

# D-Dimer

Rapid Test for the detection of D-Dimer in whole blood and plasma  
Produkt-# 21.075



**Dutch Diagnostics**

Human and animal care

## INTENDED USE

The **D-dimer cassette test** is a rapid, visual test for the qualitative detection of D-dimer in plasma or whole blood. This kit is intended as an aid in the diagnosis of disseminated intravascular coagulation (DIC), deep venous thrombosis (DVT) and pulmonary embolism. For professional in vitro diagnostic use only.

## SUMMARY

D-dimer testing was originally developed in the diagnosis of disseminated intravascular coagulation (DIC). In the 1990s, it was turned out to be useful in diagnosis of thromboembolic process.

D-dimer is a fibrin degradation product, a small protein fragment present in the blood after a blood clot is degraded by fibrinolysis. During coagulation of blood, fibrinogen is metabolized to fibrin by thrombin activation. Fibrin consists of D- and E- units. The cleavage of fibrin leads to so called D-dimers.

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 suspected of thrombotic disorders. While a negative result practically rules out thrombosis, a positive result can indicate thrombosis but does not rule out other potential etiologies. Its main use, therefore, is to exclude thromboembolic disease where the probability is low.

D-dimer testing is of clinical use when there is a suspicion of deep venous thrombosis (DVT) or pulmonary embolism (PE). In patients suspected of disseminated intravascular coagulation (DIC), D-dimer testing may aid in the diagnosis.

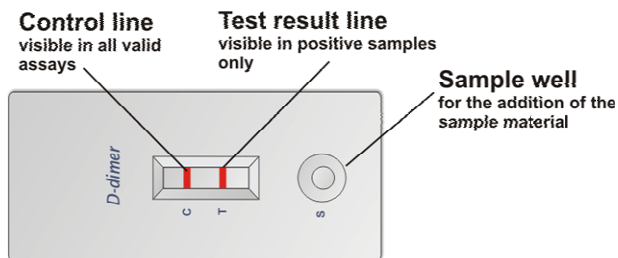
## PRINCIPLE

The **D-dimer cassette test** is intended for use in the detection of D-dimer in plasma or whole blood. This information can be used by the physician and the patient for disease management.

The **D-dimer cassette test** has been designed to detect D-dimer in plasma or whole blood through visual interpretation of color development in the test device, which is a sandwich immunoassay. The membrane was precoated with an antibody of D-dimer on the test line region (T). During the test the diluted specimen is allowed to react with a colored conjugate (anti-D-dimer antibody-gold conjugate) which was submitted on the pad inside the test cassette. The mixture then moves on the membrane chromatographically by a capillary action. If D-dimer is present in the specimen, a colored line with a specific antibody-antigen-conjugate complex will form at the test line region (T) of the membrane. This complex consists of a colored anti-D-dimer antibody, D-dimer from the specimen and the antibody immobilized on the membrane at the test line region (T).

On the other hand, a colored line will always appear at the control region (C) using another antigen-antibody reaction (with anti-mouse antibodies). This control line serves as a procedural indicator for the proper function of the device. It shows that the test procedure has been correct and membrane wicking has occurred.

A distinct color development in the test line region (T) indicates a positive result and absence of a color line in the test line region (T) suggests a negative result.



## STORAGE AND STABILITY

The test kit is to be stored at refrigeration (2-8°C) or room temperature (up to 30°C) in the sealed pouch for the duration of the shelf life.

## PRECAUTIONS

- For professional in vitro diagnostic use only!
- Do not use the kit beyond expiration date.
- Read the instructions carefully before performing the test.
- Do not use if pouch was damaged, because the test is humidity-sensitive.
- Do not open the foil pouch until you are ready to perform the test.
- Do not use twice!

- Do not eat, drink or smoke in the area where the specimen or devices are handled.
- All patient samples should be treated as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- The dilution solution contains minor amounts of sodium azide (0.09%).
- Do not pipette reagent by mouth!
- Do not spill solution into the reaction zone!
- Do not touch the reaction zone of the device to avoid contamination!
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Store and transport the test device always at 2-30°C (36°-86°F).
- Humidity and high temperature can adversely affect results.

## REAGENTS AND MATERIALS SUPPLIED

- 20 test devices
- 20 pipettes
- 1 bottle with dilution buffer ( PBS containing 0,09% NaN<sub>3</sub>)
- 1 instruction for use

## MATERIAL REQUIRED BUT NOT PROVIDED

- Specimen collection container
- lancets
- Timer

## SPECIMEN COLLECTION AND HANDLING

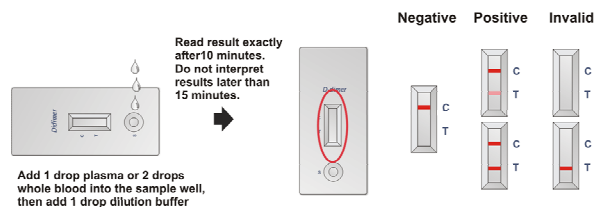
- The **D-dimer cassette test** (Whole Blood/ Plasma) can be performed using whole blood (from vein puncture or finger pad) or plasma.
- Separate plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods.
- D-dimers are very instable molecules. You can store whole blood and plasma specimens at room temperature only for 8 hours and refrigerated (4°C) only for 1 day!
- Bring specimens to room temperature prior to testing.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

## TEST PROCEDURE

Test device, buffer and patient's samples should be brought to room temperature (20-30°C) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test device from its protective pouch (bring the device to room temperature before opening the pouch to avoid condensation of moisture on the membrane). Label the device with patient or control identification.

2. Add 2 drops whole blood or 1 drop plasma (using the pipette supplied with the test) into the sample well first and then add 1 drop of dilution buffer. Avoid dropping any solution in the observation window. Start the timer!



3. Read the result exactly after 10 minutes after the addition of sample. Do not read results after 15 minutes.

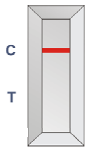
## INTERPRETATION OF RESULTS

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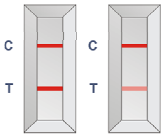
**Phone: +31 575 512 300**  
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# D-Dimer

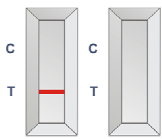
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**Negative result:** Only one red colored line appears on the control line region. No apparent red-colored line is visible on the test line region.



**Positive result:** In addition to the control line, a distinct red colored line also appears on the test line region. Note: The color intensities of the lines might vary!



**Invalid result:** If no control line appears in the C-region the test is not conclusive and must be interpreted as invalid. The absence of the control line might indicate an error in the test procedure or that the ingredients of the assay have deteriorated. Please repeat the test with a new test card paying

special attention to the instructions. If the problem persists please contact the manufacturer.

## QUALITY CONTROL

An internal procedural control is included in the test. A reddish control line appearing in the control region (C-region) of the membrane indicates proper performance of the test.

Good laboratory practice (GMP) recommends the use of external controls for the indication of the proper function of the test.

## EXPECTED VALUES

Increased concentrations of D-dimer are a sign of an active fibrinolysis and has been verified at patients with disseminated intravascular coagulation (DIC), deep venous thrombosis (DVT) and pulmonary embolism. You will find such increased concentrations as well after surgery and injury and during sickle cell anaemia, liver disease, heavy infections, sepsis, inflammation, malign disease or in older people. The concentration of D-dimer rises also during a normal pregnancy. The cut-off of the **D-dimer cassette test** is 80 ng/ml. This is the value indicating a positive result.

## PERFORMANCE CHARACTERISTICS

### Precision

Test precision was determined by blind tests with control solutions. Controls with a D-dimer-concentration of 0 ng/ml yield negative results. Controls with a D-dimer-concentration of 150 ng/ml provide positive results.

### Reproducibility

The reproducibility of the **D-dimer cassette test** was verified by blind tests performed at different days. All samples with D-dimer -concentrations of 0 ng/ml yielded negative results. All samples with D-dimer -concentrations of 150 ng/ml yielded positive results.

### Accuracy

The accuracy of the **D-dimer cassette test** was compared and checked against a commercially available test (this test has been validated against an ELISA test, the DIMERTEST GOLD EIA) with a threshold value of 80 ng/ml. The results were 100% in agreement.

### Specificity

The following substances made no interferences with this test: bilirubin up to 0,2 g/l, lipide up to 30 ng/l, serum protein up to 50 g/l, gammaglobulin and haemoglobin 1 g/l. A study with patients with rheumatoid arthritis showed no cross reactivities with the rheumatic factor.

## LIMITATIONS

- A negative result excludes disseminated intravascular coagulation (DIC), deep venous thrombosis (DVT) and pulmonary embolism at probability of 99% (2).
- A positive result is not an evidence of the existence of the diseases described above. It is an indication of deep venous thrombosis developed shortly before, because after one week the D-dimer concentrations will reach a normal level. (3)
- As in the case of any diagnostic procedure, the results obtained with this test should be used in conjunction with other information available to the physician.
- It is possible that the test does not yield any results if whole blood specimens have a high viscosity or if the whole blood specimens have been stored for more than one day. In this case the test should be repeated with a new test card using fresh specimen of the same patient.
- False positive readings can be due to various causes: liver disease, inflammation, malignancy, trauma, pregnancy, recent surgery as well as advanced age (2).
- False negative readings can occur if the sample is taken either too early after thrombus formation or if testing is delayed for several days. Additionally, a treatment with anti-coagulants prior sample collection can render the test negative because it prevents thrombus extension.
- Increased values of D-dimer after treatment with anti-coagulants show further risk of thrombosis. (4)

## REFERENCES

- Dempfle, Carl-Erik (2005): Bestimmung des D-dimer-Antigens in der klinischen Routine, Deutsches Ärzteblatt Jg. 102, Heft 7, 18. Februar 2005: A428-A432.
- Fritscher, Claudia (2007): Bedeutung der D-dimer Untersuchung in der Diagnostik der tiefen Beinvenenthrombose, Labor Aktuell Nr.7/2007, 1-8.
- 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.
- Thomas, Lothar (2008): Labor und Diagnose (Indikation und Bewertung von Laborfunden für die medizinischen Diagnostik, TH-Books Verlagsgesellschaft mbH, Frankfurt/Main, 7.Auflage, 2008.

## SYMBOLS:



For *in-vitro* diagnostic use only



For single use only



Content



Expiry date



Lot number



Storage temperature



Manufacturer



Carefully read package insert

Rev 1.5 – (GB) – 25/08/2009 (HEH)