DyonMed S.A.
Point of Care Solutions

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ISO 9001:2008 (No. 010110003)| ISO 13485:2003 (No 01210005)
by TÜV Austria Hellas

DyonDimer®
(*D-Dimer*)

Cat.no: DNWA108

Rapid test for qualitative detection in whole blood, capillary blood, serum or plasma

SUMMARY

Examination D-Dimer was originally developed for the diagnosis of disseminated intravascular coagulation. The D-Dimer is fibrin degradation products, small protein fragments present in the bloodstream after degradation through inodolisis clots. During coagulation, fibrinogen is metabolized into fibrin by the activation of thrombin. The fibre consists of D and E units. The dissolution of fibrin results in the appearance of D-Dimers.

In the '90s it was found that the D-Dimer is useful in the diagnosis of thromboembolic disease. The concentration of D-Dimers can be determined by a blood test and help in the diagnosis of thrombosis. Since their introduction in the 90s they have become an important test performed in patients with thrombotic disorders (American College of Emergency Physicians Clinical Policies Committee, 2011). In primary care, where the need for exclusion of deep venous thrombosis and pulmonary embolism is crucial now has demonstrated the imperative of using test **DyonDimer®** (Lee-Lewandrowski et al, 2009; Geersing et al 2010; van der Velde et al , 2011)

The detection levels of D-Dimers in the circulation has emerged as the most reliable laboratory tool in the diagnosis and management of a large group of clinical conditions related thrombotic processes such as (a) diagnosis of deep vein thrombosis (Pasha et al, 2010), (b) identification of individuals at increased risk of first thrombotic event (arterial and venous) and c) detecting persons increased risk of recurrent deep vein thrombosis (Cosmi et al, 2009), d) confirmation of the optimal interval secondary prophylaxis after a first episode deep vein thrombosis (Verhovsek et al, 2008, Cosmi et al, 2010), e) monitoring pregnancy, f) diagnosis and monitoring of disseminated intravascular coagulation (Tripodi, 2011).

In the process differentiate deep vein thrombosis and pulmonary embolism with algorithms analysis of clinical probability (Wells, Geneva score and their variations - Douma et al, 2011) and diagnostic imaging is required to identify the D -Dimers. It is demonstrated that the use of D-Dimers leads to a reduction of abuse of imaging methods (and therefore the intake of radiation), decreased number of admissions and the duration of hospitalization (Bayes et al, 2011).

Recent studies have highlighted the utility of D-Dimers as an early biochemical marker for early diagnosis of stroke (Montaner et al, 2010), while it is found and its usefulness in the differential diagnosis of patients low probability for myocardial infarction (Tokita et al, 2009). The use of D-Dimers can be extended in gynaecology in monitoring pregnant women for deep vein thrombosis (Chan et al 2010). Interesting perspective shows the detection application D-Dimers in patients with malignancies such as sarcoma, lung cancer (Raj et al, 2011) and colon cancer.

PRINCIPLE OF THE METHOD

DyonDimer® is a rapid qualitative immunoassay of the sandwich type colloidal gold to detect D-Dimers. The method utilizes a membrane coated with antibodies to detect D-Dimers or capillary whole blood, serum or plasma selectively and with great sensitivity. At the start of the test sample is mixed with the complex of the chromophore and begins to move through the membrane. If the sample contains an antigen, it will interact with the pre-capped complex chromophore, thereby display a colour (purple) in the line test zone (T). Both negative and positive samples should create a colour line (purple) in the Control Zone (C), which is indicated proper execution of technique, sample volume, and mode of examination.

STORAGE AND STABILITY

Store the kit at 2-30 ° C. If the kit was stored in the refrigerator, it should be transferred to room temperature before proceeding with the examination. Under these conditions, the kit is stable until the expiration date printed on the packaging.

PACKAGE CONTENTS

Each kit contains 1 individually wrapped (or multiples thereof), as follows:

-Pin-scarification
-Vial Dilution
-Sealed plastic package with test cassette and a small plastic Pasteur pipette
-1 package.

SAMPLE COLLECTION AND PREPARATION

A. Collection of whole blood, serum or plasma: Total venous blood was collected by conventional methods of blood sampling presence anticoagulant should be checked within 24 hours of collection. Ports the sample can be stored in the refrigerator. Serum or plasma should be separated to avoid haemolysis and the resulting samples should be tested immediately after separation. Serum and plasma can be stored in the refrigerator up to three days, while the long term should be stored in the freezer (-20 ° C).

B. Collection of blood capillaries.

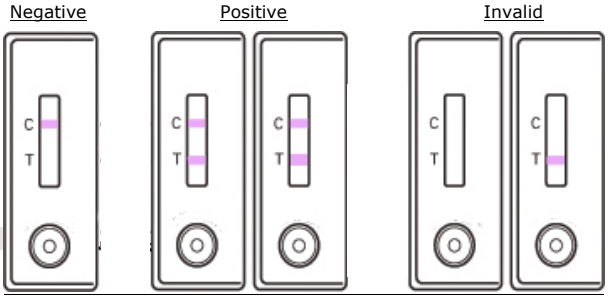
1. Remove the yellow strain on pin scarification to unlock it.
2. Disinfect the fingertip of the patient with alcohol. Knead the fingertip to increase blood circulation.
3. Apply unlocked spike the finger. In this position there is no contact of the pin with your finger.
4. Firmly press the yellow button peak spike
5. After scarification knead bored point to display one large drop of blood. The capillary blood should be used immediately.

TEST PROCEDURE-INTERPRETATION OF RESULTS

Before the examination, make sure that the plastic packaging with test cassette has come to room temperature. The test cassette must be opened only shortly before the test.

6. Turn the pierced finger of the patient and press that 1 drop (25μl) serum or plasma or 2 drops dropping capillary (or overall) blood to fall into the special round hole of the cassette test. (Alternatively you can use the plastic Pasteur pipette to collect capillary blood).
7. Immediately open the bottle and pour 2 Dilution drops in the special round hole in the cartridge.
8. Start the timer (not supplied).
9. Note the solubilized sample as a red-purple front moves zones (T) and (C). Interpret the results in 10-15 minutes. Do not interpret after 20 minutes.

Positive Results = 2 color lines.
Examination **DyonDimer®** is positive for D-Dimers if two colour lines appear. A colour purple line will appear in the test zone (T) and one purple in the Control Zone (C). This is appropriate for the presence of D-Dimers in the patient's blood. Any colour line in Zone (T) corresponds to a positive result. The colour intensity in the zone (T) can be stronger or lighter the intensity of colour in zone (C).



Negative Results = 1 colour line
The test is negative if (1) colour line appears in the Control Zone (C). The interpretation of a negative result is guaranteed in 20 minutes.

Invalid = No colour line in the Control Zone (C)
The test is invalid if after 20 minutes no matching row in the Control Zone (C), even if a colour line has appeared in the test zone (T). If this happens reread the instructions and repeat the test using a new device. If the problem persists contact Dyonmed SA

PRECAUTIONS

Precautions regarding the collection, handling, storage and disposal of samples and used kit components. Handle all specimens as if they contain infectious agents. Take precautions against microbiological hazards throughout the process. Apply standard procedures for proper disposal of specimens. The operation of the device is not affected by other known environmental factors than temperature.

RESTRICTIONS

1. Test results **DyonDimer®** should be considered with other symptoms, clinical findings or diagnostic results to a diagnosis.
2. The characteristics are valid only if the contents of the package

24-hour Help Line for Medical Devices
Tel. (+30) 211.800.8167
Strictly professional in vitro diagnostic use

DyonDimer® (D-Dimer)
Genuine Product **Point of Care®**
Produced in EU on behalf of DyonMed S.A..

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are in good condition.
3. **DyonDimer®** device is for single use only. In the event that a dissolved sample should be retested use another device.
4. The test **DyonDimer®** is exclusively for health professionals.

QUALITY CONTROL

Internal Quality Control: The colour line appears in the Zone (C) is an internal control procedure. Confirm correct specimen volume and correct technical process. A clean background is the internal negative control. If the test works correctly in the Control Zone background should be white to light pink and it should not be difficult to interpret the result.

External Quality Control: Each laboratory using the test should develop its own test instructions and Process Certification test.

FUNCTIONAL CHARACTERISTICS

1. Performance. **DyonDimer®** was tested for its ability to detect D-Dimers compared to analyst D-Dimers Dade Behring Stratus CS (golden standard). Initially all samples identified as positive or negative with the Dade Behring Stratus CS. Then the same samples were tested with **DyonDimer®**. In these conditions the yield of the device **DyonDimer®** in relation to the analyzer with the Dade Behring Stratus CS was:

Specificity and Sensitivity of the device **DyonDimer®**: 93.4% and 97.8% respectively;

-Positive Predictive Value of the device **DyonDimer®**: 95.6% *

-Negative Predictive Value of the device **DyonDimer®**: 96.6% *

-Accuracy of the device **DyonDimer®**compared to analyst Dade Behring Stratus CS 96.0% *

* for confidence interval CI = 95%

- Distinctive Limit. For measuring the distinctive boundary, solutions with concentrations of D-Dimer of 0-3600 ng / ml were tested with the device **DyonDimer®** in 5 replicates per concentration category. Under those conditions the sharp boundary was found in 150 ng / ml.

2. Specialty. Blood samples from patients positive or negative in D-Dimer transfected with fibrinogen, fibrin monomers, or other derivatives and analyzed by the device **DyonDimer®** in 10 iterations time. They have all the samples yielded the expected results, which were positive or negative regardless of interpolating factor.

3. Cross-reaction. Blood samples from patients with negative D-Dimer transfected with infecting agents below and analyzed by the device **DyonDimer®** in 10 iterations time. They have all the samples yielded the expected results, ie negative regardless of interpolating factor.

Acetaminophen, 20 mg / dl	Glucose, 2000 mg / dl
Aspirin, 20 mg / dl	Hemoglobin 500 mg / dl
Ascorbic acid, 20 mg / dl	Ketone, 40 mg / dl
Atropine, 20 mg / dl	Mestranol 3 mg / dl
Bilirubin, 10 mg / dl	Nitrate, 20 mg / dl
Caffeine, 20 mg / dl	Penicillin, 40.000 U / dl
Creatinine, 20 mg / dl	Sodium Heparin, 3 mg/dl
Albumin, 20 mg / dl	Prostatic acid phosphatase, 1000mIU/ml
Gentasic Acid, 20 mg / dl	Lithium Heparin, 3 mg/dl
Triglycerides 500 mg / ml	

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