BIO TECHNOLOGY boditech

Cardiac

ichroma™ Cardiac Triple

INTENDED USE

ichroma™ Cardiac Triple is a Fluorescence Immunoassay (FIA) for the quantitative determination of **cardiac troponin-I (Tn-I), Creatine kinase (CK-MB) and Myoglobin** in human whole blood/serum/plasma. It is useful as an aid in management and monitoring of acute myocardial infarction (AMI) and acute coronary syndrome (ACS).

For *in vitro* diagnostic use only.

INTRODUCTION

Blood protein markers play an important role in the diagnosis of AMI Tn-I, CK-MB, and Myoglobin are key members of them.

Cardiac troponins are currently the most sensitive and specific biochemical markers of myocardial necrosis. There are three types of troponin in heart muscle fibers: troponin-C, troponin-I, and troponin-T. Together they contribute to make cardiac muscle fibers contract. The clinical measurement of serum Tn-I has become an important tool in the diagnosis of the acute myocardial infarction. Serum Tn-I is more reliable than creatine kinase as a prognostic marker in people with ischemic chest pain. National and international scientific organizations have suggested the use of troponins, Tn-I and Tn-T, when implementing new diagnostic strategies in patients with acute coronary syndrome.

Creatine Kinase (CK), also known as Creatine Phosphokinase or Phospho-creatine Kinase is an enzyme expressed by various tissues and cell types. Disruption of cell membranes due to hypoxia or other injuries releases CK from the cellular cytosol into the systemic circulation. CK is a dimeric enzyme consisting of two subunits, which can be either B- (brain type) or M- (muscle type). These subunits associate to form three isoenzymic forms: CK-BB, CK-MM and CK-MB. These isoenzymes are expressed at different levels in various human tissues. Though CK-MM is the most abundant CK isoenzyme in the cardiac muscles, CK-MB constitutes about 20% of the total CK in the cardiac muscle tissue. Elevated levels of total CK is not specific to the myocardial tissue and may be observed in patients with skeletal muscle injury and certain other disorders but as CK-MB is more specific to myocardial tissue, CK–MB levels along with total CK can be considered as an important diagnostic indicator of myocardial infarction. The concentration of CK-MB in the healthy adult is below 7.0ng/ml but it shows great increases in several malignant diseases, mostly primary coronary syndrome, myocardial injury and infarction. CK-MB has been found to be more sensitive and early indicator of myocardial injury because it has a lower basal level and a much narrower normal range. Medical literature commonly reveals that following an acute myocardial infarction, CK-MB levels become elevated in 4 to 9 hours after the onset of chest pain, attain peak at 10 to 24 hours, and return to normal within 2 to 3 days. Use of CK-MB level as a percentage of total CK in the diagnosis of myocardial infraction is the most important clinical application of CK measurements in clinical chemistry.

Myoglobin is an iron- and oxygen-binding protein found in both skeletal and myocardial muscles. It acts as a transport protein and is involved in diffusion of oxygen in the muscle tissue. Myoglobin is a single-chain globular protein of 154 amino acids. It is composed of a central iron-containing 'Heme' which is enclosed in a compact bundle-like or prism-like arrangement formed by the eight right-handed α-helices[1,2]. Being a cytoplasmic protein having low molecular weight (of 17,699 Daltons), myoglobin is released into the serum more rapidly as compared to other cardiac markers upon damage to the myocardial cells. Serum concentration of myoglobin increases above the normal range as early as 1 hour after acute myocardial infarction (AMI), attains peak level in approximately 4 to 8 hours after the onset and normalize rapidly afterwards. Thus, myoglobin is better suited as a cardiac marker for early diagnosis of AMI. However, the elevated myoglobin is not specific to AMI owing to its large quantities in skeletal muscles as well. Despite its low clinical specificity and weak predictive value towards AMI, myoglobin is still a promising cardiac marker when other markers such as Creatin Kinase Isoenzyme-MB (CK-MB) and Cardiac Troponin-I (cTn-I) as well as other indicators like clinical signs and ECG are taken into account for diagnosis/confirmation of AMI[3-8]

With these important reason, this cardiac triple-TnI, CK-MB, and Myoglobin- could be a simple and useful tool for diagnosing AMI and ACS.

PRINCIPLE

The test uses a sandwich immunodetection method; dried antibodies in the detectors, once diluted with the diluent, bind with antigens in the sample to form antigen-antibody complexes. These complexes then migrate through the nitrocellulose matrix and are captured by another sets of immobilized antibodies on the test line.

The more antigens in the sample, the more antigen-antibody complexes, which leads to a stronger fluorescence signal. This signal then is interpreted by the reader to display the Tn-I/CK-MB/Myoglobin concentration in the sample.

COMPONENTS

ichroma™ Cardiac Triple consists of 'Cartridges', 'Detectors', 'Diluent' and an 'ID chip'.

- The cartridge contains a test strip, the membrane which has anti human Tn-I, anti human CK-MB and anti human Myoglobin at the test line, with chicken IgY 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 detector contains anti human Tn-I-fluorescence conjugate, anti human CK-MB-fluorescence conjugate, anti human Myoglobin-fluorescence conjugate, anti human Tn-I-biotin conjugate, anti chicken IgY-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide as a preservative in phosphate buffered saline (PBS).
- Each detector contains granule. 25 tubes of detector are packed in a pouch and packed in a box with 5 ml of diluent.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Follow 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, detector and diluent) should agree.
- Do not interchange test components between different lots or use test components after the expiration date, either of which might yield incorrect test result(s).
- Do not reuse cartridges or detector tubes. A detector tube should be used for processing of one sample only. A cartridge should be used for testing one sample only.
- The cartridge should remain sealed in its original pouch until just before use. Do not use cartridge, if pouch is damaged or has already been 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, the detector and the sample reach the room temperature for approximately 30 minutes before use.
- The instrument for ichroma™ tests may generate slight vibration during use.
- Used detectors, 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™ Cardiac Triple** will provide accurate and reliable results subject to the below conditions.
  - **ichroma™ Cardiac Triple** should be used only in conjunction with instrument for ichroma™ tests.
  - Have to use recommended anticoagulant sample.

Sample type	Recommended anticoagulant
Whole blood	heparin, Sodium citrate
Plasma	
Serum	Not applicable.

STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in an aluminum foil pouch) if stored at 4-30 °C.
- The detector and the diluent are 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(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 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-78

Components of **ichroma™ Cardiac Triple**

- Cartridge Box:
  - Cartridges 25
  - ID Chip 1
  - Instruction for Use 1
- Buffer Box
  - Detectors 25
  - Diluent 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **ichroma™ Cardiac Triple**

Please contact our sales division for more information.

- Instrument for ichroma™ tests
  - **ichroma™ II** REF FPRR021
  - **AFIAS-50** REF FPRR022

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ Cardiac Triple** is human whole blood/ serum/plasma.

- It is recommended to test the sample within 24 hours after collection.
- The serum or plasma should be separated from the clot by centrifugation within 3 hours after the collection of whole blood. If longer storage is required, e.g. if the test could not be performed within 24 hours, serum or plasma should be immediately frozen below -20 °C. The freezing storage of sample up to 3 months does not affect the quality of results.
- However, the whole blood sample should not be kept in a freezer in any case.
- Once the sample was frozen, it should be thawed only once time and only for test, because repeated freezing and thawing can result in the change of test values.

TEST SETUP

- Check the contents of **ichroma™ Cardiac Triple** : Sealed Cartridge, Detectors, Diluent and ID Chip.
- Ensure that the lot number of the cartridge matches that of the ID chip as well as the buffer box.
- Leave the sealed cartridge (if stored in refrigerator) and the buffer box 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

▶ **ichroma™ II**

< Multi Mode >

1) Transfer 150 µL of diluent using a pipette to a tube containing detector.
2) Transfer 75 µL of sample (Human whole blood/ serum/ plasma/control) to the detector tube.
3) Close the lid of the detector tube and mix the sample thoroughly by shaking it about 20 times.
4) Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
5) 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.*
6) 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.
7) Press 'Select' button on the instrument for ichroma™ tests to start the scanning process.
8) Instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
9) Read the test result on the display screen of the instrument for ichroma™ tests.

< Single Mode >

1) Transfer 150 µL of diluent using a pipette to a tube containing detector.
2) Transfer 75 µL of sample (Human whole blood/ serum/ plasma/control) to the detector tube.
3) Close the lid of the detector tube and mix the sample thoroughly by shaking it about 20 times.
4) Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
5) Inserting the device into the 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' or 'Start' button on the instrument for ichroma™

tests.

7) Cartridge goes inside the Instrument for ichroma™ tests and will automatically start scanning the sample-loaded cartridge after 12 min.
8) Read the test result on the display screen of the instrument for ichroma™ tests.

(Please refer to the ichroma™ II operation manual for complete information and operation instructions.)

▶ **AFIAS-50**

1) Insert the tip array in the tip station.
2) Insert the detector array in the Reagent station and cover the reagent station.
3) Open the diluent and insert the diluent in the diluent station.
4) Open the cover of the magazine station and pull and lift the cartridge magazine.
5) Insert the cartridges in the cartridge magazine one by one.
6) Insert the cartridge loaded cartridge magazine into the magazine station and close the cover of the magazine station.
7) Insert the sample tube into the blood collection tube rack and load the blood collection tube rack into the sampling station (loading part).
8) Tap the button which is provided in the upper side of the No. of test cartridge region to select ID chip what you want to use.
9) When the selected cartridge slot is activated, set the number of test cartridge by tapping.
10) Tap the button which is provided in the upper side of the No. of reagent region to select ID chip what you want to use.
11) When the selected slot is activated, set the number of Detector by tapping.
12) Set the number of pipette tips by tapping.
13) Tap the 'START' button on the left upper of the main screen to start test.

(Please refer to the AFIAS-50 operation manual for complete information and operation instructions.)

INTERPRETATION OF TEST RESULT

- The instrument for ichroma™ tests calculates the test result automatically and displays Tn-I, CK-MB and Myoglobin concentration of the test sample in terms of ng/mL.

Item	Tn-I [ng/ml]	CK-MB [ng/ml]	Myoglobin [ng/ml]
Reference range	≤0.04 (99th percentile)	≤7.00 (99th percentile)	≤70.00 (97.5th percentile)
Cut off	0.3	-	-
Working range	0.01-15	3-100	5-500

- **Expected Values**
  - In studies performed with the **ichroma™ Cardiac Triple** assay involving 100 healthy volunteers in Korea, the upper reference limit (99th percentile) for Tn-I was 0.03 ng/mL and CK-MB was 7 ng/ml and Myoglobin was 70 ng/ml.
  - Due to the release kinetics of Tn-I, CK-MB and Myoglobin, a result below the decision limit within the first hours of the onset of symptoms does not rule out myocardial infarction with certainty. If myocardial infarction is still suspected, repeat the test at appropriate intervals.
  - A cut-off of 0.3 ng/mL Tn-I is recommended for diagnosis of AMI, as this yields optimal performance of 91 % of sensitivity and 92.1 % of specificity. However, laboratories should establish their own diagnostic cut-off concentration based on the clinical practice at their perspective institutions.

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™ Tn-I. 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

- **Analytical sensitivity**

Whole Blood	Tn-I [ng/ml]	CK-MB [ng/ml]	Myo [ng/ml]
Limit of Blank (LoB)	0.009	0.72	1.23
Limit of Detection (LoD)	0.012	1.33	1.70
Limit of Quantitation (LoQ)	0.04	3.0	5.00
Serum/Plasma	**Tn-I [ng/ml]**	**CK-MB [ng/ml]**	**Myo [ng/ml]**
Limit of Blank (LoB)	0.008	0.66	1.23
Limit of Detection (LoD)	0.010	1.30	1.68
Limit of Quantitation (LoQ)	0.03	2.50	4.80

- **Analytical specificity**
  - Cross-reactivity
    There was no significant cross-reactivity with NT-proBNP and D-Dimer.

Cross-reactivity material	Conc. (ng/mL)
NT-proBNP	15
D-Dimer	5,000

  - Interference
    There was no significant interference with L-ascorbic acid, hemoglobin, cholesterol and D-glucose.

Interference material	Conc.
L-Ascorbic acid	8.5 mol/L
Hemoglobin	10 g/L
Cholesterol	65 mmol/L
D-Glucose	275 mmol/L

- **Precision**
  - Between lots
    One person tested three different lots of **ichroma™ Cardiac Triple**, ten times at each concentration of the control standard.
  - Between persons
    Three different persons tested **ichroma™ Cardiac Triple**; ten times at each concentration of the control standard.
  - Between days
    One person tested **ichroma™ Cardiac Triple** during five days; five times at each concentration of the control standard.
  - Between sites
    One person tested **ichroma™ Cardiac Triple** at three different sites; five times at each concentration of the control standard.

Whole blood type								
Tn-I [ng/mL]	between Lot		between person		between day		between site	
	mean	CV (%)	mean	CV (%)	mean	CV (%)	mean	CV (%)
0.5	0.48	4.3	0.51	2.5	0.50	3.1	0.49	4.1
3	3.10	6.6	3.08	3.5	3.01	6.5	2.89	3.4
10	10.10	6.0	9.94	7.4	10.05	5.8	10.00	5.1
Serum/Plasma type								
Tn-I [ng/mL]	between Lot		between person		between day		between site	
	mean	CV (%)	mean	CV (%)	mean	CV (%)	mean	CV (%)
0.5	0.48	2.1	0.51	4.8	0.49	4.1	0.49	5.8
3	3.05	1.6	3.0	5.4	3.01	3.9	3.0	6.8
10	9.9	5.2	9.9	7.1	10.05	2.0	10.1	5.4

Whole blood type								
CK-MB [ng/mL]	between Lot		between person		between day		between site	
	mean	CV (%)	mean	CV (%)	mean	CV (%)	Mean	CV (%)
10	10.2	5.2	10.01	5.7	9.8	2.7	10.0	3.5
50	48.8	4.8	49.2	3.9	50.1	5.6	48.5	3.8
100	100.1	3.5	101.0	7.3	100.8	4.3	100.3	2.1
Serum/Plasma type								
CK-MB [ng/mL]	between Lot		between person		between day		between site	
	Mean	CV (%)	Mean	CV (%)	Mean	CV (%)	Mean	CV (%)
10	10.0	2.5	10.1	5.1	10.6	2.1	9.9	2.9
50	51.2	1.9	48.9	2.5	51.7	3.3	50.5	3.5

100	99.8	5.3	101.2	3.3	98.2	2.0	103.2	3.1

Whole blood type								
Myoglobin [ng/mL]	between Lot		between person		between day		between site	
	mean	CV (%)	Mean	CV (%)	mean	CV (%)	Mean	CV (%)
12	11.9	3.3	11.1	6.8	12.5	5.3	13.1	5.3
100	99.8	6.8	102.3	5.7	103.7	4.7	100.5	6.2
325	322.1	5.0	321.0	5.1	329.2	2.2	328.3	5.8

Serum/Plasma type								
Myoglobin [ng/mL]	between Lot		between person		between day		between site	
	Mean	CV (%)	Mean	CV (%)	Mean	CV (%)	Mean	CV (%)
12	12.3	6.2	11.8	8.7	12.4	3.9	12.8	4.3
100	102.4	3.1	103.1	7.2	100.5	3.1	101.1	5.1
325	327.6	3.2	330.0	5.6	326.8	2.2	320.4	4.4

- **Accuracy**

The accuracy was confirmed by 3 different lots testing ten times each different concentration.

Whole blood type						
Tn-I [ng/mL]	Lot1		Lot2		Lot3	
	AVG	Recovery (%)	AVG	Recovery (%)	AVG	Recovery (%)
0.5	0.48	96.0	0.55	110.0	0.52	104.0
3	2.84	94.7	3.12	104.0	2.94	98.0
10	10.71	107.1	10.87	108.7	10.42	104.2

Serum/Plasma type						
Tn-I [ng/mL]	Lot1		Lot2		Lot3	
	AVG	Recovery (%)	AVG	Recovery (%)	AVG	Recovery (%)
0.5	0.51	102.0	0.48	96.0	0.49	98.0
3	3.25	108.3	2.79	93.0	3.21	107.0
10	10.5	105.0	10.02	100.2	10.51	105.1

Whole blood type						
CK-MB [ng/mL]	Lot1		Lot2		Lot3	
	AVG	Recovery (%)	AVG	Recovery (%)	AVG	Recovery (%)
10	9.15	91.5	10.13	101.3	10.23	102.3
50	53.62	107.2	48.88	97.8	51.31	102.6
100	95.1	95.1	97.81	97.8	101.01	101.0

Serum/Plasma type						
CK-MB [ng/mL]	Lot1		Lot2		Lot3	
	AVG	Recovery (%)	AVG	Recovery (%)	AVG	Recovery (%)
10	10.31	103.1	10.35	103.5	10.34	103.4
50	48.88	97.8	51.68	103.4	49.48	99.0
100	92.61	92.6	96.73	96.7	99.31	99.3

Whole blood type						
Myoglobin [ng/mL]	Lot1		Lot2		Lot3	
	AVG	Recovery (%)	AVG	Recovery (%)	AVG	Recovery (%)
12	11.89	99.1	11.53	96.1	12.1	100.8
100	102.65	102.7	98.87	98.9	103.25	103.3
325	303.01	93.2	315.69	97.1	333.15	102.5

Serum/Plasma type						
Myoglobin [ng/mL]	Lot1		Lot2		Lot3	
	AVG	Recovery (%)	AVG	Recovery (%)	AVG	Recovery (%)
12	12.33	102.8	10.93	91.1	11.84	98.7
100	98.75	98.8	105.64	105.6	101.13	101.1
325	315.6	97.1	332.84	102.4	327.65	100.8

- **Comparability**

Tn-I concentrations of 39 clinical samples were quantified independently with **ichroma™ Cardiac Triple** and Access 2 (Beckman coulter Inc. United states) as per prescribed test procedures. Test results were compared and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests were Y= 1.3901 X – 0.1033 and R = 0.9705 respectively.

CK-MB concentrations of 39 clinical samples were quantified independently with **ichroma™ Cardiac Triple** and mini Cobas e411 (Roche Diagnostics Inc. Switzerland) as per prescribed test procedures. Test results were compared and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests were Y= 0.8942 X – 0.0421 and R = 0.9944 respectively.

Myoglobin concentrations of 39 clinical samples were quantified independently with **ichroma™ Cardiac Triple** and mini VIDAS (BioMerieux Inc. France) as per prescribed test procedures. Test results were compared and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests were Y= 0.9292 X + 3.6709 and R = 0.9708 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

For technical assistance; please contact:
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