Boditech FSH Control

INTENDED USE

Boditech FSH Control is intended for the quality control of FSH assay kit manufactured/provided by Boditech Med Inc.
For *in vitro* diagnostic use only.

COMPONENTS

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

- **Boditech FSH Control** is provided in lyophilized form.
- The control contains FSH 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 FSH Control** should not be used past the expiration date.
- **Boditech FSH Control** is solely designed for the quality control of FSH cartridges manufactured/provided by Boditech Med Inc.
- All waste materials should be disposed of in accordance with the requirements of your local waste management authorities.
- No human-derived materials are contained in **Boditech FSH Control**. However, since the risk of infection and the possible existence of other pathogens cannot be ruled out completely, they should be handled as though they are capable of transmitting infectious diseases and should be disposed of as hazardous wastes.

STORAGE AND STABILITY

- Storage and stability condition of **Boditech FSH 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 FSH 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 FSH 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.

TEST PROCEDURE

Boditech FSH 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-230

Boditech FSH Control Box (2 vials)

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

INTERPRETATION OF THE RESULT

The test result of the '**Boditech FSH 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 FSH Control**
- Use of expired or contaminated **Boditech FSH Control**
- Faulty Boditech's FSH 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
	*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, please contact:
Boditech Med Inc.'s Technical Services at
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