CE

Diagnostic Kit for D-Dimer

A rapid test for measuring D-Dimer in whole blood or plasma with the use of Immunofluorescence Analyzer.

English

- For *in-vitro* diagnostic use

PACKING SPECIFICATION
25 Tests/ Kit (07CTNL5025)

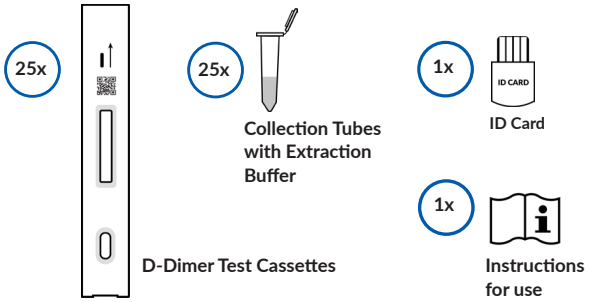
INTENDED USE
The D-Dimer Test Cassette (Whole Blood/Plasma) is based on Fluorescence Immunoassay to measure D-Dimer in human whole blood or plasma as an aid in the diagnosis of DVT and PE. The test is intended for healthcare professionals use.

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. Its formation or increase reflects the activation of coagulation and fibrinolysis system, and its plasma level can represent the production of thrombin active agent fibrin in vivo. It can be used as an indicator of thrombosis in the body. The D-dimer content in patients with thrombosis is significantly elevated[1].
In addition, studies have shown that low levels of D-Dimer (0.1-0.5 mg/L) are closely related to the occurrence of cardiovascular diseases, and high levels of D-Dimer may be early exclusion diagnostic indicators for DVT and PE[2].

PRINCIPLE
The D-Dimer Test Cassette (Whole Blood/Plasma) detects D-Dimer based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains D-Dimer, it attaches to the fluorescent microspheres-conjugated anti-D-Dimer antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of D-Dimer in the sample correlates with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and the standard curve, The concentration of D-Dimer in the sample can be calculated by Analyzer to show D-Dimer concentration in specimen.

REAGENTS
The test includes anti-D-Dimer antibody coated fluorphores and anti-D-Dimer antibody coated on the membrane.

MATERIALS PROVIDED



D-Dimer Test Cassettes

Collection Tubes with Extraction Buffer

ID Card

Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED
- Immunofluorescence Analyzer MPQuanti® (07IMA001)
- Pipettes
- Specimen Collection Containers
- Centrifuge (for serum/plasma specimen only)
- Timer

PRECAUTIONS
1. For professional *in-vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The D-Dimer Test Cassette should only be used with the Analyzer by approved medical professionals.

STORAGE AND STABILITY
1. The kit should be stored at 4 - 30 °C before the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

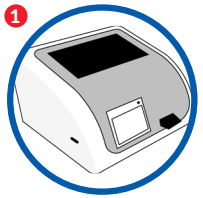
SAMPLE COLLECTION AND PREPARATION

Preperation
1. Before performing the test, please make sure that all components are brought to room temperature (15 - 30 °C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

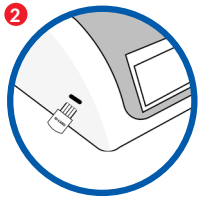
Sample Handling
1. Collect the specimen according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Plasma specimens may be stored at 2 - 8 °C for up to half-day, for long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture 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 finger stick should be tested immediately.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
4. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

Sample Dilution / Sample Stability
1. The specimen (5 µL of plasma/7.5 µL of whole blood) can be added directly with the micro pipette into the buffer.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer
3. Let the diluted sample homogenize for approximately 1 minute.
4. It is best to place the diluted sample on an ice pack and leave the sample at room temperature for no more than 8 hours.

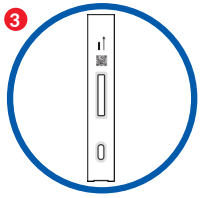
TEST PROCEDURE
Refer to Immunofluorescence Analyzer User Manual for the complete instructions on use of the Test. The test should be in room temperature.
Allow the test cassette, specimen and buffer to reach room temperature (15 - 30 °C) prior to testing.



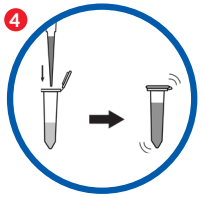
1. Turn on the Analyzer power.



2. Take out the ID card and insert it into the Analyzer ID Card Slot. Choose test mode and/or sample type according to needs.



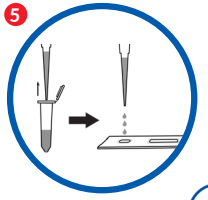
3. Remove the test cassette from the sealed foil pouch and use it within 1 hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch.



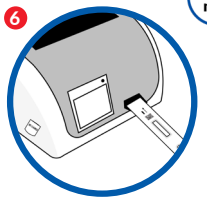
4. Place the test on a flat and clean surface.

Plasma: Pipette **5 µL of plasma** into the buffer tube, mix the specimen and the buffer well.

Whole blood: Transfer **7.5 µL of whole blood** into the buffer tube with pipette; mix the specimen and the buffer well.



5. ***Add diluted specimen with a Pipette:*** Pipette **85 µL** diluted specimen into the sample well of the test cassette. Start the timer at the same time.



6. Test results should be interpreted at **15 minutes** with the use of Immunofluorescence Analyzer.

Caution: There are different test modes of the Immunofluorescence Analyzer. The difference between them is incubation of the test cassette is outside or inside the analyzer. Choose test mode accordingly and confirm sample type. Consult the user manual of the analyzer for detailed operation information.
Operator must consult the Immunofluorescence Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

INTERPRETATION OF TEST RESULTS

Results read by Immunofluorescence Analyzer.

The result of tests for D-Dimer is calculated by Immunofluorescence Analyzer and display the result on the screen. For additional information, please refer to the user manual of Fluorescence Immunoassay Analyze.
Linearity range of D-Dimer Test is 0.1 ~ 10 mg/L.
Reference range: <0.5 mg/L.

QUALITY CONTROL

Each D-Dimer Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was tested and read properly by Immunofluorescence Analyzer. An invalid result from the internal control causes an "N/A" message on Immunofluorescence Analyzer and indicates that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control 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

1. The D-Dimer Test Cassette (Whole Blood/Plasma) is for professional *in-vitro* diagnostic use, and should only be used for the quantitative detection of D-Dimer.
2. The D-Dimer Test Cassette (Whole Blood/Plasma) will only indicate the presence of D-Dimer in the specimen and should not be used as the sole criterion for evaluating DVT and PE.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. High concentrations of D-Dimer may produce a dose hook effect, resulting in incorrect interpretation of D-Dimer levels. High dose hook effect has not been observed with this test up to 10 mg/L of D-Dimer.
5. The hematocrit level of the whole blood should be between 25% and 65%.
6. The results of D-Dimer Tests are based on measuring the levels of D-Dimer in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED VALUES

Concentrations	Clinical Reference
<0.5 ng/mL	Healthy
0.5 ~ 1.5 mg/L	Low DVT and PE risk
1.5 ~ 3 mg/L	Moderate DVT and PE risk
3 ~ 5 mg/L	High DVT and PE risk
>5 mg/L	High DVT and PE risk (Increased mortality)

PERFORMANCE CHARACTERISTICS

1. Accuracy
The test deviation ≤±15%

2. Sensitivity
The D-Dimer Test Cassette (Whole Blood/Plasma) can detect levels of D-Dimer as low as 0.1 mg/L in whole blood or plasma.

3. Detection range
0.1 ~ 10 mg/L

4. Linearity range
0.1 ~ 10 mg/L , R≥0.990

5. Precision
Intra-lot precision
Within-run precision has been determined by using 10 replicates of 2 specimens containing 0.1 mg/L, 0.5 mg/L of D-Dimer. C.V. is ≤15%.

Inter-lot precision
Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 0.1 mg/L, 0.5 mg/L of D-Dimer. C.V. is ≤15%.

6. Cross-reactivity
Cross-reactivity studies were carried out with following analytes.
HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-syphilis IgG, anti-HIV IgG, anti-*H.pylori* IgG, anti-MONO IgM, anti-Rubella IgG, anti-Rubella IgM, anti-CMV IgG, anti-CMV IgM, anti-Toxo IgG and anti-Toxo IgM positive specimens.
The results showed no cross-reactivity.

7. 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/mL	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.

8. Method comparison
The D-Dimer assay was compared with the results obtained with ADVIA2400 for 90 samples. The correlation coefficient(r) is 0.983.

BIBLIOGRAPHY

1. Adam S S, Key N S, Greenberg C S. D-dimer antigen: current concepts and future prospects[J]. Blood, 2009, 113(13):2878.
2. General Practice Notebook > D-dimer. Retrieved September 2011.

SYMBOLS

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