

DDM-W23

D-Dimer Rapid Test Device
(Whole blood/Plasma)

INTENDED USE

D-Dimer Rapid Test Device is used for the qualitative detection of D-dimer in human whole blood and plasma; The test is used as an aid in the assessment and evaluation of patients with suspected disseminated intravascular coagulation (DIC), deep vein thrombosis (DVT), and pulmonary embolism (PE).

INTRODUCTION

During blood coagulation process, fibrinogen is converted to fibrin by the activation of thrombin. The resulting fibrin monomers polymerise to form a soluble gel of non-cross-linked fibrin. This fibrin gel is then converted to cross-linked fibrin by thrombin activated Factor XIII to form an insoluble fibrin clot. Production of plasmin, the major clot-lysing enzyme, is triggered when a fibrin clot is formed. Although fibrinogen and fibrin are both cleaved by the fibrinolytic enzyme plasmin to yield degradation products, only degradation products from cross-linked fibrin contain D-dimer and are called cross-linked fibrin degradation products. Therefore, fibrin derivatives in human blood or plasma containing D-dimer are a specific marker of fibrinolysis. Elevated levels of D-dimer are an indication of active fibrinolysis and have been shown in patients with disseminated intravascular coagulation (DIC), deep vein thrombosis (DVT) and pulmonary embolism (PE). Elevated levels of D-dimer have also been reported in surgery, trauma, sickle cell disease, liver disease, severe infection, sepsis, inflammation, malignancy and in the elderly. D-dimer levels also rise during normal pregnancy but very high levels are associated with complications. A positive result indicating active fibrinolysis should be obtained with D-dimer Rapid Test Device when D-dimer levels are greater than or equal to the cut-off of approximately 500ng/ml as measured by an ELISA method.

PRINCIPLE

The D-Dimer Rapid Test Device (Whole blood//Plasma) detects D-Dimer through visual interpretation of color development in the internal strip. Anti-D-Dimer antibodies are immobilized on the test region of the membrane, and anti-mouse antibodies immobilized on the control region. During testing, the specimen reacts with anti-D-Dimer antibodies conjugated to colored particles and precoated onto the sample pad of the strip. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient D-Dimer in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

- Materials Provided
- Individually pouched test devices

Package insert

Disposable pipettes

Buffer
- Materials Required but Not provided
- Specimen collection container

Timer

Centrifuge

PRECAUTIONS

- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits 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.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.**
- 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

equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The D-Dimer Rapid Test Device (Whole Blood/Plasma) is intended for use with human whole blood or plasma specimens only.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Plasma specimens may be stored at 2-8°C for up to 3 days. 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 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- 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.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

PROCEDURE

Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.

- Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results the assay should be performed within one hour.
- Transfer 2 drops of whole blood or 1 drop of plasma to the specimen well (S) of the device with the provided disposable pipette, and add 1 drop of buffer. Start the timer.
- OR
- Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen well (S) of the test device, and add 1 drop of buffer. Start the timer. Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
- Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

C

T

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

C

T

NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

C

T

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

- The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

- The D-Dimer Rapid Test Device (Whole Blood/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of D-Dimer.
- Clinical diagnosis should not be based on the result of the D-dimer rapid test alone. The full clinical context of the patient should be included when making a diagnostic decision m taking into account

- the clinical signs and other relevant information such as the Wells pre-test probability score or equivalent.
- Negative D-dimer results can occur very occasionally even in the presence of a DVT due to other factors including the age or position of a clot, heparin therapy and when the D-dimer concentration is below the sensitivity of the test.

PERFORMANCE CHARACTERISTICS

- Sensitivity
The minimum detection limit of the D-Dimer Rapid Test Device(Whole blood/Plasma) was 500 ng/mL.
 - Detect Range and Hook Effect
The minimum detection limit of the D-Dimer Rapid Test Device (Whole /Plasma) has been shown to be able to detect from 500ng/mL to 50ug/mL. No hook effect was observed when tested the sample with D-dimer as high as 50ug/mL.
- 3Correlation
The study was performed on 149 negative plasma specimens (EIA confirmed, Roche Cobas c701) and 153 positive plasma specimens (EIA confirmed) have been tested in the assays. All results determined at 10-20 minutes.

Table: Dimer Test Device vs. EIA				
		EIA		
		+	-	Total
Dimer Test Device	+	151	16	167
	-	2	133	135
		153	149	302

Positive agreement with EIA: 151/(151+2) = 98.7 % (96.91% - 100%)*
Negative agreement with EIA: 133/(133+16) = 89.3% (84.34% - 94.26%)*
Total agreement with EIA: (151+133)/(151+2+133+16) =94.04% (91.36%- 96.72%)*
* 95% Confidence Interval
4. Interfering Substances
The following compounds have been tested using the D-Dimer Rapid Test Device (Whole Blood/Plasma) and no interference was observed.

Acetaminophen 50ug/ml	Chloramphanicol5 0ug/ml	Bilirubin 6mg/ml	Atenolol 50ug/ml
Ascorbic Acid 50ug/ml	Chlordiazepoxide 50ug/ml	Cholesterol5mg/ml	Atorvastatin Calcium 50ug/ml
Acetylsalicylic acid 50ug/ml	Cilazapril 50ug/ml	Caffeine 50ug/ml	Anisodamine 50ug/ml
Captopril 50ug/ml	Diclofenac 50ug/ml	Digoxin 50ug/ml	Erythromycin 50ug/ml
Isosorbide Mononitrate 50ug/ml	Furosemide 50ug/ml	Hydrochlorothiazide 50ug/ml	DL-Tyrosine 50ug/ml
Labetalol 50ug/ml	Oxazepam 50ug/ml	Phenobarbital 50ug/ml	Quinine50ug/ml
Triglycerdes. 15mg/ml	Trimethoprim 50ug/ml	Verapamil 50ug/ml	Felodipine 50ug/ml
Nifedipine 50ug/ml	Bisoprolol Fumarate 50ug/ml	Ramipril 50ug/ml	Metoprolol Tartrate 50ug/ml
Human albumin 110mg/ml	Hemoglobin 10mg/ml	Moracizine Hydrochloride 50ug/ml	Pentoxifyline 50ug/ml
Flunarizine Hydrochloride50ug/ml			

LITERATURE REFERENCES

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GLOSSARY OF SYMBOLS			
ρ	Catalog number	0	Temperature limitation
ι	Consult instructions for use	Λ	Batch code
I	In vitro diagnostic medical device	ε	Use by
μ	Manufacturer	T	Contains sufficient for <n> tests
σ	Do not reuse	A	Authorized representative in the European Community
Υ	CE marking according to IVD Medical Devices Directive 98/79/EC		

Y

μ

A

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