Boditech PCT Control

INTENDED USE

Boditech PCT Control is intended for the quality control of PCT assay kit manufactured/provided by Boditech Med Inc.
For *in vitro* diagnostic use only.

INTRODUCTION

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

COMPONENTS

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

- The control contains recombinant procalcitonin and sodium azide in horse serum.
- Each control vial packed in a box.

SAFETY PRECUATIONS 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 PCT Control should not be used past the expiration date.
- Boditech PCT Control is solely designed for the quality control of PCT cartridges manufactured/provided by Boditech Med Inc.
- Human source materials from which Boditech PCT 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 PCT 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 vial tightly after use.
- Once the Boditech PCT 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 substance should NOT BE RETURNED to the original vial.
- Bacterial contamination of reconstituted Boditech PCT 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 PCT 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-97

Boditech PCT Control Box (2 vials)

- Boditech PCT Control level 1 (1 mL) 1
- Boditech PCT Control level 2 (1 mL) 1
- Instruction for Use 1
- Control value & Barcode Sheet 1

INTERPRETATION OF THE RESULT

The test result of the 'Boditech PCT Control' should be consistent with the expected result of control value sheet. If the test results fall outside the expected result, repeat the test.

※ Causes of test errors

- Errors in a manner that testing is performed.
- Use of too cold or too warm Boditech PCT Control.
- Use of expired or contaminated Boditech PCT Control.
- Errors in PCT assay kit.
- Errors of Boditech's analyzer.

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.

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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
	Batch code
	Catalog number
	Caution
	Manufacturer
	Authorized representative of the European Community
	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

For Technical Assistance
Boditech Med Inc.'s Technical Services at
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E-mail: sales@boditech.co.kr

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