Boditech sphingotest® penKid® Control

INTENDED PURPOSE

Boditech sphingotest® penKid® Control is intended for the quality control of penKid assay kit manufactured/provided by Boditech Med Inc.

For *in vitro* diagnostic use only.

COMPONENTS

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

- Boditech sphingotest® penKid® Control is provided in lyophilized form.
- The control contains penKid peptide, sodium azide and horse serum.
- The control materials are contained in vials, and the vials are further packaged in a box.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use for health care professionals.
- Do not pipette by mouth.
- Exercise proper precautions that would be normally required for handling laboratory reagents.
- Boditech sphingotest® penKid® Control should not be used past the expiration date.
- No human-derived materials are contained in Boditech sphingotest® penKid® Control. However, since the risk of infection and the possible existence of other pathogens cannot be ruled out completely, they should be handled as though they are capable of transmitting infectious diseases and should be disposed of as hazardous wastes.
- All waste materials should be disposed of in accordance with the requirements of your local waste management authorities.
- Boditech sphingotest® penKid® Control contains sodium azide (NaN_3), and they may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure. Avoid contact with skin, eyes, and clothing. In case of contact, rinse immediately with running water.

LIMITATION OF THE TEST SYSTEM

- Boditech sphingotest® penKid® Control is solely designed for the quality control of penKid cartridges manufactured/ provided by Boditech Med Inc.

STORAGE AND STABILITY

- Storage and stability condition of Boditech sphingotest® penKid® 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	14 days

- Close the opened vial tightly after use.
- Once the Boditech sphingotest® penKid® 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 product should not be returned to the original vial.
- Bacterial contamination of reconstituted Boditech sphingotest® penKid® 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 sphingotest® penKid® Control is supplied in lyophilized form.

1) Carefully reconstitute each vial of lyophilized control material with exactly 1.0 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 Sales.**

MATERIALS SUPPLIED

REF CFPO-402

Boditech sphingotest® penKid® Control Box (2 vials)

- Boditech sphingotest® penKid® Control Level 1 1
- Boditech sphingotest® penKid® Control Level 2 1
- Instructions for use 1
- Control value & Barcode sheet 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately with Boditech sphingotest® penKid® Control.

Please contact our sales division for more information.

- **Boditech's instruments**
- **Boditech's penKid assay kits**

INTERPRETATION OF THE RESULT

The test result of the Boditech sphingotest® penKid® 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 Sales.**

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

QUALITY CONTROL

- Traceability: This method has been standardized against the sphingotest® penKid®.
- 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.

CONTROL	Control
Σ	Contains sufficient for <n> tests
	Consult instructions for use
	Use-by date
KR	Date of manufacture, Made in Korea
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
	Importer
	Distributor
EC REP	Authorized representative in the European Community
IVD	*In vitro* diagnostic medical device
	Device not for self-testing
	Temperature limit
CE 0123	This product fulfills the requirements of the Regulation (EU) 2017/746

If any serious incident occurs in relation to this product, please report it to Boditech Med Inc., your local distributor, and the competent authority in your country.

The Summary of Safety & Performance Report can be found here: https://ec.europa.eu/tools/eudamed

For technical assistance, please contact:
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