D-DIMER
Quanti Card

Fluorescence based immunoassay for quantitative measurement of D-Dimer in human plasma

INTRODUCTION
D-Dimer is generated as a specific soluble degradation product during fibrinolysis. Elevated D-Dimer levels are found in cases of disseminated intravascular coagulation (DIC), deep vein thrombosis (DVT) and pulmonary embolism (PE) but other circumstances may also lead to high D-Dimer levels such as old age, pregnancy, cancer, liver disease and infection. The FIA (Fluorescence immunoassay) system has a higher sensitivity when compared with latex agglutination tests thus giving an improved aid in the diagnosis for the exclusion of venous thromboembolism (VTE).

INTENDED USE
D-Dimer Quanti Card is a sensitive immunoassay for the quantitative determination of D-Dimer in human plasma with iQuant Analyzer only.

PRINCIPLE (ANTIGEN-ANTIBODY REACTION)
D-Dimer Quanti Card is a fluorescence immunoassay, based on the “sandwich” principle. The test uses capture antibody for D-Dimer immobilized on a nitrocellulose strip. The detector antibody in conjugate binds to the antigen in sample, forming antigen-antibody fluorescence complex. This complex migrates through the nitrocellulose strip by capillary action. When the complex meets the line of the corresponding immobilized antibody on the test line the fluorescence signal is produced from Immuno-complex. The greater the concentration of the antigen in sample forms the more antigen-antibody complex and leads to stronger intensity of fluorescence signal. The signal is interpreted and the result is displayed on analyzer in terms of concentration.

MATERIALS PROVIDED (10 Tests Pack)
D-Dimer Quanti Card Test kit contains following components to perform the assay:

1. D-Dimer Quanti Card (1 Test).
2. Assay Buffer
3. D-Dimer Conjugate (dried)
4. Clamp & Rod
5. Instruction for use

MATERIAL REQUIRED, BUT NOT PROVIDED
iQuant Analyzer
Micropipette & Microtips
Stop Watch

KIT PRESENTATION
10 Test Pack
25 Test Pack

STORAGE AND STABILITY
D-DIMER Quanti Card should be stored at 2-8°C in the cool & driest area available. Expiry date on the kit indicates the date beyond which kit should not be used. The kit should not be frozen & must be protected from exposure to humidity.

DESCRIPTION OF SYMBOLS USED
The following are graphical symbols used in or found on J. Mitra diagnostic products and packing. These symbols are the most common ones appearing on medical cartridges and their packing. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

	Manufactured By	IVD	In vitro diagnostic medical device
Σ	No. of tests		Instruction for use
LOT	Lot Number Batch Number	2°C 8°C	Temperature Limitation
	Manufacturing Date		Caution, see instruction for use
	Expiry Date	REF	Catalogue Number
	Do not use if package is damaged		Keep away from sunlight
	Single use only		Keep Dry

WARNING FOR USERS
⚠ **CAUTION:** ALL THE SAMPLES TO BE TESTED SHOULD BE HANDLED AS THOUGH CAPABLE OF TRANSMITTING INFECTION. NO TEST METHOD CAN OFFER COMPLETE ASSURANCE THAT HUMAN BLOOD PRODUCTS WILL NOT TRANSMIT INFECTION.

1. The use of disposable gloves and proper bio-hazardous clothing is STRONGLY RECOMMENDED while running the test.
2. In case there is a cut or wound in hand, DO NOT PERFORM THE TEST.
3. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
4. Tests are for in vitro diagnostic use only and should be run by competent person only.
5. Do not pipette by mouth.
6. All materials used in the assay and samples should be disposed off in accordance with established safety procedures.
7. Wash hands thoroughly with soap or any suitable detergent, after the use of the kit. Consult a physician immediately in case of accident or contact with eyes, in the event that contaminated material are ingested or come in contact with skin puncture or wounds.
8. Spills should be decontaminated promptly with Sodium Hypochlorite or any other suitable disinfectant.
9. D-Dimer conjugate and Assay Buffer contains Sodium Azide as a preservative. If these materials are to be disposed off through a sink or other common plumbing systems, flush with generous amounts of water to prevent accumulation of potentially explosive compounds. In addition, consult the manual guideline "Safety Management No. CDC-22", Decontamination of Laboratory Sink Drains to remove Azide salts"(Centre for Disease Control, Atlanta, Georgia, April 30, 1976).
10. Follow standard biosafety guidelines for handling & disposal of potentially infective material.
11. Use only Plasma samples collected using Sodium citrate as anti-coagulant.

PRECAUTIONS
In order to obtain reproducible results, the following instructions must be followed:

1. Use disposable gloves while handling potentially infectious samples and performing the assay Wash hands thoroughly afterwards.
2. Do not use the kit beyond the expiry date.
3. Do not mix reagents from different batches.
4. Do not open the foil pouch of the cards and D-Dimer Conjugate vial (Dried) until it attains room temperature (20-30°C).
5. Do not expose the D-Dimer Conjugate vial (Dried) to light for more than 8 hours.
6. Always reseal the unused D-DIMER Conjugate vial along with desiccant using Clamp and Rod provided and store at 2-8°C.
7. Do not re-use the test device.
8. Use separate pipette tips for each sample in order to avoid cross-contamination of samples which could cause erroneous results.
9. Follow the given test procedure and storage instructions strictly to get accurate results.

SAMPLE / SPECIMEN COLLECTION AND STORAGE
1. Only plasma samples should be used with this test. It is recommended to use fresh plasma specimen for testing.
2. If the plasma specimen cannot be tested immediately, it should be refrigerated at 2-8°C for testing within 24 hrs. For storage more than 24hrs, freeze the specimen at -20°C or below.
3. Repeated freezing and thawing of the specimen should be avoided. Thawing of frozen sample should be done one time only, just prior to proceeding for test.
4. Specimen containing precipitates or particulate matter may yield inconsistent test results. Such specimens must be centrifuged and the clear supernatant should only be used for testing.
5. The use of hemolytic, lipaemic, icteric or bacterially contaminated specimens should be avoided as it may lead to erratic results.

BEFORE YOU START
1. Plug in the iQuant analyzer. Press the Power button of the iQuant analyzer, it will take approximately 1 min for its self-checking and when the test screen will come, one can start the test procedure.
2. Plug in the iVortexer.
3. Bring the complete test kit and samples to be tested to room temperature (RT) prior to testing.

TEST PROCEDURE
1. Remove the test card from the foil pouch prior to use and place it on a flat and dry Surface. The test should be performed immediately after removing the test card from the foil Pouch.
2. Label the test cartridge with patient's name or identification number as shown in fig. (a). DO NOT write on QR Code.


Fig. (a)

3. Take out one D-DIMER Conjugate vial (Dried) from the aluminum pouch & immediately seal rest of the unused D-DIMER Conjugate vial (Dried) with desiccant in aluminum pouch with Clamp & rod.
4. Unscrew the D-DIMER Conjugate vial (Dried) & add 100 μl of Plasma sample. Close the cap of the vial by screwing action and mix well using vortexer for 30 seconds.

5. Keep the D-DIMER conjugate vial undisturbed for 1 minute & then vortex it well for 30 seconds.

6. Immediately load 50µl of above sample reagent mixture using micropipette to the sample well of the Cartridge. **Care should be taken to avoid any spillage on the QR-Code and test result window.**

7. Leave the sample loaded cartridge at room temperature for 20 minutes.

8. After 20 minutes, gently add 2 drops of assay buffer in the buffer well of the test cartridge and leave the cartridge for another 10 minutes at room temperature.

9. In the meantime, enter the patient's details in the iQuant analyzer testing window and select the D-DIMER test from the pop down menu in the testing window of the iQuant analyzer.

10. After the incubation period is over, Insert the test cartridge into the iQuant Analyzer with arrow (←) marked side on the top of cartridge facing towards the analyzer and press RUN button. Note down the value displayed on the screen of iQuant Analyzer.

Discard the D-Dimer Quanti Card immediately after reading results considering it to be potentially infectious.

D-DIMER REFERENCE RANGE	:	**<500 ng/ml.**
MEASURING RANGE	:	**50-10,000 ng/ml.**
DETECTION LIMIT	:	**50 ng/ml.**

PERFORMANCE CHARACTERISTICS OF D-DIMER QUANTI CARD

1. Precision

Intra-Assay: Within-run and between-run precision have been determined by testing 10 replicates of 3 different samples with D-Dimer concentration: 238.4ng/ml, 3224.5ng/ml and 7512.6ng/ml on the three different lots. The C.V (%) for all 3 samples is ≤ 10%.

Inter-Assay: The inter-assays were performed with 10 replicates of 3 different samples with D-Dimer concentration: 238.4ng/ml, 3224.5ng/ml and 7512.6ng/ml on three different lots on 10 sequential days. The C.V (%) for all 3 samples is ≤ 10%.

2. Accuracy

The accuracy of D-Dimer Quanti Card was checked with 75 clinical specimens, D-Dimer concentrations of 75 samples were compared with commercially available kit. All the samples are run in duplicate on D-Dimer Quanti Card. The following results were obtained:

Slope	:	0.9842
Y-Intercept	:	80.076
R^2	:	0.996

3. Specificity

There was no significant interference with the D-Dimer measurement when other biomolecules such as Bilirubin (20mg/dL), Triglyceride (1000mg/dL), Glucose (500mg/dL), Haemoglobin (500mg/dL) and Albumin (10g/dL) were added to the test specimen with much higher level than in normal blood.

LIMITATIONS AND INTERFERENCES

1. The test procedure, precautions and interpretation of results for this test must be strictly followed.
2. As with all diagnostic tests, the test result must always be correlated with clinical finding and laboratory data available.
3. Any modification to the above procedure and / or use of other reagents will invalidate the test procedure.
4. The presence of additional substances in blood samples may interfere with product performance and may cause erroneous results.

LIMITED EXPRESSED WARRANTY DISCLAIMER

The manufacturer limits the warranty to the test kit, as much as that the test kit will function as an in vitro diagnostic assay within the limitations and specifications as described in the product instruction for use, when used strictly in accordance with the instructions contained therein. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application there of.

TROUBLE SHOOTING

PROBLEM	POSSIBLE CAUSE	SOLUTION
1. Unexpected low Test Result	a) Hemolyzed sample	
	b) Use of serum sample for testing	
	c) Insufficient volume of sample used.	Repeat the test using fresh Plasma samples.
	d) Fresh Plasma sample not used.	
	e) Reading has been taken at less than the prescribed time.	Read the results at prescribed time only.
	f) Reagents used were too cold and were not brought to Room Temperature RT.	Bring the whole test kit RT before testing
	g) D-Dimer Conjugate is continuously exposed to light for more than 8 hours.	Always reseal the unused D-Dimer Conjugate Vials with clamp & rod after use. Store at 2-8˚C.
	h) Expired Test kit used.	Repeat the test using a new test kit that has not passed the expiration date.
	i) Improper i.e. less volume of reaction mixture applied to sample well of cartridge.	Use appropriate volume of reaction mixture using calibrated pipette.
2. Unexpected high test result	a) High amount of plasma sample used.	Retest using 100µl sample volume
	b) Results read beyond 10 minutes after adding assay buffer	Read the test result at 10 minutes.
	c) Improper i.e, high volume of reaction mixture applied to sample well of cartridge	Use 50 µl of reaction mixture using calibrated pipette.

REFERENCES

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in vitro diagnostic reagent, not for medicinal use

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