Boditech Cardiac Triple Control

INTENDED USE

Boditech Cardiac Triple Control is intended for the quality control of Cardiac Triple(Tn-I, CK-MB, Myoglobin) assay kit manufactured/provided by Boditech Med Inc.
For *in vitro* diagnostic use only.

COMPONENTS

Boditech Cardiac Triple Control consists of 'Boditech Cardiac Triple Control Level 1', 'Boditech Cardiac Triple Control Level 2', 'Instructions for use' and 'Control value & Barcode sheet'.

- Boditech Cardiac Triple Control is provided in ball shape lyophilized form.
- The control contains human cardiac troponin I/C complex antigen, human CK-MB protein, myoglobin antigen and horse serum.
- The control materials are contained in tubes, and the tubes are further packaged in a pouch.

SAFETY PRECAUTIONS AND WARNINGS

- For *in vitro* diagnostic use only.
- Do not pipette by mouth.
- Exercise proper precautions that would be normally required for handling laboratory reagents.
- Boditech Cardiac Triple Control should not be used past the expiration date.
- Boditech Cardiac Triple Control is solely designed for the quality control of Cardiac Triple cartridges manufactured/provided by Boditech Med Inc.
- Human-derived materials in Boditech Cardiac Triple Control were derived tested at a donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HBsAg) and Hepatitis C Virus (HCV) antibody, and found to be non-reactive. FDA-approved methods have been used to conduct these tests. However, since no method can offer complete assurance as to the absence of infectious agents, these human-derived materials and clinical samples should be handled as though they are capable of transmitting infectious diseases and should be disposed of as hazardous wastes.

STORAGE AND STABILITY

- Storage and stability condition of Boditech Cardiac Triple Control.

	Unopened	Opened (After reconstitution)
Temperature	2 ~ 8 °C	Discard the remaining amount after use as it is disposable.
Expiration date	Until expiration date on the label.	

- **It should be used ONE TIME ONLY for test.**
- Bacterial contamination of reconstituted Boditech Cardiac Triple Control will cause reductions in the stability of many components. If bacterial contamination is suspected, the tube should be discarded and a fresh tube needs to be reconstituted.

INSTRUCTIONS FOR USE

Boditech Cardiac Triple Control is supplied in ball shape lyophilized form.

1. Carefully reconstitute a tube of lyophilized control material with exactly 250 µL of sterilized distilled water at 15 ~25 °C.
2. Ensure the contents are completely dissolved by swirling the tube gently.
   (To avoid the formation of foam, do not shake the tube.)

Please refer to the instructions for use of the test cartridges for detailed test procedure.

In the event of damage to the package, contact the **Boditech Med Inc.'s Technical Services.**

MATERIALS SUPPLIED

REF CFPO-204

Boditech Cardiac Triple Control pouch (6 tubes)

- Boditech Cardiac Triple Control Level 1 (white tube) 3
- Boditech Cardiac Triple Control Level 2 (yellow tube) 3
- Instructions for use 1
- Control value & Barcode sheet 1

INTERPRETATION OF THE RESULT

The test result of the 'Boditech Cardiac Triple Control' should be consistent with the expected result of control value sheet.
If the test results fall outside the expected result, check the following for potential sources of error, and retest after resolving these matters. If the error still persists, contact the **Boditech Med Inc.'s Technical Services.**

※ Potential sources of error

- Errors in a testing process.
- Incorrect storage condition of Boditech Cardiac Triple Control.
- Use of expired or contaminated Boditech Cardiac Triple Control.
- Faulty Boditech's Cardiac Triple assay kits.
- Faulty Boditech's instruments.

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.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.

Boditech Cardiac Triple Control

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:
Boditech Med Inc.'s Technical Services at
Tel: +(82) -33-243-1400
E-mail: TS@boditech.co.kr

Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si,
Gang-won-do, 24398, Republic of Korea
Tel: +(82) -33-243-1400
Fax: +(82) -33-243-9373
www.boditech.co.kr

EC REP **Obelis s.a**
Bd. Général Wahis 53, 1030 Brussels, Belgium
Tel: +(32) -2-732-59-54
Fax: +(32) -2-732-60-03
E-mail: mail@obelis.net

CE IVD