad (coated with a gold-labelled anti-human D-Dimer monoclonal antibody), nitrocellulose membrane (the test line is coated with another anti-human D-Dimer monoclonal antibody, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

3. Sample diluent composition:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer

FIA8600 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months.

Use the test card within 1 hour once the foil pouch is opened.

Store the sample diluent at 0~30°C with a valid period of 24 months.

Store the sample diluent at 2~8°C for better results.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch is damaged.
5. Do not open pouches until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **plasma and whole blood samples**. **Sodium citrate** should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using plasma for better results.
3. If testing is delayed, plasma sample may be stored up to 3 days at 2~8°C or stored at -20°C for 1 months before testing (whole blood sample may be stored up to 3 days at 2~8°C).
4. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples.
6. SAMPLE VOLUME: **120 µl**.

TEST PROCEDURE

1. Collect specimens according to instructions for use.
2. Test card, sample and reagent should be brought to room temperature before testing.
3. Confirm SD card lot No. in according with test kit lot No.. Perform calibration when necessary (Details refer to FIA8000/8600 instructions for use).
4. On the main interface of FIA8000/FIA8600, press "ENT" button (FIA8000) or click on "Measure" icon (FIA8000/8600) to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.

7. Using sample transfer pipette, deliver **120 µl** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop **120 µl** of sample mixture into the sample port on the test card.

8. **Reaction time: 7 minutes.** Insert the test card into FIA8000 /FIA8600, press "ENT" button (FIA8000) or click on "Measure" icon (FIA8000/FIA8600) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:

1. It is required to perform calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits.
3. Make sure the test card insertion is correct and complete.

TEST RESULTS

Valid: When a purplish-red band appears at the control area (C), use FIA8000/FIA8600 to analyze the test card and get the result.

Invalid: If no colored band appears in the control area (C), the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.

Others: Dilute the sample which concentration is higher than the upper limit with sample diluent, the dilution ratio should be less than 4 times.

EXPECTED VALUE

The expected normal value for D-Dimer was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for D-Dimer is 0.50 mg/L. (The probability that value of a normal person below 0.50 mg/L is 95%.)

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.10~10.00 mg/L
Lower Detection Limit	≤0.10 mg/L
Within-Run Precision (n=10)	≤10%
Between-Run Precision	≤15%
Recovery	99%

Method Comparison:

The assay was compared with Sysmex CA7000 and Siemens

D-Dimer PLUS assay with 200 blood samples (60 positive samples and 140 negative samples). The correlation coefficient (r) for D-Dimer is 0.978.

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Samples containing interferents such as rheumatoid factor, human anti-mouse antibody and heterophile antibody may influence the results. In this case, results of this test should be used in conjunction with clinical findings and other tests. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	25 g/L	0.1 g/L

REFERENCES

1. Sarig G, Klil-Drori AJ, Chap-Marshak D, Brenner B, Drugan A. Activation of coagulation in amniotic fluid during normal human pregnancy. *Thromb Res.* 2011 Apr 18.
2. Roldán V, Marín F, Muiña B, Torregrosa JM, Hernández-Romero D, Valdés M, Vicente V, Lip GY. Plasma von Willebrand Factor Levels Are an Independent Risk Factor for Adverse Events Including Mortality and Major Bleeding in Anticoagulated Atrial Fibrillation Patients. *J Am Coll Cardiol.* 2011 Apr 11.
3. Sakamoto K, Yamamoto Y, Okamoto H, Okabe M. D-dimer is helpful for differentiating acute aortic dissection and acute pulmonary embolism from acute myocardial infarction. *Hellenic J Cardiol.* 2011 Mar-Apr; 52(2):123-127.
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on One Step

Test for D-Dimer (Colloidal Gold) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use or consult electronic instructions for use		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/European Union
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		

Thank you for purchasing One Step Test for D-Dimer (Colloidal Gold). Please read this instructions for use carefully before operating to ensure proper use.

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