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 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 ichroma™ tests to show D-Dimer concentration in the sample.

COMPONENTS

ichroma™ D-Dimer consists of 'cartridges' and 'detection buffers'.

- The cartridge contains the membrane called a test strip which has anti human D-Dimer at the test line, and streptavidin at the control line. All cartridges are individually sealed in an aluminum foil pouch containing a desiccant in a box.
- The detection buffer contains anti human D-Dimer-fluorescence conjugate, biotin-BSA-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer in phosphate buffered saline (PBS).
- The detection buffer is pre-dispensed in tubes. 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'.
- Lot numbers of all the test components (cartridge, detection buffer 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 buffers. 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 already opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with local regulations. Sample with severe hemolysis and/or hyperlipidemia must not be used.
- Allow cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for ichroma™ tests may generate slight vibration during use.
- This test is applicable in regular testing and not in emergency testing.
- Refrain from smoking or eating while sample is collected.
- Samples should be handled with caution to prevent microbial or viral contamination.
- Once the sample is mixed with solution, it must be used within 30 seconds.
- Used cartridges, detection buffers and pipette tips should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- **ichroma™ D-Dimer** will provide accurate and reliable results subject to the below conditions.
  - **ichroma™ D-Dimer** should be used only in conjunction with the Instrument for ichroma™ tests.
  - Have to use recommended anticoagulant sample.

Recommended anticoagulant
Sodium citrate

STORAGE AND STABILITY

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

- 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(s) due to the non-responsiveness of the antigen to the antibodies which is the 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 false negative result 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:
  - Cartridge 25
  - ID chip 1
  - Instruction for use 1
- Box containing Detection Buffer tubes
  - Detection buffer 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™ 100** REF FPRR029
- **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.
- The plasma should be collected in the tube which has been added coagulants.
- If the testing will be delayed more than 24 hours, samples should be frozen at -20 °C.
- The Samples stored frozen at -20 °C for 3 months showed no performance difference.
- If heated samples are used, the test may yield false positive or false negative result(s).

TEST SETUP

- Check the contents of **ichroma™ D-Dimer**: Sealed Cartridges, Detection buffers, ID chip and Instruction for use.
- Ensure that the lot number of the cartridge matches that of the detection buffers as well as the ID chip.
- 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.
- 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

<Multi Mode>

1) Transfer 10 µL of sample (Human whole blood/plasma/control) 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 10~15 times.
3) Pipette out 75 µL of a sample mixture and load 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 inaccurate 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 is marked on the cartridge especially for this purpose.
6) Press the 'Select' or Tap the 'START' button on the Instrument for ichroma™ tests to start the scanning process.
7) The 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.

<Single Mode>

1) Transfer 10 µL of sample (Human whole blood/plasma/control) 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 10~15 times.

3) Pipette out 75 μL of a sample mixture and load it into the sample well on the cartridge.
4) 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 is marked on the cartridge especially for this purpose.
5) Press the 'Select' or Tap the 'START' button on the Instrument for ichroma™ tests to start the scanning process.
6) The cartridge goes inside the instrument for ichroma™ 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 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 equivalent units).
- Working range : 50-10,000 ng/mL.
- Unit Conversion : DDU x 2 =FEU
  ex) 1 ng/mL (DDU) = 2 ng/mL (FEU)
- The cut-off (reference value) : 500 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 provided on demand 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

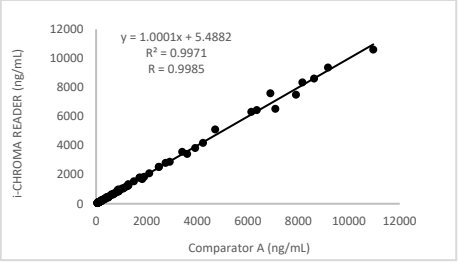
- **Specificity**
  Biomolecules such as Hemoglobin, Bilirubin, Albumin, Heparin, Triglyceride, Cefotaxim, Dopamine, Katacalcin, a-CGRP were added to the test sample(s) at concentrations much higher than their normal physiological levels in the blood. **ichroma™ D-Dimer** test did not show any significant cross-reactivity and interference with these materials.

- **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 ten times each different concentration.

Conc.	Intra Assay			Inter Assay		
(ng/mL)	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 100 standard materials were quantified independently with **ichroma™ 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	Coefficient of correlation (R)
y = 1.0001x + 5.4882	R = 0.9985



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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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CE IVD