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Boditech NORO Control

INTENDED USE
Boditech NORO Control is intended for *in vitro* diagnostic use in the quality control of Norovirus Assay Kit. **For *in vitro* diagnostic use only.**

INTRODUCTION
The use of Boditech NORO Control may be considered as an objective assessment of the precision of Norovirus Assay Kits and is an integral part of Good Laboratory Practices. Boditech NORO 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 NORO Control should not be used past the expiration date.
- Boditech NORO Control is solely designed to be provided instrument-specific calibration curves of Boditech Readers and Norovirus Assay Kits.
- Human source materials from which Boditech NORO 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 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 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 NORO Control is stable to expiration date on the label.
- Bacterial contamination of reconstituted Boditech NORO 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 NORO Control is supplied in lyophilized form.
1. Carefully reconstitute each vial 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.

※ Please refer to a package insert of AFIAS or ichroma™ NORO for detailed instructions.

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-165

Boditech NORO Control Box (2 vials)		
Boditech NORO Control level 1	(1 mL)	1
Boditech NORO Control level 2	(1 mL)	1
Instruction For Use		1

CONTROL VALUE
Boditech NORO Control composed of negative control and positive control.

Control member	Result
Boditech NORO Control Level 1	Negative
Boditech NORO Control Level 2	Positive

INTERPRETATION OF THE RESULT
The testing result of the 'Boditech NORO 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 NORO control.
- Use of expired or contaminated Boditech NORO Control.
- Errors in AFIAS NORO or ichroma™ NORO.
- Errors of AFIAS reader (AFIAS-1, AFIAS-6) or ichroma™ II.

For Technical Assistance
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