BIO TECHNOLOGY boditech

Cardiac

ichroma™ D-Dimer

INTENDED USE

ichroma™ 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 pulmonaryembolism (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-toleft 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 antibody in buffer binds to antigen in sample, forming antigen-antibody complexes, and migrates onto nitrocellulose matrix to be captured by the other immobilized-antibody on test strip.

The more antigen in sample forms the more antigen-antibody complex and leads to stronger intensity of fluorescence signal on detector antibody, which is processed by Instrument for ichroma™ tests to show D-Dimer concentration in sample.

COMPONENTS

ichroma™ D-Dimer consists of 'Cartridges', 'Detection Buffer Tubes' and an 'ID chip'.

- The cartridge contains a test strip, the membrane which has mouse monoclonal anti human D-Dimer at the test line, while 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.
- Carefully 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, ID chip and detection buffer) 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 misleading of test result(s).
- Do not reuse. A detection buffer tube should be used for processing one sample only. So should a cartridge. After a single use, both detection buffer tube and cartridge should be discarded.
- The cartridge should remain sealed in its original pouch before use. Do not use the cartridge, if is damaged or already opened.
- Do not keep the sample in a freezer, which could affect the test value of D-Dimer. Sample with severe hemolytic and hyperlipidemia cannot be used and should be recollected.
- Just before use, allow the cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes.
- **ichroma™ D-Dimer** as well as the Instrument for ichroma™ tests should be used away from vibration and/or magnetic field. During normal usage, it can be noted that Instrument for ichroma™ tests may produce minor vibration.
- Used detection buffer tubes, pipette tips and cartridges 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.
- **ichroma™ D-Dimer** will provide accurate and reliable results subject to the following conditions.
  - Use **ichroma™ D-Dimer** should be used only in conjunction with Instrument for ichroma™ tests.
  - Any anticoagulants other than **sodium citrate** should be avoided.

STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in an aluminum foil pouch) if stored at 4 – 30 °C.
- The detection buffer dispensed in a tube is stable for 20 months if stored at 2 – 8 °C.
- After the cartridge pouch is opened, the test should be performed immediately.

LIMITATION 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. The non-responsiveness of the antigen to the antibodies is most common where the epitope is masked by some unknown components, so as not to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may cause the false negative 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 CFPC-25

Components of **ichroma™ D-Dimer**

- Cartridge Box:
  - Cartridges 25
  - ID Chip 1
  - Instruction For Use 1
- Box containing Detection Buffer tubes
  - Detection Buffer Tubes 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **ichroma™ D-Dimer.**

Please contact our sales division for more information.

- Instrument for ichroma™ tests
  - **ichroma™ Reader** REF FR203
  - **ichroma™ II** REF FPRR021
  - **ichroma™ D** REF 13303
- **ichroma™ 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

- Check the contents of **ichroma™ D-Dimer**: Sealed Cartridge, Detection Buffer Tubes and ID Chip.
- Ensure that the lot number of the cartridge matches that of the ID chip as well as the detection buffer.
- Keep the sealed cartridge (if stored in refrigerator) and the detection buffer tube at room temperature for at least 30 minutes just prior to the test. Place the cartridge on a clean, dust-free and flat surface.
- Turn on the Instrument for ichroma™ tests.
- Insert the ID Chip into the ID chip port of the Instrument for ichroma™ tests**.**
- Press the 'Select' button on the Instrument for ichroma™ tests. (Please refer to the 'Instrument for ichroma™ tests Operation Manual' for complete information and operating instructions.)

TEST PROCEDURE

1) Transfer 10 µL of sample (Human whole blood / plasma / control) using a transfer 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 a sample mixture and dispense it into the sample well on the cartridge.
4) Leave the sample-loaded cartridge at room temperature for 12 minutes.
   ⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inexact test result.*
5) To scan the sample-loaded cartridge, insert it into the cartridge holder of the Instrument for ichroma™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow has been marked on the cartridge especially for this purpose.
6) Press 'Select' button on the Instrument for ichroma™ tests to start the scanning process.
7) Instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
8) Read the test result on the display screen of the Instrument for ichroma™ tests.

INTERPRETATION OF TEST RESULT

- Instrument for ichroma™ tests calculates the test result automatically and displays D-Dimer concentration of the test sample in terms of ng/mL (FEU, Fibrinogen equival units).
- The cut-off (reference value) : 500 ng/mL.
- Working range : 50-10,000 ng/mL.

QUALITY CONTROL

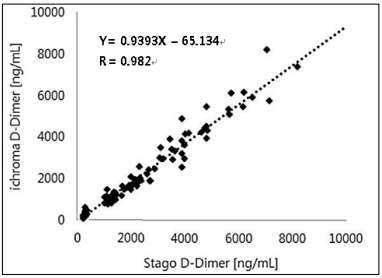
- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are not provided with **ichroma™ D-Dimer**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance. (Please refer to the instruction for use of control material.)

PERFORMANCE CHARACTERISTICS

- **Specificity**: There, in test samples, are biomolecules such as Hemoglobin, Bilirubin, Albumin, Heparin, Triglyceride, Cefotaxim, Dopamine, Katacalcin, a-CGRP in higher concentration than their normal physiological levels. But this doesn't interfere with the **ichroma™ D-Dimer** test measurements, nor occurs any significant cross-reactivity.
- **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 **ichroma™ 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 **ichroma™ D-Dimer** and Stago STA®-Liatest® D-Di 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
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
EC REP	Authorized representative of the European Community
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CE	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

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