Boditech HBsAg Control

INTENDED USE

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

INTRODUCTION

The use of Boditech HBsAg Control may be considered as an objective assessment of the precision of HBsAg Assay Kits and is an integral part of Good Laboratory Practices. Boditech HBsAg 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 HBsAg Control should not be used past the expiration date.
- Boditech HBsAg Control is solely designed to be provided instrument-specific calibration curves of Boditech Readers and HBsAg Assay Kits.
- Human source materials from which Boditech HBsAg Control is derived were tested at a donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody 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 7 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 HBsAg Control is stable to expiration date on the label.
- Bacterial contamination of reconstituted Boditech HBsAg 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 HBsAg 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-142

Boditech HBsAg Control Box (2 vials)		
Boditech HBsAg Control level 1	(1 mL)	1
Boditech HBsAg Control level 2	(1 mL)	1
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CONTROL VALUE

Boditech HBsAg Control composed of negative control and positive control.

Control Level	Result
Boditech HBsAg Control Level 1	Negative
Boditech HBsAg Control Level 2	Positive

INTERPRETATION OF THE RESULT

The testing result of the 'Boditech HBsAg 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 HBsAg Control.
- Use of expired or contaminated Boditech HBsAg Control.
- Errors in AFIAS HBsAg or ichroma™ HBsAg.
- Errors of AFIAS Reader(AFIAS-1, AFIAS-6) or ichroma™ II.

For Technical Assistance
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