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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.

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 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 to +8 °C	+2 to +8 °C	-20 to -80 °C
Expiration date	Until expiration date on the label.	1 day	14 days

- Close the opened Boditech D-Dimer Control bottle tightly after use.
- Once the Boditech D-Dimer 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 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. Avoid formation of foam. Do not shake.

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

For Technical Assistance
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