Boditech HbA1c Control

INTENDED USE

Boditech HbA1c Control is intended for the quality control of HbA1c assay kit manufactured/provided by Boditech Med Inc.
For *in vitro* diagnostic use only.

COMPONENTS

Boditech HbA1c Control consists of 'Boditech HbA1c Control Level 1', 'Boditech HbA1c Control Level 2', 'Instructions for use' and 'Control value & Barcode sheet'.

- **Boditech HbA1c Control** is provided in lyophilized form.
- The control contains HbA1c stock.
- 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 HbA1c Control** should not be used past the expiration date.
- **Boditech HbA1c Control** is solely designed for the quality control of HbA1c cartridges manufactured/provided by Boditech Med Inc.
- Human-derived materials in **Boditech HbA1c 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 HbA1c 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	20 days

- Close the opened vial tightly after use.
- Once the **Boditech HbA1c 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 HbA1c 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 HbA1c Control is supplied in lyophilized form.

1) Carefully reconstitute each vial of lyophilized control material with exactly 0.5 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-96

Boditech HbA1c Control Box (2 vials)

- Boditech HbA1c Control Level 1 1
- Boditech HbA1c Control Level 2 1
- Instructions for use 1
- Control value & Barcode sheet 1

INTERPRETATION OF THE RESULT

The test result of the '**Boditech HbA1c 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 HbA1c Control**.
- Use of expired or contaminated **Boditech HbA1c Control**.
- Faulty Boditech's HbA1c 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.

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:
Boditech Med Inc.'s Technical Services at
Tel: +(82) -33-243-1400
E-mail: TS@boditech.co.kr

Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si,
Gang-won-do, 24398, Republic of Korea
Tel: +(82) -33-243-1400
Fax: +(82) -33-243-9373
www.boditech.co.kr

EC REP **Obelis s.a**
Bd. Général Wahis 53, 1030 Brussels, Belgium
Tel: +(32) -2-732-59-54
Fax: +(32) -2-732-60-03
E-mail: mail@obelis.net

UK RP - Obelis UK Ltd.
Sandford Gate, East Point Business Park,
OX4 6LB-Oxford, UK
Tel: +(44)-1491-378012
E-mail: info@obelis.co.uk

CE UK CA IVD