SCREEN®

SCREEN IFA TEST D-DIMERO (Whole Blood/Plasma) Package Insert

REF: SC-1583-20	English

A rapid test for measuring D-Dimer in whole blood or plasma with the use of SCREEN® fluorescence Immunoassay Analyzer. For professional in vitro diagnostic use only.

INTENDED USE

The D-Dimer Test Cassette (Whole Blood/Plasma) is based on Fluorescence Immunoassay to measure D-Dimer in whole blood or plasma as an aid in the diagnosis of DVT and PE.

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 (0.1-0.5mg/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 SCREEN® 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.

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 SCREEN® D-Dimer Test Cassette should only be used with the SCREEN® 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.

SPECIMEN COLLECTION AND PREPARATION

Preparation

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 uL of plasma/7.5 uL 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 **10seconds** 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

MATERIALS

Materials Provided

- Test Cassettes
- Specimen Collection Tubes with dilution buffer
- ID Card
- Package Insert

Materials Required But Not Provided

- Timer
- Centrifuge
- SCREEN® Fluorescence Immunoassay Analyzer
- Pipette
- Specimen Collection Containers

DIRECTIONS FOR USE

Refer to SCREEN® Fluorescence Immunoassay Analyzer Operation Manual for the complete instructions on use of the Test. The test should be conducted in room temperature. **Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.**

1. Turn on the Analyzer power. Then according to the need, select “standard test” or “Quick test” mode.
2. Take out the ID card and insert it into the Analyzer port.
3. **Plasma:** Pipette **5 µL plasma** into the buffer tube, mix the specimen and the buffer well.
4. **Whole blood:** Transfer **7.5 µL 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. There are two test modes for SCREEN® Fluorescence Immunoassay Analyzer, Standard Test mode and Quick Test mode. Please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyzer for details.

“Quick test” mode: After **15 minutes** of adding sample， Insert the test cassette into the Analyzer, click “**QUICK TEST**”, fill the test information and click **"NEW TEST**" immediately. The Analyzer will automatically give the test result after a few seconds.

“Standard test” mode: Insert the test cassette into the Analyzer immediately after adding specimen, click “**STANDARD TEST**”, fill the test information and click **"NEW TEST"** at the same time, The Analyzer will automatically countdown **15 minutes**. After the countdown, the Analyzer will give the result at once.

INTERPRETATION OF RESULTS

Results read by SCREEN® Fluorescence Immunoassay Analyzer.

The result of tests for D-Dimer is calculated by SCREEN® Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyze.

Linearity range of SCREEN® D-Dimer Test is 0.1~10 mg/L.

Reference range: < 0.5 mg/L

QUALITY CONTROL

Each SCREEN® D-Dimer Test Cassette contains internal control that satisfies routing quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by SCREEN® Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on SCREEN® Fluorescence Immunoassay Analyzer indicating that the test should be repeated. An invalid result from the internal control causes an “N/A” message on SCREEN® Fluorescence Immunoassay Analyzer. 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 SCREEN® D-Dimer Rapid 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 mg/L	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

1.Accuracy

The test deviation is ≤±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: 20mg/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.

8. Method comparison

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

LITERATURE REFERENCES

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.

INDEX OF SYMBOLS

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

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Number: 146474200
Effective date: 2021-05-20