Boditech D-Dimer Control

INTENDED USE

Boditech D-Dimer Control is intended for *in vitro* diagnostic use in the quality control of D-Dimer Assay Kit.
For *in vitro* diagnostic use only.

INTRODUCTION

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

COMPONENTS

Boditech D-Dimer Control consists of 'Boditech D-Dimer Control level 1', 'Boditech D-Dimer Control level 2', 'Instruction for Use' and 'Barcode Sheet'.
- The control contains D-Dimer standard stock solution and 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 D-Dimer Control should not be used past the expiration date.
- Boditech D-Dimer Control is solely designed to be provided instrument-specific calibration curves of Boditech Readers and D-Dimer Assay Kits.
- Human source materials from which Boditech D-Dimer 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 D-Dimer Control.

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

- Close the opened Boditech D-Dimer Control bottle tightly after use.
- After use, any residual product should NOT BE RETURNED to the original vial.
- Bacterial contamination of reconstituted Boditech D-Dimer 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 D-Dimer Control is supplied in lyophilized form.
1. Carefully reconstitute each vial of lyophilized with exactly 0.5 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.
3. 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-101**

Boditech D-Dimer Control Box (2 vials)

Boditech D-Dimer Control level 1	(0.5 mL)	1
Boditech D-Dimer Control level 2	(0.5 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 D-Dimer 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
	*In vitro* diagnostic medical device
	Temperature limit
	This product fulfills the requirements of the Directive 98/79/EC on *in vitro* diagnostic medical devices
	Authorized representative of the European Community
	This product fulfills the requirements of the Part IV (*in vitro* diagnostic medical devices) of the UK MDR 2002
UK RP	UK Responsible Person

For Technical Assistance
Boditech Med Inc.'s Technical Services at
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