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Boditech Rota/Adeno Control

INTENDED USE
Boditech Rota/Adeno Control is intended for *in vitro* diagnostic use in the quality control of Rota/Adenovirus Assay Kit. **For *in vitro* diagnostic use only.**

INTRODUCTION
The use of Boditech Rota/Adeno Control may be considered as an objective assessment of the precision of Rota/Adenovirus Assay Kits and is an integral part of Good Laboratory Practices. Boditech Rota/Adeno 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 Rota/Adeno Control should not be used past the expiration date.
- Boditech Rota/Adeno Control is solely designed to be provided instrument-specific calibration curves of Boditech Readers and Rota/Adenovirus Assay Kits.
- Human source materials from which Boditech Rota/Adeno 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 Rota/Adeno Control is stable to expiration date on the label.
- Bacterial contamination of reconstituted Boditech Rota/Adeno 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 Rota/Adeno 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.

※ Please refer to a package insert of AFIAS or ichroma™ Rota/Adeno 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-164

Boditech Rota/Adeno Control Box (2 vials)		
Boditech Rota/Adeno Control level 1	(1 mL)	1
Boditech Rota/Adeno Control level 2	(1 mL)	1
Instruction For Use		1

CONTROL VALUE
Boditech Rota/Adeno Control composed of negative control and positive control.

Control member	Result
Boditech Rota/Adeno Control Level 1	Negative
Boditech Rota/Adeno Control Level 2	Positive

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

For Technical Assistance
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