

Microalbumin

Description

Since the high concentration of albumin in the blood of the healthy is filtered by kidneys, it is not detected in the urine, whereas in patients with chronic metabolic diseases such as diabetes and high blood pressure, microalbumin may be detected in the urine due to kidney dysfunction. This product is a screening test that quantifies microalbumin quickly and easily from the first urine in the morning or random concentrated urine to check the extent of kidney damage and predict the progression to kidney failure. Continuous measurement of microalbumin concentration can help patients receive appropriate treatment and confirm treatment effects.

Indication

Diabetic kidney disease, hypertensive renal disease, renal failure.

Diagnostics Value

Albumin in urine is most often caused by kidney damage from diabetes. But many other conditions such as hypertension, heart failure, cirrhosis can lead to kidney damage. The Microalbumin test can be done in 10 minutes, thus can help healthcare providers provide close to a real-time treatment program even without the full lab support.

Selection guide

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

Specification

Sample type	Urine
Sample vol.	10 µL
Assay time	12 min
Working range	2-300 mg/L
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=0.9749x + 2.1561$ $R=0.9885$
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Ordering information

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

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Anti-Müllerian Hormone (AMH)

Description

It can help assess women's ovarian reserve, predict menopause, and predict the response to controlled ovarian stimulation by measuring AMH levels quantitatively in the small amount of blood.

Indication

Assessment of ovarian reserve
 Diagnosis of ovarian dysfunction such as POI and PCOS
 Menopause prediction
 Response prediction to controlled ovarian stimulation

Diagnostics Value

The level of AMH in a woman's blood may reveal clues for abnormalities in ovarian function. The test result is independent of the menstrual cycle. With its POC arrangement, one can run the test even during the consultation, enabling clinicians to make almost real-time diagnostics.

Selection guide

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

Specification

Sample type	Serum, Plasma
Sample vol.	50 µL
Assay time	12 min
Working range	0.02-15 ng/mL
Storage	2-30°C
Shelf life	20 months

Performance

Accuracy	$y=1.0322x - 0.0178$ $R=0.9935$
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Ordering information

Cat #	CFPC-89
Test/Kit	25T/Kit

Cortisol

Description

It quantifies cortisol in the blood, predicts the response to stress, and helps diagnose endocrine dysfunction and adrenal disease.

Indication

Cushing's syndrome, Adrenal cortical dysfunction, Addison Disease, Hyperthyroidism.

Diagnostics Value

The cortisol level displays a diurnal variation. Testing the level when needed is the advantage of POC setting of this cortisol test. With its accessibility to the fingertip blood and rapid test time, one can test the cortisol level when needed for evaluation under controlled setting.

Selection guide

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

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	50/30/30 µL
Assay time	10 min
Working range	80-800 nmol/L
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=0.9856x + 12.774$ $R=0.9865$
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Ordering information

Cat #	CFPC-24
Test/Kit	25T/Kit

Follicle-stimulating Hormone (FSH)

Description

It quantifies follicle-stimulating hormone in blood to evaluate pituitary function and help diagnose early menopause, early ovarian degeneration, congenital or acquired gonadotropin development disorder or infertility.

Indication

Premature menopause, Premature ovarian failure, Precocious puberty, Sterility, abnormal menstruation.

Diagnostics Value

Practitioners in OB/GYN (obstetrics/gynecology) and infertility clinics would find this test just right for their practices. They can run the test in a POC setting with minimal sample handling, get the result in just 12 minutes, and that they can continue consulting their patients without further delays.

Selection guide

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

Specification

Sample type	Serum, Plasma
Sample vol.	150 µL
Assay time	15 min
Working range	1-100 mIU/mL
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=1.0188x - 0.0979$ $R=0.9914$
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Ordering information

Cat #	CFPC-35
Test/Kit	25T/Kit

Human Chorionic Gonadotropin (β -HCG)

Description

It helps to detect and treat abnormal pregnancy and germ cell tumors as well as early diagnosis of pregnancy by quantification of hCG in the blood.

Indication

Ovulation induction and Pregnancy, Abnormal pregnancy, hCG secreting tumor.

Diagnostics Value

The result from this β -hCG test contains clues as to the pregnancy including the potential of the miscarriage and the responsivity for the reproductive cell tumor treatment. Since this test can be done even on a POC setting, the attending physician can concentrate on consulting without having to wait for the test result to return.

Selection guide

Item / Platform	ichroma™	ichroma™ II	ichroma™ III	ichroma™-50
ichroma™ β -HCG	●	●	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	50/30/30 μ L (30 μ L for sample diluent procedure)
Assay time	15 min
Working range	5-50,000 mIU/mL
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=0.9697x + 230.16$ $R=0.9946$
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Ordering information

Cat #	CFPC-36
Test/Kit	25T/Kit

Human Chorionic Gonadotropin (β -HCG Plus)

Description

It helps to detect and treat abnormal pregnancy and germ cell tumors as well as early diagnosis of pregnancy by quantification of hCG in the blood with high sensitivity.

Indication

Ovulation induction and Pregnancy, Abnormal pregnancy, hCG secreting tumor.

Diagnostics Value

It can be used for early confirmation and monitoring of pregnancy, as well as infertility treatment and reproductive cell tumor treatment effects and recurrence monitoring by quantification of hCG in blood, so it can be useful in small and medium-sized OB/GYN (obstetrics/gynecology) clinics, fertility clinics, and labs, etc.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III
ichroma™ β -HCG Plus	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	10 μ L
Assay time	12 min
Working range	2-5,000 mIU/mL
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=0.9401x + 16.591$ $R=0.9881$
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Ordering information

Cat #	CFPC-66
Test/Kit	25T/Kit

Luteinizing Hormone (LH)

Description

It helps to evaluate pituitary function by quantifying luteinizing hormone in the blood, to diagnose pituitary gland disease, and to determine congenitally or acquired gonadotropin dysfunction.

Indication

infertility and infertility treatment, pituitary function evaluation, early ovarian failure, chronic ovulation failure.

Diagnostics Value

Practitioners in infertility and OB/Gyn (obstetrics/gynecology) would find the POC aspect especially appealing. Both provide essential information for achieving pregnancy and for examining the related functionalities. With its POC compatibilities, the test can be done even when the patient is still in consultation.

Selection guide

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

Specification

Sample type	Serum, Plasma
Sample vol.	150 µL
Assay time	15 min
Working range	1-100 mIU/mL
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=0.9939x + 1.0023$ $R=0.9870$
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Ordering information

Cat #	13010
Test/Kit	25T/Kit

Progesterone

Description

It quantifies progesterone in the blood, helping to identify women's ovarian function and pregnancy status, as well as monitoring for miscarriage or ectopic pregnancy.

Indication

Diagnosis of ovulation abnormalities, ovulation monitoring in infertility treatment, prediction of miscarriage or ectopic pregnancy.

Diagnostics Value

The progesterone test result can provide information for clinicians with infertility issues. Any infertility, OB/Gyns (obstetrics/gynecology) and field clinics away from fully equipped lab support can benefit from this test: its POC nature, fingertip blood, fast TAT and reliable results should prove its value in the field.

Selection guide

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

Specification

Sample type	Serum, Plasma
Sample vol.	30 µL
Assay time	15 min
Working range	4.45-127.20 nmol/L & 1.4-40.0 ng/mL
Storage	4-30°C
Shelf life	20 months

Performance

Accuracy	$y=0.9881x - 0.0863$ $R=0.9905$
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Ordering information

Cat #	CFPC-21
Test/Kit	25T/Kit

Prolactin (PRL)

Description

It helps to select and diagnose mammary gland development, infertility treatment and pituitary diseases by quantifying blood PRL.

Indication

Tracking the causes of infertility, amenorrhea. Prediction and monitoring of fertility, menopause.

Diagnostics Value

In OB/Gyns (obstetrics/gynecology) and infertility clinics, finding the root cause of infertility calls for a series of repeated hormone tests. Prolactin plays a vital role in this arena. The Prolactin test runs on a POC platform and a member of the staff can run the test with minimal training, facilitating the repeated tests readily available in the clinic that otherwise have to send the sample out to a third-party laboratory.

Selection guide

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

Specification

Sample type	Serum, Plasma
Sample vol.	75 µL
Assay time	10 min
Working range	1-100 ng/mL
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=1.028x - 0.305$ $R=0.983$
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Ordering information

Cat #	CFPC-27
Test/Kit	25T/Kit

T3

Description

It quantifies T3 in the blood to diagnose thyroid dysfunction quickly and accurately, helps to receive appropriate treatment, and helps to confirm the treatment effect through periodic measurement.

Indication

Hyperthyroidism, Thyroid nodule, Multinodular goiter, Graves' disease.

Diagnostics Value

It helps to diagnose thyroid dysfunction and receive appropriate treatment by quantifying T3 in blood in small & medium hospitals and helps to confirm the treatment effect through periodic measurement along with other thyroid markers (T4, TSH).

Selection guide

Item / Platform	ichroma™	ichroma™ II	ichroma™ III
ichroma™ T3	●	●	●

Specification

Sample type	Serum, Plasma
Sample vol.	75 µL
Assay time	16 min
Working range	0.77-7.70 nmol/L (0.5-5.0 ng/mL)
Storage	4-30°C
Shelf life	20 months

Performance

Accuracy	$y=0.9473x + 0.0436$ $R=0.9958$
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Ordering information

Cat #	CFPC-44
Test/Kit	25T/Kit

T4

Description

It quantifies T4 in the blood to diagnose thyroid dysfunction quickly and accurately, helps to receive appropriate treatment, and helps to confirm the treatment effect through periodic measurement.

Indication

Thyroidism, hypothyroidism, hyperthyroidism.

Diagnostics Value

It helps to diagnose thyroid dysfunction and receive appropriate treatment by quickly and accurately quantifying T4 in blood in small & medium hospitals and helps to confirm the treatment effect through periodic measurement along with other thyroid markers (T3, TSH).

Selection guide

Item / Platform	ichroma™	ichroma™ II	ichroma™ III
ichroma™ T4	●	●	●

Specification

Sample type	Serum, Plasma
Sample vol.	75 µL
Assay time	16 min
Working range	10.23-300.00 nmol/L (0.79-23.31 µg/dL)
Storage	4-30°C
Shelf life	20 months

Performance

Accuracy	$y=0.9478x + 1.0741$ $R=0.9935$
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Ordering information

Cat #	CFPC-26
Test/Kit	25T/Kit

Testosterone

Description

It helps diagnose and manage dysfunction of the sex glands in men and women by quantifying testosterone in human blood.

Indication

Hypogonadism, Erectile dysfunction, Infertility, Virilization, Polycystic Ovary Syndrome (PCOS).

Diagnostics Value

Testosterone is the primary hormone governing male development and sexuality. The lack of this hormone causes symptoms ranging from lack of sex drive to infertility. Measuring the level of this hormone is a primary step in diagnosing related symptoms. The Prolactin test can run on a POC platform, making it suitable for the on-site evaluation. The attending physician can deliver a prompt treatment regimen without waiting for the result from a third-party laboratory.

Selection guide

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

Specification

Sample type	Serum, Plasma
Sample vol.	75 µL
Assay time	15 min
Working range	1-10 ng/mL
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=0.9505x + 0.137$ $R=0.9687$
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Ordering information

Cat #	13012
Test/Kit	25T/Kit

Thyroid Stimulating Hormone (TSH)

Description

It helps to quantify the amount of TSH in a small amount of blood to achieve accurate diagnosis and optimal treatment effect (acquired US FDA 510(k); AFIAS TSH).

Indication

Thyroid gland disease (Hypothyroidism, Hyperthyroidism, etc.), Thyroid dysfunction (thyroid cancer, etc.), Subclinical thyroid dysfunctions.

Diagnostics Value

The TSH test can be administered on-site to measure the level of TSH in 12 minutes, rendering it an ideal choice for facilities away from immediate and comprehensive diagnostic support. OB/Gyns (obstetrics/gynecology), GPs (General practitioners) and pediatricians could find the test befitting their facilities.

Selection guide

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

Specification

Sample type	Serum, Plasma
Sample vol.	150 µL
Assay time	12 min
Working range	0.1-100.0 µIU/mL
Storage	4-30°C
Shelf life	20 months

Performance

Accuracy	$y=0.985x + 0.0644$ $R=0.999$
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Ordering information

Cat #	CFPC-22
Test/Kit	25T/Kit

Thyroid Stimulating Hormone (TSH Plus)

Description

It helps to obtain an accurate diagnosis and optimal treatment effect by quantifying the amount of TSH in a small amount of blood.

Indication

Thyroid gland disease (Hypothyroidism, Hyperthyroidism, etc.), Thyroid dysfunction (thyroid cancer, etc.), Subclinical thyroid dysfunctions.

Diagnostics Value

The TSH test can be administered on-site to measure the level of TSH in 12 minutes, rendering it an ideal choice for facilities away from immediate and comprehensive diagnostic support. OB/Gyns (obstetrics/gynecology), GPs (General practitioners) and pediatricians could find the test befitting their facilities.

Selection guide

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

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	35 µL
Assay time	12 min
Working range	0.1-50.0 µIU/mL
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=0.9899x + 0.0848$ $R=0.9941$
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Ordering information

Cat #	CFPC-45
Test/Kit	25T/Kit

Infection

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COVID-19 Ab

Description

Since SARS-CoV-2 virus infection (COVID-19) has symptoms very similar to other acute viral respiratory diseases and is transmitted even during asymptomatic periods, an accurate diagnosis of the virus is important for both treatment and prevention of transmission. By simply diagnosing COVID-19 using blood, this product can quickly screen early mild, asymptomatic, or acute patients, helping to prevent spread to the community with appropriate treatment.

Indication

COVID-19 prevalence history, COVID-19-related multisystem inflammatory syndrome, Plasma donor screening, immigration.

Diagnostics Value

The confirmation of COVID-19 infection requires tests on PCR, which takes hours and days. Such a test is not practical in sites where a speedy diagnosis is a priority issue. COVID-19 Ab tests provide information on the patients' immunity, helping medical professionals with the proper treatment planning with no PCR test.

Selection guide

Item / Platform	ichroma™ M2	ichroma™ II	ichroma™ III
ichroma™ COVID-19 Ab	●	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	10 µL
Assay time	10 min
Working range	Qualitative
Storage	2-30°C
Shelf life	20 months

Performance

Accuracy	Sensitivity: 95.8% Specificity: 97.0%
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Ordering information

Cat #	CFPC-114
Test/Kit	25T/Kit

COVID-19 Ag

Description

The SARS-CoV-2 virus, which causes coronavirus infection (COVID-19), has very similar symptoms to other acute viral respiratory diseases and spreads easily even in asymptomatic times. Therefore, accurate diagnosis of the virus is very important not only to treat the patient, but also to prevent transmission. This product is very useful as a rapid screening test that can help you quickly and accurately determine the presence or absence of infection with the SARS-Cov-2 antigen.

Indication

Coronavirus disease-19 (COVID-19).

Diagnostics Value

COVID-19 Ag tests have unique advantages over PCR when it comes to run screening tests in an emergency. They can perform on par with PCR systems yet run faster and are easier to use. With such accuracies and high throughputs, they will play a vital role in the combat against the COVID pandemic.

Selection guide

Item / Platform	ichroma™ M2	ichroma™ II	ichroma™ III
ichroma™ COVID-19 Ag	●	●	●

Specification

Sample type	Nasopharyngeal swab
Assay time	12 min
Working range	Qualitative
Storage	2-30°C
Shelf life	20 months

Performance

Accuracy	Clinical sensitivity: 91.9% Clinical specificity: 98.8%
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Ordering information

Cat #	CFPC-115
Test/Kit	25T/Kit

COVID-19/Flu Ag Combo

Description

The SARS-CoV-2 virus, which causes coronavirus infection (COVID-19), has very similar symptoms to other acute viral respiratory diseases and spreads easily even in asymptomatic times. Therefore, accurate diagnosis of the virus is very important not only to treat the patient, but also to prevent transmission. This product is very useful as a rapid screening test that can help you quickly and accurately determine the presence or absence of infection with the SARS-Cov-2 antigen.

Indication

Coronavirus disease-19 (COVID-19).

Diagnostics Value

COVID-19 Ag tests have unique advantages over PCR when it comes to run screening tests in an emergency. They can perform on par with PCR systems yet run faster and are easier to use. With such accuracies and high throughputs, they will play a vital role in the combat against the COVID pandemic.

Selection guide

Item / Platform	ichroma™ M2	ichroma™ II	ichroma™ III
ichroma™ COVID-19/Flu Ag Combo	●	●	●

Specification

Sample type	Nasopharyngeal swab
Assay time	20 min
Working range	Qualitative
Storage	2-30°C
Shelf life	20 months

Performance

Accuracy	COVID-19 Ag	Sensitivity: 100% / Specificity: 98.3%
	Flu A	Sensitivity: 93.8% / Specificity: 100%
	Flu B	Sensitivity: 93.8% / Specificity: 100%

Ordering information

Cat #	CFPC-117
Test/Kit	25T/Kit

COVID-19 nAb

Description

This neutralizing antibody test kit can quickly and accurately test the presence or absence of a neutralizing antibody that prevents corona-19 virus from penetrating into cells (infection) among various antibodies in the blood produced after vaccination or recovery from COVID-19.

Indication

COVID-19 vaccine efficacy monitoring, evaluation of immunity, post-treatment monitoring.

Diagnostics Value

The conventional test for neutralizing antibodies requires the 'Plaque Reduction Neutralization Test (PRNT)', which requires high-level biosecurity for virus tests and strict protocols not to mention the considerable amount of time.

The COVID-19 Neutralizing Ab (nAb) kit performs the equivalent task without resorting to PRNT, which should help medical professionals to make a timely decision on the treatment planning.

Selection guide

Item / Platform	ichroma™ M2	ichroma™ II	ichroma™ III
ichroma™ COVID-19 nAb	●	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	10 µL
Assay time	20 min
Working range	Qualitative
Storage	2-30°C
Shelf life	20 months

Performance

Accuracy (Compare to ELISA)	Clinical sensitivity: 91.9% Clinical specificity: 100%
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Ordering information

Cat #	CFPC-120
Test/Kit	25T/Kit

C-Reactive Protein (CRP)

Description

It is a POCT that can help with proper prescription and treatment by quickly and accurately measuring CRP in a very small amount of peripheral blood.

Indication

Bacterial infection, Inflammatory disease, Autoimmune disease, Tissue damage, Rheumatoid fever.

Diagnostics Value

It introduces an "All-in-one tube" so that a small amount of whole blood (10µL) can be directly taken and quantified. It can be usefully used in emergency rooms, intensive care units, small hospitals and health centers that require immediate use. This product is FDA-approved.

Selection guide

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

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	10 µL
Assay time	3 min 4 t.s.
Working range	2.5-300 mg/L
Storage	2-8°C for DB/2-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=0.99x - 1.0081$ $R=0.9933$
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Ordering information

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

Procalcitonin (PCT)

Description

Early assessment of sepsis is critical in developing the treatment plan to improve the prognosis of the patient. The ichroma™ tests help with the detection of the bacterial sepsis and the assessment of the risk of developing the septic shock.

Indication

Local infection, systemic infection (sepsis), sepsis shock, bacterial infection.

Diagnostics Value

The fast and reliable quantitative results with blood help ER clinicians make medical decisions and treatment plans early against sepsis and septic shocks as well as bacterial infections.

Selection guide

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

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	150 µL
Assay time	12 min
Working range	0.1-100.0 ng/mL
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=1.0043x + 0.0002$ R=0.9985
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Ordering information

Cat #	CFPC-23-1
Test/Kit	25T/Kit

Procalcitonin (PCT Plus)

Description

Early assessment of sepsis is critical in developing the treatment plan to improve the prognosis of the patient. The ichroma™ PCT Plus tests help with the detection of the bacterial sepsis and the assessment of the risk of developing the septic shock with high sensitivity.

Indication

Local infection, systemic infection (sepsis), sepsis shock, bacterial infection.

Diagnostics Value

The fast and reliable quantitative results with blood help ER clinicians make medical decisions and treatment plans early against sepsis and septic shocks as well as bacterial infections with high sensitivity.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III	ichroma™-50
ichroma™ PCT Plus	●	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	35 µL
Assay time	12 min
Working range	0.02-50.00 ng/mL
Storage	2-8°C for Detector tube, Detector diluent / 4-30°C for Cartridge
Shelf life	24 months

Performance

Accuracy	$y=0.9971x + 0.242$ $R=0.9923$
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Ordering information

Cat #	CFPC-64
Test/Kit	25T/Kit

Interleukin-6 (IL-6)

Description

It can quantify IL-6 through simple blood collection including capillary blood, thereby reducing complications of patients, and helping to proceed with appropriate treatment.

Indication

Bacterial infection, sepsis, stroke and cardiovascular disease, arteriosclerosis.

Diagnostics Value

It can quantify IL-6 from a small amount of blood including peripheral blood, it is useful in emergency rooms, intensive care units, etc., and can be easily used in small hospitals and public health centers. Particularly, early detection of sepsis in neonates with low immunity can reduce mortality and prevent the occurrence of antibiotic abuse and resistant bacteria by appropriate treatment, so it is useful in neonatal intensive care units (NICU).

Selection guide

Item / Platform	ichroma™ II	ichroma™ III	ichroma™-50
ichroma™ IL-6	●	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	35 µL
Assay time	12 min
Working range	2-2,500 pg/mL
Storage	2-30°C
Shelf life	20 months

Performance

Accuracy	$y=0.9355x + 6.6376$ $R=0.9967$
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Ordering information

Cat #	CFPC-116
Test/Kit	25T/Kit

Adenovirus (Adeno)

Description

Since adenovirus, which is highly contagious, causes upper respiratory disease, it can lead to a variety of complications such as pneumonia and conjunctivitis, which are quite serious in the elderly, and clinical symptoms are very similar to Kawasaki disease and bacterial infection. This product can quickly and easily diagnose adenovirus infection with high sensitivity and help to distinguish it from other infection sources.

Indication

Acute Adenovirus Respiratory Infection.

Diagnostics Value

With Adeno tests, medical practitioners can plan targeted antiviral treatments. With PCR equivalent performance of Adeno assures tests, clinicians can be assured of the chosen treatment schemes as the pathogen behind the infection is clearly identified.

Selection guide

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

Specification

Sample type	Nasopharyngeal swab
Assay time	10 min
Working range	Qualitative
Storage	1-30°C
Shelf life	18 months

Performance

Accuracy	Clinical sensitivity: 93% Clinical specificity: 98%
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Ordering information

Cat #	CFPC-96
Test/Kit	25T/Kit

Anti-streptolysin O (ASO)

Description

It is useful for quickly diagnosing GAS (group A streptococcus) infection by quantitatively detecting ASO in blood, preventing complications, and helping patients recover through appropriate antibiotic prescription.

Indication

Acute tonsillitis, laryngopharyngitis, Rheumatoid fever, scarlet fever.

Diagnostics Value

A positive test result means you recently had a strep infection, even if you had no symptoms. With a POC operational setting and rapid TAT, the ASO test can facilitate physicians to provide proactive treatment regimens even to asymptomatic patients.

Selection guide

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

Specification

Sample type	Serum, Plasma
Sample vol.	5 µL
Assay time	12 min
Working range	25-800 IU/mL
Storage	4-30°C
Shelf life	20 months

Performance

Accuracy	$y=1x+0.1999$ $R=0.9987$
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Ordering information

Cat #	CFPC-46
Test/Kit	25T/Kit

Dengue Antibody IgG/IgM

Description

Dengue fever is an acute febrile illness caused mainly by the dengue virus carried by mosquitoes (*Aedes aegypti*), and it is often asymptomatic, but after the incubation period, it also exhibits symptoms such as fever, severe headache, joint pain, and a rapid decrease in the number of white blood cells. In addition, since past infected individuals can develop fatal severe dengue fever when reinfected with dengue viruses of other serotypes, securing a patient's past infectivity is very important for proper treatment and preemptive response. This product can accurately and quickly diagnose dengue virus infection by simultaneously detecting dengue virus-specific IgG and IgM from blood and help to confirm the patient's infectivity.

Indication

Dengue Fever (DF), Dengue Hemorrhagic Fever (DHF), Dengue Shock Syndrome (DSS).

Diagnostics Value

Dengue IgG/IgM detects dengue virus-specific IgG and IgM simultaneously with finger-tip blood and distinguishes dengue virus infection from febrile diseases with similar symptoms. It also accurately identifies early infections and reinfections. Clinicians can then plan to prevent progression to severe dengue fever.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III
ichroma™ Dengue IgG/IgM	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	30 µL
Assay time	12 min
Working range	Qualitative
Storage	4-30°C
Shelf life	20 months

Performance

Accuracy	IgG : 98.3% IgM : 83.0%
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Ordering information

Cat #	CFPC-60
Test/Kit	25T/Kit

Dengue NS1 Antigen

Description

Dengue fever is an acute febrile disease caused by dengue virus, which is mainly transmitted by mosquitoes (*Aedes aegypti*). There are many asymptomatic infections, but if the cure is reinfected with another serotype dengue virus, it can develop into severe dengue fever, which is fatal. This product detects dengue virus specific NS1 from blood to diagnose dengue virus infection earlier, helping to preemptive treatment and monitoring treatment prognosis.

Indication

Dengue Fever (DF), Dengue Hemorrhagic Fever (DHF), Dengue Shock Syndrome (DSS).

Diagnostics Value

Dengue NS1 Ag detects NS1, a dengue virus-specific antigen, from finger-tip blood and quickly distinguishes dengue virus infection from other febrile diseases sharing similar symptoms.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III
ichroma™ Dengue NS1 Ag	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	75 µL
Assay time	12 min
Working range	Qualitative
Storage	4-30°C
Shelf life	20 months

Performance

Accuracy	Clinical sensitivity: 98.1% Clinical specificity: 99.1%
----------	---

Ordering information

Cat #	CFPC-62
Test/Kit	25T/Kit

Toxoplasma IgM/IgG (Toxo IgG/IgM)

Description

Toxoplasmosis, a common contagious disease, can cause miscarriage or birth defects in newborns, depending on the time of the mother's infection during pregnancy. The ichroma™ Toxo IgG/IgM test can help with prenatal management by checking for *Toxoplasma gondii* infection.

Indication

Toxoplasmosis, prenatal tests.

Diagnostics Value

Toxo IgG/IgM tests determine the presence of the Toxoplasma parasite, the duration, and/or the history of the infection with finger-prick blood in a simple and easy-to-use method. The test is also far more cost-competitive over the conventional PCR system. They suit the test needs of clinical institutions with limited access to full-featured test facilities.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III
ichroma™ Toxo IgG/IgM	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	5 µL
Assay time	12 min
Working range	Qualitative
Storage	2-30°C
Shelf life	20 months

Ordering information

Cat #	CFPC-112
Test/Kit	25T/Kit

Group A Streptococcal Infection (Strep A)

Description

Group A streptococci, which are highly contagious, cause acute upper respiratory diseases such as Scarlet fever, can cause high fever and various complications, and because reinfection and transmission are severe, rapid diagnosis and appropriate antibiotics are important. This product can quickly and easily diagnose group A streptococcal infection with high sensitivity and help to distinguish it from other infection sources such as viruses.

Indication

Acute upper respiratory tract infection (pharyngitis, tonsillitis), Strep throat, Scarlet fever.

Diagnostics Value

Strep A tests provides an affordable yet accurate diagnostic solution for Group A streptococci infection. The result from Step A tests can help clinicians devise a specific treatment plan for the patients and to minimize the risk of reinfection and general transmission.

Selection guide

Item / Platform	ichroma™ M2	ichroma™ II	ichroma™ III
ichroma™ Strep A	●	●	●

Specification

Sample type	Throat swab
Assay time	5 min
Working range	Qualitative
Storage	1-30°C
Shelf life	18 months

Performance

Accuracy	Clinical sensitivity: 93.39% Clinical specificity: 97.91%
----------	---

Ordering information

Cat #	CFPC-74
Test/Kit	25T/Kit

Hepatitis B Antibody (Anti-HBs)

Description

The presence of antibodies to the HBsAg (Anti-HBs) means that you have a permanent immunity against the hepatitis B virus. Our anti-HBs test helps you determine additional treatments and vaccinations by quickly and accurately verifying that a patient has gained sufficient immunity against the hepatitis B virus through simple measurements.

Indication

- 1) Checking the effectiveness of the hepatitis B treatment
- 2) Analysis of titer after hepatitis B vaccination

Diagnostics Value

Anti-HBs is produced after the patient recovers from hepatitis B or after the vaccination. The positive result from the Anti-HBs test indicates the patient has developed immunity enough to protect from further infection. One can run Anti-HBs tests in clinics with limited access to full-sized test facilities.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III
ichroma™ Anti-HBs	●	●

Specification

Sample type	Whole blood, Serum, Plasma
Sample vol.	50 µL
Assay time	15 min
Working range	Qualitative
Storage	2-8°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	Positive: 91.8% Negative: 99.3% Overall: 98.1%
----------	--

Ordering information

Cat #	CFPC-52
Test/Kit	25T/Kit

Hepatitis B Antigen (HBsAg)

Description

Since detection of the hepatitis B virus surface antigen (HBsAg) in the blood indicates infection with the hepatitis B virus, early detection of HBsAg is very important for treatment and prevention of transmission. This product can predict hepatitis B infection by detecting HBsAg in the blood and is useful as a screening test for confirmatory testing.

Indication

Fulminant Hepatic failure, chronic hepatitis, cirrhosis, Liver cancer.

Diagnostics Value

The hepatitis B virus can be transmitted through asymptomatic chronic carriers. It can also affect newborns, making it crucial to diagnose the virus in the early stage of infection. HBsAg tests for the HBV infection with a drop of blood, can help with the screening for the costly PCR confirmation test.

Selection guide

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

Specification

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

Performance

Accuracy	Positive: 99.1% Negative: 99.6%
----------	---------------------------------

Ordering information

Cat #	CFPC-29
Test/Kit	25T/Kit

Hepatitis C Antibody (Anti-HCV)

Description

The hepatitis C virus is mainly transmitted to the blood, and there is no vaccine and treatment is difficult. In addition, since chronic hepatitis develops into fatal liver cancer through cirrhosis, early detection and treatment are more important. This product can predict the likelihood of hepatitis C infection through antibody tests for HCV in the blood, and is useful as a screening test for confirmation tests.

Indication

Acute hepatitis C, Chronic hepatitis C

Diagnostics Value

Anti-HCV test belongs to the 3rd generation of Hepatitis C detection systems, requiring minimal sample volume, producing the accurate result in the rapid time frame. Ideal for screening tests for PCR runs.

Selection guide

Item / Platform	ichroma™ II	ichroma™ III
ichroma™ Anti-HCV	●	●

Specification

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

Performance

Accuracy	Positive: 98.97% Negative: 99.53%
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Ordering information

Cat #	CFPC-31
Test/Kit	25T/Kit

Influenza A+B

Description

The 'Flu test' helps to shorten the recovery time of the patient as well as prevent the spread to the community by prescribing an appropriate antiviral drug by distinguishing it from other viral or bacterial respiratory infections that are similar to the clinical symptoms of the Flu.

Indication

Influenza A and B infection.

Diagnostics Value

Influenza A+B test provides diagnostics against respiratory diseases faster than a PCR. The early diagnosis can help clinicians with the appropriate antiviral treatment planning.

Selection guide

Item / Platform	ichroma™ M2	ichroma™ II	ichroma™ III	ichroma™-50
ichroma™ Influenza A+B	●	●	●	●

Specification

Sample type	Nasopharyngeal swab
Assay time	10 min
Working range	Qualitative
Storage	1-30°C
Shelf life	18 months

Performance

Accuracy	Clinical sensitivity	Influenza A: 98.6%, Influenza B: 96.0%
	Clinical specificity	Influenza A: 100%, Influenza B: 100%

Ordering information

Cat #	CFPC-61
Test/Kit	25T/Kit

Influenza A+B/RSV

Description

The Influenza A+B/RSV test differentiates between two different viral respiratory infections and bacterial respiratory infections with similar clinical symptoms to prevent inappropriate antiviral or antibiotic prescriptions and shorten the recovery time of the patient through the appropriate antiviral prescription.

Indication

Influenza A and B, RSV infection.

Diagnostics Value

The Influenza A+B/RSV tests identify which of viral Flu and bacterial RSV is causing the infection. This identification should help clinicians with treatment schemes including medications, preventing exposure to unnecessary medication due to lack of information on the pathogen.

Selection guide

Item / Platform	ichroma™ M2	ichroma™ II	ichroma™ III	ichroma™-50
ichroma™ Influenza A+B/RSV	●	●	●	●

Specification

Sample type	Nasopharyngeal swab
Assay time	10 min
Working range	Qualitative
Storage	1-30°C
Shelf life	18 months

Performance

Accuracy	Clinical sensitivity	Influenza A: 96.0%, Influenza B: 98.7%, RSV: 96.0%
	Clinical specificity	Influenza A: 100%, Influenza B: 100%, RSV: 99.1%

Ordering information

Cat #	CFPC-80
Test/Kit	25T/Kit

Norovirus (NORO)

Description

Norovirus is very difficult to inactivate, so it spreads rapidly through contaminated drinking water and food (fish and shellfish, etc.) and is a major factor causing large-scale group food poisoning. Early diagnosis through ichroma™ ROTA test prevents group food poisoning through transmission and helps patients recover quickly through appropriate treatment.

Indication

Acute gastroenteritis, Norovirus gastroenteritis.

Diagnostics Value

Infections by the norovirus can spread to the community fast and can be a serious health hazard that requires an immediate response. Confirmation by ELISA or PCR takes hours and days depending on the clinical support structure. ichroma™ ROTA test can deliver the test result in 12 minutes without the PCR, which makes them an ideal choice for field clinics and care service providers for the elderly.

Selection guide

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

Specification

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

Performance

Accuracy	Clinical sensitivity: 88.6% Clinical specificity: 99.0%
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Ordering information

Cat #	CFPC-76
Test/Kit	25T/Kit

Respiratory Syncytial Virus (RSV)

Description

The RSV test helps to prevent inadequate antiviral or antibiotic prescriptions by distinguishing it from flu or bacterial respiratory infections that are similar to clinical symptoms of RSV infection, and to shorten the patient's recovery time through appropriate symptomatic therapy.

Indication

Acute Respiratory Syncytial Virus (RSV) infection.

Diagnostics Value

RSV infection has an epidemic cycle and infection symptoms similar to those of the flu but is more lethal to infants, the elderly and immune-reduced patients as antiviral agents for RSV are not available. RSV tests can help clinical practitioners without access to a PCR diagnose RSV and provide treatment plans accordingly.

Selection guide

Item / Platform	ichroma™ M2	ichroma™ II	ichroma™ III
ichroma™ RSV	●	●	●

Specification

Sample type	Nasopharyngeal swab
Assay time	10 min
Working range	Qualitative
Storage	4-30°C
Shelf life	18 months

Performance

Accuracy	Clinical sensitivity: 91.3% Clinical specificity: 100%
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Ordering information

Cat #	CFPC-88
Test/Kit	25T/Kit

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°C
Shelf life	20 months

Performance

Accuracy	Positive: 99.02% Negative: 95.23% Overall: 97.10%
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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 misdiagnosis 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°C
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°C
Shelf life	18 months

Performance

Accuracy	Clinical sensitivity: 81.9% Clinical specificity: 98.8%
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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°C
Shelf life	20 months

Performance

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

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

Autoimmune

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

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°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=1.082x - 12.038$ $R=0.9035$
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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°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=0.9954x + 1.0943$ $R=0.9982$
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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°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

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

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

Other test items

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

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°C
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°C for DB/4-30°C for Cartridge
Shelf life	20 months

Performance

Accuracy	$y=0.99198x + 0.56317$ R=0.9897
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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°C
Shelf life	20 months

Performance

		Reference ELISA result		
		Positive	Negative	Total
ichroma™ H. pylori SA	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°C
Shelf life	20 months

Performance

Accuracy	$y=1.1629x - 0.2829$ $R=0.9951$
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Ordering information

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

Molecular diagnostics

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

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 μ L sample to 100 μ L 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°C
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°C
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°C	2-30°C	2-8°C	2-8°C	-20°C	-20°C
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°C	-20°C
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°C	2-8°C
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°C	2-30°C (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 make 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 genes 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°C .

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 $^{\circ}\text{C}$	-20 $^{\circ}\text{C}$
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°C	2-8°C
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°C	2-8°C (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

ExAmpliar 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	ExAmpliar
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°C	-20°C
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)

ExAmpliar 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	ExAmpliar
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°C	-20°C
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°C	-20°C
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)

ExAmpliar 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	ExAmpliar
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°C	2-8°C (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/Molecular diagnostics/ Instruments/Accessories	108
Controls/Calibrators	109

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

Control item	Catalog No.
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



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

Vol.03_20210531

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.

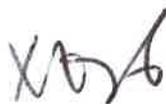
- REGULATION (EU) 2017/746 OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- DIRECTIVE 2011/65/EC OF EUROPEAN OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 8 June 2011 on the restriction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

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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)



DECLARATION OF CONFORMITY

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

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

Product: Boditech 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.

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



DECLARATION OF CONFORMITY

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

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

Product: 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,
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, 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).

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

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

Taikomi standartai: ISO 15223-1:2016, EN ISO 13485:2016, EN13612:2002,
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 d.

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

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

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



Boditech Med Inc. www.boditech.co.kr

43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Korea
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