Boditech IL-6 Control

INTENDED USE

Boditech IL-6 Control is intended for in vitro diagnostic use in the quality control of IL-6 Assay Kit.
For *in vitro* diagnostic use only.

INTRODUCTION

The use of Boditech IL-6 Control may be considered as an objective assessment of the precision of IL-6 Assay Kits and is an integral part of Good Laboratory Practices. Boditech IL-6 Control is provided in lyophilized form.

COMPONENTS

Boditech IL-6 Control consists of 'Boditech IL-6 Control level 1', 'Boditech IL-6 Control level 2', 'Instruction for Use' and 'Control value & Barcode Sheet'.
- The control contains recombinant IL-6 protein and horse serum.
- Each control vial packed in a box.

SAFETY PRECUATIONS AND WARNINGS

- For *in vitro* diagnostic use only.
- Follow instructions and procedures described in this 'Instruction for use'.
- Do not pipette by mouth.
- Exercise proper precautions that would be normally required for handling laboratory reagents.
- Boditech IL-6 Control should not be used past the expiration date.
- Boditech IL-6 Control is solely designed to be provided instrument-specific calibration curves of Boditech Readers and IL-6 Assay Kits.
- Boditech IL-6 Control is not derived from human-derived substances. However, since no method can offer complete assurance as to the absence of infectious agents, these 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 IL-6 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 IL-6 Control bottle tightly after use.
- Once the Boditech IL-6 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 IL-6 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 IL-6 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 SUPPIED

REF CFPO-296

Boditech IL-6 Control Box (2 vials)
- Boditech IL-6 Control level 1 (1 mL) 1
- Boditech IL-6 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 IL-6 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
IVD	*In vitro* diagnostic medical device
	Temperature limit
CE	This product fulfills the requirements of the Directive 98/79/EC on *in vitro* diagnostic medical devices
EC REP	Authorized representative of the European Community
UK CA	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, please contact:
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