

# Boditech D-Dimer Calibrator

## INTENDED USE

Boditech D-Dimer Calibrator is intended for *in vitro* diagnostic use in the calibration of D-Dimer Assay Kit.

**For *in vitro* diagnostic use only.**

## INTRODUCTION

The use of Boditech D-Dimer Calibrator may be considered as an objective assessment of the precision of D-Dimer Assay Kits and is an integral part of Good Laboratory Practices. Boditech D-Dimer Calibrator is provided in lyophilized form.

## COMPONENTS

Boditech D-Dimer Calibrator consists of 'Boditech D-Dimer Calibrator level 1', 'Boditech D-Dimer Calibrator level 2', 'Instruction for Use' and 'Barcode Sheet'.

- The calibrator contains D-Dimer standard stock solution 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 D-Dimer Calibrator should not be used past the expiration date.
- Boditech D-Dimer Calibrator is solely designed to be provided instrument-specific calibration curves of Boditech Readers and D-Dimer Assay Kits.
- When a certain parameter of the instrument for AFIAS test is calibrated from Cal/QC mode, the system displays fluorescence intensity of each test instead of its actual result.
- Human source materials from which Boditech D-Dimer Calibrator 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 D-Dimer Calibrator.

	Unopened	Opened (After reconstitution)
Temperature	2 ~ 8 °C	2 ~ 8 °C
Expiration date	Until expiration date on the label.	1 day

- Close the opened Boditech D-Dimer Calibrator bottle tightly after use.
- After use, any residual product should NOT BE RETURNED to the original vial.
- Bacterial contamination of reconstituted Boditech D-Dimer Calibrator 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 D-Dimer Calibrator 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 30 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-113**

Boditech D-Dimer Calibrator Box (2 vials)	
Boditech D-Dimer Calibrator level 1 (0.5 mL)	1
Boditech D-Dimer Calibrator level 2 (0.5 mL)	1
Instruction for Use	1
Calibrator 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

Tel: +82 (33) 243-1400

E-mail: sales@boditech.co.kr



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## Boditech D-Dimer kalibratorius

### PASKIRTIS

Boditech D-Dimer kalibratorius skirtas in vitro diagnostiniam naudojimui D-Dimer tyrimo rinkinio kalibravimui.

**Tik in vitro diagnostikai.**

### IVADAS

Boditech D-Dimer kalibratoriaus naudojimas gali būti laikomas objektyviu D-Dimer tyrimo rinkinių tikslumo įvertinimu ir yra neatsiejama geros laboratorinės praktikos dalis. Boditech D-Dimer kalibratorius tiekiamas liofilizuota forma.

### KOMPONENTAI

Boditech D-Dimer kalibratorių sudaro „Boditech D-Dimer kalibratoriaus 1 lygis“, „Boditech D-Dimer kalibratoriaus 2 lygis“, „Naudojimo instrukcija“ ir „Brūkšninio kodo lapas“.

- Kalibratoriuje yra D-Dimer standartinio tirpalo ir arklio serumo.
- Kiekvienas kalibratoriaus buteliukas supakuotas į dėžutę.

### SAUGOS PRIEMONĖS IR ĮSPĖJIMAI

- Tik in vitro diagnostikai.
- Nelašinkite pipete naudodami burną.
- Imkitės tinkamų atsargumo priemonių, kurių paprastai prireiktų dirbant su laboratoriniais reagentais.
- Boditech D-Dimer kalibratoriaus negalima naudoti pasibaigus tinkamumo laikui.
- Boditech D-Dimer kalibratorius yra sukurtas tik tam, kad būtų pateiktos Boditech nuskaitymo įrenginių ir D-Dimer tyrimo rinkinių kalibravimo kreivės.
- Kai tam tikras AFIAS testų instrumento parametras kalibruojamas Cal/QC režime, sistema parodys kiekvieno testo fluorescencijos intensyvumą o ne tikrąjį rezultatą.
- Žmogaus kilmės medžiagos, iš kurių gaunamas Boditech D-Dimer kalibratorius, buvo donorų lygmeniu ištyrta dėl žmogaus imunodeficitu viruso (ŽIV 1, ŽIV 2) antikūnų, hepatito B paviršiaus antigeno (HBsAg) ir hepatito C viruso (HCV) antikūnų ir buvo nustatyta, kad medžiagos yra NEREAKTYVIOS. Šiems tyrimams atlikti buvo naudojami FDA patvirtinti metodai. Tačiau, kadangi joks metodas negali visiškai užtikrinti, kad nėra infekcinių medžiagų, šios žmogaus kilmės medžiagos ir visi pacientų mėginiai turėtų būti tvarkomi taip, lyg galintys perduoti infekcines ligas, ir turėtų būti šalinami kaip pavojingos atliekos.

### SANDĖLIAVIMAS IR STABILUMAS

- Boditech D-Dimer kalibratoriaus laikymo ir stabilumo sąlygos.

Bendrujų reikalavimų 6 p.

	Neatidarius	Atidarius (po ištirpinimo)
Temperatūra	+2 iki +8 °C	+2 iki +8 °C
Galiojimo laikas	Iki galiojimo laiko pabaigos, nurodytos etiketėje	1 diena

- Po naudojimo sandariai uždarykite atidarytą Boditech D-Dimer kalibratoriaus buteliuką.
- Po naudojimo produkto likučių NEGALIMA GRAŽINTI į originalų buteliuką.
- Ištirpinto Boditech D-Dimer kalibratoriaus užteršimas bakterijomis sumažins daugelio komponentų stabilumą. Jei įtariamas bakterinis užteršimas, buteliuką reikia išmesti ir paruošti naują buteliuką.

### NAUDOJIMO INSTRUKCIJOS

Boditech D-Dimer kalibratorius tiekiamas liofilizuota forma.

1. Kiekvieną liofilizuotos formos buteliuką atsargiai ištirpinkite tiksliai 0,5 ml sterilizuoto distiliuoto vandens.
2. Uždarykite buteliuką ir leiskite pastovėti 30 minučių prieš naudojimą. Švelniai sukdami įsitikinkite, kad turinys visiškai ištirpo. Venkite putų susidarymo. Nekratykite. Išsamią tyrimo procedūrą rasite testo kasečių pakuotės lapeliuose. Išmeskite visas išmestas medžiagas pagal vietinių atliekų tvarkymo institucijų reikalavimus. Jei pakuotė pažeista, susisiekite su **Boditech Med Inc. techninė tarnyba**.

### **TIEKIAMOS MEDŽIAGOS**

#### **REF CFPO-113**

Boditech D-Dimer kalibratoriaus dėžutė (2 buteliukai)	
Boditech D-Dimer kalibratoriaus 1 lygis (0.5 mL)	1
Boditech D-Dimer kalibratoriaus 2 lygis (0.5 mL)	1
Naudojimo instrukcija	1
Kalibratoriaus vertės ir brūkšninio kodo lapas	1

### **KOKYBĖS KONTROLĖ**

- Kokybės kontrolės testai yra geros bandymų praktikos dalis, siekiant patvirtinti laukiamus rezultatus ir tyrimo pagrįstumą, todėl jie turėtų būti atliekami reguliariais intervalais.
- Kontroliniai testai turi būti atliekami iš karto atidarius naują testo partiją, siekiant užtikrinti, kad testo rezultatai nepasikeistų.
- Kokybės kontrolės testai taip pat turėtų būti atliekami kiekvieną kartą, kai kyla klausimų dėl testo rezultatų pagrįstumo.

Techninei pagalbai susisiekite su **Boditech Med Inc. techninė tarnyba**:

Tel.: +82 (33) 243-1400

El. paštu: [sales@boditech.co.kr](mailto:sales@boditech.co.kr)



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## **ATITIKTIES DEKLARACIJA**

Gamintojas: Boditech Med Incorporated  
43, Geoduri, Dongnaemyeon  
Chuncheon, Gangwondo, 24398  
REPUBLIC OF KOREA

Europos atstovas: OBELIS S.A  
Bd. Geberal Wahis 53,  
1030 Bruselis,  
Belgija

Produktas: Boditech Tn-I Plus kalibratorius  
Produkto nr.: CFPO-113

Klasifikacija: KITI ( neįtrauktas į IVDD II priedą, nesavavaldis tyrimo įrenginys).

Atitikties vertinimo būdas: SAVAIMIS DEKLARACIJOS BŪDAS, REMIANTIS  
BŪDAS: IVVD III PRIEDU.

Šiuo dokumentu mes skelbiame, kad aukščiau minėti produktai atitinka Tarybos direktyvos, in vitro diagnostinių medicininių produktų direktyvos 98/79/EB, sąlygas. Visi lydintys dokumentai laikomi gamintojo patalpose.

Taikomi standartai: EN ISO 15223-1:2021, EN ISO 13485:2016,  
EN 13612:2002, EN ISO 23640:2015,  
EN 13641:2002, EN ISO 14971:2019,  
EN ISO 13975:2003, EN ISO 17511:2021,  
EN ISO 18113-1:2011, EN ISO 18113-2:2011

Išdavimo vieta ir data: Chuncheon, Korėja, 2022 metų gegužės mėn. 20 diena

Parašas: /parašas/  
Dr. Eui Yul Choi/generalinis direktorius

Išversta teisingai pagal mano žinias ir įsitikinimus. Tekstas yra išverstas teisingai ir tiksliai bei be pakeitimų prasmėje.  
Aš esu užtikrintas, kad lietuvių kalbos vertimas atitinka originalų dokumentą.

Vaidas Vilmantas (MB „Beikeris“, įm .k. 304539005)



# DECLARATION OF CONFORMITY

Manufacturer: Boditech Med Inc.  
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si,  
Gang-won-do, 24398, Republic of Korea

European Representative: OBELIS S.A.  
Bd. Général Wahis 53, 1030 Brussels, Belgium

Product: Boditech D-Dimer Calibrator  
Cat. No. : CFPO-113

Classification: Others  
(Neither listed in the annex II of the IVDD, Non-self-testing device)

Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for In Vitro Diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

Standards applied: EN ISO 15223-1:2021, EN ISO 13485:2016, EN 13612:2002,  
EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2019,  
EN 13975:2003, EN ISO 17511:2021, EN ISO 18113-1:2011,  
EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, May 20, 2022

Signature:

  
Dr. Eui Yul Choi / CEO

<b>MATERIAL SAFETY DATA SHEET</b>	Document No.	BT-MSDS520
	Rev. No.	03
	Rev. Date	2022. 05. 12

## I. General Information

- A. Product Name/Catalogue Number  
: Boditech D-Dimer Calibrator / CFPO-113
- B. Recommended use of the chemical and restriction on use
- Recommended use: In vitro diagnostic Medical Device
  - Restriction on use: For in vitro diagnostic use only.
- C. Manufacturer  
: Boditech Med Inc.
- D. Address  
: 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea
- E. Emergency Phone No.  
: +82-33-243-1400

## II. Hazard Identification

GHS classification of the product and national or regional

GHS classification	Not applicable
IMDG Code	Not applicable

GHS label elements including precautionary

Symbols	No data available
Signal word	No data available
Hazard statements	No data available

Precautionary statements

Prevention	No data available
Reaction	No data available
Storage	No data available
Disposal	No data available

Other hazards

NEPA	No data available
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### III. Composition/Information on Ingredients

Component	Synonyms	Classification No.	Concentration
Horse serum	No data available	No data available	99 %
Sodium Azide	NaN <sub>3</sub> -	26628-22-8	0.1%

We recommend handling all chemicals with caution.

### IV. First Aid Measures

- In case of eye contact
  - : Remove from source of exposure. Wash with copious amounts of water for at least 15 minutes. If irritation or signs of toxicity occur, seek medical attention.
- In case of skin contact
  - : Remove from source of exposure. Wash affected area with soap and water. If irritation or signs of toxicity occur, seek medical attention.
- If inhaled
  - : Get medical attention immediately. Remove to fresh air. If not breathe, give cardiopulmonary resuscitation. If breathing is difficult, give oxygen and continue to monitoring.
- If swallowed
  - : If irritation or signs of toxicity occur, seek medical attention.
- \* The following symptoms may occur: Irreversible eye damage.
- \* Medical conditions aggravated by exposure: Pre-existing eye ailments. Hypersensitivity.
- \* This material should be considered as being potentially infectious.

### V. Fire Fighting Measures

- Recommended extinguishing media
  - : Suitable extinguishing agents including CO<sub>2</sub>, WATER SPRAY or regular form.
- Specific hazard from the chemical
  - : Non-flammable, Corrosive or toxic gases and fume may be occurred in fire-emergency. Inhalation may be harmful.
- Special measure for fire-fighters
  - : Rescuers need to note the personal protective equipment. If not danger, remove containers. Non-flammable, Corrosive or toxic gases and fume may be occurred in fire-emergency. Inhalation may be harmful.
- Protective Equipment and precautions for Fire fighters
  - : Chemical resisted protective equipment for fire-fighter.

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	Rev. No.	03
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## VI. Accidental Release Measures

- Personal precautions
  - \* If not danger, stop to leak
  - \* Do not contact with exposed material without protective equipment
  - \* Note the avoid conditions and materials
  - \* Do not breathe dust / fume / gas / mist / vapours / spray
- Environmental precautions
  - : No data available
- Methods and materials for purification and cleaning up
  - : After absorbed exposed materials, clean up with cleaner and water

## VII. Handling and Storage

- Precaution for safe handling
  - \* Avoid skin friction.
  - \* Note the avoid conditions and materials from fire or flame.
- \* Protective equipment: Chemical resisted protective goggles, gloves, clothes and mask
- Method for safe handling
  - \* Note the avoid conditions and materials.
  - \* Store container tightly closed in a well-ventilated area.
- \* Storage temperature: low temperature

## VIII. Exposure controls and Personal protection

- Engineering management
  - : Good insulation and ventilation should be sufficient to control airborne levels.
- Personal protective equipment

Respiratory protection	Chemical resisted respiratory protection
Hand protection	Chemical resisted protective gloves
Eye protection	Chemical resisted eye protection
Skin and body protection	Chemical resisted protective clothes
- Standard of exposure	
Chemical	No data available
Biological	No data available

## MATERIAL SAFETY DATA SHEET

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Rev. No.	03
Rev. Date	2022. 05. 12

### IX. Physical and Chemical properties

State	Solid
Odor	No data available
Odor threshold value	No data available
pH	No data available
Melting/Freezing point	No data available
Initial boiling point or boiling range	No data available
Flash point	No data available
Evaporating rate	No data available
Lower explosion limit	No data available
Upper explosion limit	No data available
Vapor pressure	No data available
Water solubility	No data available
Density	No data available
Vapor density	No data available
Specific gravity	1.01 (water=1)
N-octan/water partition coefficient	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	No data available
Molecular weight	No data available

### X. Stability and Reactivity

Chemical stability	- Irritation or toxic gases and fume may be occurred in fire-emergency - Inhalation may harmful
Conditions to avoid	Heat, high temperature
Materials to avoid	No data available
Hazardous decomposition products formed under fire conditions	Irritation or toxic gases and fume may be occurred in fire-emergency

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Document No.	BT-MSDS520
Rev. No.	03
Rev. Date	2022. 05. 12

### XI. Toxicological Information

Information on the likely routes of exposure	No data available
Acute toxicity	No data available
Skin corrosion/Irritation	No data available
Serious eye damage/Eye irritation	No data available
Respiratory/Skin sensitization	No data available
Germ cell mutagenicity	No data available
Carcinogenicity	No data available
Reproductive toxicity	No data available
Specific target organ toxicity (single exposure)	No data available
Specific target organ toxicity (repeated exposure)	No data available
Aspiration hazard	No data available

### XII. Ecological Information

Toxicity	No data available
Persistence and degradability	No data available
Bio-accumulative potential	No data available
Mobility in soil	No data available
Other adverse effects	No data available

### XIII. Disposal Considerations

Not available

### XIV. Transport Information

IMDG Code	No data available
DRF	No data available
RID	No data available
ADR	No data available

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	Rev. No.	03
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AND	No data available
IATA	Non-Hazardous for Air Transport

## XV. Regulatory Information

Korea Industrial Safety and Health Act	No data available
Korea Hazardous Materials Safety Control Act	No data available
Korea Toxic Chemical Control Act	No data available
Korea Wastes Control Act	No data available
Other internal and foreign acts	No data available

## XVI. Other Notes

Limitations: The information and recommendations set forth in this MSDS are believed to be correct as of this date.