

Boditech CK-MB Control

INTENDED USE

Boditech CK-MB Control is intended for *in vitro* diagnostic use in the quality control of CK-MB Assay Kit.

For *in vitro* diagnostic use only.

INTRODUCTION

The use of Boditech CK-MB Control may be considered as an objective assessment of the precision of CK-MB Assay Kits and is an integral part of Good Laboratory Practices. Boditech CK-MB Control is provided in lyophilized form.

COMPONENTS

Boditech CK-MB Control consists of 'Boditech CK-MB Control level 1', 'Boditech CK-MB Control level 2', 'Instruction for Use' and 'Control value & Barcode Sheet'.

- The control contains Human CK-MB protein and horse serum
- Each control vial packed in a box.

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 CK-MB Control should not be used past the expiration date.
- Boditech CK-MB Control is solely designed to be provided instrument-specific calibration curves of Boditech Readers and CK-MB Assay Kits.
- Human source materials from which Boditech CK-MB Control is derived were 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 source materials and all patient samples should be handled as though capable of transmitting infectious diseases and should be disposed of as hazardous wastes.

STORAGE AND STABILITY

- Storage and stability condition of Boditech CK-MB Control.

	Unopened		Opened (After reconstitution)	
	Temperature	2 ~ 8 °C	2 ~ 8 °C	-20 ~ -80 °C
Expiration date	Until expiration date on the label.	1 day	7 days	

- Close the opened Boditech CK-MB Control bottle tightly after use.
- Once the Boditech CK-MB Control was frozen, it should be used ONE TIME ONLY for test, because repeated freezing and thawing can result in the change of test values.
- After use, any residual product should NOT BE RETURNED to the original vial.
- Bacterial contamination of reconstituted Boditech CK-MB Control will cause reductions in the stability of many components. If bacterial contamination is suspected, the vial should be discarded and a fresh vial needs to be reconstituted.

INSTRUCTIONS FOR USE

Boditech CK-MB Control is supplied in lyophilized form.

1. Carefully reconstitute each vial of lyophilized with exactly 1 mL of sterilized distilled water.
2. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.

Please refer to package inserts of the test cartridges for detailed test procedure.

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities.

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

MATERIALS SUPPLIED

REF CFPO-243














Boditech CK-MB Control Box (2 vials)	
Boditech CK-MB Control level 1 (1 mL)	1
Boditech CK-MB Control level 2 (1 mL)	1
Instruction for Use	1
Control value & Barcode Sheet	1

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.

Boditech CK-MB Control

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
	<i>In vitro</i> diagnostic medical device
	Temperature limit
	This product fulfills the requirements of the Directive 98/79/EC on <i>in vitro</i> diagnostic medical devices
	Authorized representative of the European Community
	This product fulfills the requirements of the Part IV (<i>in vitro</i> diagnostic medical devices) of the UK MDR 2002
	UK Responsible Person

For technical assistance, please contact:
Boditech Med Inc.'s Technical Services at
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