

EU DECLARATION OF CONFORMITY

Manufacturer: **Boditech Med Inc.**
 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si,
 Gang-won-do, 24398, Republic of Korea
 (SRN: KR-MF-000011028)

European Representative: **Obelis s.a.**
 Bd. Général Wahis, 53, 1030 Brussels, Belgium
 (SRN: BE-AR-000000106)

Product: **ichroma™ II**
 - Catalog No.: FPRR021
 - Basic UDI-DI: 880613301004BJ

Intended use: ichroma™ II is an analyzer intended for use in conjunction with fluorescence immunoassay (FIA) kits for quantitative, semi-quantitative and qualitative measurements of various analytes. For *in vitro* diagnostic use only.

Classification: Class A (Rule 5)
 - According to the Annex VIII of the REGULATION (EU) 2017/746

Conformity Assessment Route: According to the Annex II and Annex III of the REGULATION (EU) 2017/746

We, Boditech Med Inc., herewith declare under our sole responsibility that the above-mentioned product is in conformity with the following European Union harmonisation legislation.

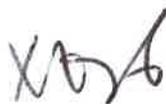
- REGULATION (EU) 2017/746 OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- DIRECTIVE 2011/65/EC OF EUROPEAN OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

All supporting documentation is retained under the premises of the manufacturer

Standards applied: EN ISO 13485:2016, EN 13612:2002, EN ISO 14971:2019,
 EN ISO 15223-1:2021, EN ISO 18113-1:2011, EN ISO 18113-3:2011,
 EN 61010-1:2010, EN 61010-2-101:2017, EN 61326-2-6:2020,
 EN 62304:2006, EN 62366-1:2015, ISO/TR 20416:2020, IEC 62321:2008

Place, Date of Issue: Chuncheon, Korea, August 11, 2022

Signature:



Sung Joong Kim / PRRC

Boditech Med Inc. www.boditech.co.kr

43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, KOREA
 바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373

DOC-IVDR-I-1 (Rev. 01)

ES atitikties deklaracija

Gamintojas: Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si,
Gang-won-do, 24398, Korėjos Respublika
(SRN: KR-MF-000011028)

Atstovas Europoje: Obelis s.a.
Bd. General Wahis, 53, 1030 Brussels, Belgija
(SRN: BE-AR-000000106)

Produktas: ichroma™ II
- Katalogo nr.: FPRR021
- Pagrindinis UDI-ID: 880613301004BJ

Paskirtis: ichroma™ II yra analizatorius, skirtas naudoti kartu su fluorescencinių imunitirimų (FIA) rinkiniais kiekybiniais, pusiau kiekybiniais ir kokybiniais įvairių analičių matavimams.

Klasifikacija: A klasė (5 taisyklė)
- Pagal (ES) Reglamento 2017/746 VIII priedą

Atitikties įvertinimo būdas: Pagal (ES) Reglamento 2017/746 II ir III priedus

Mes, Boditech Med Inc., šiuo dokumentu pagal savo atsakomybę skelbiame, kad nurodyti produktai atitinka Europos Sąjungos darniąją teisiją.

- 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos (ES) Reglamentas 2017/746 dėl *in vitro* diagnostikos medicinos prietaisų ir panaikinanti Direktyvą 98/79/EB ir Komisijos sprendimą 2010/227/ES.
- 2011 m. birželio 8 d. Europos Parlamento ir Tarybos Direktyva 2011/65/EB dėl tam tikrų pavojingų medžiagų elektrinėje ir elektroninėje įrangoje naudojimo ribojimo.

Visa palaikomoji dokumentacija saugoma gamintojo patalpose.

Taikomi standartai: EN ISO 13485:2016, EN 13612:2002, EN ISO 14971:2019,
EN ISO 15223-1:2021, EN ISO 18113-1:2011, EN ISO 18113-3:2011,
EN 61010-1:2010, EN 61010-2-101:2017, EN 61326-2-6:2020,
EN 62304:2006, EN 62366-1:2015, ISO/TR 20416:2020, IEC 62321:2008

Išleidimo vieta, data: Chuncheon, Korėja, 2022 m. rugpjūčio 11 d.

Parašas: /parašas/
Sung Joong Kim / PRRC

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)



Boditech Med Inc. www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si,
Gang-won-do, 24398, Korėjos Respublika
Tel.: +82-33-243-1400 Faks.: +82-33-243-9373

DOC-IVDR-1-1 (perž. 01)

DECLARATION OF CONFORMITY

2.2.4 t.s.

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 CRP Control**
Cat. No. : CFPO-100

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

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: **i-CHROMA™ CRP kontrolė**
Produkto nr.: CFPO-100

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 15223-1:2016, 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

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.

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DECLARATION OF CONFORMITY

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Gang-won-do, 24398, Republic of Korea

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

Product: **ichroma™ CRP**
Cat. No. : i-CHROMA CRP-25

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,
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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

ATITIKTIES DEKLARACIJA

Gamintojas: Boditech Med Incorporated
43, Geodudanj 1, Dongnae-myeon
Chuncheon-si, Gang-won-do, 24398
REPUBLIC OF KOREA

Europos atstovas: OBELIS S.A.
Bd.General Wahis 53,
1030 Briuselis
Belgija

Produktas: ***ichroma CRP***
Kat.Nr.: ***i-CHROMA™ CRP-25***

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

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14971:2012, EN ISO 17511:2003, EN ISO 18113-
1:2011, EN ISO 18113-2:2011

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

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

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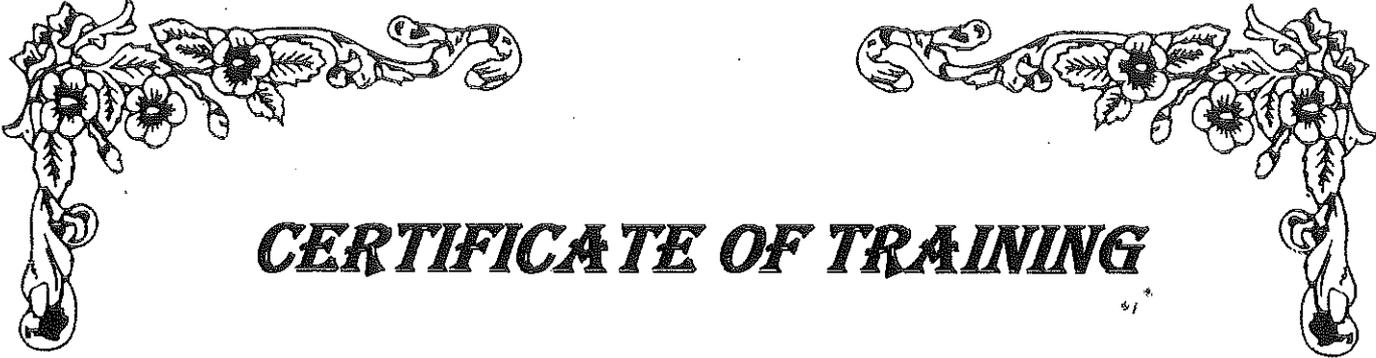
Vaidas Vilmantas (MB „Beikeris“, įm .k. 304539005)



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RA-DOC-II-06 (Per.06)



CERTIFICATE OF TRAINING

*In honor of your outstanding performance and dedication,
we gladly present this to*

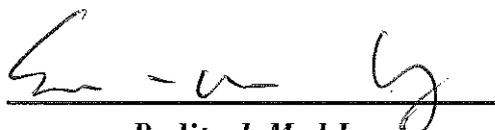
Arunas Matelis

*For the completion of the training requirement in accordance
with provisions of Boditech Med Inc.
to use ichroma, AFSAS and Hemoforma Plus.*

Certificate No. BT20181024-2

Date of Issuance: 2018. Oct. 24

Authorized by Dr. Soon-cheol Hong, Director



Boditech Med Inc.

Mokymų sertifikatas

*Pagerbdami jūsų išskirtinį pasirodymą ir atsidavimą,
mes su džiaugsmu įteikiame šį sertifikatą*

Arūnui Mateliui

*Už baigtus mokymus pagal „Boditech Med Inc.“
reikalavimus, naudoti I-Chroma, Afias ir Hemochroma
Plus prietaisus.*

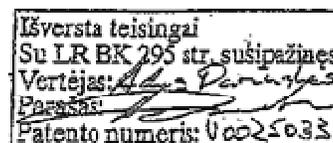
Sertifikato Nr.BT20181024-2

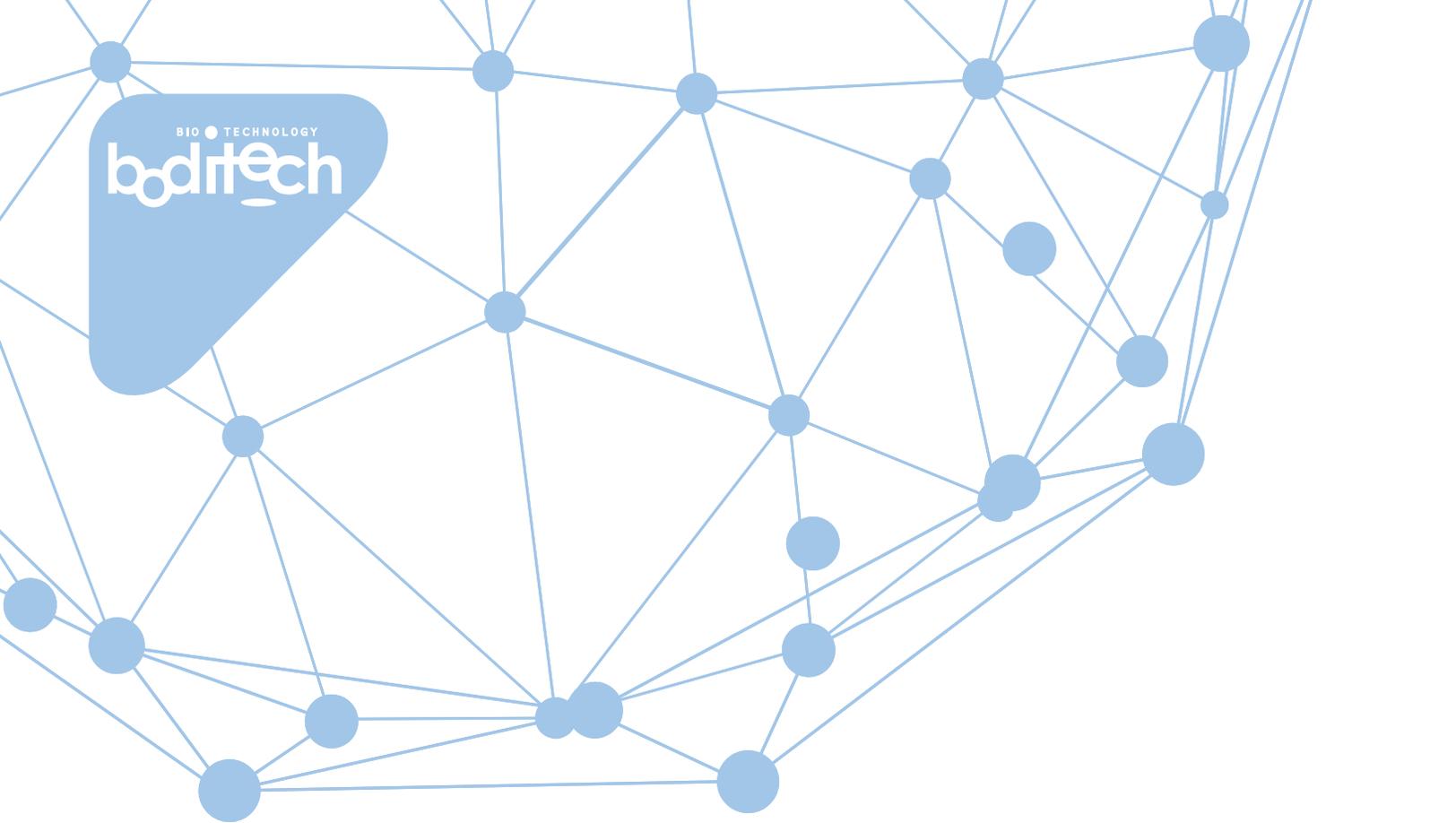
Išdavimo data: 2018m. spalio mėn. 24 d.

Dr.Soon-cheol Hong, Direktorius

/parašas/

Boditech Med.Inc.





ichromaTM
Total solution for
In-Vitro Diagnostic
Boditech Med Inc.

Vol.03

BIO ● TECHNOLOGY
boditech



Index

Introduction

Overview/Global networks	4
History	5
Parameter table	6

Instruments

10-16

ichroma™ II	10
ichroma™ III	11
ichroma™-50	12
ichroma™ M2	13
ichroma™ M3	14
hemochroma PLUS	15
i-chamber	16

Test items

Cardiac

20-30

Brain natriuretic peptide (BNP)	20
Cardiac triple (Tn-I, CK-MB, Myoglobin)	21
Creatine kinase MB isoenzyme (CK-MB)	22
D-Dimer	23
High-sensitivity C-Reactive Protein (hsCRP)	24
Myoglobin	25
N-terminal proBNP (NT-proBNP)	26
Troponin-I (Tn-I)	27
Troponin-I (Tn-I Plus)	28
Troponin-T (Tn-T)	29
Suppression of tumorigenicity 2 (ST2)	30

Cancer

32-38

Alpha-Fetoprotein (AFP)	32
Alpha-Fetoprotein (AFP Plus)	33
Carcinoembryonic antigen (CEA)	34
Carcinoembryonic antigen (CEA Plus)	35
Fecal Occult Blood (iFOB)	36
Prostate Specific Antigen (PSA)	37
Prostate Specific Antigen (PSA Plus)	38

Diabetes

40-42

Cystatin C	40
Hemoglobin A1c (HbA1c)	41
Microalbumin	42

Hormone

44-56

Anti-Müllerian Hormone (AMH)	44
Cortisol	45
Follicle-stimulating Hormone (FSH)	46
Human Chorionic Gonadotropin (β -hCG)	47
Human Chorionic Gonadotropin (β -hCG Plus)	48
Luteinizing Hormone (LH)	49
Progesterone	50
Prolactin (PRL)	51
Triiodothyronine (T3)	52
Thyroxine (T4)	53
Testosterone	54
Thyroid Stimulating Hormone (TSH)	55
Thyroid Stimulating Hormone (TSH Plus)	56



**Total solution for
In-Vitro Diagnostic
Boditech Med Inc.**



Infection 58-82

COVID-19 Ab	58
COVID-19 Ag	59
COVID-19/Flu Ag Combo	60
COVID-19 nAb	61
C-reactive Protein (CRP)	62
Procalcitonin (PCT)	63
Procalcitonin (PCT Plus)	64
Interleukin-6 (IL-6)	65
Adenovirus (Adeno)	66
Anti-streptolysin O (ASO)	67
Dengue Antibody IgG/IgM (Dengue IgG/IgM)	68
Dengue NS1 Antigen (Dengue NS1 Ag)	69
Toxoplasma IgM/IgG (Toxo IgG/IgM)	70
Group A Streptococcal Infection (Strep A)	71
Hepatitis B Antibody (Anti-HBs)	72
Hepatitis B Antigen (HBsAg)	73
Hepatitis C Antibody (Anti-HCV)	74
Influenza A+B	75
Influenza A+B/RSV	76
Norovirus (Noro)	77
Respiratory Syncytial Virus (RSV)	78
Rotavirus (Rota)	79
Rotavirus and Adenovirus (Rota/Adeno)	80
Mycoplasma	81
IGRA-TB (IFN- γ release assay-tuberculosis)	82

Autoimmune 84-86

Rheumatoid Arthritis (RF IgM)	84
Total IgE	85
Anti-CCP Plus	86

Other test items 88-91

Calprotectin	88
Ferritin	89
<i>Helicobacter pylori</i> Stool Antigen (H. Pylori SA)	90
Vitamin D	91

Molecular diagnostics 94-106

NuActor	94
ExAmplar	95
NuActor Viral RNA extraction kit	96
NuActor Viral DNA extraction kit	97
NuActor sputum DNA extraction kit	98
ExAmplex COVID-19 PCR 3-gene Lyo kit	99
ExAmplex COVID-19 PCR 3-gene kit	100
ExAmplex Influenza A/B SARS-CoV-2 PCR kit	101
ExAmplar COVID-19 real-time PCR kit (L)	102
ExAmplar Quanti-HBV v1.0 60T	103
ExAmplar Quanti-HCV v1.0 60T	104
ExAmplar Quanti-HIV v1.0 60T	105
ExAmplar MTB kit v2.0 72T	106

Catalog number index 108-109

Test items/Molecular diagnostics/ Instruments	108
Controls/Calibrators	109

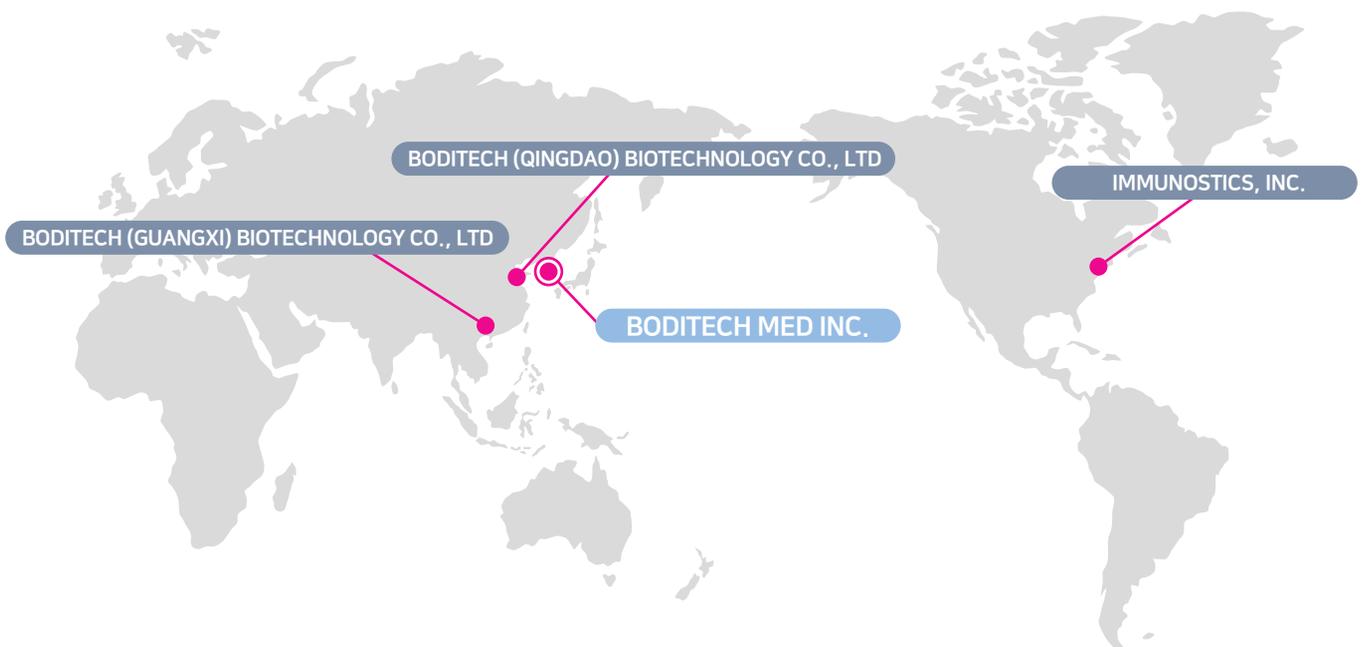


Overview

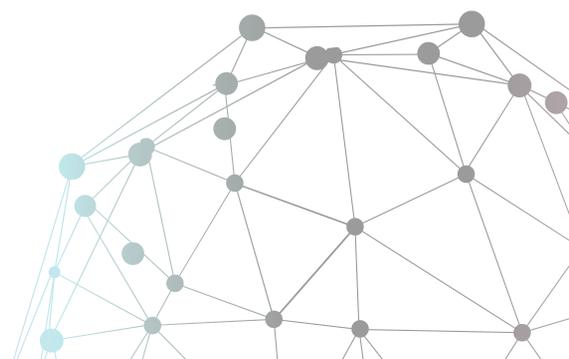
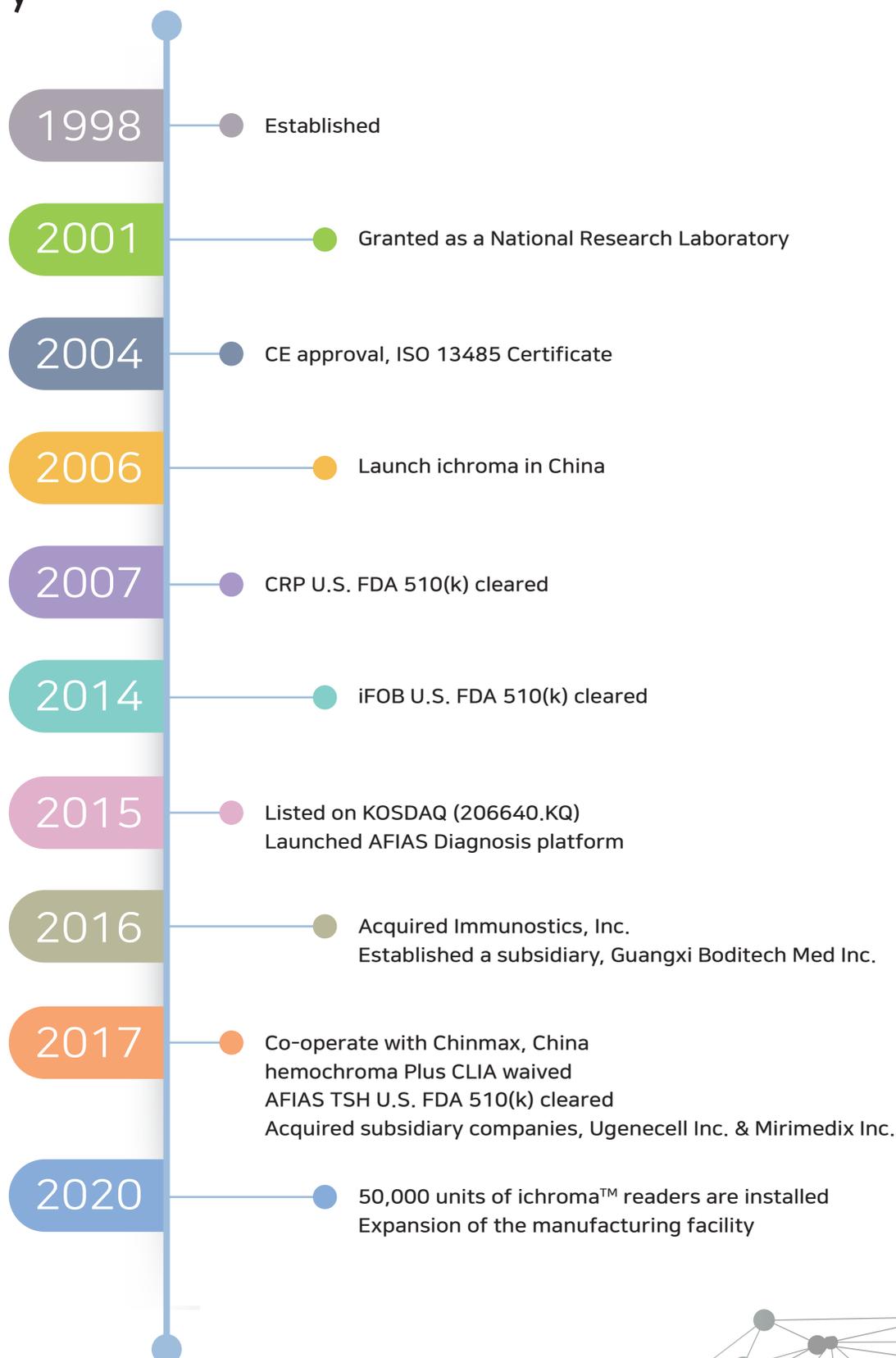
Since the establishment in 1998, Boditech Med Inc. has been providing high quality in vitro diagnostic analyzers and reagents to customers over 120 countries worldwide. As a leading manufacturer in IVD market, Boditech Med Inc. can help you provide high quality, cost-effective, user-friendly IVD products for those who require such solution. Providing various platforms from small manual analyzers to full-automatic analyzers, you can test most areas including infectious, diabetes, cardiac, hormone, and even cancer markers with one of your choices. With our continuous investment into Research & Development, we aim to improve existing products while developing new products so that our customers will have more choices with our platform. IVD is our passion and with more than 20 years of experience developing diagnostic biomarkers we believe in producing high quality and wider range of products that can provide various solutions to enhance human health and wellness.



Global Networks



History



ichroma™ Parameters

Category	item	ichroma™ II ichroma™ III	ichroma™-50	ichroma™ M2	ichroma™ M3	Sample type	Working range	Test time (min)	
Cardiac	Tn-I	●				S/P	0.1-50.0 ng/mL	12	
	Tn-I Plus	●	●			W/S/P	0.01-15 ng/mL	12	
	CK-MB	●	●			W/S/P	3-100 ng/mL	12	
	D-Dimer	●	●			WB/P	50-10,000 ng/mL	12	
	NT-proBNP	●	●			W/S/P	10-30,000 pg/mL	12	
	Myoglobin	●	●			W/S/P	5-500 ng/mL	12	
	hsCRP	●				W/S/P	0.1-10.0 mg/L	3	
	Cardiac Triple	●	●			W/S/P	Tn-I: 0.01-15 ng/mL CK-MB: 3-100 ng/mL Myoglobin: 5-500 ng/mL	12	
	ST2	●	●			W/S/P	3.1-200 ng/mL	12	
	BNP	●				W/S/P	10 - 20,000 pg/mL	12	
Troponin T	●				W/S/P	5-5,000 pg/mL	12		
Cancer	PSA	●				W/S/P	0.1-100.0 ng/mL (WB: 0.5-100.0 ng/mL)	15	
	PSA Plus	●				W/S/P	0.07-50 ng/mL	12	
	AFP	●				W/S/P	5-350 ng/mL	15	
	AFP Plus	●				W/S/P	0.5-350 ng/mL	12	
	CEA	●				S/P	1-500 ng/mL	12	
	CEA Plus	●				S/P	0.5-200 ng/mL	12	
Diabetes	iFOB Neo	●	●			Feces	25-1,000 ng/mL	10	
	HbA1c	●				WB	(NGSP) 4-15%	12	
	Microalbumin	●				Urine	2-300 mg/L	12	
Hormone	Cystatin C	●				S/P	0.1-7.5 mg/L	10	
	TSH	●				S/P	0.1-100.0 µIU/mL	12	
	TSH Plus	●				W/S/P	0.1-50 µIU/mL	12	
	T3	●				S/P	0.77-7.70 nmol/L	16	
	T4	●				S/P	10.23-300.00 nmol/L	16	
	FSH	●				S/P	1-100 mIU/mL	15	
	Progesterone	●				S/P	4.45-127.20 nmol/L	15	
	β-HCG	●	●			W/S/P	5-50,000 mIU/mL	15	
	β-HCG Plus	●				W/S/P	2-5,000 mIU/mL	12	
	LH	●				S/P	1-100 mIU/mL	15	
	PRL	●				S/P	1-100 ng/mL	10	
	Testosterone	●				S/P	1-10 ng/mL	15	
	Cortisol	●				W/S/P	80-800 nmol/L	10	
	AMH	●				S/P	0.02-15 ng/mL	12	
	Infection	COVID-19 Ab	●		●		W/S/P	Qualitative	10
		COVID-19 Ag	●		●		NS	Qualitative	12
		COVID-19/Flu Ag Combo	●		●		NS	Qualitative	20
COVID-19 nAb		●		●		W/S/P	Qualitative	20	
CRP		●	●		●	W/S/P	2.5-300 mg/L	3	
hsCRP All-in-one		●	●			W/S/P	0.5-200 mg/L	3	
PCT		●	●			W/S/P	0.1-100.0 ng/mL	12	
PCT Plus		●	●			W/S/P	0.02-50 ng/mL	12	
IL-6		●	●			W/S/P	2-2,500 pg/mL	12	
ASO		●				S/P	25-800 IU/mL	12	
Dengue NS1 Ag		●				W/S/P	Qualitative	12	
Dengue IgG/IgM		●				W/S/P	Qualitative	12	
HBsAg		●				W/S/P	Qualitative	12	
Anti-HBs		●				W/S/P	Qualitative	15	
Anti-HCV		●				W/S/P	Qualitative	12	
Influenza A+B		●	●		●	NS	Qualitative	10	
RSV		●			●	NS	Qualitative	10	
Influenza A+B/RSV		●	●		●	NS	Qualitative	10	
NORO		●				Feces	Qualitative	12	
ROTA		●				Feces	Qualitative	12	
Adeno		●				NS	Qualitative	10	
Rota/Adeno		●				Feces	Qualitative	12	
Strep A		●			●	Throat swab	Qualitative	5	
Mycoplasma		●	●		●	Throat swab	Qualitative	10	
IGRA-TB		●	●			P	Qualitative	15	
IGRA-TB 25		●				P	Qualitative	15	
Toxo IgG/IgM		●				W/S/P	Qualitative	12	
RF IgM		●				W/S/P	8-200 IU/mL	5	
Autoimmune		Anti-CCP Plus	●				W/S/P	3.5-300 U/mL (Semi-quantitative)	12
		Total IgE	●				W/S/P	1-1,000 IU/mL	12
Other test items	Ferritin	●				S/P	10-1,000 ng/mL	10	
	Vitamin D	●				S/P	8-70 ng/mL	28	
	Calprotectin	●	●			Feces	10-1,000 mg/kg feces	10	
	H. pylori SA	●				Feces	Qualitative	12	

ichromax™

Instruments

ichroma™ II	10
ichroma™ III	11
ichroma™-50	12
ichroma™ M2	13
ichroma™ M3	14
hemochroma PLUS	15
i-chamber	16

Advanced Compact Immunofluorescence Analyzer

ichroma™ II

ichroma™ II is a compact, easy-to-use diagnostic immuno-analyzer to measure the presence of various biomarkers for cardiac, cancer, hormones, infectious diseases, autoimmune diseases, and metabolic diseases.

- ▶ High performance with reliability
- ▶ Small, compact & light
- ▶ Multi-test function
- ▶ LIS/HIS compatible



Specification

Item	ichroma™ II Specification
Dimensions	276 mm (L) x 220 mm (W) x 91 mm (H)
Weight	1.3 Kg
Power supply	DC 12V/5A, AC/DC Adaptor Input 100-240V ~ 50/60Hz, 1.8A, Output DC 12V/5A (AA battery) DC 1.5V X 4ea
Data output	LCD / Internal Printer / RS232
Operation temperature	15-35°C (59-95°F)
Memory	1,000 Patient results / 1,000 QC results 500 ID chips / 100 User IDs
Interface	1 RS232 Port / 4 USB Ports 1 LAN Port / 1 SD Card Slot
Display LCD	7" Touch-screen
Cat#	FPRR021

High-throughput Immunofluorescence Analyzer

ichroma™ III

ichroma™ III accepts cartridges for various biomarkers in random sequence and process them in a preset temperature, even combines test parameters with differing incubation period. The user will prepare each cartridge before inserting it to the system, one at a time.

- ▶ Random access for various parameters
- ▶ Continuous testing
- ▶ Flexible temperature control
- ▶ Patient ID handwriting & HL7 compatible



Specification

Item	ichroma™ III Specification
Dimensions	240 mm (W) x 465 mm (L) x 341 mm (H)
Weight	11 Kg
Power supply	Input power source : 100~240 AC Rated frequency : 50 ~ 60 Hz Rated current: 2.5~1.0A
Data output	LCD / Internal Printer / USB OTG / RS232
Operation temperature	Temperature 15- 35°C
Memory	5,000 Patients results / 1,000 QC results 500 ID chips / 100 User IDs
Interface	1 RS232C Port 1 USB OTG Port for connecting PC 4 USB Ports / 1 LAN Port / 1 SD Card Slot
Display LCD	7" Touch-screen
Cat#	FPRR037

World First Automated Dry Immunoassay System

ichroma™-50

ichroma™-50 can automatically process 50 tests per batch. The user will load samples in blood tubes, up to 50 at a time, and the system takes care of the rest. You can run two differing biomarkers, 25 each as well. The system can process 80 samples max an hour and is fully HL7 comparable.

- ▶ High-throughput results (up to 80 tests in an hour)
- ▶ Various sample types (serum, plasma, whole blood, fingertip blood, and stool)
- ▶ Can run two differing biomarkers, 25 each per a bay.
- ▶ LIS/HIS Compatible



Specification

Item	ichroma™-50 Specification
Dimensions	610 mm (L) x 610 mm (W) x 606 mm (H)
Weight	49 Kg
Power supply	110-240V AC, 47~63 Hz, 1.1-2.2A
Data output	LCD / Internal Printer / RS232
Operation temperature	15-35°C (59-95°F)
Memory	5,000 Patient results / 5,000 QC results 10 User IDs
Throughput	Up to 80 tests / hour
Interface	1 RS232 Port / 4 USB Ports 1 LAN Port / 1 SD Card Slot / 1 mini USB Port
Display LCD	10.1" TFT LCD (touch screen)
Cat#	FPRR022

Respiratory Solution Analyzer

ichroma™ M2

ichroma™ M2 is a compact, hand-held immunoassay reader platform that shares cartridges with other platforms from Boditech Med. It can run on external batteries to enhance its mobility. We optimized the system for delivering diagnostics for respiratory infections such as COVID-19, influenza, and RSV.

- ▶ Portable and compact with high performance
- ▶ One-click operation for user convenience
- ▶ Cost-effective
- ▶ Power supply with portable charger

**Specification**

Item	ichroma™ M2 Specification
Dimensions	165 mm (L) x 95 mm (W) x 55 mm (H)
Weight	300 g
Power supply	Input: 100-240 V ~ 50/60Hz / Adaptor 5V 1A
Data output	LCD
Operation temperature	15-30°C
Interface	RS232C (factory only)
Technology	TRF
Cat#	FPRR031

Specialized Solution Analyzer

ichroma™ M3

ichroma™ M3 is a compact, hand-held immunoassay reader platform that shares cartridges with other platforms from Boditech Med. It can run on external batteries to enhance its mobility. ichroma M3 is configured to run CRP tests only.

- ▶ Portable and compact with high performance
- ▶ One-click operation for user convenience
- ▶ Cost-effective
- ▶ Power supply with portable charger

**Specification**

Item	ichroma™ M3 Specification
Dimensions	165 mm (L) x 95 mm (W) x 55 mm (H)
Weight	300 g
Power supply	Input: 100-240 V ~ 50/60Hz / Adaptor 5V 1A
Data output	LCD
Operation temperature	15-35°C
Interface	RS232C (factory only)
Technology	Fluorescence
Cat#	FPRR035

Total Hemoglobin Meter

hemochroma PLUS

hemochroma PLUS is a handheld device that can run tests for anemia. One uses a disposable test cuvette to pick up sample blood from the fingertip. It accommodates tube bloods with a pipette. Each test takes 3~5 seconds and the user can transmit the result to a host computer.

- ▶ US FDA 510(K) CLIA waived
- ▶ Quick test results in 3 seconds
- ▶ User-friendly graphic interface
- ▶ Stores 1,000 results onboard



Specification

Item	hemochroma PLUS Specification
Dimensions	106.5 mm (L) x 151.0 mm (W) x 38.5 mm (H)
Weight	215 ± 3 g
Power supply	Battery (AA 1.5V x 4ea) / USB power
Data output	LCD, thermal printer (option)
Operation temperature	10~40°C
Measuring time	3 sec
Detection range	5.0~25.6 g/dL
Sample	Whole blood (Capillary, tube blood (15 µL))
Memory	Test results up to 1,000
Interface	1 RS232 Port / 1 USB Port
Display LCD	3.2" TFT color LCD
Cat#	FPRR016

i-chamber

The i-chamber is an auxiliary device for the ichroma (ichroma™, ichroma™ II) systems and provides an environment set to the correct temperature to the ichroma cartridge when heating is required between tests. You can improve the reliability of your test results by keeping the temperature constant, one of the environmental factors that can cause unexpected errors in your test results.



Specification

Item	i-chamber Specification
Dimensions	190.0 mm (L) x 120.6 mm (W) x 108.0 mm (H)
Weight	1.5 kg (± 0.3 kg)
Power supply	DC 12V, 5A
Data output	LCD (16 x 4 characters)
Operation temperature	15-35°C (59-95°F)
Slots	6
Interface	1 Mini USB Port
Cat#	FPRR009

Test items

Cardiac	20-30
Cancer	32-38
Diabetes	40-42
Hormone	44-56
Infection	58-82
Autoimmune	84-86
Other test items	88-91
Molecular diagnostics	94-106
Catalogue number index	108-109



Cardiac

Brain natriuretic peptide (BNP)	20
Cardiac triple (Tn-I, CK-MB, Myoglobin)	21
Creatine kinase MB isoenzyme (CK-MB)	22
D-Dimer	23
High-sensitivity C-Reactive Protein (hsCRP)	24
Myoglobin	25
N-terminal proBNP (NT-proBNP)	26
Troponin-I (Tn-I)	27
Troponin-I (Tn-I Plus)	28
Troponin-T (Tn-T)	29
Suppression of tumorigenicity 2 (ST2)	30

BNP

Description

BNP, a heart-specific protein produced in the left ventricle of the heart, increases in blood concentration when the movement of the heart's left ventricle is cumulatively increased for abnormal reasons. This product quickly and quantitatively measures BNP in the blood to help diagnose and assess the severity of heart diseases, including congestive heart failure (CHF).

Indication

Acute Heart failure, Congestive Heart Failure.

Diagnostics Value

BNP levels are simple and objective measures of cardiac function. These measurements can diagnose (congestive) heart failure, including diastolic dysfunction. The BNP test result is particularly useful for ruling out heart failure in the ER. The BNP test may run with fingertip blood and delivers reliable results in 12 minutes so that clinicians can proactively respond.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III
ichroma™ BNP	●	●

Specification

Sample type	Whole blood, Plasma
Sample vol.	35 µL
Assay time	12 min
Working range	5 - 5,000 pg/mL
Storage	2-30°C
Shelf life	20 months

Performance

Accuracy	$y=0.9919x + 0.3835$ $R=0.9958$
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Ordering information

Cat #	CFPC-121
Test/Kit	25T/Kit

Cardiac triple (Tn-I, CK-MB, Myoglobin)

Description

This product is capable of simultaneously measuring the three most clinically proven cardiovascular disease markers (Tn-I, CK-MB, Myoglobin) at once, providing fast and accurate results for myocardial infarction.

Indication

Acute myocardial infarction, Acute coronary syndrome.

Diagnostics Value

Three biomarkers Tn-I, CK-MB and Myoglobin reveal differing information on cardiac damages. Cardiac Triple measures all of them at the same time to help clinicians assess the situation with one test. The rapid TAT should be important in ER or other urgent care facilities.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III	ichroma™-50
ichroma™ Cardiac triple	●	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	75 µL
Assay time	12 min
Working range	Tn-I: 0.01-15.00 ng/mL
	CK-MB: 3-100 ng/mL
	Myoglobin: 5-500 ng/mL
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	Tn-I	$y=1.3901x - 0.1033$ and $R=0.9705$
	CK-MB	$y=0.8942x - 0.0421$ and $R=0.9944$
	Myoglobin	$y=0.9292x + 3.6709$ and $R=0.9708$

Ordering information

Cat #	CFPC-78
Test/Kit	25T/Kit

Creatine Kinase MB (CK-MB)

Description

CK-MB increased rapidly in a short time when cardiac muscle cells are damaged. At the emergency room, it is possible to determine the heart damage by checking the change in the concentration of CK-MB when repeatedly measured at intervals of 4-6 hours. However, since there are individual differences in the normal blood concentration of CK-MB, it is recommended to cross-measure additional cardiovascular markers such as Troponin I to determine the presence or absence of heart damage for a reliable diagnosis.

Indication

(Acute)myocardial infarction, Primary Coronary Syndrome.

Diagnostics Value

The level of CK-MB, together with Troponin I and other cardiac-related biomarker levels, plays a vital role in assessing the AMI. It can provide close to the real-time value of CK-MB in the ER and equivalent facilities to help clinicians to produce up a treatment plan.

Selection guide

Item / Platform	ichroma™	ichroma™ II	ichroma™ III	ichroma™-50
ichroma™ CK-MB	●	●	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	75 µL
Assay time	12 min
Working range	3-100 ng/mL
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=1.0182x - 2.66$ and $R=0.9847$
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Ordering information

Cat #	CFPC-33
Test/Kit	25T/Kit

D-Dimer

Description

D-dimer is formed only when blood clots generated in blood vessels are decomposed, so it can be detected in the blood when acute or chronic inappropriate blood clots are generated. It is useful for diagnosing diseases caused by blood clots and monitoring the progress and treatment of diseases.

Indication

Deep Vein Thrombosis, Diffuse or disseminated intravascular coagulation, Various embolisms including PE and strokes.

Diagnostics Value

It produces the level of D-dimer in patient blood in 12 minutes. Attending clinicians can integrate this information with other pertinent parameters to assess the coagulation status of the patient. For example, a positive D-dimer result means that the patient has to undergo further imaging in order to diagnose whether or not he or she has DVT or PE.

Selection guide

Item / Platform	ichroma™	ichroma™ II	ichroma™ III	ichroma™-50
ichroma™ D-Dimer	●	●	●	●

Specification

Sample type	Whole blood, Plasma
Sample vol.	10 µL
Assay time	12 min
Working range	50-10,000 ng/mL
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=0.9393x - 65.134$ and $R=0.982$
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Ordering information

Cat #	CFPC-25
Test/Kit	25T/Kit

High-sensitivity C-Reactive Protein (hsCRP)

Description

As a high sensitive CRP test, it can detect or predict chronic cardiovascular diseases including atherosclerosis and acute myocardial infarction by quantifying this with hsCRP test for high-risk cardiovascular disease.

Indication

Acute coronary syndrome, Stroke, Peripheral arterial disease, Complications after myocardial infarction, such as heart failure.

Diagnostics Value

It is an 'all-in-one' type diagnosis system that maximizes the user's convenience. It helps predict the occurrence and progression of cardiovascular diseases by quantifying CRP with high sensitivity from a small amount of blood.

Selection guide

Item / Platform	ichroma™	ichroma™ II	ichroma™ III
ichroma™ hsCRP	●	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	100 µL
Assay time	3 min
Working range	0.1-10 mg/L
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=1.0273x - 0.0289$ $R=0.9989$
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Ordering information

Cat #	CFPC-6
Test/Kit	25T/Kit

Myoglobin

Description

Myoglobin is a useful marker that can detect myocardial infarction before any other cardiac marker because the blood concentration reaches the highest level 3 to 6 hours after the first heart pain begins when myocardial necrosis occurs. If both myoglobin test results are negative, it can be confirmed that it is not an acute myocardial infarction. Therefore, using this product, you can quickly check for acute myocardial infarction and proceed with appropriate treatment.

Indication

Acute myocardial infarction (AMI).

Diagnostics Value

It helps early diagnosis and treatment of acute myocardial infarction by quickly and accurately detecting myoglobin from blood.

Selection guide

Item / Platform	ichroma™	ichroma™ II	ichroma™ III	ichroma™-50
ichroma™ Myoglobin	●	●	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	10 µL
Assay time	12 min
Working range	5-500 ng/mL
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=0.9893x + 0.4756$ and $R=0.9955$
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Ordering information

Cat #	CFPC-37
Test/Kit	25T/Kit

NT-proBNP

Description

If the movement of the left ventricle of the heart is increased cumulatively for an abnormal reason, the concentration of NT-proBNP in the blood also increases significantly, so that the diagnosis and severity of heart failure can be assessed. It can quickly and quantitatively measure NT-proBNP in the blood to help diagnose and assess the severity of heart diseases, including congestive heart failure (CHF).

Indication

Exclusion test for heart failure diagnosis.

Diagnostics Value

The NT-proBNP test can determine the level of NTproBNP in the blood as fast as 12 minutes. The rapid turn-around should be a critical issue in ER or for paramedics in confirming the cardiac event.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III	ichroma™-50
ichroma™ NT-proBNP	●	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	10 µL
Assay time	12 min
Working range	10-30,000 pg/mL
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=0.9267x - 74.988$ and $R=0.9906$
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Ordering information

Cat #	CFPC-77
Test/Kit	25T/Kit

Troponin-I (Tn-I)

Description

Troponin T (Tn-I) can help quickly diagnose myocardial infarction and myocardial necrosis by quantifying the concentration of Tn-I in blood sensitively and specifically.

Indication

Acute myocardial infarction, acute coronary syndrome.

Diagnostics Value

This test can provide quick and accurate information to distinguish between myocardial infarction and other types of heart abnormalities. It can prove useful in ERs where urgent decisions are called for.

Selection guide

Item / Platform	ichroma™	ichroma™ II	ichroma™ III
ichroma™ Tn-I	●	●	●

Specification

Sample type	Serum, Plasma
Sample vol.	75 µL
Assay time	12 min
Working range	0.1-50.0 ng/mL
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=1.645x - 0.1831$ $R=0.9890$
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Ordering information

Cat #	13011
Test/Kit	25T/Kit

Troponin-I (Tn-I Plus)

Description

Troponin I (Tn-I) can diagnose myocardial infarction and myocardial necrosis at an early stage by quantifying the concentration of Tn-I in the blood with high sensitivity, preventing progression to severe and helping treatment.

Indication

Acute myocardial infarction, acute coronary syndrome.

Diagnostics Value

This test can provide quick and accurate information to distinguish between myocardial infarction and other types of heart abnormalities. It can prove useful in ERs where urgent decisions are called for.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III	ichroma™-50
ichroma™ Tn-I Plus	●	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	50 µL
Assay time	12 min
Working range	0.01-15.00 ng/mL
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=1.3924x - 0.0465$ $R=0.9910$
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Ordering information

Cat #	CFPC-65
Test/Kit	25T/Kit

Troponin-T (Tn-T)

Description

Troponin T is known for its sensitivity and specificity to myocardial damage and is a marker for the diagnosis of myocardial infarction and myocardial necrosis. It helps diagnose myocardial infarction and necrosis by measuring the concentration of Tn-T in blood sensitively and specifically.

Indication

Acute myocardial infarction, acute coronary syndrome.

Diagnostics Value

The presence of a cardiac-specific troponin in the circulation at levels above normal is a meaningful evidence of damage to cardiac muscle cells. Tests for the cause and status of the patients can be time-pressed in cases of myocardial infarction. It can provide on-site information on the level of TnT, which would be an essential component for the final assessment for the ongoing cardiac event.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III
ichroma™ Tn-T	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	35 µL
Assay time	12 min
Working range	10 – 20,000 pg/mL
Storage	2-30°C
Shelf life	20 months

Performance

Accuracy	$y=1.0128x + 1.8257$ $R=0.9884$
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Ordering information

Cat #	CFPC-122
Test/Kit	25T/Kit

ST2

Description

ST2, a cardiac marker for heart failure, is a very stable and independent diagnostic kit that is not affected by various condition of individual patients. The ST2 test is very useful in identifying and managing the risk of chronic heart disease by providing fast and accurate information on heart stress.

Indication

Heart failure, Severity of the HF.

Diagnostics Value

ST2 would prove itself in emergency rooms as clinicians can check the blood ST2 level in 12 minutes to study the severity of heart failure.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III	ichroma™-50
ichroma™ ST2	●	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	75 µL
Assay time	12 min
Working range	3.1-200 ng/mL
Storage	2-30°C
Shelf life	20 months

Performance

Accuracy	$y=0.9822x + 0.9738$ and $R=0.9908$
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Ordering information

Cat #	CFPC-100
Test/Kit	25T/Kit

Cancer

Alpha-Fetoprotein (AFP)	32
Alpha-Fetoprotein (AFP Plus)	33
Carcinoembryonic antigen (CEA)	34
Carcinoembryonic antigen (CEA Plus)	35
Fecal Occult Blood (iFOB)	36
Prostate Specific Antigen (PSA)	37
Prostate Specific Antigen (PSA Plus)	38

Alpha-Fetoprotein (AFP)

Description

High levels of AFP in adults may indicate the possibility of the liver, the ovaries, or the testicles, as well as noncancerous liver diseases such as cirrhosis and hepatitis. The AFP plus measures the level of AFP to help diagnose or rule out related abnormalities.

Indication

Liver cancer, Viral hepatitis, Ovarian cancer, Testicular cancer.

Diagnostics Value

It is useful for monitoring the patient's treatment response and recurrence of cancer through periodic measurement as well as regular screening tests for early detection by quantifying AFP in blood.

Selection guide

Item / Platform	ichroma™	ichroma™ II	ichroma™ III
ichroma™ AFP	●	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	30/15/15 µL
Assay time	15 min
Working range	5-350 ng/mL
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=0.9521x + 1.3237$ $R=0.9856$
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Ordering information

Cat #	i-CHROMA AFP-25
Test/Kit	25T/Kit

Alpha-Fetoprotein (AFP Plus)

Description

High levels of AFP in adults may indicate the possibility of the liver, the ovaries, or the testicles, as well as noncancerous liver diseases such as cirrhosis and hepatitis. The AFP plus measures the level of AFP to help diagnose or rule out related abnormalities.

Indication

Liver cancer, Viral hepatitis, Ovarian cancer, Testicular cancer.

Diagnostics Value

The clinician may administer an AFP plus test to help confirm or rule out liver cancer and associated abnormalities. With its fast turnaround time and the convenience of POC configurations, the clinician should find it an excellent addition to the clinic to help with the diagnosis without the conventional delay for the test result to return.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III
ichroma™ AFP Plus	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	35 µL
Assay time	12 min
Working range	0.5-350 ng/mL
Storage	2-30°C
Shelf life	20 months

Performance

Accuracy	$y=0.9612x + 0.2573$ $R=0.9903$
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Ordering information

Cat #	CFPC-73
Test/Kit	25T/Kit

Carcinoembryonic antigen (CEA)

Description

A high level of CEA in adults can be a sign of certain types of cancers in organs like the colon and rectum, prostate, ovary, lung, thyroid, or liver. The CEA test measures the level of CEA in the patient blood.

Indication

Colorectal cancer, Lung cancer. Rectal cancer, Pancreatitis.

Diagnostics Value

It is useful for monitoring the patient's treatment response and recurrence of cancer through periodic measurement by CEA in blood.

Selection guide

Item / Platform	ichroma™	ichroma™ II	ichroma™ III
ichroma™ CEA	●	●	●

Specification

Sample type	Serum, Plasma
Sample vol.	150 µL
Assay time	12 min
Working range	1-500 ng/mL
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=0.9857x - 1.108$ $R=0.996$
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Ordering information

Cat #	13013
Test/Kit	25T/Kit

Carcinoembryonic antigen (CEA Plus)

Description

A high level of CEA in adults can be a sign of certain types of cancers in organs like the colon and rectum, prostate, ovary, lung, thyroid, or liver. The CEA test measures the level of CEA in the patient blood with high sensitivity, including treatment response and recurrence of cancer patients.

Indication

Cancer (Rectal, lung, breast, liver, pancreatic, stomach, ovarian).

Diagnostics Value

The CEA test can often help foresee if the cancer is spreading to other parts. It can also help tell how well the cancer is responding to the treatment. The CEA test can provide pertinent information in 12 minutes with the fingertip blood and even run while the patient is still in a consultation session.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III
ichroma™ CEA Plus	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	35 µL
Assay time	12 min
Working range	0.5-200 ng/mL
Storage	2-30°C
Shelf life	20 months

Performance

Accuracy	$y=0.9909x + 0.5479$ $R=0.9962$
----------	---------------------------------

Ordering information

Cat #	CFPC-72
Test/Kit	25T/Kit

Fecal Occult Blood (iFOB)

Description

FOB test is a universal screening test that detects Fecal Occult Blood (FOB), a very tiny amount of blood mixed in the feces. It does not have the risk of complications and not need dietary restrictions to the patient. Therefore, it is possible to check the presence or absence of gastrointestinal lesions quickly and easily without the patient's discomfort.

Indication

Colorectal cancer, Hemorrhoids, Polyps, Colitis.

Diagnostics Value

The iFOB Neo test provides an alternative approach to screening for abnormalities in digestive tracts. One can even run the test with the patient still in consultation room in 10 minutes. The negative result from the test rules out the bleeding related problem.

Selection guide

Item / Platform	ichroma™	ichroma™ II	ichroma™ III	ichroma™-50
ichroma™ iFOB Neo	●	●	●	●

Specification

Sample type	Feces
Sample vol.	10 mg
Assay time	10 min
Working range	25-1,000 ng/mL
Storage	4-30°C
Shelf life	20 months

Performance

Accuracy	$y=1.0296x - 5.9682$ $R=0.9919$
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Ordering information

Cat #	CFPC-15-1
Test/Kit	25T/Kit

Prostate Specific Antigen (PSA)

Description

Screening for the prostate cancer & monitoring the effects of the treatment. It helps in the early detection of prostate diseases such as enlarged prostate and prostatitis and prostate cancer by quantifying PSA in male blood, as well as observation of treatment effects and monitoring of recurrence.

Indication

Prostatitis, Benign Prostatic Hyperplasia (BPH), Prostate Cancer.

Diagnostics Value

The PSA test is only one test for screening for signs of prostate cancer. It is much less invasive than the digital rectal exam that may ensue depending on the result of the PSA test. Though not specific to prostate cancer, the PSA test can provide vital primary information about prostate cancer in just 15 minutes in a POC settings.

Selection guide

Item / Platform	ichroma™	ichroma™ II	ichroma™ III
ichroma™ PSA	●	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	S/P: 75 µL / WB: 35 µL (Capillary tube)
Assay time	15 min
Working range	S/P : 0.1-100 ng/mL WB : 0.5-100 ng/mL
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=1.0283x - 0.0973$ $R=0.992$
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Ordering information

Cat #	i-CHROMA PSA-25
Test/Kit	25T/Kit

Prostate Specific Antigen (PSA Plus)

Description

It helps in the early detection of prostate diseases such as enlarged prostate and prostatitis and prostate cancer by quantifying PSA in male blood, as well as observation of treatment effects and monitoring of recurrence.

Indication

Prostate Cancer, Prostatitis, Benign Prostatic Hyperplasia (BPH).

Diagnostics Value

PSA is still the best tool we have for early diagnosis and screening of prostate abnormalities. The PSA test can return the result in 12 minutes with finger-tip blood in a POC setting.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III
ichroma™ PSA Plus	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	35 µL
Assay time	12 min
Working range	0.07-50 ng/mL
Storage	2-30°C
Shelf life	20 months

Performance

Accuracy	$y=0.9715x + 0.1662$ $R=0.9865$
----------	---------------------------------

Ordering information

Cat #	CFPC-71
Test/Kit	25T/Kit

Diabetes

Cystatin C	40
Hemoglobin A1c (HbA1c)	41
Microalbumin	42

Cystatin C

Description

Cystatin C (Cys C), an endogenous marker of renal function, is decomposed in the kidneys in the case of healthy individuals, so the blood concentration maintains a constant concentration even in various physical conditions or acute inflammatory reactions. However, in the case of renal failure, the concentration of Cys C in the blood increases due to a decrease in renal function, so the renal function can be evaluated by checking the renal glomerular filtration rate (GFR). This product quickly and easily quantifies the Cys C in the blood to help diagnose kidney function abnormalities and receive optimal treatment.

Indication

Renal function, Diabetic kidney disease, Post kidney-transplant monitoring, kidney function monitoring during chemotherapy.

Diagnostics Value

It is easy to use in small and medium-sized hospitals and laboratories as Cystatin C(Cys C), a sensitive renal function marker, is useful for evaluating the severity of disease and monitoring the progress and treatment effect.

Selection guide

Item / Platform	ichroma™	ichroma™ II	ichroma™ III
ichroma™ Cystatin C	●	●	●

Specification

Sample type	Serum, Plasma
Sample vol.	10 µL
Assay time	10 min
Working range	0.1-7.5 mg/L
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=0.93334x + 0.14119$ R=0.980
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Ordering information

Cat #	CFPC-43
Test/Kit	25T/Kit

HbA1c

Description

The measurement of the amount of glycated hemoglobin (HbA1c) is a highly reliable test unlike existing blood glucose tests, which are greatly affected by the patient's diet, and provides a stable indicator for predicting various diabetes complications. This product is a standardized product certified by NGSP (National Glycohemoglobin Standardization Program). It helps diabetic diagnosis, treatment, and prognosis by quickly and accurately measuring the glycated hemoglobin concentration (%) in a small amount of blood including peripheral blood over the past 3 months.

Indication

Diabetes.

Diagnostics Value

It can measure glycated hemoglobin with simple blood collection, select and diagnose pre-diabetes earlier, and check the therapeutic effect, so it can be usefully used by selecting suitable equipment according to scale in almost all medical fields, from relatively large medical facilities to small facilities such as public health centers and clinics.

Selection guide

Item / Platform	ichroma™	ichroma™ II	ichroma™ III
ichroma™ HbA1c	●	●	●

Specification

Sample type	Whole blood
Sample vol.	5 µL
Assay time	12 min
Working range	4-15 % (NGSP)
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=1.0025x - 0.2003$ $R=0.9855$
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Ordering information

Cat #	CFPC-38
Test/Kit	25T/Kit