Boditech CRP Control

INTENDED USE

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

COMPONENTS

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

- Boditech CRP Control is provided in liquid form.
- The control contains CRP antigen and horse serum.
- The control materials are contained in tubes, and the tubes are further packaged in a box.

SAFETY PRECUATIONS 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 CRP Control should not be used past the expiration date.
- Boditech CRP Control is solely designed for the quality control of CRP cartridges manufactured/provided by Boditech Med Inc.
- Human-derived materials in Boditech CRP Control 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-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 CRP Control.

	Unopened	Opened (After reconstitution)
Temperature	2 ~ 8 °C	2 ~ 8 °C
Expiration date	Until expiration date on the label	28 days

- Close the opened tube tightly after use.
- After use, any residual substance should not be returned to the original tube.
- Any contamination of opened Boditech CRP Control will cause reductions in the stability of components. If any contamination is suspected, the tube should be discarded and a fresh tube needs to be used.

TEST PROCEDURE

Boditech CRP Control is supplied in liquid form.

1. Thoroughly mix the contents of the tube before each use by gently inverting for several times.
2. When removed from the refrigerator, allow the vial to stand for about 30 minutes before using the control.

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-100

Boditech CRP Control Box (2 tubes)

- Boditech CRP Control Level 1 (0.5 mL) 1
- Boditech CRP Control Level 2 (0.5 mL) 1
- Instructions for use 1
- Control value & Barcode sheet 1

INTERPRETATION OF THE RESULT

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

Boditech CRP Control

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: sales@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