Boditech Anti-CCP Control

INTENDED USE

Boditech Anti-CCP Control is intended for *in vitro* diagnostic use in the quality control of ichroma™ Anti-CCP Assay Kit. **For *in vitro* diagnostic use only.**

INTRODUCTION

Boditech Anti-CCP Control consists of 'Boditech Anti-CCP Control level 1', 'Boditech Anti-CCP Control level 2', 'Instruction for Use' and 'Control value & Barcode Sheet'.

- The control contains anti-CCP stock and BSA, Sodium azide in PBS
- Each control vial packed in a box.

COMPONENTS

The use of Boditech Anti-CCP Control may be considered as an objective assessment of the precision of ichroma™ Anti-CCP Assay Kits and is an integral part of Good Laboratory Practices. Boditech Anti-CCP Control is provided in lyophilized form.

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 Anti-CCP Control should not be used past the expiration date.
- Boditech Anti-CCP Control is solely designed to be provided instrument-specific calibration curves of Boditech Readers and ichroma™ Anti-CCP Assay Kits.
- Human source materials from which Boditech Anti-CCP Control is derived 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 source materials and all patient samples should be handled as though capable of transmitting infectious diseases and should be disposed of as hazardous wastes.

STORAGE AND STABILITY

- Opened: Store refrigerated (+2 to +8°C). Once reconstituted, stable for 7days if kept capped in original container and free from contamination. After use, any residual product should not be returned to the original vial.
- Unopened: Store refrigerated (+2 to +8°C).
- Boditech Anti-CCP Control is stable to expiration date on the label.
- Bacterial contamination of reconstituted Boditech Anti-CCP 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.

INSTRUCTIONS FOR USE

Boditech Anti-CCP Control is supplied in lyophilized form.

1. Carefully reconstitute each vial of lyophilized with exactly **0.5 mL of sterilized distilled water.**
2. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.
3. Follow the procedure according to the instruction for use provided with the kit.

Please refer to package insets of the test cartridges for detailed test procedure.

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities.
In the event of damage to the package, contact the **Boditech Med Inc.'s Technical Services.**

MATERIALS SUPPLIED

REF CFPO-125

Boditech Anti-CCP Control Box (2 vials)	
Boditech Anti-CCP Control Level 1 (0.5 mL)	1
Boditech Anti-CCP Control Level 2 (0.5 mL)	1
Instruction For Use	1
Control value & Barcode Sheet	1

MATERIALS SUPPLIED

- 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.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.

QUALITY CONTROL

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For Technical Assistance
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