Document No. : INS-PGCO-EN-UKCA Revision Date : March 1, 2023 (Rev. 00)



Boditech Progesterone Control

INTENDED USE

Boditech Progesterone Control is intended for the quality control of Progesterone assay kit manufactured/provided by Boditech Med Inc.

For in vitro diagnostic use only.

COMPONENTS

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

- Boditech Progesterone Control is provided in lyophilized form.
- The control contains Progesterone 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 Progesterone Control** should not be used past the expiration date.
- Boditech Progesterone Control is solely designed for the quality control of Progesterone 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 Progesterone 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 Progesterone Control.
- Close the opened vial tightly after use.
- Once the Boditech Progesterone Control was frozen, it

	Unopened	Opened (After reconstitution)	
Temperature	2~8°C	2~8°C	-80 ~ -20 °C
Expiration date	Until expiration date on the label.	1 day	21 days

- 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
 Progesterone 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 Progesterone Control is supplied in lyophilized form.

- Carefully reconstitute each vial of lyophilized control material with exactly 1 mL of sterilized distilled water.
- 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.)

<u>Please refer to the instructions for use of the test cartridges</u> <u>for detailed test procedure.</u>

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

MATERIALS SUPPLIED

REF CFPO-238

Boditech Progesterone Control Box (2 vials)

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

INTERPRETATION OF THE RESULT

The test result of the 'Boditech Progesterone 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 Progesterone Control
 - Use of expired or contaminated Boditech Progesterone Control
 - Faulty Boditech's Progesterone 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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Boditech Progesterone Control

Note: Please refer to the table below to identify various symbols.

$\overline{\Sigma}$	Sufficient for <n> tests</n>
(i	Read instruction for use
	Use by Date
LOT	Batch code
REF	Catalog number
\triangle	Caution
	Manufacturer
IVD	In vitro diagnostic medical device
X	Temperature limit
CE	This product fulfills the requirements of the Directive 98/79/EC on <i>in vitro</i> diagnostic medical devices
EC REP	Authorized representative of the European Community
UK	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

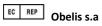
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