Boditech RF IgM Control

INTENDED USE

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

INTRODUCTION

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

COMPONENTS

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

- The control contains Rheumatoid factor control serum 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 RF IgM Control should not be used past the expiration date.
- Boditech RF IgM Control is solely designed to be provided instrument-specific calibration curves of Boditech Readers and RF IgM Assay Kits.
- Human source materials from which Boditech RF IgM 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 an 1 week 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 RF IgM Control is stable to expiration date on the label.
- Bacterial contamination of reconstituted Boditech RF IgM 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 RF IgM 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-103

Boditech RF IgM Control Box (2 tubes)		
Boditech RF IgM Control level 1	(0.2 mL)	1
Boditech RF IgM Control level 2	(0.2 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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