

Boditech TSH Control

INTENDED USE

Boditech TSH Control is intended for the quality control of TSH Assay Kit manufactured/provided by Boditech Med Inc.

For *in vitro* diagnostic use only.

COMPONENTS

Boditech TSH Control consists of 'Boditech TSH Control Level 1', 'Boditech TSH Control Level 2', 'Instructions for use' and 'Control value & Barcode sheet'.

- Boditech TSH Control is provided in lyophilized form.
- The control contains TSH standard stock solution and horse serum.
- The control materials are contained in vials, and the vials are further packaged 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 TSH Control should not be used past the expiration date.
- Boditech TSH Control is solely designed for the quality control of TSH cartridges manufactured/provided by Boditech Med Inc.
- Human-derived materials in Boditech TSH Control were derived 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-derived materials and clinical samples should be handled as though they are capable of transmitting infectious diseases and should be disposed of as hazardous wastes.
- All waste materials should be disposed of in accordance with the requirements of your local waste management authorities.

STORAGE AND STABILITY

- Storage and stability condition of Boditech TSH Control.

	Unopened	Opened (After reconstitution)	
Temperature	2 ~ 8 °C	2 ~ 8 °C	-80 ~ -20 °C
Expiration date	Until expiration date on the label.	7 days	21 days

- Close the opened vial tightly after use.
- Once the Boditech TSH 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 TSH 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 TSH Control is supplied in lyophilized form.

- 1) Carefully reconstitute each vial of lyophilized control material with exactly 1 mL of sterilized distilled water.
- 2) Close the vial and allow it to stand for 30 minutes before use. Ensure the contents are completely dissolved by swirling the vial gently.
(To avoid the formation of foam, do not shake the vial.)

Please refer to the instructions for use of the test cartridges for detailed test procedure.

In the event of damage to the package, contact the **Boditech Med Inc.'s Technical Services.**

MATERIALS SUPPLIED

REF CFPO-228

Boditech TSH Control box (2 vials):

- | | |
|---------------------------------|---|
| - Boditech TSH Control Level 1 | 1 |
| - Boditech TSH Control Level 2 | 1 |
| - Instructions for use | 1 |
| - Control value & Barcode sheet | 1 |

INTERPRETATION OF THE RESULT

The test result of the 'Boditech TSH Control' should be consistent with the expected result of control value sheet.

If the test results fall outside the expected result, check the following for potential sources of error, and retest after resolving these matters. If the error still persists, contact the **Boditech Med Inc.'s Technical Services.**














- ※ Potential sources of error
 - Errors in a testing process
 - Incorrect storage condition of Boditech TSH Control
 - Use of expired or contaminated Boditech TSH Control.
 - Faulty Boditech's TSH assay kits.
 - Faulty Boditech's instruments.

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.
- 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
	<i>In vitro</i> diagnostic medical device
	Temperature limit
	This product fulfills the requirements of the Directive 98/79/EC on <i>in vitro</i> diagnostic medical devices
	Authorized representative of the European Community
	This product fulfills the requirements of the Part IV (<i>in vitro</i> diagnostic medical devices) of the UK MDR 2002
	UK Responsible Person

For technical assistance, please contact:
Boditech Med Inc.'s Technical Services at
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