Boditech Tn-I Plus Control

INTENDED USE

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

SUMMARY AND PRINCIPLE

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

COMPONENTS

Boditech Tn-I Plus Control consists of 'Boditech Tn-I Plus Control level 1', 'Boditech Tn-I Plus Control level 2', 'Instruction for Use' and 'Control value & Barcode Sheet'.

- The control contains Human Cardiac Troponin I/C Complex Antigen 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 Tn-I Plus Control should not be used past the expiration date.
- Boditech Tn-I Plus Control is solely designed to be provided instrument-specific calibration curves of Boditech Readers and Tn-I Assay Kits.
- Human source materials from which Boditech Tn-I Plus 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 Tn-I Plus Control.

Unopened	
Temperature	**Expiration date**
+2 to +8 °C	Until expiration date on the label.

Opened (After reconstitution)	
Temperature	**Expiration date**
+2 to +8 °C	1 day
-20 to -80 °C	7 days

- Close the opened Boditech Tn-I Plus Control bottle tightly after use.
- Once the Boditech Tn-I Plus 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 Tn-I Plus 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 Tn-I Plus 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-212**

Boditech Tn-I Plus Control Box (2 vials)		
Boditech Tn-I Plus Control level 1	(1 mL)	1
Boditech Tn-I Plus 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.

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