# Boditech Ferritin Control

## INTENDED USE

Boditech Ferritin Control is intended for the quality control of Ferritin assay kit manufactured/provided by Boditech Med Inc.
For in vitro diagnostic use only.

## COMPONENTS

Boditech Ferritin Control consists of 'Boditech Ferritin Control Level 1', 'Boditech Ferritin Control Level 2', 'Instructions for use' and 'Control value & Barcode sheet'.

- Boditech Ferritin Control is provided in lyophilized form.
- The control contains ferritin protein stock and horse serum
- The control materials are contained in vials, and the vials are further packaged 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 Ferritin Control should not be used past the expiration date.
- Boditech Ferritin Control is solely designed for the quality control of Ferritin cartridges manufactured/provided by Boditech Med Inc.
- Human-derived materials in Boditech Ferritin Control were derived 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-derived materials and clinical samples should be handled as though they are capable of transmitting infectious diseases and should be disposed of as hazardous wastes.

## STORAGE AND STABILITY

- Storage and stability condition of Boditech Ferritin Control.

| | Unopened | Opened (after reconstitution) | |
|---|---|---|---|
| **Temperature** | 2 ~ 8 °C | 2 ~ 8 °C | -80 ~ -20 °C |
| **Expiration date** | Until expiration date on the label. | 7 days | 1 month |

- Close the opened vial tightly after use.
- Once the Boditech Ferritin Control was frozen, it should be used one time only for test, because repeated freezing and thawing can result in the change of test values.
- After use, any residual substance should not be returned to the original vial.
- Bacterial contamination of reconstituted Boditech Ferritin 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.

## TEST PROCEDURE

Boditech Ferritin Control is supplied in lyophilized form.

1) Carefully reconstitute each vial of lyophilized control material with exactly 0.5 mL of sterilized distilled water.
2) Close the vial and allow it to stand for 30 minutes before use. Ensure the contents are completely dissolved by swirling the vial gently.
   (To avoid the formation of foam, do not shake the vial.)

**Please refer to the instructions for use of the test cartridges for detailed test procedure.**

In the event of damage to the package, contact the **Boditech Med Inc.'s Technical Services.**

## MATERIALS SUPPLIED

**REF CFPO-99**

Boditech Ferritin Control box (2 vials):

- Boditech Ferritin Control Level 1 1
- Boditech Ferritin Control Level 2 1
- Instructions for use 1
- Control value & Barcode sheet 1

## INTERPRETATION OF THE RESULT

The test result of the 'Boditech Ferritin Control' should be consistent with the expected result of control value sheet.
If the test results fall outside the expected result, check the following for potential sources of error, and retest after resolving these matters. If the error still persists, contact the **Boditech Med Inc.'s Technical Services.**

※ Potential sources of error
- Errors in a testing process
- Incorrect storage condition of Boditech Ferritin Control
- Use of expired or contaminated Boditech Ferritin Control.
- Faulty Boditech's Ferritin assay kits.
- Faulty Boditech's instruments.

## 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.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.

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**Note:** Please refer to the table below to identify various symbols.

| | |
|---|---|
|  | Sufficient for <n> tests |
|  | Read instruction for use |
|  | Use by Date |
|  | Batch code |
|  | Catalog number |
|  | Caution |
|  | Manufacturer |
|  | *In vitro* diagnostic medical device |
|  | Temperature limit |
|  | This product fulfills the requirements of the Directive 98/79/EC on *in vitro* diagnostic medical devices |
|  | Authorized representative of the European Community |
|  | This product fulfills the requirements of the Part IV (*in vitro* diagnostic medical devices) of the UK MDR 2002 |
| **UK RP** | UK Responsible Person |

For technical assistance, please contact:
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