Boditech MxA/CRP Control

INTENDED USE

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

COMPONENTS

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

- **Boditech MxA/CRP Control** is provided in lyophilized form.
- The control contains MxA recombinant protein, Human C-reactive protein and sodium azide (NaN_3) as a preservative in 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 MxA/CRP Control** should not be used past the expiration date.
- **Boditech MxA/CRP Control** is solely designed for the quality control of MxA/CRP cartridges manufactured/provided by Boditech Med Inc.
- Human-derived materials in **Boditech MxA/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.
- **Boditech MxA/CRP Control** contains sodium azide (NaN_3), and they may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure. Avoid contact with skin, eyes, and clothing. In case of contact, rinse immediately with running water.

STORAGE AND STABILITY

- Storage and stability condition of **Boditech MxA/CRP 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	30 days

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

1) Carefully reconstitute each vial of lyophilized control material with exactly 1.0mL 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-382

Boditech MxA/CRP Control box (2 vials):

- Boditech MxA/CRP Control Level 1 — 1
- Boditech MxA/CRP Control Level 2 — 1
- Instructions for use — 1
- Control value & Barcode sheet — 1

INTERPRETATION OF THE RESULT

The test result of the '**Boditech MxA/CRP Control**' should be consistent with the expected result of control value sheet. If the test results fall outside the expected result, repeat the test.

※ Possible causes of test errors

- Errors in a testing process
- Incorrect storage condition of **Boditech MxA/CRP Control**
- Use of expired or contaminated **Boditech MxA/CRP Control**
- Faulty Boditech's MxA/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.

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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
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:
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