Boditech CRP Control

INTENDED USE

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

INTRODUCTION

The use of Boditech CRP Control may be considered as an objective assessment of the precision of CRP Assay Kits and is an integral part of Good Laboratory Practices. Boditech CRP Control is provided in liquid form.

COMPONENTS

Boditech CRP Control consists of 'Boditech CRP Control level 1', 'Boditech CRP Control level 2', 'Instruction for Use' and 'Barcode Sheet'.

- The control contains CRP antigen stock and Horse serum
- Each control vial packed in a box.

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 CRP Control should not be used past the expiration date.
- Boditech CRP Control is solely designed to be provided instrument-specific calibration curves of Boditech Readers and CRP Assay Kits.
- Human source materials from which Boditech CRP 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

- Opened: Store refrigerated (+2 to +8 °C). Once reconstituted, stable for 28 days at (+2 to +8 °C) if kept capped in original container and free from contamination. After use, any residual product should not be returned to the original tube.
- Unopened: Store refrigerated (+2 to +8°C).
- Boditech CRP Control is stable to expiration date on the label.
- Bacterial contamination of reconstituted Boditech CRP Control will cause reductions in the stability of many components. If bacterial contamination is suspected, the tube should be discarded and a fresh tube needs to be reconstituted.

INSTRUCTIONS FOR USE

Boditech CRP Control is supplied in liquid form.

1. Thoroughly mix the contents of the tube before each use by gently inverting for several times.
2. Follow the procedure according to the instruction for use provided with the kit.

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-100

Boditech CRP Control Box (2 tubes)		
Boditech CRP Control level 1	(0.5 mL)	1
Boditech CRP Control level 2	(0.5 mL)	1
Instruction For Use		1
Control value & Barcode Sheet		1

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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