QDx Instacheck™ D-Dimer

INTENDED USE

QDx Instacheck™ D-Dimer is a fluorescence Immunoassay (FIA) for the quantitative determination of D-Dimer in human whole blood/ plasma. It is useful as an aid in management and monitoring of post therapeutic evaluation of thromboembolic disease patients.
For *in vitro* diagnostic use only.

INTRODUCTION

D-dimer, a degradation product of cross-linked fibrin formed during activation of the coagulation system, is commonly used to exclude thromboembolic disease in outpatients suspected of having deep venous thrombosis (DVT) and pulmonary embolism (PE).[1] DVT and PE is relatively common and can cause sudden, fatal embolic events in the pulmonary arteries and other regions. [2-3]

Measurement of the D-Dimer level in plasma has been used as a screening strategy for subclinical DVT. A systematic review reported that a normal range of a highly sensitive D-dimer level accurately ruled out DVT in patients classified as having a low or moderate clinical probability of DVT. The DVT is a high-risk factor for the stroke because of advanced age, hemiplegia, and coagulation disorders, and DVT can cause paradoxical embolic stroke via a right-to left shunt. Thus, it is important to monitor the level of D-Dimer the incidence and characteristics of DVT in acute stroke patients.[4-7] The Plasma D-dimer level has proven to be useful for DVT screening in chronic stroke patients undergoing rehabilitation.[8-10] National and international scientific organizations have suggested the use of these markers when implementing new diagnostic strategies in patients with coronary syndrome. Since D-Dimer is well known to be an important prognostic indicator of heart diseases, its most definitive role is on monitoring post-treatment clinical status and the post therapeutic evaluation of patients.

PRINCIPLE

The test uses a sandwich immunodetection method; the detector antibodies in buffer bind to antigens in the sample, forming antigen-antibody complexes, and migrate onto nitrocellulose matrix to be captured by the other immobilized-antibodies on test strip.

More antigens in the sample will form more antigen-antibody complexes which lead to stronger fluorescence signal by detector antibodies, which is processed by instrument for QDx Instacheck™ tests to show D-Dimer concentration in the sample.

COMPONENTS AND REAGENTS

QDx Instacheck™ D-Dimer consists of 'cartridges', 'detection buffer tubes', 'ID chip', and 'instruction for use'.

- The cartridge contains the membrane called a test strip, which has mouse monoclonal anti human D-Dimer at the test line, and streptavidin at the control line.
- Each cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed cartridges are packed in a box which also contains an ID chip.
- The detection buffer contains mouse monoclonal anti human D-Dimer-fluorescence conjugate, biotin-BSA-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.
- The detection buffer is pre-dispensed in a separate tube. 25 detection buffer tubes are packaged in a box and further packed in a Styrofoam box with ice-pack for the shipment

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow the instructions and procedures described in this 'instruction for use'.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge, detection buffer tube and ID chip) must match each other.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield incorrect of test result(s).
- Do not reuse cartridges or detection buffer tubes. A cartridge should be used for testing one sample only. A detection buffer tube should be used for processing of one sample only.
- The cartridge should remain sealed in its original pouch until just before use. Do not use the cartridge, if pouch is damaged or has already been opened.
- Do not keep the sample in a freezer, which could affect the test value of D-Dimer. Sample with severe hemolysis and hyperlipidemia must not be used.
- Allow the cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for QDx Instacheck™ tests may generate slight vibration during use.
- Used cartridges, detection buffer tubes, and pipette tips should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- An exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.
- **QDx Instacheck™ D-Dimer** will provide accurate and reliable results subject to the below conditions.
  - **QDx Instacheck™ D-Dimer** should be used only in conjunction with instrument for **QDx Instacheck™** tests.
- Have to use recommended anticoagulant sample.

Recommended anticoagulant
Sodium citrate

STORAGE AND STABILITY

Component	Storage Temperature	Shelf life
Cartridge	4 - 30 °C	20 months
Detection buffer tube	2 - 8 °C	20 months

- After the cartridge pouch is opened, the test should be performed immediately.

LIMITATIONS OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.
- The test may yield false negative result(s) due to the non-responsiveness of the antigen to the antibodies which is most common if the epitope is masked by some unknown components, so therefore not being able to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may also cause the false negative results as it makes antigen unrecognizable by the antibodies.

- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

MATERIALS SUPPLIED

REF IFPC-14

Components of QDx Instacheck™ D-Dimer

- **Cartridge Box:**
  - Cartridges 25
  - ID Chip 1
  - Package Insert 1
- **Detection buffer box**
  - Detection buffer tubes 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **QDx Instacheck™ D-Dimer**. Please contact our sales division for more information.

- **QDx Instacheck™ Reader** REF FPRR010
- **QDx Instacheck™ II** REF FPRR021
- **Printer** REF FPRR007
- **Boditech D-Dimer Control** REF CFPO-101

SAMPLE COLLECTION AND PROCESSING

The sample type is human whole blood/plasma.

- Please test the sample within 24 hours after collection.
- The plasma should be separated from the clot by centrifugation within 3 hours after the collection of whole blood.
- Do not keep the sample in a freezer, which could affect the test value of D-Dimer.

TEST SETUP

1. Check the contents of **QDx Instacheck™ D-Dimer**: Sealed cartridges, detection buffer tubes, ID Chip and Instruction for use.
2. Ensure that the lot number of the cartridge matches that of the detection buffer tube as well as an ID Chip.
3. If the sealed cartridge and the detection buffer have been stored in a refrigerator, place them on a clean and flat surface at room temperature for at least 30 minutes before testing.
4. Turn on the instrument for QDx Instacheck™ test.
   (Please refer to the 'instrument for QDx Instacheck™ tests Operation Manual' for complete information and operating instructions.)

TEST PROCEDURE

[Single mode]

1. Transfer 10 µL of human whole blood/plasma using a pipette to a tube containing the detection buffer.
2. Close the lid of the detection buffer tube and mix the sample thoroughly by shaking it about 10 times. (The sample mixture must be used immediately.)
3. Pipette out 75 µL of the sample mixture and load it into the sample well on the cartridge.
4. Inserting the cartridge into the holder of the instrument for QDx Instacheck™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow is marked on the test cartridge especially for this purpose.
5. Press the 'SELECT' button or Tap the 'START' button on the instrument for QDx Instacheck™ tests.
6. Cartridge goes inside the instrument for QDx Instacheck™ tests and will automatically start scanning the sample-loaded cartridge after 12 minutes.
7. Read the test result on the display screen of the Instrument for QDx Instacheck™ Tests.

[Multi mode]

1. Transfer 10 µL of human whole blood/plasma using a pipette to a tube containing the detection buffer.
2. Close the lid of the detection buffer tube and mix the sample thoroughly by shaking it about 10 times. (The sample mixture must be used immediately.)
3. Pipette out 75 µL of the above sample mixture and load it into the sample well on the cartridge.
4. Leave the cartridge at room temperature for 12 minutes before inserting the device into the holder.
   ⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inaccurate test result.*
5. To scan the sample-loaded cartridge, insert it into the cartridge holder of the QDx Instacheck™ Tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow is marked on the cartridge especially for this purpose.
6. Press the 'SELECT' button or Tap the 'START' button on the instrument for QDx Instacheck™ test to start the scanning process.
7. Instrument for QDx Instacheck™ tests will start scanning the sample-loaded cartridge immediatel
8. Read the test result on the display screen of the instrument for QDx Instacheck™ tests.

INTERPRETATION OF TEST RESULT

- The Instrument for QDx Instacheck™ tests calculates the test result automatically and displays D-Dimer concentration of the test sample in terms of ng/mL (FEU, Fibrinogen equival units).
- Cut-off (reference value): 500 ng/mL
- Unit Conversion : DDU x 2 =FEU
  ex) 1 ng/mL (DDU) = 2 ng/mL (FEU)
- Working range: 50-10,000 ng/mL

QUALITY CONTROL

- Control tests should be performed as a part of the good testing practice to confirm the expected quality control results and validity of the assay as well as to ensure accuracy of the test results with clinical samples.
- A quality control test should be performed at regular intervals. Before testing the clinical sample using a new test kit, control standards should be tested to confirm the test procedure, and to verify whether the test produces the expected quality control results. Quality control tests should also be performed whenever there is any question concerning the validity of the results obtained.
- Control standards are not provided with QDx Instacheck™ D-Dimer. For more information regarding obtaining the control standards, contact the technical section at Diasys Diagnostics India Private Limited.
- Internal Control: QDx Instacheck™ D-Dimer has an in-built quality control indicator that satisfies the routine quality control requirements. This internal control test is performed each time a clinical sample is tested. A valid control indicates that the cartridge was inserted and read properly by the QDx Instacheck™ Reader. An invalid result from the internal control leads to display an error message on the QDx Instacheck™ Reader indicating that the test should be repeated. Control material are not provided

with **QDx Instacheck™ D-Dimer.** For more information regarding obtaining the control materials, contact the technical section at Diasys Diagnostics India Private Limited.

PERFORMANCE CHARACTERISTICS

- **Analytical specificity**

- **Cross-reactivity**

Biomolecules such as below the ones in the table were added to the test sample(s) at concentrations much higher than their normal physiological levels in the blood. **QDx Instacheck™ D-Dimer** test results did not show any significant cross-reactivity with these biomolecules.

Biomolecules	Concentration
Free bilirubin	17 mg/dL
Conjugated bilirubin	21 mg/dL
Hemoglobin	500 mg/dL
Lipemia	50 g/L
Rheumatoid factor	500 iU/mL

- **Interference**

Interference materials such as below the ones in the table were added to the test sample(s) the same as the below concentrations. **QDx Instacheck™ D-Dimer** test results did not show any significant interference with these materials.

Interference materials	Concentration
Bilirubin (conjugated)	40 mg/dl
Triglyceride	643 mg/dl
Hemoglobin	500 mg/dl
Protein (Albumin)	1 g/dl
Cefotaxim	90 mg/dl
Vancomycin	3.5 mg/ml
Dopamine	13 mg/dl
Noradrenaline	2 µg/ml
Dobutamine	11.2 µg/ml
Heparin	8000 U/l
Furosemide	2 mg/dl
Katacalcin	30 ng/ml
a-CGRP*	30 ng/ml
Calcitonin Salmon	30 µg/ml
Calcitonin Eel	30 µg/ml
EDTA	3.4 µmol/L
Sodium citrate	96 mg/ml

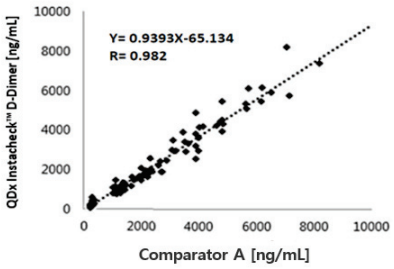
- **Precision**

The intra-assay precision was calculated by one evaluator, who tested different concentration of control standard ten times each with three different lots of **QDx Instacheck™ D-Dimer.** The inter-assay precision was confirmed by 3 different evaluators with 3 different lots, testing three times each different concentration.

Conc. (ng/mL)	Intra Assay			Inter Assay		
	Mean	SD	CV%	Mean	SD	CV%
100	100.37	3.36	3.35	101.73	5.29	5.21
1000	1003.35	39.22	3.91	1014.5	17.93	1.77
5000	4944.20	177.63	3.59	4999.00	119.21	2.39

- **Comparability**

D-Dimer concentrations of 110 plasma samples were quantified independently with **QDx Instacheck™ D-Dimer** and Comparator A as per prescribed test procedures. Test results were compared, and their compatibility was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests were Y=0.9393X-65.134 and R=0.982 respectively.



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Note: Please refer to the table below to identify various symbols.

	Sufficient for <n> tests
	Read instruction for use
	Use by Date
	Batch code
	Catalog number
	Caution
	Manufacturer
	Authorized representative of the European Community
	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

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Revision No. 03
Date of last revision: June 21, 2021