Rotavirus (ROTA)

Description

Rotavirus is highly infectious even with a small number of fewer than 100 copies, causing severe dehydration symptoms due to frequent watery diarrhea accompanied by fever, vomiting, and abdominal pain, especially in infants and young children, and in severe cases can lead to death. ichroma™ ROTA test diagnoses infected people earlier prevent outbreaks and allow quick and appropriate treatment.

Indication

Acute gastroenteritis, Rotavirus gastroenteritis.

Diagnostics Value

ROTA tests do not require ELISA or PCR. This makes it an ideal choice for neonatal and children's clinics for detecting ROTA infection promptly before they spread to the general population.

Selection guide

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

Specification

Sample type	Feces
Sample vol.	Spot
Assay time	12 min
Working range	Qualitative
Storage	4-30℃
Shelf life	20 months

Performance

Accuracy	Positive: 99.02% Negative: 95.23% Overall: 97.10%

Ordering information

Cat #	CFPC-75
Test/Kit	25T/Kit

Rotavirus and Adenovirus (ROTA/Adeno)

Description

Rotavirus causes severe diarrhea in infants and infants under the age of 2 worldwide, and intestinal adenovirus causes gastroenteritis mainly in children under 3 years old, immunosuppressed patients and bone marrow transplant patients. Differential diagnosis with ichroma™ Rota/Adeno reduces antibiotic abuse and midiagnosis and helps with proper treatment.

Indication

Acute gastroenteritis, Rotavirus gastroenteritis, Adenovirus gastroenteritis.

Diagnostics Value

ichroma™ Rota/Adeno test kits identify the virus type of the rotavirus and the adenovirus sharing identical symptoms. These POC tests can help reduce the likelihood of misuse of antibiotics in neonatal clinics and children's hospitals.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III
ichroma™ Rota/Adeno	●	●

Specification

Sample type	Feces
Sample vol.	Spot
Assay time	12 min
Working range	Qualitative
Storage	4-30℃
Shelf life	20 months

Performance

Accuracy	Sensitivity	Rota 98.2%, Adeno 95%
	Specificity	Rota 95.7%, Adeno 96.2%

Ordering information

Cat #	CFPC-79
Test/Kit	25T/Kit

Mycoplasma

Description

Mycoplasma causes acute pneumonia with high fever and complications through upper respiratory infection, and it must be treated with specific antibiotics with severe side effects. Therefore, it is necessary to distinguish mycoplasma from common bacterial and viral infections. This test detects mycoplasma specifically and helps to shorten the patient's recovery time by prescribing appropriate antibiotics.

Indication

Mycoplasma infection, Mycoplasma pneumonia.

Diagnostics Value

Mycoplasma is highly contagious and can be dangerous for the elderly and children. One needs specific antibiotics for the treatment. Mycoplasma tests will help clinicians with the diagnosis and the treatment planning against Mycoplasma by providing an early diagnosis.

Selection guide

Item / Platform	ichroma™ M2	ichroma™ II	ichroma™ III	ichroma™-50
ichroma™ Mycoplasma	●	●	●	●

Specification

Sample type	Throat swab
Assay time	10 min
Working range	Qualitative
Storage	1-30℃
Shelf life	18 months

Performance

Accuracy	Clinical sensitivity: 81.9% Clinical specificity: 98.8%

Ordering information

Cat #	CFPC-94
Test/Kit	25T/Kit

IGRA-TB (IFN-γ release assay-tuberculosis)

Description

Patients with latent tuberculosis or reduced immunity can be converted into active tuberculosis patients with lethal transmission, so proactive treatment and response are required. ichroma™ IGRA-TB is a unique product that combines a highly specific cell-mediated immune response (CMI) against *Mycobacterium tuberculosis* and a highly sensitive lateral flow detection system. It can help fight tuberculosis by detecting latent tuberculosis in the simplest, fastest, and most accurate way.

Indication

Latent tuberculosis, LTB.

Diagnostics Value

IGRA-TB provides easy-to-use, rapid, and cost-effective diagnostics for latent TBs and can replace the time-consuming and costly ELISA based tests. These features would facilitate the utility at the level of public health centers or equivalent and third-party laboratories.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III	ichroma™-50
ichroma™ IGRA-TB	●	●	●

Specification

Sample type	Whole blood
Sample vol.	1 mL × 3 tubes
Assay time	15 min
Working range	Qualitative
Storage	4-30℃
Shelf life	20 months

Performance

Accuracy (Compared to Qunatiferon-Plus)	Positive percent agreement: 81.6% Negative percent agreement: 97.5%

Ordering information

Cat #	CFPC-86	CFPC-86-1
Test/Kit	100T/Kit (300 cartridges)	50T/Kit (150 cartridges)

Autoimmune

Rheumatoid Arthritis (RF IgM)

Description

It helps to diagnose rheumatoid arthritis, distinguish it from other types of arthritis and other inflammatory diseases, and ensure proper treatment by rapidly and accurately quantifying RF IgM in blood.

Indication

Rheumatoid arthritis, autoimmune disease.

Diagnostics Value

It helps diagnose rheumatoid factor (RA) in the blood with high sensitivity and distinguishes it from other types of arthritis and other inflammatory diseases, thereby helping active treatment to minimize complications and tissue damage.

Selection guide

Item / Platform	ichroma™	ichroma™ II	ichroma™ III
ichroma™ RF IgM	●	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	10/5/5 µL
Assay time	5 min
Working range	8-200 IU/mL
Storage	2-8℃ for DB/4-30℃ for Cartridge
Shelf life	20 months

Performance

Accuracy	y=1.082x - 12.038 R=0.9035

Ordering information

Cat #	CFPC-39
Test/Kit	25T/Kit

Total IgE

Description

It quantifies IgE in blood to support diagnosing of acute allergic diseases.

Indication

Allergic disease (Type 1 hypersensitivity reaction), autoimmune disease, Job's syndrome.

Diagnostics Value

It can be usefully used in small and medium hospitals including emergency rooms, as it can specifically detect immunoglobulin E in blood to diagnose excessive acute allergies and provide appropriate treatment to patients.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III
ichroma™ Total IgE	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	100/50/50 µL
Assay time	12 min
Working range	1-1,000 IU/mL
Storage	2-8℃ for DB/4-30℃ for Cartridge
Shelf life	20 months

Performance

Accuracy	y=0.9954x + 1.0943 R=0.9982

Ordering information

Cat #	CFPC-91
Test/Kit	25T/Kit

Anti-CCP Plus

Description

It helps to diagnose and provide appropriate treatment for chronic systemic autoimmune diseases and rheumatism by quantifying Anti-CCP in the blood.

Indication

Rheumatoid arthritis, autoimmune disease.

Diagnostics Value

It supports to diagnose rheumatoid arthritis at an earlier stage by quantifying anti-citrulline peptide antibody (Anti-CCP) in the blood to minimize complications and tissue damage by distinguishing it from other types of arthritis and other inflammatory diseases. Furthermore, it is useful for monitoring the effectiveness of treatment and treatment as appropriate.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III
ichroma™ Anti-CCP Plus	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	5 µL
Assay time	12 min
Working range	3.5-300 U/mL
Storage	2-8℃ for DB/4-30℃ for Cartridge
Shelf life	20 months

Performance

Accuracy	Positive: 93.9% Negative: 96.0% Overall: 94.9%

Ordering information

Cat #	CFPC-97
Test/Kit	25T/Kit

Other test items

Calprotectin

Description

The elevated level of fecal calprotectin may indicate a case of intestinal inflammation including IBD. This test can tell apart the IBD from the non-inflammatory bowel disease: the level stays low with the latter. It measures the level of fecal calprotectin to help differentiate those seemingly similar diseases.

Indication

Inflammatory bowel disease (IBD): Ulcerative Colitis (UC), Crohn's disease (CD)
Irritable bowel syndrome (IBS)

Diagnostics Value

The test value can render the status of the inflammatory bowel disease (IBD) and the response to the therapy. The calprotectin test would provide the essential information for the diagnosis and monitoring of the therapeutic progress.

Selection guide

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

Specification

Sample type	Feces
Sample vol.	10 mg
Assay time	10 min
Working range	10-1,000 mg/kg feces
Storage	4-30℃
Shelf life	20 months

Performance

Accuracy	y=1.0602x - 2.9932 R=0.9866

Ordering information

Cat #	CFPC-83
Test/Kit	25T/Kit

Ferritin

Description

It helps in the diagnosis of diseases related to iron metabolisms, such as iron deficiency and excess, as well as inflammation and tumors.

Indication

Iron deficiency anemia, anemia of chronic disease, Hemolytic anemia, Hereditary hemochromatosis, acute-phase reactants (APR), tumor marker.

Diagnostics Value

The Ferritin test measures the level of ferritin in blood to provide answers on iron metabolic disorders such as iron deficiency anemia and iron excess, as well as inflammation and tumor development, helping to provide appropriate treatment to patients.

Selection guide

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

Specification

Sample type	Serum, Plasma
Sample vol.	30 µL
Assay time	10 min
Working range	10-1,000 ng/mL
Storage	2-8℃ for DB/4-30℃ for Cartridge
Shelf life	20 months

Performance

Accuracy	y=0.99198x + 0.56317 R=0.9897

Ordering information

Cat #	CFPC-32
Test/Kit	25T/Kit

H. pylori SA

Description

H. pylori SA is an antigen produced by the immune system to cope with the *H. Pylori* infection. The level of the antigen examined through the stool serves as a more reliable indicator of the infection than by the one via a blood test, which does not tell if the infection is still active.

Indication

Chronic gastritis, gastric ulcers conditions, duodenal ulcers, stomach cancer etc.

Diagnostics Value

It is designed to be POC compatible, enabling a physician to make the diagnostics on-site, without the lengthy delay with the conventional test. With the immediate result on hand, the clinician can deliver diagnostics and treatment plans in the shortest time possible to maximize the patient's convenience.

Selection guide

Item / Platform	ichroma™	ichroma™ II	ichroma™ III
ichroma™ H. pylori SA	●	●	●

Specification

Sample type	Feces
Sample vol.	10 mg
Assay time	12 min
Working range	Qualitative
Storage	4-30℃
Shelf life	20 months

Performance

		Reference ELISA result		
ichroma™ H. pylori SA		Positive	Negative	Total
	Positive	102	1	103
	Negative	3	54	57
	Total	105	55	160

- Percent positive agreement = 97.1%
- Percent negative agreement = 98.2%
- Overall percent agreement = 97.5%

Ordering information

Cat #	CFPC-81
Test/Kit	25T/Kit

Vitamin D

Description

Vitamin D is closely related to bone formation, as well as autoimmune regulation, metabolic function, and cancer prevention. This product is useful to check for association with vitamin D when abnormal calcium, phosphorus, and parathyroid hormone (PTH) levels are observed in a patient. In addition, when starting drug treatment for bone disease, bone weakness, or osteoporosis, it is useful for diagnosis and monitoring of vitamin D prescription treatment through periodic quantification of vitamin D. The quality of this product is monitored by participating in CDC's Vitamin D Standardization Certification Program (VDSCP) every quarter.

Indication

Deficiency of Vitamin D, Excess of Vitamin D.

Diagnostics Value

Vitamin D plays an essential role in making strong bones. The vitamin D test kits come in dry format, eliminating the need for cold chain logistics. With the room temperature storage and its operation on a POC platform, one can integrate the vitamin D test into a routine on-site diagnostic service.

Selection guide

Item / Platform	ichroma™	ichroma™ II	ichroma™ III
ichroma™ Vitamin D	●	●	●

Specification

Sample type	Serum, Plasma
Sample vol.	50 µL
Assay time	28 min
Working range	8-70 ng/mL
Storage	4-30℃
Shelf life	20 months

Performance

Accuracy	y=1.1629x - 0.2829 R=0.9951

Ordering information

Cat #	CFPC-47
Test/Kit	25T/Kit

Molecular diagnostics

Fully Automated Extraction Solution

NuActor

Fully automatic nucleic acid (RNA/DNA) extraction system that can quickly and easily extract high-purity nucleic acids from small amount of samples with a ready-to-use cartridge and Tabletop style extractor.

- 8 extraction/run in < 13 min: quick result
- Reagent-ready Cartridge; Ready-to-use cartridge
- Room Temperature Storage: stable performance
- 200 µL sample to 100 µL elution: concentrated nucleic acid
- Viral RNA, DNA and sputum DNA extraction kits are available (Exclusive NuActor cartridges)

Specification

Item	NuActor Specification
Dimensions	240 mm (L) x 240 mm (W) x 260 mm (H)
Weight	6.98 Kg
Power supply	100-240V AC(50/60 Hz), 60W
Throughput	8 samples
Operation temperature	15-40℃
Memory	N/A
Interface	Touch-screen LCD
Cat#	FPRR032

Fast and Simple Viral-Load Analyzer

ExAmplar

A cost-effective and compact analyzer based on PCR that detects virus/bacteria quantitatively or qualitatively in a short time using ready-to-use cartridges.

- 8 Reaction/run in 30 min (DNA) / 45-55 min (RNA): quick result
- Compact, light and low power consumption (~2.88 kg)
- Small footprint
- Stand-alone

Specification

Item	ExAmplar Specification
Dimensions	200 mm (L) x 240 mm (W) x 180 mm (H)
Weight	2.88 Kg
Power supply	100-240V AC(50/60 Hz), 110W
Data output	SD card
Operation temperature	15-40℃
Memory	+5,000 test results
Interface	Touch-screen LCD
Cat#	FPRR030

NuActor Viral RNA extraction kit

Description

This product is provided as ready-to-use cartridges for extracting viral RNA. Samples are placed in a cartridge, and the cartridge is mounted on a NuActor instrument, and it is automatically processed to extract highly purified viral RNA quickly and simply.

Indication

Applicable for Serum / Plasma / VTM / UTM samples.

Diagnostics Value

Stable results in molecular biological diagnostic tests depend on the purity and stability of the extracted RNA used. This product automatically extracts high-purity virus RNA from human blood (serum/plasma) and respiratory swab samples (VTM, UTM) by introducing a cartridge-type all-in-one extraction kit.

Selection guide

Item / Platform	NuActor	ExAmplar
Viral RNA extraction kit	●	
ExAmplex COVID-19 PCR 3-gene Lyo kit		●
ExAmplex Influenza A/B SARS-CoV-2 PCR kit		●
ExAmplar COVID-19 real-time PCR kit (L)		●
Quanti-HCV v1.0 60T		●
Quanti-HIV v1.0 60T		●

Specification

	Viral RNA extraction kit	ExAmplex COVID-19 PCR 3-gene Lyo kit	ExAmplex Influenza A/B SARS-CoV-2 PCR kit	ExAmplar COVID-19 real-time PCR kit (L)	Quanti-HCV v1.0 60T	Quanti-HIV v1.0 60T
Sample type	Serum/Plasma VTM/UTM	Swab, sputum	Swab, sputum	Swab, sputum	Serum/Plasma	Serum/Plasma
Sample vol.	200 µL	5 µL	5 µL	5 µL	5 µL	5 µL
Assay time	<13 min	<55 min (RNA)	<55 min (RNA)	<55 min (RNA)	<45 min (RNA)	<45 min (RNA)
Storage	15-35℃	2-30℃	2-8℃	2-8℃	-20℃	-20℃
Shelf life	12 months	12 months	12 months	12 months	12 months	12 months

Ordering information

	Viral RNA extraction kit	ExAmplex COVID-19 PCR 3-gene Lyo kit	ExAmplex Influenza A/B SARS-CoV-2 PCR kit	ExAmplar COVID-19 real-time PCR kit (L)	Quanti-HCV v1.0 60T	Quanti-HIV v1.0 60T
Cat #	UFPK-1	UFPK-7	UFPK-6	UFPK-4	UFPK-11	UFPK-12
Test/Kit	96	96	96	48	60 (+ 36 controls)	60 (+ 36 controls)

NuActor Viral DNA extraction kit

Description

This product is provided as ready-to-use cartridges for extracting viral DNA. Samples are placed in a cartridge, and the cartridge is mounted on a NuActor instrument, and it is automatically processed to extract highly purified viral DNA quickly and simply.

Indication

Viral DNA purification from human serum/plasma.

Diagnostics Value

Stable results in molecular biological diagnostic tests depend on the purity and stability of the extracted DNA used. This product introduced a cartridge-type all-in-one extraction kit that automatically extracts high-purity viral DNA from human blood (serum/plasma) and provides stable results.

Selection guide

Item / Platform	NuActor	ExAmplar
Viral DNA Extraction kit	●	
Quanti-HBV v1.0 60T		●

Specification

	Viral DNA Extraction kit	Quanti-HBV v1.0 60T
Sample type	Serum/Plasma	Serum/Plasma
Sample vol.	200 µL	5 µL
Assay time	<13 min	<30 min (DNA)
Storage	15-35℃	-20℃
Shelf life	12 months	12 months

Ordering information

	Viral DNA Extraction kit	Quanti-HBV v1.0 60T
Cat #	UFPK-2	UFPK-2
Test/Kit	96	60 (+36 controls)

NuActor sputum DNA extraction kit

Description

Tuberculosis is the most deadly infectious disease in human history. About 10 million patients infected by tuberculosis occur every year. This kit is a DNA extraction kit required for Tuberculosis PCR testing. It is used with NuActor, an automatic nucleic acid extraction device, to easily extract DNA of Mycobacterium tuberculosis from sputum samples.

Indication

Extraction of bacterial DNA from human Sputum sample.

Diagnostics Value

Sputum samples for tuberculosis testing are difficult to handle due to the high risk of infection. This kit helps to extract bacterial DNA quickly and easily from sputum samples.

Selection guide

Item / Platform	NuActor	ExAmplar
Sputum DNA Extraction Kit	●	
MTB v2.0 72T		●

Specification

	Sputum DNA extraction Kit	MTB v2.0 72T
Sample type	Sputum	Sputum
Sample vol.	250 µL	2.5 µL
Assay time	<13 min	<30 min (DNA)
Storage	15-35℃	2-8℃
Shelf life	12 months	12 months

Ordering information

	Sputum DNA extraction Kit	MTB v2.0 72T
Cat #	UFPK-3	UFPK-5
Test/Kit	96	72 (+12 controls)

ExAmplex COVID-19 PCR 3-gene Lyo kit

(for open system)

Description

This product detects two COVID-19 confirmation genes, and one Pan-corona gene with high accuracy. This product is provided as a single-test unit with ready-to-use form that can be stored at room temperature. It can be used immediately without the process of reaction mixture preparation by the user. After dissolving the dried reaction bead with a diluent, user can simply perform PCR for COVID-19 testing by just adding RNA extracted beforehand.

Indication

SARS-CoV-2 infection (ORF1ab gene, N gene, Sarbeco E gene detection), Coronavirus disease-19 (COVID-19).

Diagnostics Value

The SARS-CoV-2 virus shares common symptoms with other respiratory diseases. It is contagious even in the asymptomatic stage, which makes it imperative to diagnose the virus early to provide timely treatment and to prevent further transmissions. Since this product is designed to increase diagnostics accuracy by detecting 2 confirmation gene of SARS-CoV-2 as well as 1 Pan-corona gene, it helps to prevent spread of disease by early detection of COVID-19. In addition, this kit is stable at room temperature, so it can be easily used even in environments where frozen delivery conditions are not available or freezer storage facilities are not available.

Selection guide

Item / Platform	NuActor	ExAmplar
Viral RNA extraction kit	●	
ExAmplex COVID-19 PCR 3-gene Lyo kit		●

Specification

	Viral RNA extraction kit	ExAmplex COVID-19 PCR 3-gene Lyo kit
Sample type	Swab (VTM/UTM)	Swab, Sputum
Sample vol.	200 µL	5 µL
Assay time	<13 min	<55 min (RNA)
Storage	15-35℃	2-30℃ (Lyophilized)
Shelf life	12 months	12 months

Ordering information

	Viral RNA extraction kit	ExAmplex COVID-19 PCR 3-gene Lyo kit
Cat #	UFPK-1	UFPK-7
Test/Kit	96	96

ExAmplex COVID-19 PCR 3-gene kit (Liquid)

(for open system)

Description

This product detects two COVID-19 confirmation genes, and one Pan-corona gene with high accuracy. Users makes reaction mix by mixing primer mix and enzyme mix solution and can perform PCR for COVID-19 testing by adding RNA extracted beforehand to the reaction mix.

Indication

SARS-CoV-2 infection (ORF1ab gene, N gene, Sarbeco E gene detection), Coronavirus disease-19 (COVID-19).

Diagnostics Value

The SARS-CoV-2 virus shares common symptoms with other respiratory diseases. It is contagious even in the asymptomatic stage, which makes it imperative to diagnose the virus early to provide timely treatment and to prevent further transmissions. Since this product is designed to increase diagnostics accuracy by detecting 2 confirmation gene of SARS-CoV-2 as well as 1 Pan-corona gene, it helps to prevent spread of disease by early detection of COVID-19. This kit is provided as liquid form which needs to be stored in -20℃.

Selection guide

Item / Platform	NuActor	ExAmplar
Viral RNA extraction kit	●	
ExAmplex COVID-19 PCR 3-gene kit		●

Specification

	Viral RNA extraction kit	ExAmplex COVID-19 PCR 3-gene kit
Sample type	Swab (VTM/UTM)	Swab, Sputum
Sample vol.	200 µL	5 µL
Assay time	<13 min	<55 min (RNA)
Storage	15-35℃	-20℃
Shelf life	12 months	12 months

Ordering information

	Viral RNA extraction kit	ExAmplex COVID-19 PCR 3-gene kit
Cat #	UFPK-1	UFPK-9
Test/Kit	96	96

ExAmplex Influenza A/B SARS-CoV-2 PCR kit

(for open system)

Description

A highly stable, ready-to-use PCR kit that can diagnose COVID-19 and Influenzas (Flu A, Flu B) simultaneously from a single sample collection.

Indication

COVID-19 (N gene), Influenza A (M gene), Influenza B (HA gene).

Diagnostics Value

This is a product that maximizes user convenience and storage so that RT-PCR products can be used even in areas where frozen delivery is difficult or in an environment that does not have a freezer storage facility. It helps to enable accurate antiviral treatment by simultaneously diagnosing single or multiple infections of COVID-19 and Flu (A & B) from one sample easily.

Selection guide

Item / Platform	NuActor	ExAmplar
Viral RNA extraction kit	●	
ExAmplex Influenza A/B SARS-CoV-2 PCR kit		●

Specification

	Viral RNA extraction kit	ExAmplex Influenza A/B SARS-CoV-2 PCR kit
Sample type	Swab (VTM/UTM)	Swab, Sputum
Sample vol.	200 µL	5 µL
Assay time	<13 min	<55 min (RNA)
Storage	15-35℃	2-8℃
Shelf life	12 months	12 months

Ordering information

	Viral RNA extraction kit	ExAmplex Influenza A/B SARS-CoV-2 PCR kit
Cat #	UFPK-1	UFPK-6
Test/Kit	96	96

ExAmplar COVID-19 real-time PCR kit (L)

Description

Highly stable and ready-to-use PCR kit for COVID-19 diagnosis.

Indication

SARS-CoV-2 infection
(RdRp, E gene detection),
Coronavirus disease-19 (COVID-19).

Diagnostics Value

This is the user-friendly RT-PCR kit for COVID-19 detection which is highly stable during storage as well as delivery. It provides a very easy operation protocol and is highly acceptable to decentralized laboratories where freezing storage or cold-chain logistics is limited. This can help to diagnose SARS-COV-2 infection and to isolate the infected person so that it can be treated quickly and prevent transmission.

Selection guide

Item / Platform	NuActor	ExAmplar
Viral RNA extraction kit	●	
ExAmplar COVID-19 real-time PCR kit (L)		●

Specification

	Viral RNA extraction kit	ExAmplar COVID-19 real-time PCR kit (L)
Sample type	Serum/Plasma/VTM/UTM	Swab, Sputum
Sample vol.	200 µL	5 µL
Assay time	<15 min	<55 min (RNA)
Storage	15-35℃	2-8℃ (Lyophilized)
Shelf life	12 months	12 months

Ordering information

	Viral RNA extraction kit	ExAmplar COVID-19 real-time PCR kit (L)
Cat #	UFPK-1	UFPK-4
Test/Kit	96	up to 48

ExAmplar Quanti-HBV

Description

The viral loads of hepatitis B virus (HBV) in the blood are an important indicator used to determine the patient's prognosis, whether antiviral therapy is administered, and to evaluate the response after treatment. This product can perform PCR to quantify the viral load of HBV immediately by simply dissolving the dry reagent with a diluent and adding DNA extracted beforehand.

Indication

Acute and chronic HBV infection, antiviral therapy monitoring.

Diagnostics Value

Since hepatitis B is easily transmitted through asymptomatic chronic carriers and vertical infection through pregnant women is possible, it is important to prevent transmission and chronicity through appropriate antiviral treatment. Since this product maximizes user convenience and stability, it is possible to diagnose the hepatitis B viral infection quickly and accurately by quantitatively measuring the viral load of HBV even in environments where frozen shipping and frozen storage facilities are not available.

Selection guide

Item / Platform	NuActor	ExAmplar
Viral DNA extraction kit	●	
Quanti-HBV v1.0 60T		●

Specification

	Viral DNA extraction kit	Quanti-HBV v1.0 60T
Sample type	Serum/Plasma	Serum/Plasma
Sample vol.	200 µL	5 µL
Assay time	<13 min	<30 min (DNA)
Storage	15-35℃	-20℃
Shelf life	12 months	12 months

Ordering information

	Viral DNA extraction kit	Quanti-HBV v1.0 60T
Cat #	UFPK-2	RAB-003
Test/Kit	96	60 (+36 controls)

ExAmplar Quanti-HCV

Description

The titer of hepatitis C virus (HCV) in the blood is an important index used to evaluate the therapeutic effect of direct-acting antiviral therapy (DAA) for confirming the prognosis of patients and for treatment. This product can perform PCR to quantify the viral load of HCV immediately by simply dissolving the dry reagent with a diluent and adding DNA extracted beforehand.

Indication

Acute and chronic HCV infection, DAA (Direct Acting Antivirals) therapy monitoring.

Diagnostics Value

DAA treatment, which has recently emerged as a treatment therapy for hepatitis C, is very expensive and has side effects such as drug interaction and drug resistance. By maximizing user convenience and storage, this product helps to identify hepatitis C virus infection and maximize treatment effects by quantitatively measuring the viral load of HCV easily and reliably even in environments where frozen shipping and frozen storage facilities are not available.

Selection guide

Item / Platform	NuActor	ExAmplar
Viral RNA extraction kit	●	
Quanti-HCV v1.0 60T		●

Specification

	Viral RNA extraction kit	Quanti-HCV v1.0 60T
Sample type	Serum/Plasma	Serum/Plasma
Sample vol.	250 µL	2.5 µL
Assay time	<13 min	<45 min (RNA)
Storage	15-35℃	-20℃
Shelf life	12 months	12 months

Ordering information

	Viral RNA extraction kit	Quanti-HCV v1.0 60T
Cat #	UFPK-1	RAC-004
Test/Kit	96	60 (+36 controls)

ExAmplar Quanti-HIV

Description

Highly stable, ready-to-use, and sensitive PCR kit for diagnosis of HIV infection and monitoring of patients under ART (Anti-Retroviral Treatment) by HIV viral load quantification.

Indication

HIV infection and/or monitoring patients under ART (Anti-Retroviral Treatment)
> HIV infection, antiretroviral treatment (ART) monitoring.

Diagnostics Value

Since this product is an RT-PCR kit for HIV detection that maximizes user convenience and storage, it is possible to quantitatively measure the viral load of HIV easily and reliably even in areas where frozen delivery is difficult or in an environment that does not have a freezer storage facility.

Selection guide

Item / Platform	NuActor	ExAmplar
Viral RNA extraction kit	●	
Quanti-HIV v1.0 60T		●

Specification

	Viral RNA extraction kit	Quanti-HIV v1.0 60T
Sample type	Serum/Plasma	Serum/Plasma
Sample vol.	200 µL	5 µL
Assay time	<13 min	<45 min (RNA)
Storage	15-35℃	-20℃
Shelf life	12 months	12 months

Ordering information

	Viral RNA extraction kit	Quanti-HIV v1.0 60T
Cat #	UFPK-1	RAC-013
Test/Kit	96	60 (+36 controls)

ExAmplar MTB kit v2.0

Description

Tuberculosis is a common and fatal respiratory infectious disease caused primarily by infection with Mycobacterium tuberculosis (MTB). MTB complexes such as *M. bovis, M. africanum, M. microti, M. caprae and M. canettii*, including *M. tuberculosis*, have 99.9% similar genomes to each other. Therefore, rapid and accurate detection of infection causative bacteria is very important for the prevention of transmission of tuberculosis and selection of an appropriate antituberculosis agent for treatment. This product can perform PCR to diagnose the MTB complex immediately by simply dissolving the dry reagent with a diluent and adding DNA extracted beforehand.

Indication

Mycobacterium tuberculosis complex
(*M. tuberculosis, M. bovis, M. africanum, M. microti, M. caprae and M. canettii*)

Diagnostics Value

This product is a PCR kit for MTB complex detection that maximizes user convenience and storage. Users can stably store the product even in an environment that does not have a refrigeration facility for delivery and storage. It is possible to accurately identify M. tuberculosis by conducting an examination.

Selection guide

Item / Platform	NuActor	ExAmplar
Sputum DNA Extraction Kit	●	
MTB v2.0 72T kit		●

Specification

	Sputum DNA Extraction Kit	MTB v2.0 72T kit
Sample type	Sputum	Sputum
Sample vol.	250 µL	2.5 µL
Assay time	<13 min	<30 min (DNA)
Storage	15-35℃	2-8℃ (Lyophilized)
Shelf life	12 months	12 months

Ordering information

	Sputum DNA Extraction Kit	MTB v2.0 72T kit
Cat #	UFPK-3	UFPK-5
Test/Kit	96	72 (+24 controls)

Catalogue number index

Test items

Test item	Catalog No.
	ichroma™
Adeno	CFPC-96
AFP	i-CHROMA AFP-25
AFP Plus	CFPC-73
AMH	CFPC-89
Anti-CCP Plus	CFPC-97
Anti-HBs	CFPC-52
Anti-HCV	CFPC-31
ASO	CFPC-46
BNP	CFPC-121
Calprotectin	CFPC-83
Cardiac Triple	CFPC-78
CEA	13013
CEA Plus	CFPC-72
CK-MB	CFPC-33
Cortisol	CFPC-24
COVID-19 Ab	CFPC-114
COVID-19 Ag	CFPC-115
COVID-19/Flu Ag Combo	CFPC-117
COVID-19 nAb	CFPC-120
CRP	i-CHROMA CRP-25
Cystatin C	CFPC-43
D-Dimer	CFPC-25
Dengue IgG/IgM	CFPC-60
Dengue NS1 Ag	CFPC-62
Ferritin	CFPC-32
FSH	CFPC-35
H. pylori SA	CFPC-81
HbA1c	CFPC-38
HBsAg	CFPC-29
hsCRP	CFPC-6
iFOB Neo	CFPC-15-1
IGRA-TB	CFPC-86/CFPC-86-1
IL-6	CFPC-116
Influenza A+B	CFPC-61
Influenza A+B/RSV	CFPC-80
LH	13010
Microalbumin	i-CHROMA MAU-25
Mycoplasma	CFPC-94
Myoglobin	CFPC-37
NORO	CFPC-76
NT-proBNP	CFPC-77
PCT	CFPC-23-1
PCT Plus	CFPC-64
PRL	CFPC-27
Progesterone	CFPC-21
PSA	i-CHROMA PSA-25
PSA Plus	CFPC-71
RF IgM	CFPC-39
ROTA	CFPC-75
Rota/Adeno	CFPC-79
RSV	CFPC-88
ST2	CFPC-100
Strep A	CFPC-74

Test item	Catalog No.
	ichroma™
T3	CFPC-44
T4	CFPC-26
Testosterone	13012
Tn-I	13011
Tn-I Plus	CFPC-65
Total IgE	CFPC-91
Toxo IgG/IgM	CFPC-112
Troponin T	CFPC-122
TSH	CFPC-22
TSH Plus	CFPC-45
Vitamin D	CFPC-47
β-HCG	CFPC-36
β-HCG Plus	CFPC-66

Instruments

Instrument	Catalog No.
ichroma™ II	FPRR021
ichroma™ III	FPRR037
ichroma™-50	FPRR022
ichroma™ M2	FPRR031
ichroma™ M3	FPRR035
hemochroma PLUS	FPRR016
i-chamber	FPRR009

Molecular Diagnostics

Molecular Diagnostics	Catalog No.
NuActor	FPRR032
ExAmplar	FPRR030
NuActor Viral RNA extraction kit	UFPK-1
NuActor Viral DNA extraction kit	UFPK-2
NuActor sputum DNA extraction kit	UFPK-3
ExAmplex COVID-19 PCR 3-gene Lyo kit	UFPK-7
ExAmplex COVID-19 PCR 3-gene kit	UFPK-9
ExAmplex Influenza A/B SARS-CoV-2 PCR kit	UFPK-6
ExAmplar COVID-19 real-time PCR kit (L)	UFPK-4
ExAmplar Quanti-HBV v1.0 60T	RAB-003
ExAmplar Quanti-HCV v1.0 60T	RAC-004
ExAmplar Quanti-HIV v1.0 60T	RAC-013
ExAmplar MTB kit v2.0 72T	UFPK-5

Controls

Control item	Catalog No.
Boditech AFP Control	CFPO-248
Boditech AFP Plus Control	CFPO-249
Boditech AMH Control	CFPO-214
Boditech Anti-CCP Plus Control	CFPO-288
Boditech Anti-HBs Control	CFPO-144
Boditech Anti-HCV Control	CFPO-143
Boditech BNP Control	CFPO-304
Boditech Calprotectin Control	CFPO-221
Boditech Cardiac Control	CFPO-98
Boditech Cardiac Triple Control	CFPO-204
Boditech CEA Control	CFPO-246
Boditech CEA Plus Control	CFPO-247
Boditech CK-MB Control	CFPO-243
Boditech Cortisol Control	CFPO-236
Boditech COVID-19 Ab Control	CFPO-292
Boditech COVID-19 Ag Control	CFPO-293
Boditech COVID-19 nAb Control	CFPO-303
Boditech COVID-19/Flu Ag Control	CFPO-298
Boditech CRP Control	CFPO-100
Boditech D-Dimer Control	CFPO-101
Boditech Dengue IgG/IgM Control	CFPO-280
Boditech Dengue NS1 Ag Control	CFPO-282
Boditech Ferritin Control	CFPO-99
Boditech FSH Control	CFPO-230
Boditech H.pylori Ag Control	CFPO-222
Boditech HbA1c Control	CFPO-96
Boditech HBsAg Control	CFPO-142
Boditech hCG Control	CFPO-232
Boditech hCG Plus Control	CFPO-233
Boditech Hormone Control	CFPO-95
Boditech IGRA-TB Control	CFPO-294
Boditech iFOB Neo Control	CFPO-14
Boditech IL-6 Control	CFPO-296
Boditech LH Control	CFPO-234
Boditech MAU Control	CFPO-4
Boditech Myoglobin Control	CFPO-244
Boditech NORO Control	CFPO-165
Boditech NT-proBNP Control	CFPO-245
Boditech PCT Control	CFPO-97
Boditech PCT Plus Control	CFPO-225
Boditech PRL Control	CFPO-226
Boditech Progesterone Control	CFPO-238
Boditech PSA Control	CFPO-250
Boditech PSA Plus Control	CFPO-251
Boditech RF IgM Control	CFPO-103
Boditech Rota Control	CFPO-170
Boditech Rota/Adeno Control	CFPO-164
Boditech ST2 Control	CFPO-289
Boditech T3 Control	CFPO-240
Boditech T4 Control	CFPO-237
Boditech Testosterone Control	CFPO-239
Boditech Tn-I Control	CFPO-241
Boditech Tn-I Plus Control	CFPO-212
Boditech Total IgE Control	CFPO-219
Boditech Troponin T Control	CFPO-306
Boditech TSH Control	CFPO-228
Boditech TSH Plus Control	CFPO-229
Boditech Tumor Marker Control	CFPO-94
Boditech Vitamin D Control	CFPO-102

Calibrators

Calibrator item	Catalog No.
Boditech AFP Calibrator	CFPO-274
Boditech AFP Plus Calibrator	CFPO-275
Boditech AMH Calibrator	CFPO-215
Boditech BNP Calibrator	CFPO-305
Boditech Cardiac Calibrator	CFPO-110
Boditech Cardiac Triple Calibrator	CFPO-205
Boditech CEA Calibrator	CFPO-272
Boditech CEA Plus Calibrator	CFPO-273
Boditech CK-MB Calibrator	CFPO-269
Boditech Cortisol Calibrator	CFPO-262
Boditech CRP Calibrator	CFPO-112
Boditech D-Dimer Calibrator	CFPO-113
Boditech Dengue IgG/IgM Calibrator	CFPO-281
Boditech Dengue NS1 Ag Calibrator	CFPO-283
Boditech Ferritin Calibrator	CFPO-111
Boditech FSH Calibrator	CFPO-256
Boditech HbA1c Calibrator	CFPO-108
Boditech hCG Calibrator	CFPO-258
Boditech hCG Plus Calibrator	CFPO-259
Boditech Hormone Calibrator	CFPO-107
Boditech IL-6 Calibrator	CFPO-297
Boditech LH Calibrator	CFPO-260
Boditech Myoglobin Calibrator	CFPO-270
Boditech NT-proBNP Calibrator	CFPO-271
Boditech PCT Calibrator	CFPO-109
Boditech PCT Plus Calibrator	CFPO-223
Boditech PRL Calibrator	CFPO-252
Boditech PSA Calibrator	CFPO-276
Boditech PSA Plus Calibrator	CFPO-277
Boditech ST2 Calibrator	CFPO-290
Boditech T3 Calibrator	CFPO-266
Boditech T4 Calibrator	CFPO-263
Boditech Testosterone Calibrator	CFPO-265
Boditech Tn-I Calibrator	CFPO-267
Boditech Total IgE Calibrator	CFPO-220
Boditech Troponin T Calibrator	CFPO-307
Boditech Tn-I Plus Calibrator	CFPO-213
Boditech TSH Calibrator	CFPO-254
Boditech TSH Plus Calibrator	CFPO-255
Boditech Tumor Marker Calibrator	CFPO-106

BIO TECHNOLOGY

Total solution for In-Vitro Diagnostic
Boditech Med Inc.

Vol.03_20210531

Infection

ichroma™
CRB

2.2.1 t.s. Reagentai tinkami CRB tyrimui iš kapiliarinio kraujo mėginio panaudai pateikiamu analizatoriumi

NUMATYTAS NAUDOJIMAS

ichroma™ CRP yra fluorescencinis imuninis tyrimas (FIT), skirtas kiekybiniam C reaktyvaus baltymo (CRB) nustatymui žmogaus visame kraujyje / serume / plazmoje. Tai naudinga pagalbinė priemonė, kuri naudojama norint suvaldyti ir stebėti autoimunines ligas ir infekcinius procesus, tokius kaip reumatoidinis artritas.

Skirtas tik *in vitro* diagnostiniam naudojimui.

ĮVADAS

C reaktyvus baltymas (CRB) yra susintetinamas kepenyse kaip atsakas interleukinui 6 ir gerai žinomas kaip vienas iš klasikinių ūmios fazės markerių ir kaip uždegimo žymuo. CRB yra pirmas ūmios fazės baltymas ir išskirtinai jautrus sisteminis uždegimo ir audinio pažeidimo žymuo. Ūmios fazės atsakas apima nespecifines fiziologines ir biochemines šiltakraujų gyvūnų reakcijas į daugelio tipų audinių pažeidimus, infekcijas, uždegimus ir piktybinių navikų formas. CRB kiekis serume gali padidėti nuo normalaus < 5 mg/L lygio iki 500 mg/L vykstant bendrajai nespecifinei organizmo reakcijai į infekciją ir kitus ūminius uždegiminius reiškinius. Kurį laiką, CRB koncentracijos matavimas buvo naudojamas kaip klinikinė priemonė stebėti autoimunines ligas ir infekcinius procesus, tokius kaip reumatoidinis artritas.[1,2]

PRINCIPAS

Testui naudojamas „sumuštinio“ principu paremtas imuninio tyrimo metodas. Buferiniame tirpale esantys specifiniai antikūnai prisijungia prie mėginyje esančių antigenų, sudaro antigenų ir antikūnų kompleksus ir migruoja ant nitroceliuliozės matricos, kur juos užfiksuoja kiti imobilizuoti antikūnai, esantys ant tyrimo juostelės.

Kuo daugiau antigenų mėginyje, tuo daugiau susidarys antigeno-antikūnų kompleksų ir tuo intensyvesnis bus fluorescencinis signalas, kurį apdoroja prietaisas ichroma™ CRP tyrimams, kad parodytų CRB koncentraciją mėginyje.

SUDEDAMOSIOS DALYS

ichroma™ CRP susideda iš „kasečių“, „buferinis tirpalo“ ir „mėginio paėmimo priemonių“.

- Kasetėje yra tyrimo juostelė, kurios membrana turi žmogaus CRB antikūnų, o kontrolinėje linijoje – streptavidino. Visos kasetės yra atskirai supakuotos aliuminio folijos maišelyje, kuriame yra sausiklis.
- Buferinio tirpalo sudėtyje yra žmogaus CRB antikūnų fluorescencinio konjuguoto tirpalo, BSA-biotino-fluorescencinio konjugato, galvijų serumo albumino (BSA) kaip stabilizatoriaus ir natrio azido fosfatiniu buferiniu tirpalu (PBS) kaip konservanto.
- Buferinis tirpalas išpilstytas dozėmis į mėgintuvėlius. Visi mėgintuvėliai supakuoti į buferinio tirpalo dėžutes, kurios ir toliau pakuojamos į polistirolo dėžutę su ledo paketu gabenimui.

ĮSPĖJIMAI IR ATSARGUMO PRIEMONĖS

- Skirtas tik *in vitro* diagnostiniam naudojimui.
- Sekite instrukcijas ir laikykitės metodo eigos, apibūdintos šiose „Naudojimosi instrukcijose“.
- Naudokite tik šviežius mėginius ir venkite tiesioginės saulės šviesos.
- Visų testo komponentų (testo kasetės, buferinio tirpalo ir identifikavimo lusto) partijos numeriai turi sutapti.
- Nesukeiskite tarpusavyje skirtingų partijų testo komponentų ir nenaudokite testo sudedamųjų dalių po to, kai jų galiojimo laikas pasibaigęs, nes bet kuris iš tokių komponentų gali nulemti klaidingą(-us) testo rezultatą(-us).

- Nenaudokite kasečių ar buferinio tirpalo mėgintuvėlių pakartotinai. Kasetė turi būti naudojama tik vienam mėginiui tirti. Aptikimo buferio mėgintuvėlis turi būti naudojamas tik vienam mėginiui apdoroti. Iki naudojimo testo kasetė turi būti laikoma supakuota aliuminio folijos maišelyje. Nenaudokite testo kasetės, jeigu pakuotė buvo pažeista ar iš anksto atidaryta.
- Užšaldyti mėginiai turi būti atšildomi tik vieną kartą. Gabenimui mėginius supakuokite pagal vietos reglamentus. Mėginiai su smarkia hemolize ir / ar hiperlipidemija neturi būti naudojami.
- Prieš pat naudojimą palaikykite testo kasetę, buferinį tirpalą ir mėginį kambario temperatūroje apytiksliai 30 minučių.
- ichroma™ testų instrumentas naudojimo metu gali nežymiai vibruoti.
- Panaudoti kasetės, buferinio tirpalo mėgintuvėlis ir mėginio surinkimo priemonės turi būti tvarkomi atsargiai ir utilizuojami pagal tinkamą metodą, laikantis atitinkamų vietinių reglamentų.
- Didesnių natrio azido kiekių poveikis gali lemti tam tikras sveikatos problemas, pavyzdžiui, traukulius, žemą kraujospūdį ir pulso dažnį, sąmonės praradimą, plaučių pažeidimą ir kvėpavimo nepakankamumą.
- **ichroma™ CRP** lems tikslius ir patikimus tyrimo rezultatus esant toliau išvardintoms sąlygoms.

– **ichroma™ CRP** turi būti naudojamas tik drauge su prietaisu, skirtu ichroma™ testams.

– Rekomenduojama naudoti mėginius su antikoaguliantais.

Rekomenduojamas antikoaguliantas
K_2EDTA, K_3EDTA, natrio heparinas

TESTO SISTEMOS APRIBOJIMAI

- Testas gali lemti klaidingą(-us) teigiamą(-us) rezultatą(-us) dėl kryžminių reakcijų ir (arba) nespecifinio tam tikrų mėginio sudedamųjų dalių sulipimo su specifiniais antikūnais.
- Tyrimo rezultatas (-ai) gali būti klaidingai neigiamas (-i) dėl antigenų nereagavimo į antikūnus, kuris dažniausiai pasireiškia, jei epitopą maskuoja nežinomos sudedamosios dalys, todėl antikūnai negali jo aptikti Rezultatas taip pat gali būti klaidingai neigiamas dėl antigenų nestabilumo ar degradavimo laikui bėgant ir (arba) veikiant temperatūrai – tokiu atveju antikūnai negali atpažinti antigenų.
- Visos klinikinės diagnozės pagal šio testo rezultatus turi būti paremtos išsamiu atitinkamo gydytojo įvertinimu, įskaitant klinikinius simptomus ir kitų susijusių testų rezultatus.
- Kai kasetės folijos pakuotė praplėšiama tyrimas turi būti atliekamas nedelsiant.

LAIKYMAS IR STABILUMAS

Sandėliavimo sąlygos		
Komponentas	Sandėliavimo temperatūra	Galiojimo laikas
Kasetė	2-30 ^{0}C	20 mėnesių
Buferinis tirpalas	2-8 ^{0}C	20 mėnesių

TIEKIAMOS MEDŽIAGOS

REF i-CHROMA CRP-25

ichroma™ CRP sudedamosios dalys

- Testo kasetės dėžutėje yra:
  - Kasetės 25
  - Identifikavimo lustas 1
  - Naudojimosi instrukcijos 1
  - Mėginio surinkimo priemonė 25
  - Atsarginis kasetės užspaudžiamas maišelis 1
- Buferinio tirpalo dėžutėje yra:
  - Buferinis tirpalas 25

REIKALINGOS MEDŽIAGOS, KURIOS TIEKIAMOS PAGAL POREIKĮ

Toliau išvardytus gaminius galima įsigyti atskirai nuo **ichroma™ CRP**. Dėl išsamesnės informacijos prašome susisiekti su mūsų pardavimų padaliniu.

- Instrumentas ichroma™ testams
  - **ichroma™ Reader REF** FR203
  - **ichroma™ II REF** FPRR021

- **ichroma™-50** **REF** FPRR022
- **ichroma™ III** **REF** FPRR037

- **Spausdintuvas** **REF** FPRR007
- **Boditech CRB kontrolė** **REF** CFPO-100

MĖGINIO PAĖMIMAS IR APDOROJIMAS

Mėginių tipas, tinkantis **ichroma™ CRP**, yra žmogaus kraujas / serumas / plazma.

- Rekomenduojama mėginio tyrimą atlikti per 24 valandas nuo jo paėmimo.
- Serumas ir plazma turi būti atskiriami nuo krešulių centrifuguojant per 3 valandas po pilno kraujo paėmimo.
- Mėginiai savaitę laiko iki tyrimo gali būti laikomi 2-8 ^{0}C. Jeigu tyrimas atidedamas ilgiau nei savaitei, mėginius reikia užšaldyti -20 °C.
- Mėginiai, laikomi užšaldyti -20 °C 6 mėnesius, neparodė jokių našumo skirtumų.
- Vis dėlto, viso kraujo mėginiai jokiais atvejais neturėtų būti laikomi šaldiklyje.
- Mėginį užšaldžius, jis turi būti atšildomas vieną kartą ir tik tyrimui, nes pakartotinis užšaldymas ir atšildymas gali lemti testo verčių pasikeitimus.

TESTO SĄRANKA

- Patikrinkite **ichroma™ CRP** sudedamąsias dalis, kaip toliau aprašyta: sandarias kasetes, buferinio tipalo, mėginio surinkimo priemonės, ID lustą ir naudojimo instrukcijas.
- Įsitikinkite, kad kasečių partijos numeris atitinka buferinio tirpalo bei ID lusto numerius.
- Jeigu sandari kasetė ir buferinio tirpalo buvo laikomi šaldytuve, atneškite juos ant švaraus ir plokščio paviršiaus kambario temperatūroje mažiausiai 30 minučių prieš tyrimą.
- Įjunkite ichroma™ testų prietaisą.
  (Prašom peržiūrėti prietaiso, skirto ichromta™ testams, „Naudojimo vadovą“ tam, kad gautumėte išsamią informaciją bei naudojimosi instrukcijas.

TESTO PROCEDŪRA

► ichroma™ Reader / ichroma™ II / ichroma™ III

<Multi rėžimas>

1) Padarykite punkciją buferinio tirpalo mėgintuvėlio viršuje, įdėdami tuščią mėgino surinkimo priemonę. 3 t.s.

2) Mėginių surinkimo priemone paimkite 10 µL (žmogaus viso kraujo / serumo / plazmos / kontrolės) mėginio.

3) Sujunkite mėginių surinkimo priemonę ir buferinio tirpalo mėgintuvėlį į vieną.

4) Kratykite 10 ar daugiau kartų, kol mėginys išeis iš mėginio surinkimo priemonės apvertimo būdu. Buferio ir mėginio mišinys turi būti sunaudotas per 30 sekundžių.

5) Nuimkite dangtelį nuo surinkto mėgintuvėlio viršaus. Prieš lašindami ant kasetės, ant popierinio rankšluosčio lašinkite du lašus mišinio.

6) Į kasetės mėginio duobutę įlašinkite tik du lašus mišinio.

7) Prieš įdėdami prietaisą į laikiklį, palikite kasetę kambario temperatūroje 3 minutes. 4 t.s.

⚠ *Pasibaigus inkubaciniam laikui, nedelsdami nuskaitykite įdėtą mėginio kasetę. Jei ne, bandymo rezultatas bus netikslus.*

8) Norėdami nuskaityti reakcijos kasetę su mėginiu, įdėkite ją į instrumento kasetės laikiklį ir atlikite ichroma™ testus. Prieš įstumdami ją iki galo į kasetės laikiklį, įsitikinkite, kad kasetė yra tinkamai nukreipta. Specialiai šiam tikslui ant kasetės pažymėta rodyklė.

9) Norėdami pradėti nuskaitymo procesą, paspauskite „Select“ arba bakstelėkite mygtuką „START“ ant prietaiso ichroma™ testams.

10) ichroma™ testų prietaisas nedelsdamas pradės nuskaityti reakcijos kasetę su mėginiu.

11) Perskaitykite testo rezultatą ichroma™ testų prietaiso ekrane.

<Single režimas>

1) Tyrimo procedūra yra tokia pati kaip ir „Multi testams 1) – 4)“.

2) Nuimkite dangtelį nuo surinkto mėgintuvėlio viršaus. Prieš lašindami ant kasetės, ant popierinio rankšluosčio lašinkite du lašus reagento.

2) Į kasetės mėginio duobutę įlašinkite tik du lašus mišinio.

3) Norėdami nuskaityti reakcijos kasetę su mėginiu, įdėkite ją į instrumento kasetės laikiklį ir atlikite ichroma™ testus. Prieš įstumdami ją iki galo į kasetės laikiklį, įsitikinkite, kad kasetė yra tinkamai nukreipta. Specialiai šiam tikslui ant kasetės pažymėta rodyklė.
4) Norėdami pradėti nuskaitymo procesą, paspauskite „Select“ arba bakstelėkite mygtuką „START“ ant prietaiso ichroma™ testams.
5) Kasetė patenka į instrumentą ichroma™ testams atlikti ir po 3 minučių automatiškai pradės nuskaityti reakcijos kasetę su mėginiu.
6) Perskaitykite testo rezultatą ichroma™ testų prietaiso ekrane.

► **ichroma™-50**

1) Įdėkite antgalių masyvą į antgalių zoną.
2) Įdėkite buferinį tirpalą į reagentų zoną ir uždenkite reagentų dalį.
3) Atidarykite buferinį tirpalą ir įdėkite jį į zoną skirtą buferiniam tirpalui.
4) Atidarykite dėtuvės dalies dangtelį ir patraukite bei pakelkite kasetės dėtuvę.
5) Kasetes į kasetės dėtuves įdėkite atskirai.
6) Įdėkite kasete įkrautą kasetės dėtuvę į dėtuvės dalį ir uždarykite dėtuvės dangtelį.
7) Mėginio mėgintuvėlį įdėkite į kraujo paėmimo mėgintuvėlių stovą, o kraujo paėmimo mėgintuvėlių stovą įdėkite į mėginių ėmimo dalį (pakrovimo dalis).
8) Bakstelėkite mygtuką, esantį viršutinėje tiriamosios kasetės numerio srities pusėje, kad pasirinktumėte ID lustą, kurį norite naudoti.
9) Kai suaktyvinamas pasirinktos kasetės lizdas, paliesdami nustatykite tiriamųjų kasečių skaičių.
10) Bakstelėkite mygtuką, esantį viršutinėje reagento srities numerio pusėje, kad pasirinktumėte ID lustą, kurį norite naudoti.
11) Kai pasirinktas lizdas suaktyvinamas, paliesdami nustatykite aptikimo buferio skaičių.
12) Bakstelėdami nustatykite pipetės antgalių skaičių.
13) Norėdami pradėti testą, bakstelėkite mygtuką „START“, esantį pagrindinio ekrano viršutiniame kairiajame kampe.
(Išsamią informaciją ir naudojimo instrukcijas rasite ichroma™-50 naudojimo vadove.)

TESTO REZULTATŲ INTERPRETAVIMAS

- Prietaisas ichroma™ testams automatiškai apskaičiuoja tyrimo rezultatą ir rodo CRB koncentraciją tiriamajame mėginyje mg/l.
- Ribinė vertė (referencinė vertė): 10 mg/L.
- Darbinis diapazonas: 2,5-300 mg/L. 7 t.s.
- Hematokrito poveikis
  ichroma™ Reader viso kraujo CRB yra sukalibruotas taip, kad būtų galima nuskaityti CRB koncentraciją kraujo mėginyje, kurio hematokritas yra 40%. Jei faktinė hematokrito vertė nukrypsta nuo 40%, rezultatas turi būti pakoreguotas padauginus iš atitinkamo koeficiento lentelėje:

Hct (%)	Koeficientas	Hct (%)	Koeficientas
20-29	0.8	56-58	1.4
30-36	0.9	59-61	1.5
37-42	1.0	62-63	1.6
43-47	1.1	64-65	1.7
48-51	1.2	66-67	1.8
52-55	1.3	68-69	1.9

- Nuorodinis intervalas, HCT:
  - Moterys: 35-44 %
  - Vyrai: 39-48 %

KOKYBĖS KONTROLĖ

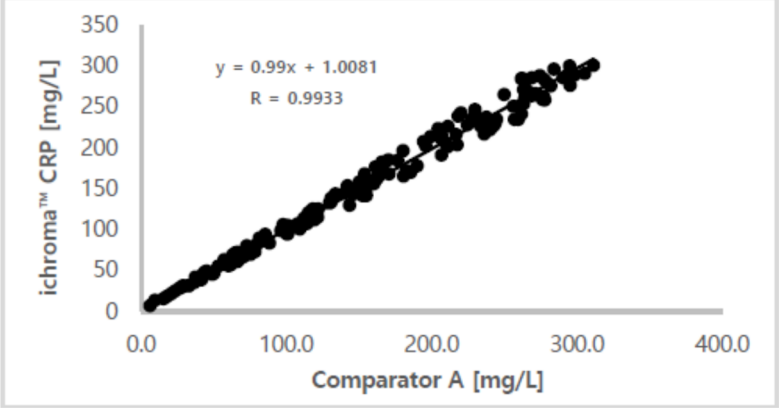
- Kokybės kontrolės testai yra gerosios tyrimų praktikos dalis, būtina laukiamų rezultatų patvirtinimui ir tyrimo patikimumo įvertinimui. Jie turi būti atliekami pastoviais intervalais.
- Kokybės kontrolės testai taip pat turi būti atliekami tais atvejais, kai yra bet kokia abejonė, susijusi su testo rezultatų patikimumu.
- Kontrolinės medžiagos nėra tiekiamos drauge su **ichroma™CRP**. Dėl išsamesnės informacijos, susijusios su kontrolinių medžiagų įsigijimu, susisiekite su Boditech Med Inc. pardavimų padaliniu, skirtu pagalbai.
  (Prašome žiūrėti kontrolinių medžiagų naudojimo instrukcijas.)

NAŠUMO CHARAKTERISTIKOS

- **Analitinis jautrumas**
  Analitinis ichroma™ CRP jautrumas buvo nustatytas 10 kartų testuojant su trimis reagentų partijomis. Analitinis ichroma™ CRP sistemos jautrumas buvo 0,5 mg/l.
- **Specifiškumas**
  Biomolekulių, tokių kaip hemoglobinas, CEA, AFP, ALT, troponinas I, CK-MB, albuminas ir serumo amiloidas P, buvo pridėta į tiriamąjį (-ius) mėginį (-ius), kurių koncentracija yra daug didesnė nei normalus fiziologinis kiekis kraujyje. **ichroma™ CRP** testo rezultatai neparodė jokio reikšmingo kryžminio reaktyvumo su šiomis biomolekulėmis.
- **Preciziškumas**
  - Vidinis tyrimas
    Tyrimo preciziškumą apskaičiavo vienas vertintojas, kuris dvidešimt kartų išbandė skirtingą kontrolinio standarto koncentraciją su trimis skirtingomis **ichroma™ CRP** partijomis.
  - Išorinis tyrimas
    Tyrimų preciziškumą patvirtino 3 skirtingi vertintojai su 3 skirtingomis partijomis, dešimt dienų tirdami po dešimt kartų kiekvieną skirtingą koncentraciją.

CRP	Vidinis tyrimas			Išorinis tyrimas		
(mg/L)	Vidurkis	SD	CV (%)	Vidurkis	SD	CV (%)
5.0	5.06	0.3	6.7	5.11	0.4	7.1
40.0	39.95	3.0	7.6	40.18	3.1	7.6
150.0	150.46	5.9	3.9	150.15	4.5	3.0

- **Linijiškumas**
  Didelis kiekis (300 mg/l) buvo atskiestas mažu kiekiu (2,5 mg/l) iki šių galutinių procentų; 100 %, 75 %, 50 %, 25 %, 10 %, 5 % ir 0 %. Mėginys buvo tiriamas trimis egzemplioriais per vieną analitinį paleidimą kiekviename CRP lygyje. Tiesinės regresijos koeficientas buvo R=0,997.
- **Palyginamumas**
  CRP koncentracijos 166 mėginiuose buvo kiekybiškai įvertintos nepriklausomai, naudojant **ichroma™ CRP (ichroma™ Reader)** ir lyginamąjį įrenginį A (*iliustracijoje Comparator A*), kaip nurodyta pagal nustatytas tyrimo procedūras. Tyrimo rezultatai buvo lyginami, o jų palyginamumas tiriamas naudojant tiesinę regresiją ir koreliacijos koeficientą (R). Tiesinė regresija ir koreliacijos koeficientas tarp dviejų testų buvo atitinkamai Y=0,99X + 1,0081 ir R = 0,9933.



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9. Oh SW, Moon JD, Park SY, et al. Evaluation of fluorescence hs-CRP immunoassay for point-of–care testing. Clin Chim Acta 2005; 356:172-177.
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Pastaba: Peržiūrėkite toliau esančią lentelę tam, kad galėtumėte identifikuoti įvairius simbolius.

	Pakanka <n> testų
	Skaitykite naudojimosi instrukciją
	Tinkamas naudoti iki
LOT	Partijos kodas
REF	Katalogo numeris
	Įspėjimas
	Gamintojas
	Autorizuotas Europos bendrijos atstovas
IVD	*In vitro* diagnostinė medicininė priemonė
	Temperatūros ribos
	Nenaudokite pakartotinai
CE	Šis produktas atitinka 98/79/EC direktyvos, skirtos *in vitro* diagnostinėms medicininėms priemonėms, reikalavimus.

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CE IVD

Infection

ichroma™ CRP

INTENDED USE

ichroma™ CRP is a fluorescence Immunoassay (FIA) for the quantitative determination of CRP in human whole blood/serum/ plasma. It is useful as an aid in management and monitoring of autoimmune diseases and infectious processes, such as rheumatoid arthritis.
For *in vitro* diagnostic use only.

INTRODUCTION

The C-Reactive Protein (CRP) is synthesized by the liver in response to interleukin-6 and well known as one of the classical acute-phase reactants and as a marker of inflammation. CRP is the first acute-phase protein to be described and is an exquisitely sensitive systemic marker of inflammation and tissue damage. The acute-phase response comprises the nonspecific physiological and biochemical responses of endothermic animals to most forms of tissue damage, infection, inflammation, and malignant neoplasia. The serum CRP level may rise from a normal level of <5 mg/L to 500 mg/L during the body's general, non-specific response to infectious and other acute inflammatory events. For some time, the measurement of CRP concentration has been used as a clinical tool for monitoring autoimmune diseases and infectious processes, such as rheumatoid arthritis.[1,2]

PRINCIPLE

The test uses a sandwich immunodetection method; the detector antibodies in buffer bind to antigens in the sample, forming antigen-antibody complexes, and migrate onto nitrocellulose matrix to be captured by the other immobilized-antibodies on test strip.

More antigens in the sample will form more antigen-antibody complexes which lead to stronger fluorescence signal by detector antibodies, which is processed by instrument for ichroma™ tests to show CRP concentration in the sample.

COMPONENTS

ichroma™ CRP consists of 'cartridges', 'detection buffers' and 'sample collectors'.

- The cartridge contains the membrane called a test strip which has anti human CRP at the test line, and streptavidin at the control line. All cartridges are individually sealed in an aluminum foil pouch containing a desiccant in a box.
- The detection buffer contains anti-human CRP fluorescence conjugate, BSA-biotin-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.
- The detection buffer is pre-dispensed in a tube. Detection buffers are packaged in detection buffer box and further packed in a Styrofoam box with ice-pack for the shipment.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow instructions and procedures described in this 'Instruction for use'.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge, detection buffer and ID chip) must match each other.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield incorrect test result(s).
- Do not reuse cartridges or detection buffer tubes. A cartridge should be used for testing one sample only. A detection buffer tube should be used for processing of one sample only.
- The cartridge should remain sealed in its original pouch until just before use. Do not use the cartridge, if pouch is damaged or has already been opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with local regulations. Sample with severe hemolysis and/or hyperlipidemia must not be used.
- Allow the cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for ichroma™ tests may generate slight vibration during use.
- Used cartridges, detection buffers and sample collectors should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- An exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.
- **ichroma™ CRP** will provide accurate and reliable results subject to the below conditions.
  - Use **ichroma™ CRP** should be used only in conjunction with instrument for ichroma™ tests.
  - Have to use recommended anticoagulant sample.

Recommended anticoagulant
K_2 EDTA, K_3 EDTA, Sodium heparin

STORAGE AND STABILITY

Storage condition		
Component	Storage Temperature	Shelf life
Cartridge	2 - 30 °C	20 months
Detection buffer	2 - 8 °C	20 months

- After the cartridge pouch is opened, the test should be performed immediately.

LIMITATION OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.
- The test may yield false negative result(s) due to the non-responsiveness of the antigen to the antibodies which is the most common if the epitope is masked by some unknown

components, so therefore not being able to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may also cause false negative result as it makes antigen unrecognizable by the antibodies.

- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician in conjunction with clinical symptoms and other relevant test results.

MATERIALS SUPPLIED

REF i-CHROMA CRP-25

Components of **ichroma™ CRP**

- Cartridge Box:
  - Cartridge 25
  - ID Chip 1
  - Instruction for Use 1
  - Sample Collector 25
- Box containing Detection Buffer
  - Detection buffer 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **ichroma™ CRP**.

Please contact our sales division for more information.

- Instrument for ichroma™ tests
  - **ichroma™ Reader** REF FR203
  - **ichroma™ II** REF FPRR021
  - **ichroma™-50** REF FPRR022
  - **ichroma™ III** REF FPRR037
- **Printer** REF FPRR007
- **Boditech CRP Control** REF CFPO-100

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ CRP** is human whole blood/serum /plasma.

- It is recommended to test the sample within 24 hours after collection.
- The serum or plasma should be separated from the clot by centrifugation within 3 hours after the collection of whole blood.
- Samples may be stored for a week at 2-8℃ prior to being tested. If testing will be delayed more than a week, samples should be frozen at -20℃.
- Samples stored frozen -20℃ for 6 months showed no performance difference.
- However, the whole blood sample should not be kept in a freezer in any case.
- As a repeated freeze-thaw cycle may affect the test result, do not refreeze previously frozen samples.

TEST SETUP

- Check the contents of **ichroma™ CRP**: Sealed Cartridges, Detection buffers, Sample collectors, ID Chip and Instruction for use.
- Ensure that the lot number of the cartridges matches that of the detection buffers as well as an ID chip.
- If the sealed cartridge and the detection buffer have been stored in a refrigerator, place them on a clean and flat surface at room temperature for at least 30 minutes before testing.
- Turn on the instrument for ichroma™ tests.
  (Please refer to the 'Instrument for ichroma™ tests Operation Manual' for complete information and operating instructions.)

TEST PROCEDURE

▶ichroma™ Reader/ ichroma™ II/ ichroma™ III

<Multi Mode>

1) Make a puncture on the top of a detection buffer by inserting an empty sample collector.
2) Draw 10 µL (Human whole blood/serum/plasma/control) of sample with a sample collector. 3 t.s.
3) Assemble the sample collector and the detection buffer into one.
4) Shake 10 times or more until the sample out of the sample collector by inversion. The mixture of the buffer and the sample has to be used within 30 seconds.
5) Remove the cap off the top of assembled tube. Discard two drops of reagent onto the paper towel before applying to a cartridge.
6) Load only two drops of the mixture onto the sample well of the cartridge.
7) Leave the cartridge at room temperature for 3 min before inserting the device into the holder.
   ⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inaccurate test result.*
8) To scan the sample-loaded cartridge, insert it into the cartridge holder of the instrument for ichroma™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow is marked on the cartridge especially for this purpose.
9) Press the 'Select' or Tap the 'START' button on the instrument for ichroma™ tests to start the scanning process.
10) The instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
11) Read the test result on the display screen of the instrument for ichroma™ tests.

< Single Mode >

1) The test procedure is same with "Multi test 1) – 4)".
2) Remove the cap off the top of assembled tube. Discard two drops of reagent onto the paper

towel before applying to a cartridge.
2) Load only two drops of the mixture onto the sample well of the cartridge.
3) Inserting the device into the holder of the instrument for ichroma™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow is marked on the cartridge especially for this purpose.
4) Press the 'Select' or Tap the 'START' button button on the instrument for ichroma™ tests.
5) The cartridge goes inside the Instrument for ichroma™ tests and will automatically start scanning the sample-loaded cartridge after 3 min.
6) Read the test result on the display screen of the instrument for ichroma™ tests.

▶ **ichroma™-50**

1) Insert the tip array in the tip station.
2) Insert the detection buffer array in the reagent station and cover the reagent station.
3) Open the detection buffer and insert it in the detection buffer station.
4) Open the cover of the magazine station and pull and lift the cartridge magazine.
5) Insert the cartridges in the cartridge magazine individually.
6) Insert the cartridge loaded cartridge magazine into the magazine station and close the cover of the magazine station.
7) Insert the sample tube into the blood collection tube rack and load the blood collection tube rack into the sampling station (loading part).
8) Tap the button located in the upper side of the No. of test cartridge region to select ID chip what you want to use.
9) When the selected cartridge slot is activated, set the number of test cartridge by tapping.
10) Tap the button located in the upper side of the No. of reagent region to select ID chip what you want to use.
11) When the selected slot is activated, set the number of detection buffer by tapping.
12) Set the number of pipette tips by tapping.
13) Tap the 'START' button on the left upper of the main screen to start test.
(Please refer to the ichroma™-50 operation manual for complete information and operation instructions.)

INTERPRETATION OF TEST RESULT

- Instrument for ichroma™ tests calculates the test result automatically and displays CRP concentration of the test sample in terms of mg/L.
- The cut-off (reference value): 10 mg/L
- Working range: 2.5-300 mg/L
- Effect of Hematocrit

The CRP Whole Blood of ichroma™ Reader is calibrated to read the CRP serum concentration of a blood sample with a hematocrit of 40%. If the actual hematocrit value deviates from 40%, the result should be corrected by multiplying with the respective factor in the table: deviates from 40%, the result should be corrected by multiplying with the respective factor in the table:

Hct (%)	Factor	Hct (%)	Factor
20-29	0.8	56-58	1.4
30-36	0.9	59-61	1.5
37-42	1.0	62-63	1.6
43-47	1.1	64-65	1.7
48-51	1.2	66-67	1.8
52-55	1.3	68-69	1.9

Reference range, HCT:
- Woman: 35-44%
- Men: 39-48%

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.
- Control materials are provided on demand with **ichroma™ CRP**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance.
(Please refer to the instruction for use of control material.)

PERFORMANCE CHARACTERISTICS

- **Analytical sensitivity**

Analytical sensitivity of **ichroma™ CRP** was determined by testing 10 times with three lots of reagents. Analytical sensitivity of **ichroma™ CRP** system was 0.5 mg/L.

- **Specificity**

Biomolecules such as hemoglobin, CEA, AFP, ALT, Troponin I, CK-MB, Albumin and serum amyloid P were added to the test sample(s) at concentration much higher than their normal physiological levels in the blood. ichroma CRP test results did not show any significant cross-reactivity with these biomolecules.

- **Precision**

- Intra-assay
The intra-assay precision was calculated by one evaluator, who tested different concentration of control standard twenty times each with three different lots of **ichroma™ CRP.**
- Inter-assay
The inter-assay precision was confirmed by 3 different evaluators with 3 different lots, testing ten times each different concentration for ten days.

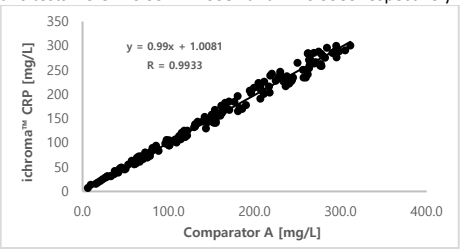
CRP (mg/L)	Intra-assay			Inter-assay		
	Mean	SD	CV (%)	Mean	SD	CV (%)
5.0	5.06	0.3	6.7	5.11	0.4	7.1
40.0	39.95	3.0	7.6	40.18	3.1	7.6
150.0	150.46	5.9	3.9	150.15	4.5	3.0

■ **Linearity**

The high pool (300 mg/L) was diluted with the low pool (2.5 mg/L) to the following final percentages; 100%, 75%, 50%, 25%, 10%, 5% and 0%. Sample was assayed in triplicate in one analytical run at each CRP level. The coefficient of linear regression was R=0.997.

■ **Comparability**

CRP concentrations of 166 samples were quantified independently with **ichroma™ CRP (ichroma™ Reader)** and Comparator A as per prescribed test procedures. Test results were compared, and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests were Y=0.99X + 1.0081 and R = 0.9933 respectively.



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8. Brooks DE, Devine DV, Harris PC, et al. RAMP(TM): A rapid, quantitative whole blood immunochromatographic platform for point-of-care testing. Clin Chem 1999; 45:1676-1678.
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10. Claus DR, Osmond AP, Gewurz H. Radioimmunoassay of human C-reactive protein and levels in normal sera. J. Lab. Clin Med 1976;87:120-128.

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

	Sufficient for <n> tests
	Read instruction for use
	Use by Date
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
EC REP	Authorized representative of the European Community
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CE	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

For technical assistance; please contact:
Boditech Med Inc.'s Technical Services
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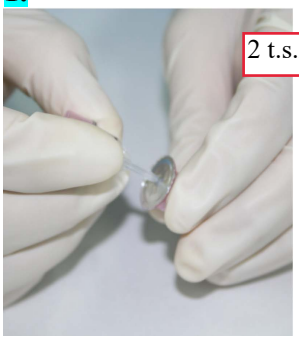
Tel: +(32)-2-732-59-54
Fax: +(32)-2-732-60-03
E-Mail: mail@obelis.net

CE IVD

i-Chroma CRB tyrimo procedūra

1.

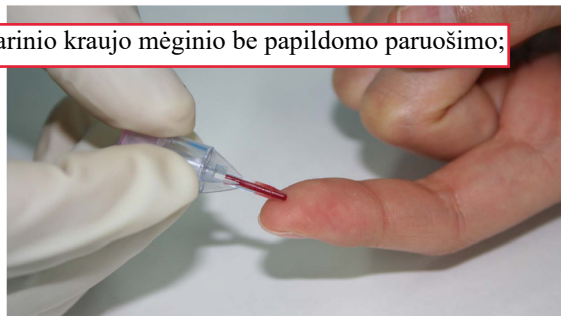


Pradūrkite buferio buteliuko apsauginę foliją naudodami plastikinį kraujo surinkimo kapiliarą.

2 t.s.2. Tyrimas atliekamas iš kapiliarinio kraujo mėginio be papildomo paruošimo;

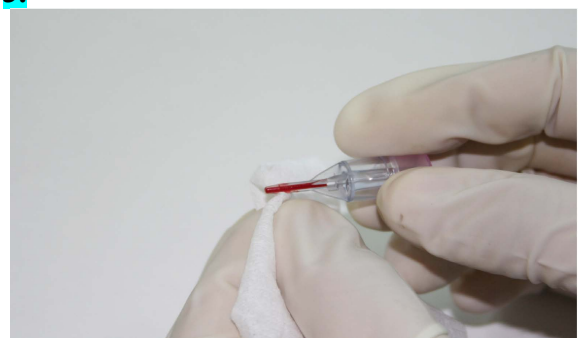
3 t.s.

2.



Kapiliarinį, veninį kraują, serumą, plazmą ar CRB kontrolę (10µl) paimkite naudodami platikinį kraujo surinkimo kapiliarą. Kapiliaras turi būti užpildytas mėginiu pilnai.

3.

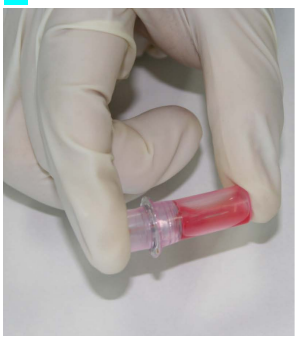


Jei reikia, kraujo perteklių nuo kapiliaro išorės pašalinkite naudodami popierinę servetėlę.

4.

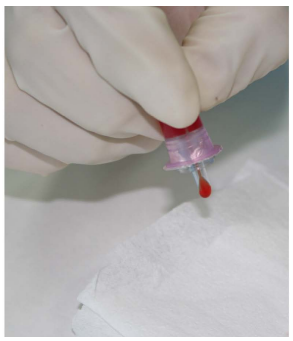
Įstatykite plastikinį kraujo surinkimo kapiliarą į buferio mėgintuvėlį taip kaip parodyta paveikslėlyje.

5.



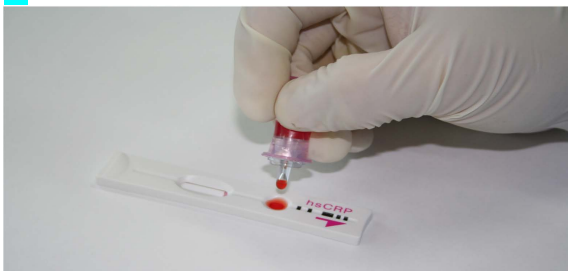
Švelniai pavartykite mėgintuvėlį 5 kartus, kad kraujas iš kapiliaro susimaišytų su buferiu.

6.



Nuimkite apsauginį kamštelį (žr. pav.) Pirmus du (2) lašus mėginio užlašinkite ant popierinės servetėlės.

7.



Po to, du (2) lašus mėginio užlašinkite ant testo prietaiso “mėginio šulinėlio” ir įstatykite testo prietaisą į analizatoriaus laikiklį. Du (2) kartus paspauskite “Select” mygtuką. Instrumentas automatiškai pradės skenuoti testo prietaisą **3-5 min.**

7 t.s.

CRB NORMA: < 10 mg/L

CRB matavimo ribos: 2,5-300 mg/L

Įgaliotas atstovas Lietuvoje

Uždaroji akcinė bendrovė
Aviečių g. 16, LT-08418 VILNIUS
Tel. (8~5) 278 68 50,
Faks. (8~5) 279 67 28
El. paštas: spirit@interlux.lt
http://www.interlux.lt

i-Chroma CRB tyrimo procedūra

i-CHROMA CRB

Kiekybiniam CRB (C- reaktyvinio baltymo) įvertinimui (**2,5-300 mg/L.)**

LAIKYMO SĄLYGOS

• **Detekcijos buferį** laikykite šaldytuve **2° - 8°C.** Jis išlaiko stabilumą **18 mėnesių**, jei laikomas nurodytose sąlygose.

• Išėmus **Detekcijos buferį** iš šaldytuvo**, palaikykite jį 40 min.,** kad sušiltų iki kambario temperatūros.

• ***i*-CHROMA hsCRP** testo kasetes laikykite **4 - 30°C** originalioje pakuotėje. ***i*-CHROMA hsCRP** testo kasetes išlaiko stabilumą **18 mėnesių** (sandarioje pakuotėje) jei laikomos **4 - 30°C** temperaturoje.

• **Jei testus laikote šaldytuve**, išėmę, palaikykite juos originalioje pakuotėje mažiausiai **10 minučių**, kol jie pasieks kambario temperatūrą.

MĖGINIŲ PARUOŠIMAS

Tyrimui naudojami **serumo, plazmos arba kraujo mėginiai (10 µl).**

• **Serumo mėginiai:** paimkite kraują į mėgintuvėlį be antikoagulianto ir palaukite, kol jis pilnai sukrešės. Siekiant išvengti hemolizės, atskirkite serumą nuo leukocitų trombocitų frakcijos kaip galima greičiau. **Plazmos mėginiai:** paimkite kraują į mėgintuvėlį su EDTA. Kitų antikoaguliantų poveikis plazmos mėginiams nėra įvertintas. Jei tyrimo negalite atlikti per valandą nuo mėginio paruošimo, serumo/plazmos mėginį reikia užšaldyti -20oC. **Jei naudojamas kraujo mėginys,** jis turi būti tiriamas iškart po paėmimo.

• Mėginiai turi būti homogeniški ir kambario temperatūros.

2 t.s.

PROCEDŪRA

1. Testo prietaisą **padėkite ant lygaus paviršiaus**.
2. **Įstatykite** į instrumentą **ID lustą**. Patikrinkite, ar testo prietaiso serijos numeris sutampa su ID lusto numeriu.
3. Išimkite iš šaldytuvo **vieną mėgintuvėlį Detekcijos buferio** ir palaikykite kambario temperatūroje kelias minutes. Pradūrkite buferio buteliuko **apsauginę foliją** naudodami platikinį kraujo surinkimo kapiliarą
4. Kapiliarinį, veninį kraują, serumą, plazmą ar CRB kontrolę paimkite naudodami **platikinį kraujo surinkimo kapiliarą**. Kapiliaras turi būti užpildytas mėginiu pilnai (**10 µl).** 3 t.s.
5. Įstatykite plastikinį kraujo surinkimo kapiliarą į buferio mėgintuvėlį taip kaip parodyta paveikslėlyje**.** Švelniai pavartykite **mėgintuvėlį 5 kartus**, kad kraujas iš kapiliaro susimaišytų su buferiu.
6. Nuimkite apsauginį kamštelį, pirmus **du (2) lašus** mėginio užlašinkite ant popierinės servetėlės.
7. Po to, **du (2) lašus** mėginio užlašinkite ant testo prietaiso “mėginio šulinėlio” ir įstatykite testo prietaisą į analizatoriaus laikiklį.
8. **Single Test Mode:** **Įstatę testo prietaisą** į analizatoriaus laikiklį, paspauskite **“SELECT”** mygtuką 2 kartus. Instrumentas automatiškai pradės skenuoti testo prietaisą **3 min.**

NORMA: < 10 mg/L

Boditech CRP Control

INTENDED USE
Boditech CRP Control is intended for *in vitro* diagnostic use in the quality control of CRP Assay Kit. **For *in vitro* diagnostic use only.**

INTRODUCTION
The use of Boditech CRP Control may be considered as an objective assessment of the precision of CRP Assay Kits and is an integral part of Good Laboratory Practices. Boditech CRP Control is provided in liquid form.

COMPONENTS
Boditech CRP Control consists of 'Boditech CRP Control level 1', 'Boditech CRP Control level 2', 'Instruction for Use' and 'Barcode Sheet'.

- The control contains CRP antigen stock 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 CRP Control should not be used past the expiration date.
- Boditech CRP Control is solely designed to be provided instrument-specific calibration curves of Boditech Readers and CRP Assay Kits.
- Human source materials from which Boditech CRP 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
- Opened: Store refrigerated (+2 to +8 °C). Once reconstituted, stable for 28 days at (+2 to +8 °C) if kept capped in original container and free from contamination. After use, any residual product should not be returned to the original tube.
- Unopened: Store refrigerated (+2 to +8°C).
- Boditech CRP Control is stable to expiration date on the label.
- Bacterial contamination of reconstituted Boditech CRP Control will cause reductions in the stability of many components. If bacterial contamination is suspected, the tube should be discarded and a fresh tube needs to be reconstituted.

INSTRUCTIONS FOR USE
Boditech CRP Control is supplied in liquid form.

1. Thoroughly mix the contents of the tube before each use by gently inverting for several times.
2. Follow the procedure according to the instruction for use provided with the kit.

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-100**

Boditech CRP Control Box (2 tubes)		
Boditech CRP Control level 1	(0.5 mL)	1
Boditech CRP Control level 2	(0.5 mL)	1
Instruction For Use		1
Control 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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CE

2.2.2 Dviejų lygių kontrolė

Boditech CRB kontrolė

PASKIRTIS

Boditech CRB kontrolė yra skirta *in vitro* diagnostinei CRB tyrimo rinkinio kokybės kontrolei. **Tik *in vitro* diagnostikai.**

PRISTATYMAS

Boditech CRB kontrolės naudojimas gali būti laikomas objektyviu CRB tyrimo rinkinio tikslumo įvertinimu ir integralia geros laboratorijos praktikos dalimi. Boditech CRP kontrolė tiekiama skysta forma.

SUDĖTIS

Boditech CRB kontrolė susideda iš Boditech CRB kontrolės 1 lygis, Boditech CRP kontrolės 2 lygis, instrukcija ir brūkšninio kodo lapas.

- Į kontrolės sudėtį įeina CRB antigenas ir arklio serumas.
- Kiekviena kontrolė supakuota į atskirą pakuotę.

SAUGUMO ATSARGUMO PRIEMONĖS IR PERSPĖJIMAI

- Tik *in vitro* diagnostikai.
- Nelašinkite pipete naudodami burną.
- Taikykite tinkamas atsargumo priemones, kurios įprastai reikalaujamos tvarkant laboratorinius reagentus.
- Boditech CRP kontrolė neturi būti naudojama pasibaigus jos galiojimo laikui.
- Boditech CRP kontrolė išskirtinai sukurta pateikti Boditech Readers ir CRP tyrimo rinkinių instrumentui specifines kalibracijos kreives.
- Žmogaus kilmės medžiagos, iš kurių pagaminta Boditech CRP kontrolė, buvo tirtos donoro lygiu dėl žmogaus imunodeficito 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

- Atidarius: sandėliuoti šaldytuve (+2^{0}C iki +8^{0}C). Ištirpintas produktas stabilus 28 dienas +2^{0}C iki +8^{0}C temperatūroje, jeigu produktas laikomas originalioje talpykloje ir yra neužterštas. Panaudojus likęs produktas neturi būti grąžinamas į originalų buteliuką.
- Neatidarius: sandėliuoti šaldytuve (+2^{0}C iki +8^{0}C).
- Boditech CRP kontrolė stabili iki galiojimo laiko pabaigos, nurodytos ant etiketės.
- Ištirpintos Boditech CRP kontrolės bakterinis užteršimas sumažins daugumos komponentų stabilumą. Jeigu įtariate bakterinį užteršimą, buteliuką utilizuokite ir ištirpinkite naują buteliuką.

NAUDOJIMO INSTRUKCIJOS

Boditech CRP kontrolė tiekiama skysta forma.

1. Prieš kiekvieną naudojimą švelniai kelis kartus vartydami buteliuką gerai išmaišykite buteliuko turinį.
2. Laikykitės su rinkiniu tiekiamose naudojimo instrukcijose pateikiamų procedūrų.

Bet kokias medžiagas utilizuokite pagal Jūsų vietos atliekų tvarkymo kompetentingos įstaigos reikalavimus.
Jeigu pakuotė yra pažeista, susisiekite su **Boditech Med Inc. technine pagalba**.

TIEKIAMOS MEDŽIAGOS

REF: CFPO-100

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

KOKYBĖS KONTROLĖ

- Kokybės kontrolės tyrimai yra gerosios tyrimų praktikos dalis ir atliekami siekiant patvirtinti numatomus rezultatus ir tyrimo galiojimą. Juos reikia atlikti reguliariai.
- Kontrolinius tyrimus reikia atlikti iš karto po to, kai atidaroma nauja tyrimų partija, siekiant įsitikinti, kad nepakito tyrimo charakteristikos.
- Kokybės kontrolės tyrimus taip pat reikia atlikti, jei kyla klausimų dėl tyrimų rezultatų galiojimo.

Dėl techninės pagalbos kreipkitės į
Boditech Med Inc. techninė pagalba
Tel.: +82 (33) 243-1400
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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)