Boditech Anti-HCV Control

INTENDED USE

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

INTRODUCTION

The use of Boditech Anti-HCV Control may be considered as an objective assessment of the precision of Anti-HCV Assay Kits and is an integral part of Good Laboratory Practices. Boditech Anti-HCV 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-HCV Control should not be used past the expiration date.
- Boditech Anti-HCV Control is solely designed to be provided instrument-specific calibration curves of Boditech Readers and Anti-HCV Assay Kits.
- Human source materials from which Boditech Anti-HCV Control is derived were tested at a donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody and Hepatitis B Surface Antigen (HBsAg), 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 14 day 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-HCV Control is stable to expiration date on the label.
- Bacterial contamination of reconstituted Boditech Anti-HCV 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-HCV Control is supplied in lyophilized form.

1. Carefully reconstitute each vial of lyophilized with exactly 1 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.

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-143

Boditech Anti-HCV Control Box (2 vials)

Boditech Anti-HCV Control level 1	(1 mL)	1
Boditech Anti-HCV Control level 2	(1 mL)	1
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CONTROL VALUE

Boditech Anti-HCV Control composed of negative control and positive control.

Control Level	Result
Boditech Anti-HCV Control Level 1	Negative
Boditech Anti-HCV Control Level 2	Positive

INTERPRETATION OF THE RESULT

The testing result of the 'Boditech Anti-HCV Control' should be in agreement with expected result. If the test results fall outside the expected result, repeat the test.
Indication for the wrong test result

- Errors in a manner that testing is performed.
- Use of too cold or too warm Boditech Anti-HCV Control.
- Use of expired or contaminated Boditech Anti-HCV Control.
- Errors in AFIAS Anti-HCV or ichroma™ Anti-HCV.
- Errors of AFIAS Reader(AFIAS-1, AFIAS-6) or ichroma™ II.

For Technical Assistance
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