Boditech COVID-19 Ab Control

INTENDED USE

Boditech COVID-19 Ab Control is intended for *in vitro* diagnostic use in the quality control of SARS-CoV-2 IgG/IgM assay kit.
For *in vitro* diagnostic use only.

INTRODUCTION

The use of Boditech COVID-19 Ab Control may be considered as an objective assessment of the precision of SARS-CoV-2 IgG/IgM assay kits and is an integral part of Good Laboratory Practices. Boditech COVID-19 Ab Control is provided in lyophilized form.

COMPONENTS

Boditech COVID-19 Ab Control consists of 'Boditech COVID-19 Ab Control level 1', 'Boditech COVID-19 Ab Control level 2', 'Instruction for Use' and 'Barcode Sheet'.

- The level 1 control contains sucrose as stabilizer and sodium azide as a preservative in Tris-HCl.
- The level 2 control contains SARS-CoV-2 IgG/IgM standard stock, Sodium chloride and sodium azide as a preservative in Tris-HCl.
- Each control vial packed in a box.

SAFETY PRECUATIONS 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 COVID-19 Ab Control should not be used past the expiration date.
- Human source materials from which Boditech COVID-19 Ab 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

- Storage and stability condition of Boditech COVID-19 Ab Control.

	Unopened	Opened (After reconstitution)
Temperature	2 ~ 30 °C	2 ~ 8 °C
Expiration date	Until expiration date on the label.	2 weeks

- Close the opened Boditech COVID-19 Ab Control bottle tightly after use.
- After use, any residual product should NOT BE RETURNED to the original vial.
- Bacterial contamination of reconstituted Boditech COVID-19 Ab 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 COVID-19 Ab 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 5 minutes before use. Ensure contents are completely dissolved by swirling gently.
   Avoid formation of foam. Do not shake.

Please refer to package inserts 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-292**

Boditech COVID-19 Ab Control Box (2 vials)	
Boditech COVID-19 Ab Control level 1 (0.5 mL)	1
Boditech COVID-19 Ab Control level 2 (0.5 mL)	1
Instruction for Use	1
Barcode Sheet	1

CONTROL VALUE

Boditech COVID-19 Ab Control composed of negative control and positive control.

Boditech COVID-19 Ab Control	Result	
	IgG	IgM
Level 1	Negative	Negative
Level 2	Positive	Positive

INTERPRETATION OF THE RESULT

The testing result of the 'Boditech COVID-19 Ab 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 COVID-19 Ab Control.
- Use of expired or contaminated Boditech COVID-19 Ab Control.
- Errors in ichroma™ COVID-19 Ab or AFIAS COVID-19 Ab.
- Errors of Boditech's readers.

QUALITY CONTROL

- 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.

For Technical Assistance
Boditech Med Inc.'s Technical Services at
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