

Boditech D-Dimer Control

INTENDED USE

Boditech D-Dimer Control is intended for *in vitro* diagnostic use in the quality control of D-Dimer Assay Kit.

For *in vitro* diagnostic use only.

INTRODUCTION

The use of Boditech D-Dimer Control 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 Control is provided in lyophilized form.

COMPONENTS

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

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

- Storage and stability condition of Boditech D-Dimer Control.

	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 Control bottle tightly after use.
- After use, any residual product should NOT BE RETURNED to the original vial.
- Bacterial contamination of reconstituted Boditech D-Dimer 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.

INSTRUCTIONS FOR USE

Boditech D-Dimer Control 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.
3. 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-101**

Boditech D-Dimer Control Box (2 vials)

Boditech D-Dimer Control level 1 (0.5 mL)

Boditech D-Dimer Control level 2 (0.5 mL)

Instruction for Use

Control value & Barcode Sheet

1.6 t.s. Dviejų
lygių kokybės
kontrolė

1

1

1

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



Boditech Med Inc.

43, Geodudanji 1-gil, Dongnae-myeon,

Chuncheon-si, Gang-won-do, 24398

Republic of Korea

Tel: +(82) -33-243-1400

Fax: +(82) -33-243-9373

www.boditech.co.kr



Obelis s.a

Bd. Général Wahis 53, 1030 Brussels, BELGIUM

Tel: +(32) -2-732-59-54

Fax: +(32) -2-732-60-03

E-Mail: mail@obelis.net



Boditech D-Dimer kontrolė

PASKIRTIS

Boditech D-Dimer kontrolė yra skirta *in vitro* diagnostinei D-Dimer tyrimo rinkinio kokybės kontrolei. **Tik *in vitro* diagnostikai.**

PRISTATYMAS

Boditech D-Dimer kontrolė naudojimas gali būti laikomas objektyviu D-Dimer tyrimo rinkinio tikslumo įvertinimu ir integralia geros laboratorijos praktikos dalimi. Boditech D-Dimer kontrolė tiekama liofilizuota forma.

SUDĖTIS

Boditech D-Dimer kontrolės rinkinį sudaro: Boditech D-Dimer kontrolė 1 lygis, Boditech D-Dimer kontrolė 2 lygis, Naudojimo instrukcija ir Brūkšninio kodo lapas.

- Kontrolėje yra D-Dimer standartinis pradinis tirpalas ir arklis serumas.
- Kiekvienas kontrolinis buteliukas supakuotas į dėžutę.

SAUGUMO ATSARGUMO PRIEMONĖS IR PERSPĖJIMAI

- Tik *in vitro* diagnostikai.
- Nelašinkite pipete naudodami burną.
- Taikykite tinkamas atsargumo priemones, kurios įprastai reikalaujamos tvarkant laboratorinius reagentus.
- Boditech D-Dimer kontrolė neturi būti naudojama pasibaigus jos galiojimo laikui.
- Boditech D-Dimer kontrolė išskirtinai sukurta pateikti Boditech Readers ir D-Dimer tyrimo rinkinių instrumentui specifines kalibracijos kreives.
- Žmogaus kilmės medžiagos, iš kurių pagaminta Boditech D-Dimer kontrolė, buvo tirtos donoro lygiu dėl žmogaus imunodeficit viruso (ŽIV 1, ŽIV 2) antikūnų, hepatito B paviršiaus antigeno (HBsAg) ir hepatito C viruso (HCV) antikūnų. Pastarosios buvo nustatytos kaip NEREAKTYVIOS. FDA patvirtinti metodai naudojami atliekant šiuos testus. Tačiau, kadangi jokie metodai negali visiškai užtikrinti infekcinių medžiagų nebuvimo, šios žmogaus kilmės medžiagos ir paciento mėginiai turi būti tvarkomi kaip galintys perduoti infekcines ligas. Taip pat pastarieji turi būti utilizuojami kaip pavojingos atliekos.

SANDĖLIAVIMAS IR STABILUMAS

- Boditech D-Dimer kontrolės sandėliavimo ir stabilumo sąlygos

Bendrųjų reikalavimų 6 p.

	Neatidarius	Atidarius (ištirpinus)
Temperatūra	2 °C iki 8 °C	2 °C iki 8 °C
Galiojimo laikas	Iki galiojimo laiko pabaigos, nurodytos ant etiketės	1 diena

- Po kiekvieno naudojimo sandariai uždarykite Boditech D-Dimer kontrolės buteliuką.
- Bet kokio produkto likučiai NETURI BŪTI GRAŽINAMI į originalų buteliuką.
- Ištirpintos Boditech D-Dimer kontrolės bakterinis užteršimas sumažins daugumos komponentų stabilumą. Jeigu įtariate bakterinį užteršimą, buteliuką utilizuokite ir išstirpinkite naują buteliuką.

NAUDOJIMO INSTRUKCIJOS

Boditech D-Dimer kontrolė tiekama liofilizuota forma.

1. Atsargiai išstirpinkite kiekvieną liofilizuotą buteliuką su 0.5 mL sterilizuoto distiliuoto vandens.
2. Uždarykite buteliuką ir leiskite pastovėti 30 minučių iki naudojimo. Švelniai sukuriuodami įsitikinkite, kad medžiaga pilnai ištirpo.
3. Venkite putų susidarymo. Nekratykite.

Bet kokias medžiagas utilizuokite pagal Jūsų vietos atliekų tvarkymo kompetentingos įstaigos reikalavimus.

Jeigu pakuotė yra pažeista, susisieki su **Boditech Med Inc. technine pagalba.**

TIEKIAMOS MEDŽIAGOS

REF: CFPO-101

Boditech D-Dimer kontrolės dėžutė (2 buteliukai)	
Boditech D-Dimer 1 kontrolės lygis (0.5 mL)	1
Boditech D-Dimer 2 kontrolės lygis (0.5 mL)	1
Naudojimo instrukcijos	1
Kontrolės vertės ir brūkšninio kodo lapas	1

KOKYBĖS KONTROLĖ

- Kokybės kontrolės testai yra geros tyrimų praktikos dalis siekiant patvirtinti tikėtinus rezultatus ir tyrimo valdymą. Jie turi būti atliekami reguliariais intervalais.

- Kontrolės testai turi būti atliekami nedelsiant po naujos testo partijos atidarymo, kad įsitikinti, jog testo našumas nėra paveiktas.

- Kokybės kontrolės testai privalo būti atliekami tada, kai yra abejonų dėl testo rezultatų validumo.

Dėl techninės pagalbos kreipkitės į

Boditech Med Inc. techninė pagalba

Tel.: +82 (33) 243-1400

El. paštas: sales@boditech.co.kr

Boditech Med Inc.

43, Geodudanji 1-gil, Dongnae-myeon,

Chuncheon-si, Gang-won-do, Korėja

Tel.: +82 -33-243-1400 / Faks.: +82 -33-243-9373

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DECLARATION OF CONFORMITY

Manufacturer: Boditech Med Incorporated
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 Control
Cat. No. : CFPO-101

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 15223-1:2016, EN ISO 13485:2016, EN 13612:2002,
EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012,
EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, October 23, 2019

Signature:


Dr. Eui Yul Choi / CEO

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* D-Dimer kontrolė
Produkto nr.: CFPO-101

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: ISO 15223-1:2016, EN ISO 13485:2012, EN 13612:2002, EN ISO 23640:2015, EN ISO 13641:2002, EN 14971:2012, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011,

Išdavimo vieta ir data: Chuncheon, Korėja, 2019 metų spalio mėn. 23 diena

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

Signature:


Dr. Eui Yul Choi / CEO

MATERIAL SAFETY DATA SHEET

Document No.	BT-MSDSC32
Rev. No.	05
Rev. Date	2022. 05. 09

I. General Information

- A. Product Name/Catalogue Number
: Boditech D-Dimer Control / CFPO-101
- 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 ₃ -	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 CO₂, 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.

VI. Accidental Release Measures

- Personal precautions
 - * If not danger, stop to leak

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- * 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

IX. Physical and Chemical properties

State	Solid
Odor	No data available
Odor threshold value	No data available

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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

XI. Toxicological Information

Information on the likely routes of exposure	No data available
Acute toxicity	No data available
Skin corrosion/Irritation	No data available

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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
AND	No data available
IATA	Non-Hazardous for Air Transport

XV. Regulatory Information

Korea Industrial Safety and Health Act	No data available
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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.