

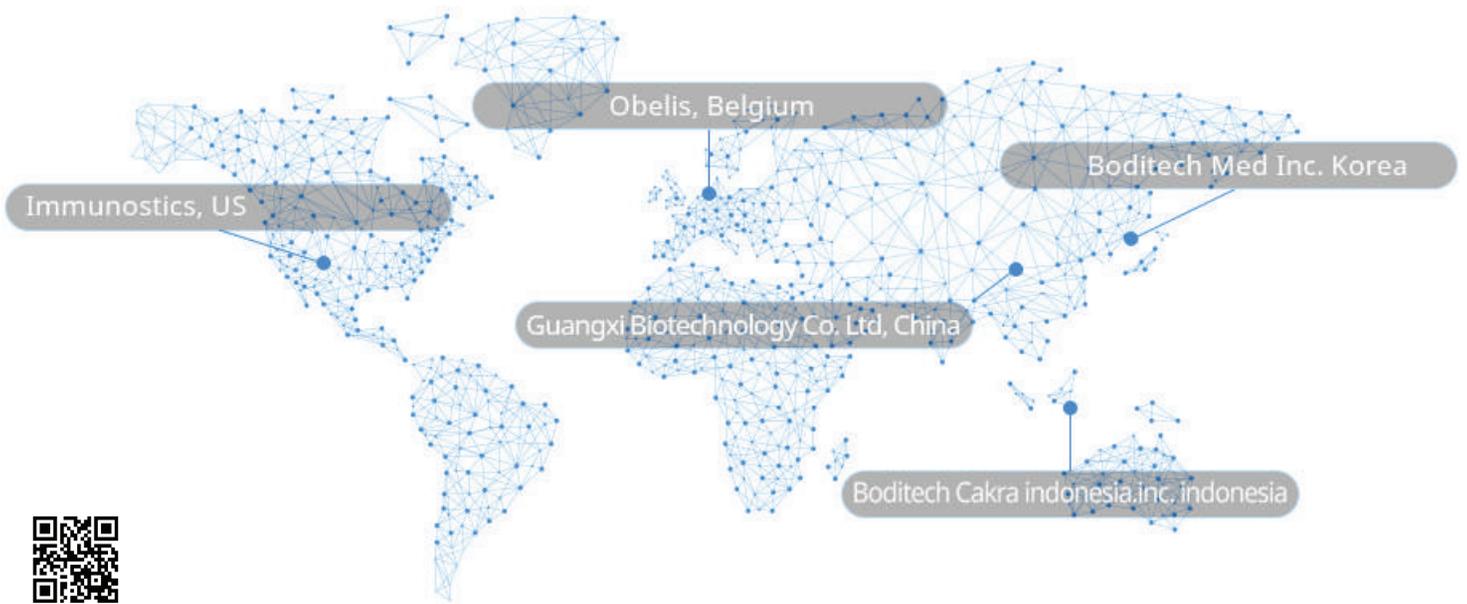
BIO ● TECHNOLOGY  
boditech

V00.171031

# Boditech product catalog



Boditech Med Inc. pursues its fundamental corporate value 'Respect for Life' with a focus on high quality, user friendliness products. Boditech is making relentless efforts to develop world-class in vitro diagnostics instruments and reagents. The goal is to provide everyone with safe and convenient diagnostic products to improve human health and well-being.



## Overview

Since the establishment in 1998, Boditech Med Inc. has provided high quality in vitro diagnostics analyzers and reagents to customers worldwide. The company has significantly grown at a tremendous rate over the years. Boditech is currently committed to providing over 90 countries with several analyzers called ichroma™, AFIAS and Hemochroma Plus.

Boditech will continue its efforts to enhance human health and wellness by providing a wider range of diagnostic biomarkers and automated analyzers throughout the world.

## History

- 1998 Established
- 2001 Obtained as a National Research Laboratory
- 2004 CE approval, ISO 13485 Certificate
- 2006 Launch ichroma in China
- 2007 CRP U.S. FDA 510(k) cleared
- 2014 iFOB U.S. FDA 510(k) cleared
- 2015 Listed on KOSDAQ (206640.KQ)
- 2016 Aquired Immunostics, Inc.
- 2017 Hemochroma PLUS  
U.S. FDA CLIA Waived  
AFIAS TSH U.S. FDA 510(k)

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# ichroma™ Parameters

Product class	Test items	Sample type	Working ranges	ichroma™	ichroma™ II	ichroma™-50
Cardiac	Tn-I	S/P	0.1-50.0 ng/mL	●	●	
	Tn-I Plus	WB/S/P	0.01-15.00 ng/mL		●	
	CK-MB	WB/S/P	3-100 ng/mL	●	●	
	D-Dimer	WB/P	50-10,000 ng/mL	●	●	
	NT-proBNP	WB/S/P	10-30,000 pg/mL		●	
	Myoglobin	WB/S/P	5-500 ng/mL	●	●	
	hsCRP	WB/S/P	0.1-10.0 mg/L	●	●	
	Cardiac Triple	WB/S/P	Tn-I: 0.01-15.00 ng/mL CK-MB: 3-100 ng/mL Myoglobin: 5-500 ng/mL		●	
Cancer	PSA	S/P	0.1-100.0 ng/mL	●	●	
		WB	0.5-100.0 ng/mL	●	●	
	PSA Plus	WB/S/P	0.07-50.00 ng/mL		●	
	AFP	WB/S/P	5-350 ng/mL	●	●	
	AFP Plus	WB/S/P	0.5-350.0 ng/mL		●	
	CEA	S/P	1-500 ng/mL	●	●	
	CEA Plus	WB/S/P	0.5-200.0 ng/mL		●	
iFOB	Feces	25-1,000 ng/mL	●	●		
Diabetes	HbA1c	WB	(NGSP) 4-15 %	●	●	
	Microalbumin	Urine	2-300 mg/L	●	●	
	Cystatin C	S/P	0.1-7.5 mg/L	●	●	
Hormone	TSH	S/P	0.1-100.0 µIU/mL	●	●	
	TSH Plus	WB/S/P	0.1-50.0 µIU/mL		●	
	T3	S/P	0.77-7.70 nmol/L	●	●	
	T4	S/P	10.23-300.00 nmol/L	●	●	
	FSH	S/P	1-100 mIU/mL	●	●	
	FSH Plus	WB/S/P	0.1-110.0 mIU/mL		●	
	Progesterone	S/P	4.45-127.20 nmol/L	●	●	
	hCG	S/P	2-3,000 mIU/mL	●	●	●
	β-hCG	WB/S/P	5-50,000 mIU/mL	●	●	
	β-hCG Plus	WB/S/P	2-5,000 mIU/mL		●	
	LH	S/P	1-100 mIU/mL	●	●	
	LH Plus	WB/S/P	0.1-100.0 mIU/mL		●	
	PRL	S/P	1-100 ng/mL	●	●	
	PRL Plus	WB/S/P	0.5-200 ng/mL		●	
	Testosterone	S/P	1-10 ng/mL	●	●	
Cortisol	WB/S/P	80-800 nmol/L	●	●		
Infection	CRP	WB/S/P	2.5-300.0 mg/L	●	●	●
	PCT	WB/S/P	0.1-100.0 ng/mL	●	●	●
	PCT Plus	WB/S/P	0.02-50.00 ng/mL		●	●
	ASO	S/P	25-800 IU/mL	●	●	
	HBsAg	WB/S/P	0-300 COI		●	
	Anti-HBs	WB/S/P	0-500 mIU/mL		●	
	Anti-HCV	WB/S/P	0-300 COI		●	
	ROTA	Feces	qualitative		●	
	Rota/Adeno	Feces	qualitative		●	
	NORO	Feces	qualitative		●	
	Dengue NS1 Ag	WB/S/P	qualitative		●	
	Dengue IgG/IgM	WB/S/P	qualitative		●	
	Zika IgG/IgM	WB/S/P	qualitative		●	
	HIV Ag/Ab	WB/S/P	qualitative		●	
	Influenza A+B	Nasopharyngeal swap Nasal aspirates	qualitative		●	
	Strep A	Nasopharyngeal swap Nasal aspirates	4 x 10 <sup>3</sup> cfu/test		●	
	Influenza/RSV	Nasopharyngeal swap Nasal aspirates	qualitative		●	
	Rheumatoid Arthritis	RF IgM	WB/S/P	8-200 IU/mL	●	●
Anti-CCP		WB/S/P	5-200 U/mL		●	
Others	Ferritin	S/P	10-1,000 ng/mL	●	●	
	Ferritin Plus	WB/S/P	1.5-1,000 ng/mL		●	
	Vitamin D	S/P	8-70 ng/mL	●	●	
	Calprotectin	Feces	10-1,000 mg/kg	●	●	●
	iFOB/Calp. Combo	Feces	iFOB: 25-1,000 ng/mL Calprotectin: 10-1,000 mg/kg		●	●
	H. pylori SA	Feces	qualitative	●	●	

## AFIAS Parameters

Product class	Test items	Sample type	Working ranges
<b>Cardiac</b>	Tn-I Plus	WB/S/P	0.01-15.00 ng/mL
	CK-MB	WB/S/P	3-100 ng/mL
	D-Dimer	WB/P	50-10,000 ng/mL
	NT-proBNP	WB/S/P	10-30,000 pg/mL
	Myoglobin	WB/S/P	2-500 ng/mL
<b>Cancer</b>	PSA	WB/S/P	0.5-100.0 ng/mL
	AFP	WB/S/P	5-350 ng/mL
	CEA	S/P	1-500 ng/mL
<b>Diabetes</b>	HbA1c	WB	(NGSP) 4-15 %
	Microalbumin	Urine	2-300 mg/L
<b>Hormone</b>	TSH	S/P	0.09-80.00 $\mu$ IU/mL
		WB	0.4-80.0 $\mu$ IU/mL
	T3	S/P	0.77-7.70 nmol/L
	T4	S/P	10.23-300.00 nmol/L
	FSH	WB/S/P	1-100 mIU/mL
	Total $\beta$ hCG	WB/S/P	5-50,000 mIU/mL
	LH	S/P	1-100 mIU/mL
	PRL	WB/S/P	1-100 ng/mL
	Testosterone	S/P	1-10 ng/mL
Cortisol	WB/S/P	80-800 nmol/L	
<b>Infection</b>	CRP	WB/S/P	0.5-200.0 mg/L
	PCT	WB/S/P	0.1-100.0 ng/mL
	PCT Plus	WB/S/P	0.02-50.00 ng/mL
	ROTA	Feces	qualitative
	Rota/Adeno	Feces	qualitative
	NORO	Feces	qualitative
	HBsAg	WB/S/P	0-300 COI
	Anti-HBs	WB/S/P	0-500 mIU/mL
	Anti-HCV	WB/S/P	0-300 COI
	Dengue NS1 Ag	WB/S/P	qualitative
	Dengue IgG/IgM	WB/S/P	qualitative
	Zika IgG/IgM	WB/S/P	qualitative
	HIV Ag/Ab	WB/S/P	qualitative
<b>Others</b>	Ferritin	S/P	10-1,000 ng/mL

Some items are not available in USA



# immuno-analyzer

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# ichroma™ II

## Advanced compact immuno-analyzer

- ▶ QC & system check
- ▶ Multi-timer function
- ▶ Battery & AC operated
- ▶ LIS / HIS connectivity



ichroma™ II is an automatic or semiautomatic in-vitro diagnostic device that measures the concentration of analytes, contained in blood, urine, or other samples, in quantitative or semi-quantitative ways. Compared to the first-generation device, ichroma™, ichroma™ II has an improved user interface and display and an advanced optical system, which provide the user with disease test options in wide range.

In addition, ichroma™ II was designed to improve data input efficiency and wireless communication connectivity through separately sold accessories and program update can be easily proceeded using SD card. The use of batteries improves portability, which is one of the biggest advantages of point-of-care testing (POCT) equipment, and ensures reliable testing in unstable power environments.

### Specification

Item	Specification
Cat#	FPRR021
Dimensions	276 mm (L) x 220 mm (W) x 91 mm (H)
Weight	1.3 kg
Power supply	DC 12V/5A, AC/DC Adaptor, (AA battery) DC 1.5V X 4ea Input 100-240V ~ 50/60Hz, 1.8A, Output DC 12V/5A
Data output	LCD / Internal Printer / LAN
Operation temperature	15 ~ 35°C (59 ~ 95°F)
Memory	1,000 patient results 1,000 QC results 500 ID chips 100 User IDs
Interface	RS-232 1 Port USB 4 Ports LAN 1 Port SD Card Slot 1 Port
Display LCD	7" touch color LCD



# AFIAS-6

## Versatile Desktop immuno-analyzer

- ▶ Automated desktop analyzer
- ▶ 10, 30, and 50  $\mu$ L fingertip blood (C-Tip)
- ▶ 6 different tests on 6 different channels
- ▶ Bay random access (2 bays)
- ▶ LIS ready (LAN/WiFi)
- ▶ US FDA 510(K)



AFIAS platform is a fluorescence-scanning instrument to be used in conjunction with various AFIAS tests which are based on antigen-antibody reaction and fluorescence technology (Fluorescence Immuno-Assay). AFIAS uses a semiconductor diode laser as the excitation light source for illuminating the sample-loaded AFIAS cartridge(s) inserted in its cartridge slot(s); thereby triggering fluorescence from the fluorochrome-labeled complexes of analyte accumulated at the test line on the cartridge membrane. For some specified items such as TSH, CRP, PCT and HbA1c, small volume (10, 30 or 50  $\mu$ L) of whole blood from a finger or heel can be used for quantitative testing using a C-tip (capillary tip).

### Specification

Item	Specification
Cat#	FPRR020
Dimensions	420 mm (L) x 336 mm (W) x 293 mm (H)
Weight	15.1 Kg
Power supply	100-240V AC, 50~60 Hz, 1.8A
Data output	LCD / Internal Printer / RS-232 Port
Operation temperature	15 ~ 35°C (59 ~ 95°F)
Memory	5,000 patient results 5,000 QC results 500 ID chips 100 User IDs
Throughput	Up to 36 tests / hour
Interface	RS-232 1 Port USB 4 Ports LAN 1 Port SD Card Slot 1 Port
Display LCD	7" Touch-screen



# AFIAS-1

## Versatile Desktop immuno-analyzer

- ▶ 1 channel
- ▶ LIS / HIS connectivity
- ▶ All-in-one cartridge
- ▶ 10, 30, and 50  $\mu$ L Fingertip blood (C-Tip)
- ▶ Walk away function
- ▶ LIS ready (LAN / WiFi)



AFIAS platform is a fluorescence-scanning instrument to be used in conjunction with various AFIAS tests which are based on antigen-antibody reaction and fluorescence technology (Fluorescence Immuno-Assay). AFIAS uses a semiconductor diode laser as the excitation light source for illuminating the sample-loaded AFIAS cartridge(s) inserted in its cartridge slot(s); thereby triggering fluorescence from the fluorochrome-labeled complexes of analyte accumulated at the test line on the cartridge membrane. For some specified items such as TSH, CRP, PCT and HbA1c, small volume (10, 30 or 50 $\mu$ L) of whole blood from a finger or heel can be used for quantitative testing using a C-tip (capillary tip).

### Specification

Item	Specification
Cat#	FPRR019
Dimensions	320.6 mm (L) x 180.6 mm (W) x 206.4 mm (H)
Weight	4.0 Kg
Power supply	Input 100-240V AC, 50-60 Hz, 1.5A, Output DC 12V/5A
Data output	LCD / Internal Printer / USB OTG Port
Operation temperature	15 ~ 35°C (59 ~ 95°F)
Memory	5,000 patient results 5,000 QC results 500 ID chips 100 User IDs
Throughput	Up to 10 tests / hour
Interface	USB OTG 1 Port USB 4 Ports LAN 1 Port SD Card Slot 1 Port
Display LCD	5" Touch-screen



# ichroma™-50

## World first automated dry immunoassay system

- ▶ Fully automated high throughput
- ▶ No extra cost for consumables
- ▶ Up to 80 tests/hour
- ▶ Up to 50 samples/set
- ▶ LIS ready (LAN / WiFi)
- ▶ FDA 510(K)



ichroma™-50 is an automatic immunoassay analyzer that measures the concentration of targeted analyte in body fluids such as blood, urine, and other samples. ichroma™-50 is designed for processing / analyzing large volumes of samples and can carry up to 80 tests per hour (depending on the type of item). In the case of blood samples, the ichroma™-50 removes the inconvenience of transferring the samples separately for testing because it collects sample from 3 ml blood tubes, which are commonly used worldwide, and provides automated testing results. The ichroma™-50 is suitable for medical institutions that need to process / analyze large volumes of samples, such as large / general hospitals and blood banks, and can efficiently manage test results with advanced storage capabilities and LIS / HIS connectivity.

### Specification

Item	Specification
Cat#	FPRR022
Dimensions	610 mm (L) x 610 mm (W) x 606 mm (H)
Weight	49 Kg
Power supply	110-240V AC, 47~63 Hz, 1.1-2.2A
Data output	LCD / built-in Printer / RS-232 Port
Operation temperature	15 ~ 35°C (59 ~ 95°F)
Memory	5,000 patient results 5,000 QC results 500 ID chips 100 User IDs
Throughput	Up to 80 tests/hour
Interface	RS-232 1 Port USB 4 Ports LAN 1 Ports LCD / Built-in printer SD Card / Slot 1 Port Mini USB 1 Port
Display LCD	10.1" TFT LCD (touch screen)



# ichroma™

## Economical compact immuno-analyzer



- ▶ 3-15 minutes per test (depending on the parameter)
- ▶ 1.2 kgs, compact & sturdy
- ▶ LIS / HIS connectivity
- ▶ FDA 510(K)



The ichroma™ reader is a first-generation portable fluorescent scanner that analyzes blood, urine, and other samples and displays measurement results on the screen. More than 30 immunoassay test cartridges can be measured using the ichroma™ reader.



### Specification

Item	Specification
Cat#	FR203
Dimensions	250 mm (L) x 185 mm (W) x 80 mm (H)
Weight	1.2 Kg
Power supply	100-240 V AC, 50~60 Hz
Data output	LCD / Printer (option)
Operation temperature	15 ~ 35°C (59 ~ 95°F)
Interface	RS-232 1 Port
Display LCD	5 Lines LCD



# ichroma™ M

True mobile immuno-analyzer with sensitivity of auto-analyzer

- ▶ High accuracy
- ▶ Simple to use
- ▶ True mobile (Battery operated)



## \* Time-resolved fluorescence



ichroma™ M is a small, battery operated true mobile diagnostic device with new sensitive technology, comparable to accuracy of auto-analyzer. With respiratory tests panel and high sensitivity, ichroma™ M will bring the test laboratory on your palm.

## Specification

Item	Specification
Cat#	FPRR026
Dimensions	202 mm (L) x 83 mm (W) x 45 mm (H)
Weight	350 g
Power supply	Battery (AA 1.5V x 4ea)
Data output	LCD / USB mini B
Operation temperature	15 ~ 35°C (59~95°F)
Throughput	Up to 80 tests/hour
Interface	Mini USB 1 Port
Display LCD	3.5 in LCD



# hemochroma PLUS

## Total Hemoglobin meter

- ▶ Fast and Simple
- ▶ Cuvette with Dual Sample Inlets
- ▶ Capillary blood + Tube blood
- ▶ US FDA CLIA Waived



hemochroma PLUS is an in vitro diagnostic device dedicated to quantitative testing of total hemoglobin concentration in the blood. It is lightweight with small dimensions and battery operated. It is easy to operate and convenient. It provides accurate and reliable inspection results compared with large analyzers.

### Specification

Item	Specification
Cat#	FPRR005
Dimensions	106.5 mm (L) x 151.0 mm (W) x 38.5 mm (H)
Weight	215 ± 3 g
Power supply	Battery (AA 1.5V x 4ea) / Adaptor / USB power
Data output	LCD, thermal printer (option)
Operation temperature	15 ~ 35°C (59 ~ 95°F)
Measuring time	3 sec
Detection range	5.0-25.6 g/dL
Sample	Whole blood (Capillary, tube blood (15 µL))
Memory	Test results up to 1,000
Interface	RS-232 1 Port USB
Display LCD	3.2" TFT color LCD



## i-chamber



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

### Specification

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

## HandyRay Laser Lancing Device



HandyRay is a modern lancet device equipped with laser technology. With help of laser technology, collecting fingertip blood requires no needle and waste. HandyRay also reduces the pain and helps fast recovery of skin.

### Specification

Item	Specification
Laser level range	1~5 step
Repetition	Single shot operation
Laser class	Class IV Laser
Battery charger	Max 4.2Vdc
Pulse durations	250us
Disposable	Cap (100ea/box)



# Cardiac

CK-MB	15
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# Creatine Kinase (CK-MB)

Creatine Kinase (CK), also known as Creatine Phosphokinase or Phospho-creatine Kinase is an enzyme expressed by various tissues and cell types. Disruption of cell membranes due to hypoxia or other injury releases CK from the cellular cytosol into the systemic circulation. CK is a dimeric enzyme consisting of two subunits, which can be either B- (brain type) or M- (muscle type).



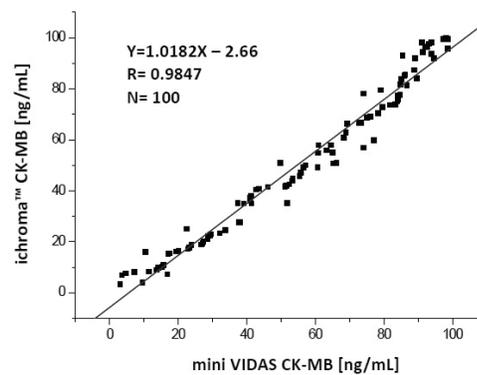
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ CK-MB	•	•		
AFIAS CK-MB			•	

## Specification

	ichroma™ CK-MB	AFIAS CK-MB
Sample type	WB/S/P	WB/S/P
Sample vol.	75 µL	100 µL
Assay time	12 min	12 min
Working range	3-100 ng/mL	3-100 ng/mL
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ CK-MB	CFPC-33	25T/Kit
AFIAS CK-MB	SMFP-13	24T/Kit



# D-Dimer

D-Dimer, a degradation product of cross-linked fibrin formed during activation of the coagulation system, is commonly used to exclude thromboembolic disease in outpatients suspected of having deep venous thrombosis (DVT) and pulmonary embolism.

## Selection Guide

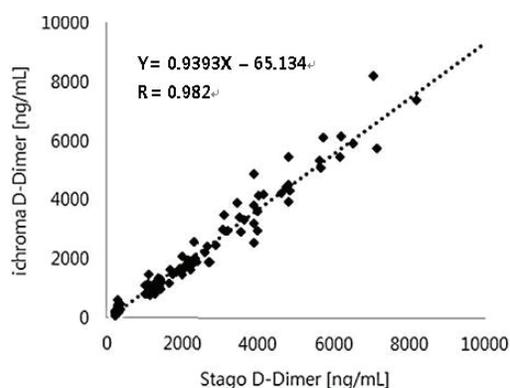
Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ D-Dimer	•	•		
AFIAS D-Dimer			•	



## Specification

	ichroma™ D-Dimer	AFIAS D-Dimer
Sample type	WB/P	WB/P
Sample vol.	10 µL	100 µL
Assay time	12 min	12 min
Working range	50-10,000 ng/mL	50-10,000 ng/mL
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ D-Dimer	CFPC-25	25T/Kit
AFIAS D-Dimer	SMFP-4	24T/Kit



# High-sensitivity C-Reactive Protein (hsCRP)

A growing body of evidence has supported the idea that cardiovascular diseases including coronary heart disease, ischemic stroke, and acute myocardial infarction, develop, at least in part, because of a chronic low-level CRP of the vascular endothelium. Apparently, high-sensitivity CRP (hsCRP) is emerging as the strongest and most independent predictive risk factor for atherosclerosis and CVD. American Heart Association (AHA) and the Centers for Disease Control and Prevention (CDC) issued a statement regarding use of C reactive protein to assess risk of cardiovascular diseases.



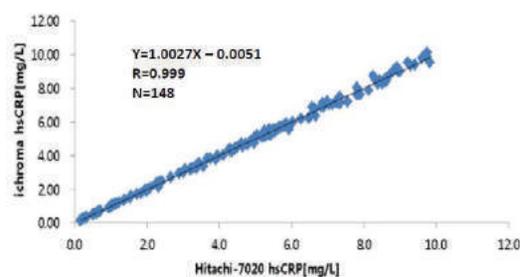
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ hsCRP	•	•		

## Specification

	ichroma™ hsCRP
Sample type	WB/S/P
Sample vol.	10 µL
Assay time	3 min
Working range	0.1-10 mg/L
Performance	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge
Shelf life	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ hsCRP	CFPC-6	25T/Kit



# Myoglobin

Myoglobin is an iron- and oxygen-binding protein found in both skeletal and myocardial muscles. It acts as a transport protein and is involved in diffusion of oxygen in the muscle tissue. Myoglobin is released into the serum more rapidly as compared to other cardiac markers upon damage to the myocardial cells.



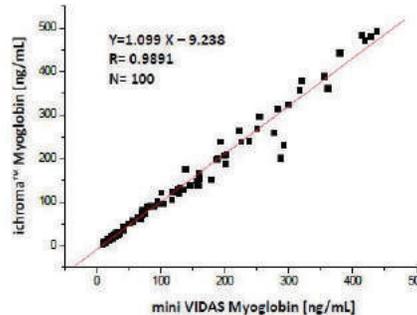
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ Myoglobin	•	•		
AFIAS Myoglobin			•	

## Specification

	ichroma™ Myoglobin	AFIAS Myoglobin
Sample type	WB/S/P	WB/S/P
Sample vol.	10 µL	100 µL
Assay time	12 min	12 min
Working range	5-500 ng/mL	2-500 ng/mL
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ Myoglobin	CFPC-37	25T/Kit
AFIAS Myoglobin	SMFP-34	24T/Kit



# NT-proBNP

NT-proBNP immunoassays are widely used and are now considered to be a useful marker and have a high degree of diagnostic accuracy in clinical practice and cardiovascular research as a diagnostic tool for the occurrence and severity of heart failure (HF). Therefore NT-proBNP measurements in human blood are helpful not only for the cardiac disease diagnosis but also for evaluation of patients with suspected HF and assessment of severity of the disease.



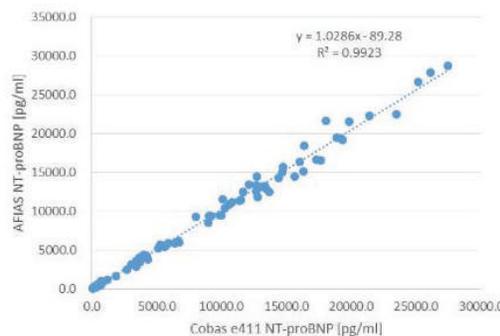
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ NT-proBNP		•		
AFIAS NT-proBNP			•	

## Specification

	ichroma™ NT-proBNP	AFIAS NT-proBNP
Sample type	WB/S/P	WB/S/P
Sample vol.	50 µL	100 µL
Assay time	12 min	12 min
Working range	10-30,000 pg/mL	10-30,000 pg/mL
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ NT-proBNP	CFPC-49	25T/Kit
AFIAS NT-proBNP	SMFP-36	24T/Kit



# Troponin-I (Tn-I)

Cardiac troponins are currently the most sensitive and specific biochemical markers of myocardial necrosis. There are three types of troponin in heart muscle fibers. Those are troponin-C, -I, and -T. Together they contribute to make cardiac muscle fibers contract. Serum Tn-I is a more reliable than creatine kinase as a prognostic marker in people with ischemic chest pain.

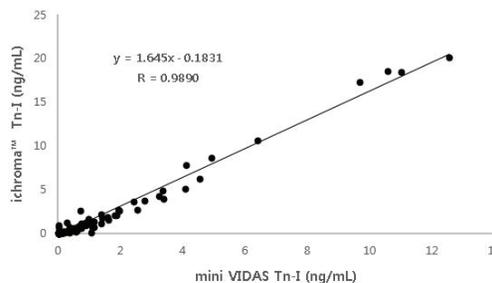
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ Tn-I	•	•		
ichroma™ Tn-I Plus		•		
AFIAS Tn-I Plus			•	

## Specification

	ichroma™ Tn-I	ichroma™ Tn-I Plus	AFIAS Tn-I Plus
Sample type	S/P	WB/S/P	WB/S/P
Sample vol.	75 µL	50 µL	100 µL
Assay time	12 min	12 min	12 min
Working range	0.1-50.0 ng/mL	0.01- 15.00 ng/mL	0.01- 15.00 ng/mL
Performance	CV < 10%	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ Tn-I	13011	25T/Kit
ichroma™ Tn-I Plus	CFPC-65	25T/Kit
AFIAS Tn-I Plus	SMFP-35	24T/Kit





# Cardiac Triple

Blood protein markers play an important role in the diagnosis of acute myocardial infarction (AMI) and acute coronary syndrome (ACS). Cardiac troponin-I (Tn-I), creatine kinase (CK-MB), and myoglobin are key members of them. CK-MB levels can be considered as an important diagnostic indicator of myocardial infarction and has been found to be more sensitive and early indicator of myocardial injury. Tn-I is more reliable than creatine kinase as a prognostic marker in people with ischemic chest pain. Myoglobin is a promising cardiac marker when other markers such as CK-MB and Tn-I as well as other indicators like clinical signs and ECG are taken into account for diagnosis/confirmation of AMI.



## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ Cardiac Triple		•		

## Specification

	ichroma™ Cardiac Triple
Sample type	WB/S/P
Sample vol.	75 µL
Assay time	12 min
Working range	Tn-I: 0.01-15.00 ng/mL CK-MB: 3-100 ng/mL Myoglobin: 5-500 ng/mL
Performance	CV<10%
Storage	2-8°C for DB / 4-30°C for Cartridge
Shelf life	20 months

## Ordering information

	Cat #	Test/Kit
ichroma™ Cardiac Triple	CFPC-78	25T/Kit



# Cancer

AFP	23
CEA	24
iFOB	25
PSA	26



# Alpha-Fetoprotein (AFP)

Alpha-fetoprotein (AFP) is a alpha1-globulin family of human plasma proteins. AFP is produced primarily in the liver of developing fetus. It can be found in maternal blood and in amniotic fluid since it is secreted into fetal serum. A great increase of AFP concentration in several malignant diseases mostly is primary hepatocellular carcinoma and non-seminomatous testicular cancer. Since AFP is well known to be an important prognostic indicator of non-seminomatous testicular cancer, its most definitive role is on monitoring post-treatment clinical status and the post therapeutic evaluation of patients.

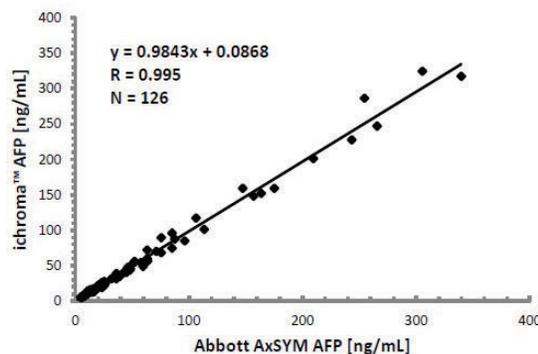
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ AFP	•	•		
ichroma™ AFP Plus		•		
AFIAS AFP			•	

## Specification

	ichroma™ AFP	ichroma™ AFP Plus	AFIAS AFP
Sample type	WB/S/P	WB/S/P	WB/S/P
Sample vol.	30/15/15 µL	35 µL	100 µL
Assay time	15 min	12 min	15 min
Working range	5-350 ng/mL	0.5-350.0 ng/mL	5-350 ng/mL
Performance	CV < 10%	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ AFP	i-CHROMA AFP-25	25T/Kit
ichroma™ AFP Plus	CFPC-73	25T/Kit
AFIAS AFP	SMFP-27	24T/Kit





# CEA

CEA is an oncofetal glycoprotein, which is found at high levels in the fetal colon and at lower levels in the normal adult colonic epithelium. CEA occurs at abnormally high levels in several benign disorders and in some malignant tumors, including those of the stomach, small intestine, colon, rectum, pancreas, liver, breast, ovary, cervix, and lung. Serum CEA levels have been useful in monitoring individuals for the recurrence of cancer.

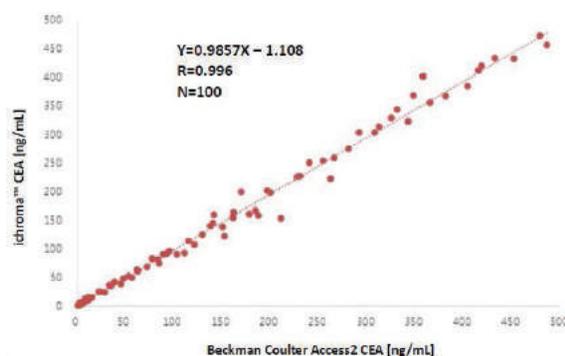
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ CEA	•	•		
ichroma™ CEA Plus		•		
AFIAS CEA			•	

## Specification

	ichroma™ CEA	ichroma™ CEA Plus	AFIAS CEA
Sample type	S/P	WB/S/P	S/P
Sample vol.	150 µL	35 µL	200 µL
Assay time	12 min	12 min	12 min
Working range	1-500 ng/mL	0.5-200.0 ng/mL	1-500 ng/mL
Performance	CV < 10%	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ CEA	13013	25T/Kit
ichroma™ CEA Plus	CFPC-72	25T/Kit
AFIAS CEA	SMFP-21	24T/Kit





# Fecal Occult Blood (iFOB)

▶ FDA 510(k)

Colorectal cancer is the third most common cancer in the world, with about 1 million new cases and more than 500,000 deaths per year. The standard Guaiac-FOB test has low sensitivity to clinically significant colorectal neoplasia and has low specificity due to its non-specificity for human Hb. To overcome these potential problems in immunochemical test, ichroma™ iFOB uses specific monoclonal antibodies against human Hb as capture and detection buffer.



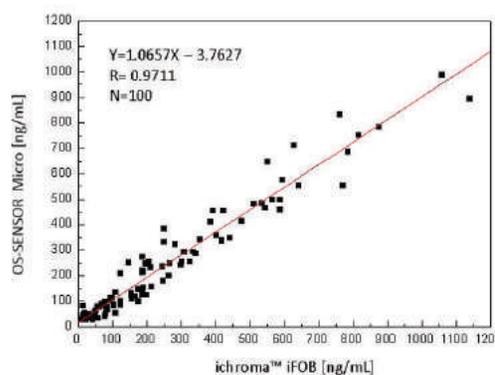
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ iFOB	•	•		
ichroma™ iFOB Neo	•	•		•

## Specification

	ichroma™ iFOB	ichroma™ iFOB Neo
Sample type	Feces	Feces
Sample vol.	Spot	10 mg
Assay time	10 min	10 min
Working range	25-1,000 ng/mL	25-1,000 ng/mL
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	4-30°C
Shelf life	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ iFOB	CFPC-15	25T/Kit
ichroma™ iFOB Neo	CFPC-15-1	25T/Kit



# Prostate Specific Antigen (PSA)

Prostate specific antigen (PSA), a neutral serine protease with chymotrypsin-like activity, is composed of a single polypeptide chain of 237 amino acids. PSA is exclusively synthesized by the prostate epithelium and mainly released into the semen. Normally very small amounts of PSA are secreted and detected in male blood. The blood level of PSA is often elevated in men with prostate cancer.

## Selection Guide

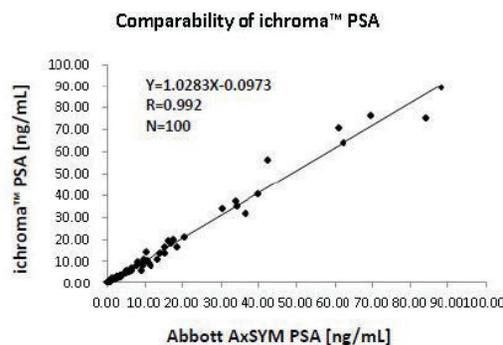
Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ PSA	•	•		
ichroma™ PSA Plus		•		
AFIAS PSA			•	

## Specification

	ichroma™ PSA	ichroma™ PSA Plus	AFIAS PSA
Sample type	WB/S/P	WB/S/P	WB/S/P
Sample vol.	75 µL	35 µL	100 µL
Assay time	15 min	12 min	15 min
Working range	S/P : 0.1-100.0 ng/mL WB : 0.5-100.0 ng/mL	0.07-50.00 ng/mL	0.5-100.0 ng/mL
Performance	CV < 10%	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months	20 months



## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ PSA	i-CHROMA PSA-25	25T/Kit
ichroma™ PSA Plus	CFPC-71	25T/Kit
AFIAS PSA	SMFP-9	24T/Kit



# Diabetes

Cystatin C	28
HbA1c	29
Microalbumin	30



# Cystatin C

The level of serum cystatin C has been proposed as a simple, accurate, and rapid endogenous marker of glomerular filtration rate (GFR) in research and clinical practice. The measurement of serum cystatin C may detect mild to moderate decrease in GFR that are not evident with the serum creatinine measurement. In kidney transplant patients, cystatin C was reported to be more sensitive than serum creatinine for detecting decreases in GFR and delayed graft function, offering an opportunity for timely intervention.



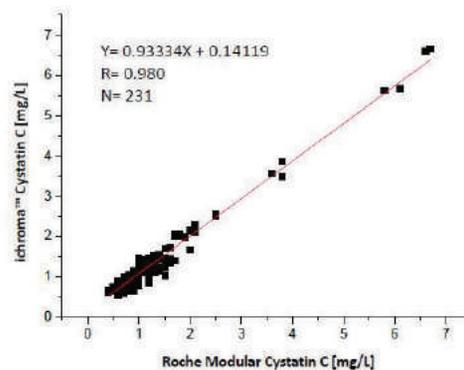
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ Cystatin C	•	•		

## Specification

	ichroma™ Cystatin C
Sample type	S/P
Sample vol.	10 µL
Assay time	10 min
Working range	0.1-7.5 mg/L
Performance	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge
Shelf life	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ Cystatin C	CFPC-43	25T/Kit



# HbA1c

Glycated protein is formed post-translationally through the slow, nonenzymatic reaction between glucose and amino groups on proteins. HbA1c is a clinically useful index of mean glycemia during the preceding 120 days, the average life span of erythrocytes. Carefully controlled studies have documented a close relationship between the concentrations of HbA1c and mean glycemia. HbA1c is considered as a more reliable parameter in monitoring glycemia over the glycemic reading with the conventional glucometer.



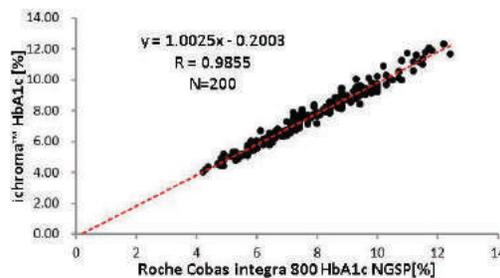
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ HbA1c	•	•		
AFIAS HbA1c			•	

## Specification

	ichroma™ HbA1c	AFIAS HbA1c
Sample type	WB	WB
Sample vol.	5 µL	10 µL
Assay time	12 min	10 min
Working range	4-15 % (NGSP)	4-15 % (NGSP)
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ HbA1c	CFPC-38	25T/Kit
AFIAS HbA1c	SMFP-28	24T/Kit



# Microalbumin

A Microalbumin test evaluates the presence of a protein called albumin in urine. Albumin is normally found in the blood and filtered by the kidneys. When the kidneys are working properly, albumin is not present in urine. However, when the kidneys are damaged, small amounts of albumin leak into the urine. A urine microalbumin test can be done on a sample of urine collected randomly (usually after the first time you urinate in the morning), a sample collected over a 24-hour period, or a sample collected over a specific period, such as 4 hours or overnight.



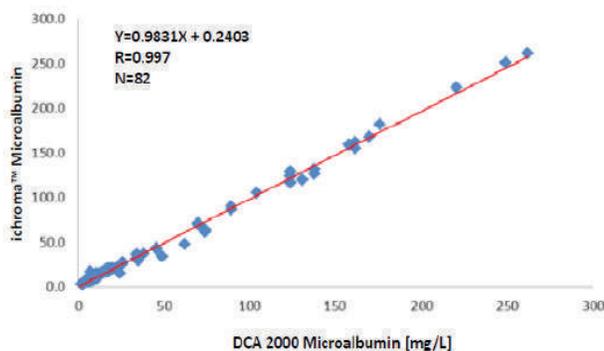
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ Microalbumin	•	•		
AFIAS Microalbumin			•	

## Specification

	ichroma™ Microalbumin	AFIAS Microalbumin
Sample type	Urine	Urine
Sample vol.	10 µL	100 µL
Assay time	12 min	12 min
Working range	2-300 mg/L	2-300 mg/L
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ Microalbumin	i-CHROMA MAU-25	25T/Kit
AFIAS Microalbumin	SMFP-30	24T/Kit



# Hormone

Cortisol	32
FSH	33
hCG	34
$\beta$ -hCG	35
LH	36
Progesterone	37
Prolactin	38
T3	39
T4	40
Testosterone	41
TSH	42



# Cortisol

Cortisol is a potent hormone known as a glucocorticoid that affects the metabolism of carbohydrates, proteins, and fats, but especially glucose. Cortisol test is performed on patients who may have malfunctioning adrenal glands. Cortisol level normally rises and falls during the day. It peaks its highest level between 6 and 8 AM and gradually falls, reaching its lowest point around midnight. When cortisol level is measured, blood specimen is usually collected at 8 AM and again at 4 PM. It should be noted that normal values may be adjusted in individuals who have worked during the night and slept during the day for long periods of time.



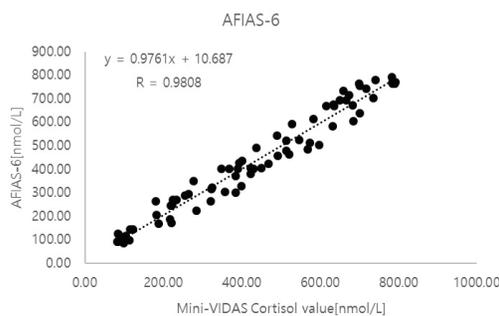
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ Cortisol	•	•		
AFIAS Cortisol			•	

## Specification

	ichroma™ Cortisol	AFIAS Cortisol
Sample type	WB/S/P	WB/S/P
Sample vol.	50/30/30 µL	100 µL
Assay time	10 min	10 min
Working range	80-800 nmol/L	80-800 nmol/L
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ Cortisol	CFPC-24	25T/Kit
AFIAS Cortisol	SMFP-22	24T/Kit



# Follicle-stimulating Hormone (FSH)

Follicle-stimulating hormone (FSH) is synthesized and secreted by gonadotrophs of the anterior pituitary gland. The alpha subunits of LH, FSH, TSH, and hCG are identical, and contain 92 amino acids. FSH has a beta subunit of 118 amino acids (FSHB), which confers its specific biologic action and is responsible for interaction with the FSH-receptor. FSH regulates the development, growth, pubertal maturation, and reproductive processes of the body. FSH and Luteinizing hormone (LH) act synergistically in reproduction.



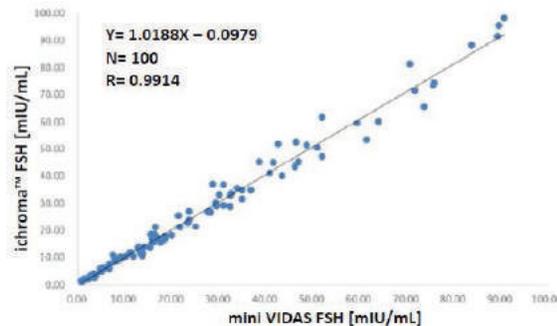
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ FSH	•	•		
ichroma™ FSH Plus		•		
AFIAS FSH			•	

## Specification

	ichroma™ FSH	ichroma™ FSH Plus	AFIAS FSH
Sample type	S/P	WB/S/P	WB/S/P
Sample vol.	150 µL	150 µL	200 µL
Assay time	15 min	12 min	12 min
Working range	1-100 mIU/mL	0.1-110.0 mIU/mL	1-100 mIU/mL
Performance	CV < 10%	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ FSH	CFPC-35	25T/Kit
ichroma™ FSH Plus	CFPC-70	25T/Kit
AFIAS FSH	SMFP-5	24T/Kit

# Human Chorionic Gonadotropin (hCG)

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after implantation. hCG can be detected in the urine and serum of pregnant women as early as 6 to 15 days after conception. The concentration of hCG increases to 50 mIU/ml one-week post implantation and reaches to about 100 mIU/ml at the time of the first missed menstrual period and the peak at 100,000-200,000 mIU/ml at the first trimester.



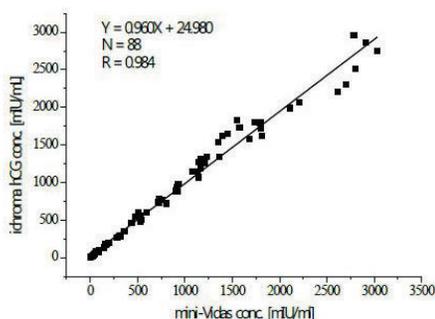
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ hCG	•	•		•

## Specification

	ichroma™ hCG
Sample type	S/P
Sample vol.	75 µL
Assay time	15 min
Working range	2-3,000 mIU/mL
Performance	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge
Shelf life	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ hCG	CFPC-40	25T/Kit



# Human Chorionic Gonadotropin ( $\beta$ -hCG)

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after implantation. It is heterodimeric, with an  $\alpha$  (alpha) subunit identical to that of luteinizing hormone (LH), follicle-stimulating hormone (FSH), thyroid-stimulating hormone (TSH), and  $\beta$  (beta) subunit that is unique to hCG. The  $\beta$ -subunit of hCG ( $\beta$ -hCG) contains 145 amino acids, encoded by six highly homologous genes that are arranged in tandem and inverted pairs on chromosome 19q13.3. The vast majority of the outer amino acids are hydrophilic. hCG can be detected in the urine and serum of pregnant women as early as 6 to 15 days after conception.



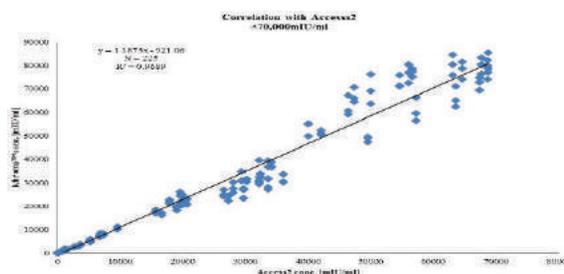
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ $\beta$ -hCG	•	•		
ichroma™ $\beta$ -hCG Plus		•		
AFIAS Total $\beta$ hCG			•	

## Specification

	ichroma™ $\beta$ -hCG	ichroma™ $\beta$ -hCG Plus	AFIAS Total $\beta$ hCG
Sample type	WB/S/P	WB/S/P	WB/S/P
Sample vol.	50/30/30 $\mu$ L	10 $\mu$ L	100 $\mu$ L
Assay time	15 min	12 min	15 min
Working range	5-50,000 mIU/mL	2-5,000 mIU/mL	5-50,000 mIU/mL
Performance	CV < 10%	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ $\beta$ -hCG	CFPC-36	25T/Kit
ichroma™ $\beta$ -hCG Plus	CFPC-66	25T/Kit
AFIAS Total $\beta$ hCG	SMFP-3	24T/Kit



## Luteinizing Hormone (LH)

Luteinizing hormone (LH) is produced in both men and women from the anterior pituitary gland in response to gonadotrophin releasing hormone (GnRH), which is released by the hypothalamus. LH, also called interstitial cell-stimulating hormone (ICSH) in men, is a glycoprotein with a molecular weight of approximately 30,000 Da. In women, LH helps regulate the menstrual cycle and egg production (ovulation). The level of LH in a woman's body varies with the phase of the menstrual cycle. It increases rapidly just before ovulation occurs, about midway through the cycle (day 14 of a 28-day cycle). This is called an LH surge together during the monthly menstrual cycle. In men, LH stimulates the production of testosterone, which plays a role in sperm production.



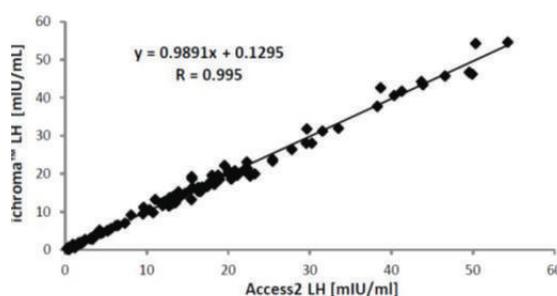
### Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ LH	•	•		
ichroma™ LH Plus		•		
AFIAS LH			•	

### Specification

	ichroma™ LH	ichroma™ LH Plus	AFIAS LH
Sample type	S/P	WB/S/P	WB/S/P
Sample vol.	150 µL	35 µL	200 µL
Assay time	15 min	12 min	12 min
Working range	1-100 mIU/mL	0.1-100.0 mIU/mL	1-100 mIU/mL
Performance	CV < 10%	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 Month	20 Month	20 Month

### Performance



### Ordering information

	Cat #	Test/Kit
ichroma™ LH	13010	25T/Kit
ichroma™ LH Plus	CFPC-69	25T/Kit
AFIAS LH	SMFP-6	24T/Kit



# Progesterone

Progesterone also known as P4 (pregn-4-ene-3,20-dione) is a C-21 steroid hormone involved in the female menstrual cycle, pregnancy (supports gestation) and embryogenesis of humans and other species. Progesterone is essential for the regulation of normal female reproductive functions. The major physiological actions of progesterone are: a) in the uterus and ovary: induction of ovulation, facilitation of implantation, and maintenance of early pregnancy; b) in the mammary gland: lobular-alveolar development in preparation for milk secretion; c) in the brain: neurobehavioral expression associated with sexual responsiveness and d) in the bone: prevention of bone loss.



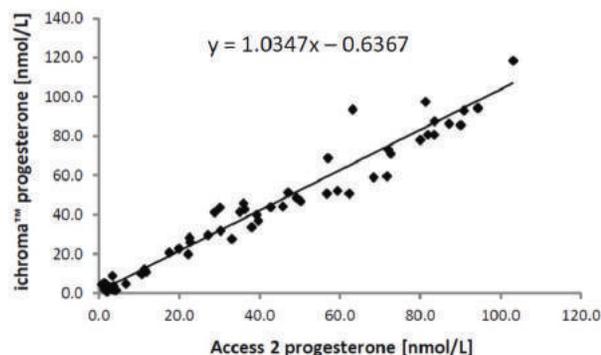
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ Progesterone	•	•		

## Specification

	ichroma™ Progesterone
Sample type	S/P
Sample vol.	30 µL
Assay time	15 min
Working range	4.45-127.20 nmol/L & 1.4-40.0 ng/mL
Performance	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge
Shelf life	20 Month

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ Progesterone	CFPC-21	25T/Kit



# Prolactin (PRL)

Human Prolactin (PRL: lactogenic hormone) is secreted from the anterior pituitary gland in both men and women. PRL is a single chain polypeptide hormone with a molecular weight of approximately 23 kDa. Normal women have slightly higher basal level of PRL than men; apparently, there is an estrogen-related rise at puberty and a corresponding decrease at menopause. During pregnancy, PRL level increases progressively to 10 and 20 times of normal value, declining to non-pregnant levels by 3-4 weeks post-partum.

## Selection Guide

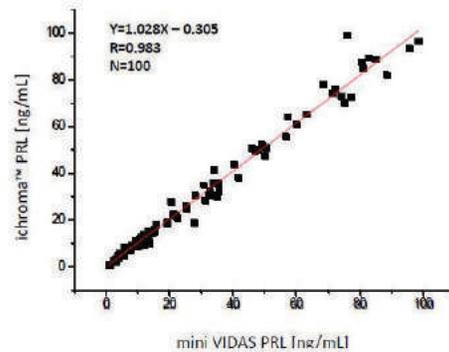
Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ PRL	•	•		
ichroma™ PRL Plus		•		
AFIAS PRL			•	

## Specification

	ichroma™ PRL	ichroma™ PRL Plus	AFIAS PRL
Sample type	S/P	WB/S/P	WB/S/P
Sample vol.	75 µL	75 µL	100 µL
Assay time	10 min	12 min	10 min
Working range	1-100 ng/mL	0.5-200.0 ng/mL	1-100 ng/mL
Performance	CV < 10%	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 Month	20 Month	20 Month



## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ PRL	CFPC-27	25T/Kit
ichroma™ PRL Plus	CFPC-68	25T/Kit
AFIAS PRL	SMFP-8	24T/Kit



# T3

3,5,3' Triiodothyronine (T3) is a thyroid hormone with a molecular weight of 651 daltons. T3 circulates in the blood as an equilibrium mixture of free and protein bound hormone. T3 is bound to thyroxin binding globulin (TBG), prealbumin, and albumin. The actual distribution of T3 among these binding proteins is controversial as estimates range from 38-80 % for TBG, 9-27 % for prealbumin, and 11-35 % for albumin.



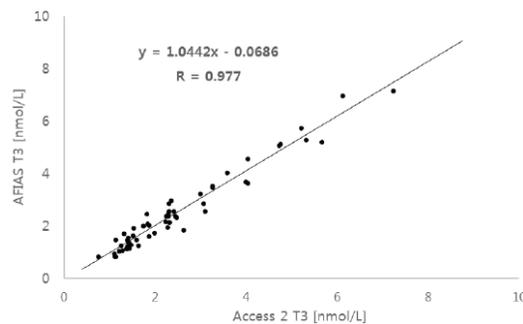
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ T3	•	•		
AFIAS T3			•	

## Specification

	ichroma™ T3	AFIAS T3
Sample type	S/P	S/P
Sample vol.	75 µL	150 µL
Assay time	16 min	10 min
Working range	0.77-7.70 nmol/L	0.77-7.70 nmol/L
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ T3	CFPC-44	25T/Kit
AFIAS T3	SMFP-18	24T/Kit



# T4

Thyroxine (T4) is one of two major hormones produced by the thyroid gland (the other is called triiodothyronine, or T3). T4 and T3 are regulated by a sensitive feedback system involving the hypothalamus and the pituitary gland. The hypothalamus releases the thyrotropin releasing hormone (TRH), which stimulates the pituitary to release the thyroid stimulating hormone (TSH). This causes the thyroid to release T3 and T4 and these in turn regulate the release of TRH and TSH via a feedback control mechanism.



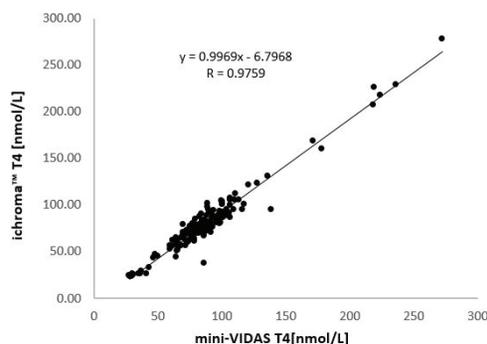
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ T4	•	•		
AFIAS T4			•	

## Specification

	ichroma™ T4	AFIAS T4
Sample type	S/P	S/P
Sample vol.	75 µL	150 µL
Assay time	16 min	10 min
Working range	10.23-300.00 nmol/L	10.23-300.00 nmol/L
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ T4	CFPC-26	25T/Kit
AFIAS T4	SMFP-19	24T/Kit



# Testosterone

Testosterone (17β-hydroxyandrost-4-en-3-one) is an anabolic steroid synthesized primarily by Leydig cells in the testes of male, the ovary of female, and adrenal glands of both sexes. It is synthesized from cholesterol, androstenediol, Dehydroepiandrosterone (DHEA), progesterone, and pregnenolone acting as some of the intermediate substrates.



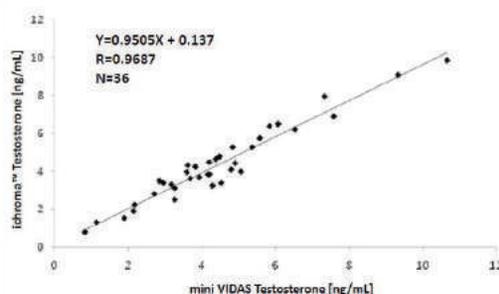
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ Testosterone	•	•		
AFIAS Testosterone			•	

## Specification

	ichroma™ Testosterone	AFIAS Testosterone
Sample type	S/P	S/P
Sample vol.	75 µL	200 µL
Assay time	15 min	15 min
Working range	1-10 ng/mL	1-10 ng/mL
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ Testosterone	13012	25T/Kit
AFIAS Testosterone	SMFP-29	24T/Kit

# Thyroid Stimulating Hormone (TSH)

► FDA 510(k)

The determination of serum or plasma levels of thyroid stimulating hormone (TSH or thyrotropin) is recognized as an important measurement in the assessment of thyroid function. When there is a high level of thyroid hormone in the blood, less TRH is released by the hypothalamus, so less TSH is secreted by the pituitary. The opposite action will occur when there are decreased levels of thyroid hormones in the blood. This process, known as a negative feedback mechanism, is responsible for maintaining the proper blood levels of these hormones.

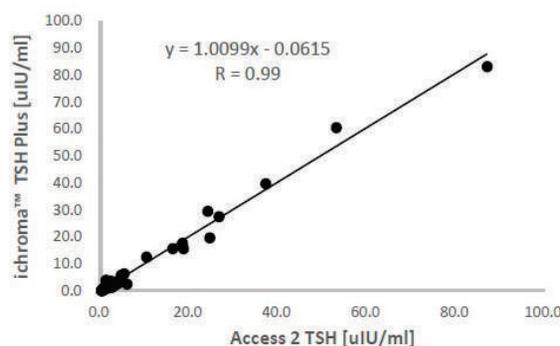
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ TSH	•	•		
ichroma™ TSH Plus		•		
AFIAS TSH			•	

## Specification

	ichroma™ TSH	ichroma™ TSH Plus	AFIAS TSH
Sample type	S/P	WB/S/P	WB/S/P
Sample vol.	150 µL	35 µL	100/200/200 µL (50 µL for C-tip)
Assay time	12 min	12 min	15 min
Working range	0.1-100.0 µIU/mL	0.1-50.0 µIU/mL	S/P: 0.09-80.00 µIU/mL WB: 0.4-80.0 µIU/mL
Performance	CV<10%	CV<10%	CV<10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ TSH	CFPC-22	25T/Kit
ichroma™ TSH Plus	CFPC-45	25T/Kit
AFIAS TSH	SMFP-20	24T/Kit





# Infection

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# C-Reactive Protein (CRP)

▶ FDA 510(k)

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.



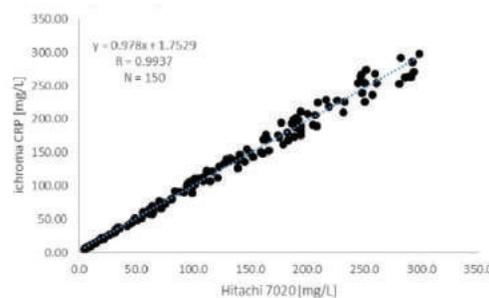
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™_50
ichroma™ CRP	•	•		•
AFIAS CRP			•	

## Specification

	ichroma™ CRP	AFIAS CRP
Sample type	WB/S/P	WB/S/P
Sample vol.	10 µL	100 µL (10 µL for C-tip)
Assay time	3 min	3 min
Working range	2.5-300.0 mg/L	0.5-200.0 mg/L
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ CRP	i-CHROMA CRP-25	25T/Kit
AFIAS CRP	SMFP-2	24T/Kit



# Procalcitonin(PCT)

Boditech PCT is a quantitative analytic reagent for the procalcitonin (PCT) in human whole blood, serum, and plasma based on high sensitivity fluorescence immunoassay (FIA) and is used with ichroma & AFIAS. PCT can be useful for monitoring or managing sepsis or bacterial infections.



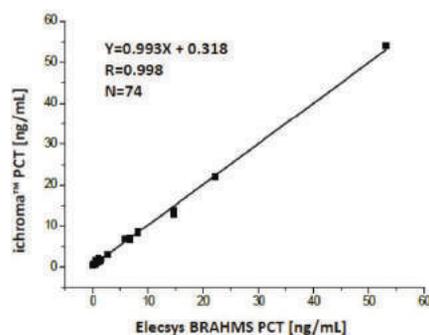
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ PCT	•	•		•
ichroma™ PCT Plus		•		•
AFIAS PCT			•	
AFIAS PCT Plus			•	

## Specification

	ichroma™ PCT	ichroma™ PCT Plus	AFIAS PCT	AFIAS PCT Plus
Sample type	WB/S/P	WB/S/P	WB/S/P	WB/S/P
Sample vol.	150 µL	35 µL	200 µL (50 µL)	100 µL (30 µL)
Assay time	12 min	12 min	12 min	12 min
Working range	0.1-100.0 ng/mL	0.02- 50.00 ng/mL	0.1-100.0 ng/mL	0.02- 50 ng/mL
Performance	CV < 10%	CV < 10%	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C for DB / 4-30°C for Cartridge	2-8°C	2-8°C
Shelf life	20 months	20 months	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ PCT	CFPC-23	10T/Kit
ichroma™ PCT Plus	CFPC-64	25T/Kit
AFIAS PCT	SMFP-7	24T/Kit
AFIAS PCT Plus	SMFP-32	24T/Kit

# Anti-streptolysin O (ASO)

ASO is an antibody produced in human blood against streptolysin O made from an infection of Streptococcus bacteria. An elevated or rising ASO titer may demonstrate recent streptococcal infections. Some autoimmune responses, glomerulonephritis, acute tonsillitis, scarlet fever, and rheumatic fever may be associated with streptococcal infections.

Even if ASO titers may vary due to several factors including population and age.



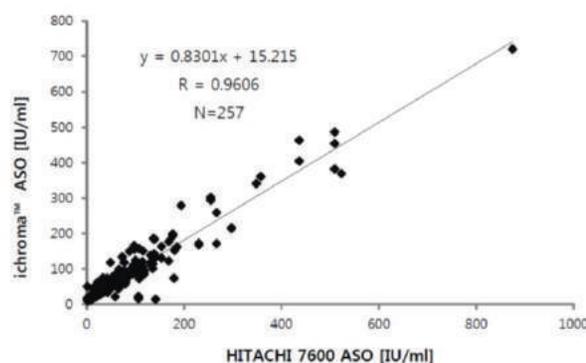
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ ASO	•	•		

## Specification

	ichroma™ ASO
Sample type	S/P
Sample vol.	5 µL
Assay time	12 min
Working range	25-800 IU/mL
Performance	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge
Shelf life	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ ASO	CFPC-46	25T/Kit



# Dengue NS1 Antigen

Dengue NS1 Ag is a qualitative analytic reagent for the dengue NS1 antigen test based on high sensitivity fluorescence immunoassay (FIA). Innovative technology enables Dengue NS1 Ag accuracy of ELISA test, with easy and simple procedure of rapid test. Dengue NS1 Ag test provides detection of Dengue antigen for primary and secondary infection.



## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ Dengue NS1 Ag		•		
AFIAS Dengue NS1 Ag			•	

## Specification

	ichroma™ Dengue NS1 Ag	AFIAS Dengue NS1 Ag
Sample type	WB/S/P	WB/S/P
Sample vol.	75 µL	100 µL
Assay time	12 min	12 min
Working range	qualitative	qualitative
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance

Sensitivity	Specificity
95.9%	98.2%

## Ordering information

	Cat #	Test/Kit
ichroma™ Dengue NS1 Ag	CFPC-62	25T/Kit
AFIAS Dengue NS1 Ag	SMFP-44	24T/Kit

# Dengue Antibody IgG/IgM

Dengue IgG/IgM is a qualitative analytic reagent for the dengue IgG/IgM test based on high sensitivity fluorescence immunoassay (FIA). Innovative technology enables Dengue IgG/IgM accuracy of ELISA test, with easy and simple procedure of rapid test. Dengue IgG/IgM provides antibody test to cover for primary and secondary infection.



## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ Dengue IgG/IgM		•		
AFIAS Dengue IgG/IgM			•	

## Specification

	ichroma™ Dengue IgG/IgM	AFIAS Dengue IgG/IgM
Sample type	WB/S/P	WB/S/P
Sample vol.	10 µL	50 µL
Assay time	12 min	12 min
Working range	qualitative	qualitative
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance

Sensitivity	Specificity
IgM: 95.4%	IgM: 98.7%
IgG: 100%	IgG: 100%

## Ordering information

	Cat #	Test/Kit
ichroma™ Dengue IgG/IgM	CFPC-60	25T/Kit
AFIAS Dengue IgG/IgM	SMFP-41	24T/Kit

# Hepatitis B Antigen (HBsAg)

The hepatitis B virus (HBV) is responsible for hepatic lesions, as in fulminant acute hepatitis or chronic hepatitis that can result in cirrhosis and hepatocellular carcinoma. Detection of the Hepatitis B virus surface antigen (HBsAg) in serum or plasma indicates an infection caused by the hepatitis B virus. It is the first marker to appear during the disease. Clinical and biological symptoms appear two to three weeks after the initial infection with HBV. Presence of HBsAg can be as short as a few days or as long as several years. If HBsAg persists for more than six months, the hepatitis is classified as 'chronic'. Due to existence of numerous asymptomatic chronic carriers, screening for HBsAg is required for each blood donation and for each pregnancy to enable the newborns of the carrier mother to receive prophylactic treatment.



## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ HBsAg		•		
AFIAS HBsAg			•	

## Specification

	ichroma™ HBsAg	AFIAS HBsAg
Sample type	WB/S/P	WB/S/P
Sample vol.	75 µL	100 µL
Assay time	12 min	12 min
Working range	0-300 COI	0-300 COI
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance

Sensitivity	Specificity
99.8%	99.2%

## Ordering information

	Cat #	Test/Kit
ichroma™ HBsAg	CFPC-29	25T/Kit
AFIAS HBsAg	SMFP-15	24T/Kit

# Hepatitis B Antibody (Anti-HBs)

Viral hepatitis is a serious global health problem affecting over two billion people worldwide and approximately one million people die each year due to cirrhosis of the liver and hepatocellular carcinoma (HCC), which are commonly associated with chronic hepatitis. The risk of developing chronic infection by HBV varies inversely with age and is highest for infants infected at birth compared to older children and adults. Determination of antibodies directed against HBV surface antigen (Anti-HBs) is used to evaluate a person's immune status to HBV infection or to aid in the laboratory diagnosis of HBV infection when used in conjunction with other laboratory methods. The test is performed to assess the need for vaccination (if Anti-HBs is absent or below levels considered protective), following completion of vaccination against HBV in high risk groups (healthcare workers, Chronic renal failure patients, HIV infected persons), or to monitor recovery from acute HBV infection. The presence of Anti-HBs following acute infection generally indicates recovery and immunity from reinfection.



## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™_50
ichroma™ Anti-HBs		•		
AFIAS Anti-HBs			•	

## Specification

	ichroma™ Anti-HBs	AFIAS Anti-HBs
Sample type	WB/S/P	WB/S/P
Sample vol.	50 µL	100 µL
Assay time	15 min	15 min
Working range	0-500 mIU/mL	0-500 mIU/mL
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance

Sensitivity	Specificity
98.7%	98.5%

## Ordering information

	Cat #	Test/Kit
ichroma™ Anti-HBs	CFPC-52	25T/Kit
AFIAS Anti-HBs	SMFP-16	24T/Kit

# Hepatitis C Antibody (Anti-HCV)

Hepatitis C virus (HCV) infection is a worldwide public health problem with a global prevalence of 2-3 %. HCV is a frequent cause of chronic liver diseases such as hepatitis. HCV is the main reason for liver transplantation in the developed world and, it is primarily transmitted via blood. After 1-3 weeks of acute HCV infection, HCV RNA becomes detectable in blood and rapidly increases. About 50-80 % of HCV infected patients progress to chronic infection. Once it becomes chronic hepatitis, it can cause persistent liver injury without spontaneous recovery leading to cirrhosis and HCC. Most (60-80 %) patients with chronic hepatitis show no symptoms, but some can experience abdominal discomfort, fatigue, nausea, muscle pain, arthritis, or weight loss. Serologic assays testing is needed to confirm HCV infection. Physical examination, treatment and history taking should be done to understand the routes of transmission and block further reinfection. Detection of anti-HCV in serum or plasma is used for screening of a high-risk group and for diagnosis of acute or chronic hepatitis C.



## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ Anti-HCV		•		
AFIAS Anti-HCV			•	

## Specification

	ichroma™ Anti-HCV	AFIAS Anti-HCV
Sample type	WB/S/P	WB/S/P
Sample vol.	30 µL	100 µL
Assay time	12 min	12 min
Working range	0-300 COI	0-300 COI
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance

Sensitivity	Specificity
98.5%	99.1%

## Ordering information

	Cat #	Test/Kit
ichroma™ Anti-HCV	CFPC-31	25T/Kit
AFIAS Anti-HCV	SMFP-17	24T/Kit

# Human Immunodeficiency Virus (HIV Ag/Ab)

HIV Ag/Ab is 4th generation HIV test based on high sensitivity fluorescence immunoassay (FIA). Innovative technology enables HIV Ag/Ab test accuracy of ELISA test, with easy and simple procedure of rapid test. HIV Ag/Ab test provides HIV antigen and antibody (type 1 and 2) test to cover the whole serological detection of the HIV infection.



## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ HIV Ag/Ab		•		
AFIAS HIV Ag/Ab			•	

## Specification

	ichroma™ HIV Ag/Ab	AFIAS HIV Ag/Ab
Sample type	WB/S/P	WB/S/P
Sample vol.	30 µL	50 µL
Assay time	15 min	15 min
Working range	qualitative	qualitative
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance

Sensitivity	Specificity
Ag: >2 IU/mL / Ab: 100%	Ag: 100% / Ab: 99.1%

## Ordering information

	Cat #	Test/Kit
ichroma™ HIV Ag/Ab	CFPC-58	25T/Kit
AFIAS HIV Ag/Ab	SMFP-39	24T/Kit



# Influenza A+B

The Influenza virus, a single-stranded RNA virus, belongs to the family orthomyxoviridae and is known as 'seasonal influenza', due to the fact that in temperate climate it tends to occur in the winter months.

Influenza, or flu, known as 'febrile respiratory illness' can cause mild to severe symptoms, such as a high fever, chills, headache, muscle pains coughing and even death. This product is for in vitro diagnostic medical devices with which the infection of influenza A or B viruses can be determined within 10 minutes, much quicker and easier than the conventional diagnostic methods like PCR or viral culture which takes more than 24 to 48 hours for diagnosis.



## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™ M
ichroma™ Influenza A+B		•		•

## Specification

	ichroma™ Influenza A+B
Sample type	Nasopharyngeal swab/Nasal aspirates
Assay time	10 min
Working range	qualitative
Performance	CV < 10%
Storage	1-30°C
Shelf life	18 months

## Performance

Sensitivity	Specificity
A: 98.6%, B: 96.0%	A: 100%, B: 100%

## Ordering information

	Cat #	Test/Kit
ichroma™ Influenza A+B	CFPC-61	25T/Kit



## Influenza/Respiratory Syncytial Virus (RSV)

The Influenza virus, a single-stranded RNA virus, belongs to the family orthomyxoviridae and is known as 'seasonal influenza'. Human respiratory syncytial virus (HRSV) is a syncytial virus that causes respiratory tract infections. It is a major cause of lower respiratory tract infections and hospital visits during infancy and childhood. The ichroma Influenza/RSV test for the rapid in vitro qualitative detection and discrimination of Influenza A virus, Influenza B virus and respiratory syncytial virus (RSV) in nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors. The test is intended for use as an aid in the differential diagnosis of Influenza A, Influenza B, and RSV in humans.



### Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™ M
ichroma™ Influenza/RSV		•		•

### Specification

	ichroma™ Influenza/RSV
Sample type	Nasopharyngeal swab/Nasal aspirates
Assay time	10 min
Working range	qualitative
Performance	CV < 10%
Storage	1-30°C
Shelf life	18 Months

### Performance

Sensitivity	Specificity
A: 98.6%, B: 96.0%	A: 100%, B: 100%

### Ordering information

	Cat #	Test/Kit
ichroma™ Influenza/RSV	CFPC-80	25T/Kit



# Norovirus (NORO)

Norovirus, sometimes referred to as the winter vomiting bug in the UK and Ireland, is the most common cause of viral gastroenteritis in humans. It affects people of all ages. The virus is transmitted by fecally contaminated food or water, by person-to-person contact, and via aerosolization of vomited virus and subsequent contamination of surfaces. Norovirus infection is characterized by nausea, vomiting, watery diarrhea, abdominal pain, and in some cases, loss of taste. A person usually develops symptoms of gastroenteritis 12 to 48 hours after being exposed to norovirus. General lethargy, weakness, muscle aches, headaches, and low-grade fevers may occur. The disease is usually self-limiting, and severe illness is rare.



## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ NORO		•		
AFIAS NORO			•	

## Specification

	ichroma™ NORO	AFIAS NORO
Sample type	Feces	Feces
Sample vol.	spot	spot
Assay time	12 min	12 min
Working range	qualitative	qualitative
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance

Sensitivity	Specificity
99%	87.6%

## Ordering information

	Cat #	Test/Kit
ichroma™ NORO	CFPC-76	25T/Kit
AFIAS NORO	SMFP-26	24T/Kit



# Rotavirus (ROTA)

Rotavirus is the most common cause of diarrheal disease among infants and young children. It is a genus of double-stranded RNA viruses in the family Reoviridae. The virus is transmitted by the fecal-oral route. It infects and damages the cells that line the small intestine and causes gastroenteritis (which is often called “stomach flu” despite having no relation to influenza). Rota test is a qualitative analytic reagent for the Rota viral antigen test based on high sensitivity fluorescence immunoassay (FIA). Innovative technology enables Rota test accuracy of auto-analyzer, with easy and simple automated process.



## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ ROTA		•		
AFIAS ROTA			•	

## Specification

	ichroma™ ROTA	AFIAS ROTA
Sample type	Feces	Feces
Sample vol.	spot	spot
Assay time	12 min	12 min
Working range	qualitative	qualitative
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance

Sensitivity	Specificity
99.03%	97.09%

## Ordering information

	Cat #	Test/Kit
ichroma™ ROTA	CFPC-75	25T/Kit
AFIAS ROTA	SMFP-25	24T/Kit



# Rotavirus and Adenovirus

Rotavirus is the most common cause of diarrheal disease among infants and young children. It is a genus of double-stranded RNA viruses in the family Reoviridae. Enteric adenoviruses 40 and 41 cause gastroenteritis, usually in children. The oral transmission of the virus typically causes no or mild disease. Rota/Adeno test is a qualitative analytic reagent for the Rota and Adeno (type 40 and 41) viral antigen combination test based on high sensitivity fluorescence immunoassay (FIA).



## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ Rota/Adeno		•		
AFIAS Rota/Adeno			•	

## Specification

	ichroma™ Rota/Adeno	AFIAS Rota/Adeno
Sample type	Feces	Feces
Sample vol.	spot	spot
Assay time	12 min	12 min
Working range	qualitative	qualitative
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months

## Performance

Sensitivity	Specificity
Rota 99% Adeno 100%	Rota 99% Adeno 97%

## Ordering information

	Cat #	Test/Kit
ichroma™ Rota/Adeno	CFPC-79	25T/Kit
AFIAS Rota/Adeno	SMFP-43	24T/Kit



# Group A Streptococcal Infection (Strep A)

A group A streptococcal infection is an infection with group A streptococcus (GAS). Streptococcus pyogenes comprises the vast majority of the Lancefield group A streptococci, and is often used as a synonym for GAS. However, *S. dysgalactiae* can also be group A. *S. pyogenes* is a beta-hemolytic species of Gram positive bacteria that is responsible for a wide range of both invasive and noninvasive infections. Infection of GAS may spread through direct contact with mucus or sores on the skin. GAS infections can cause >500,000 deaths per year. Despite the emergence of antibiotics as a treatment for group A  $\beta$ -hemolytic streptococcus, infection of GAS is an increasing problem, particularly on the continent of Africa.



## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™ M
ichroma™ Strep A		•		•

## Specification

	ichroma™ StrepA
Sample type	Nasopharyngeal swab/Nasal aspirates
Assay time	5 min
Working range	qualitative
Performance	CV < 10%
Storage	1-30°C
Shelf life	18 months

## Performance

Sensitivity	Specificity
96.3%	98.0%

## Ordering information

	Cat #	Test/Kit
ichroma™ Strep A	CFPC-74	25T/Kit



# Zika Antibody IgG/IgM

Zika IgG/IgM is a qualitative analytic reagent for the Zika IgG/IgM test based on high sensitivity fluorescence immunoassay (FIA). Zika IgG/IgM is the world first immunoassay that enables fast and accurate test of Zika IgG/IgM for patients. Zika IgG/IgM provides compact and fast test result, with the accuracy of ELISA test.



## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ Zika IgG/IgM		•		
AFIAS Zika IgG/IgM			•	

## Specification

	ichroma™ Zika IgG/IgM	AFIAS Zika IgG/IgM
Sample type	WB/S/P	WB/S/P
Sample vol.	30 µL	50 µL
Assay time	12 min	12 min
Working range	qualitative	qualitative
Performance	CV < 10%	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months



## Performance

Sensitivity	Specificity
IgM: 100% IgG: 97%	IgM: 98% IgG: 97%

## Ordering information

	Cat #	Test/Kit
ichroma™ Zika IgG/IgM	CFPC-59	25T/Kit
AFIAS Zika IgG/IgM	SMFP-40	24T/Kit



# Rheumatoid Arthritis

Anti-CCP	61
Rheumatoid Arthritis (RF IgM)	62



# Anti-CCP

Rheumatoid Arthritis (RA) is a common, systemic autoimmune disease that 0.5-1.0% of the world population is affected. RA is characterized by chronic inflammation of the synovium which can lead to progressive joint destruction, disability, and mortality. As joint damage is irreversible, early therapeutic intervention is of paramount importance for the prognosis of patients. An anti-CCP assay is capable to detect the autoantibodies against citrullinated proteins which have a relatively high sensitivity (reportedly between 50-75%) for rheumatoid arthritis and extremely high specificity (about 90%) for RA. Its high specificity is why the anti-CCP test has become an important part of the diagnostic process for RA.



## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ Anti-CCP		•		

## Specification

	ichroma™ Anti-CCP
Sample type	WB/S/P
Sample vol.	10/5/5 µL
Assay time	12 min
Working range	5-200 U/mL
Performance	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge
Shelf life	20 months

## Performance

Sensitivity	Specificity
85.0%	98.0%

## Ordering information

	Cat #	Test/Kit
ichroma™ Anti-CCP	CFPC-51	25T/Kit



# Rheumatoid Arthritis (RF IgM)

Rheumatoid arthritis (RA) is the most common chronic autoimmune arthritis worldwide, leading to disability and substantial economic costs. It is a chronic and systemic inflammatory disorder that may affect many tissues and organs, but principally attacks synovial joints. About 1% of the world's population is afflicted by rheumatoid arthritis, women three times more often than men. Onset is most frequent between the ages of 40 and 50, but people of any age can be affected. It can be a disabling and painful condition, which can lead to substantial loss of functioning and mobility if not adequately treated.



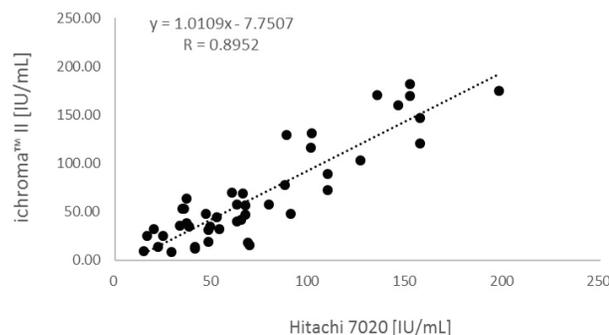
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ RF IgM	•	•		

## Specification

	ichroma™ RF IgM
Sample type	WB/S/P
Sample vol.	10/5/5 µL
Assay time	5 min
Working range	8-200 IU/mL
Performance	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge
Shelf life	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ RF IgM	CFPC-39	25T/Kit



## Others

Ferritin	64
Vitamin D	65
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iFOB/Calp. Combo	67
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# Ferritin

Ferritin, a major iron storage protein, is essential to iron homeostasis and is involved in a wide range of physiologic and pathologic processes. Ferritin makes iron available for critical cellular processes while protecting lipids, DNA, and proteins from the potentially toxic effects of iron. In clinical medicine, ferritin is predominantly utilized as a marker of total body iron stores. In cases of iron deficiency and overload, serum ferritin serves a critical role in both diagnosis and management. It is clear that low ferritin values less than reference range are usually representative of body iron deficiency.

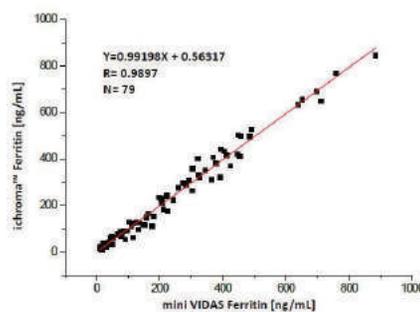
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™_50
ichroma™ Ferritin	•	•		
ichroma™ Ferritin Plus		•		
AFIAS Ferritin			•	

## Specification

	ichroma™ Ferritin	ichroma™ Ferritin Plus	AFIAS Ferritin
Sample type	S/P	WB/S/P	S/P
Sample vol.	30 µL	10 µL	100 µL
Assay time	10 min	12 min	10 min
Working range	10-1,000 ng/mL	1.5-1,000 ng/mL	10-1,000 ng/mL
Performance	CV<10%	CV<10%	CV<10%
Storage	2-8°C for DB / 4-30°C for Cartridge	2-8°C for DB / 4-30°C for Cartridge	2-8°C
Shelf life	20 months	20 months	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ Ferritin	CFPC-32	25T/Kit
ichroma™ Ferritin Plus	CFPC-67	25T/Kit
AFIAS Ferritin	SMFP-23	24T/Kit





# Vitamin D

Vitamin D from the diet or dermal synthesis from sunlight is biologically inactive and is a fat soluble steroid hormone involved in the active intestinal absorption of calcium and in the regulation of its homeostasis. In humans, the most important compounds in this group are vitamin D3 (also known as cholecalciferol) and vitamin D2 (ergocalciferol). In the liver, cholecalciferol (vitamin D3) is converted to calcidiol, 25-hydroxycholecalciferol (abbreviated 25(OH)D3). Ergocalciferol (vitamin D2) is converted in the liver to 25- hydroxyergocalciferol (25(OH)D2). It is widely known that circulating 25(OH)D is the best indicator of vitamin D status. 25(OH)D3 is then converted in the kidneys (by the enzyme 25(OH)D-a-hydroxylase) into 1,25-(OH)2D3, a steroid hormone that is the active form of vitamin D. It can also be converted into 24-hydroxycalcidiol in the kidneys via 24-hydroxylation.



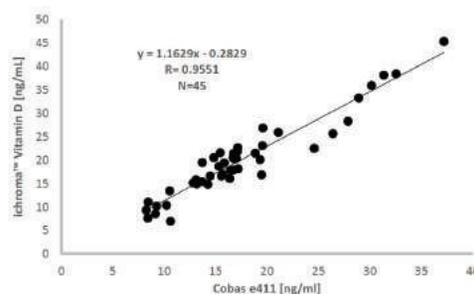
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ Vitamin D	•	•		

## Specification

	ichroma™ Vitamin D
Sample type	S/P
Sample vol.	50 µL
Assay time	28 min
Working range	8-70 ng/mL
Performance	CV < 10%
Storage	2-8°C for DB / 4-30°C for Cartridge
Shelf life	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ Vitamin D	CFPC-47	25T/Kit



# Calprotectin

The amount of calprotectin reflects the number of participating neutrophils in this inflammation. This has been amply confirmed in intestinal inflammatory diseases by the significant correlation between fecal calprotectin levels and other measures of acute inflammation. The concentration of calprotectin in feces has been shown to correlate well with the “gold standard” 111Indium-labeled leukocyte test and to the severity of the intestinal inflammation. Calprotectin appears to be distributed homogeneously in feces and is stable for up to 7 days at room temperature.



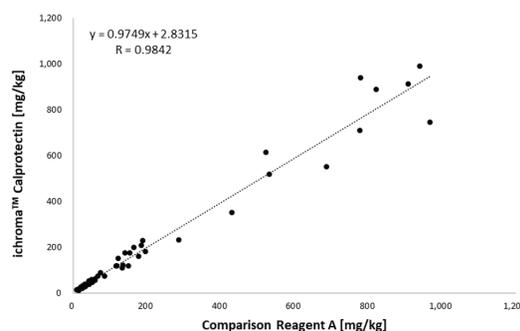
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ Calprotectin	•	•		•

## Specification

	AFIAS/ichroma Calprotectin
Sample type	feces
Sample vol.	10 mg
Assay time	10 min
Working range	10-1,000 mg/kg feces
Performance	CV < 10%
Storage	4-30°C
Shelf life	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ Calprotectin	CFPC-83	25T/Kit



# iFOB/Calprotectin

Abdominal pain, rectal bleeding, or altered defecation pattern are patient complaints frequently encountered by general practitioners (GPs). Most of these complaints have a nonorganic background, and the prevalence of organic bowel disease (OBD)—including inflammatory bowel disease (IBD) and colorectal cancer (CRC)—in primary care patients is approximately 7%. Distinguishing OBD from non-OBD needs to be timely, and the diagnostic workup aims at not missing OBD patients, who require subsequent work-up and referral to secondary care. Eligible tests to meet this need are biomarkers such as fecal calprotectin and immunochemical fecal occult blood tests (iFOBTs). Several calprotectin and iFOBTs are currently available, including various ELISA methods and, more recently, point-of-care (POC) tests. POC tests may be advantageous in clinical settings such as primary care, if a rapid turnaround time is a necessity for improving patient care and a small number of specimens need to be evaluated at any given time.



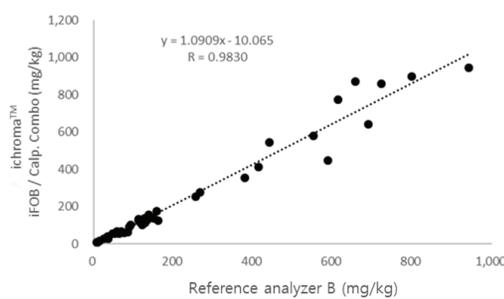
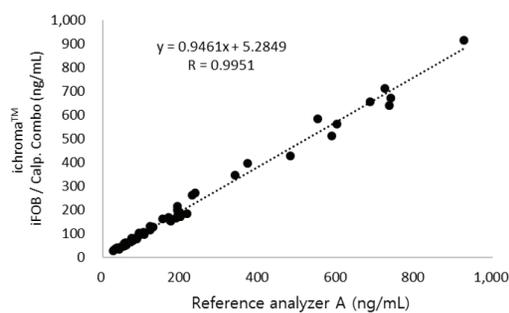
## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ iFOB/Calp. Combo		•		•

## Specification

	ichroma™ iFOB/Calp. Combo
Sample type	feces
Sample vol.	10 mg
Assay time	10 min
Working range	iFOB: 25-1,000 ng/mL Calprotectin: 10-1,000 mg/kg
Performance	CV < 10%
Storage	4-30°C
Shelf life	20 months

## Performance



## Ordering information

	Cat #	Test/Kit
ichroma™ iFOB/Calp. Combo	CFPC-84	25T/Kit



# H. pylori SA

Helicobacter pylori (H. pylori) infections are usually harmless, but they're responsible for the majority of ulcers in the stomach and small intestine. H. pylori is a common type of bacteria that usually infects the stomach. Infection by H. pylori has been implicated in the pathogenesis of gastro-duodenal diseases. Several guidelines on H. pylori infection from around the world indicate that eradication of H. pylori would result in a reduction of the incidence of gastroduodenal diseases, including gastric cancer, and would decrease new infections in future generations.



## Selection Guide

Item / Platform	ichroma™	ichroma™ II	AFIAS-1/6	ichroma™-50
ichroma™ H. pylori SA	•	•		

## Specification

	ichroma™ H. pylori SA
Sample type	feces
Sample vol.	10 mg
Assay time	12 min
Working range	qualitative
Performance	CV<10%
Storage	4-30°C
Shelf life	20 months

## Ordering information

	Cat #	Test/Kit
ichroma™ H. pylori SA	CFPC-81	25T/Kit

## Catalogue Number Index

Test items	Catalog No.	
	AFIAS	ichroma™
AFP	SMFP-27	i-CHROMA AFP-25
AFP Plus	-	CFPC-73
Anti-CCP	-	CFPC-51
Anti-HBs	SMFP-16	CFPC-52
Anti-HCV	SMFP-17	CFPC-31
ASO	-	CFPC-46
β-hCG	-	CFPC-36
β-hCG Plus	-	CFPC-66
Cardiac Triple	-	CFPC-78
Calprotectin	-	CFPC-83
CEA	SMFP-21	13013
CEA Plus	-	CFPC-72
CK-MB	SMFP-13	CFPC-33
Cortisol	SMFP-22	CFPC-24
CRP	SMFP-2	i-CHROMA CRP-25
Cystatin C	-	CFPC-43
D-Dimer	SMFP-4	CFPC-25
Dengue IgG/IgM	SMFP-41	CFPC-60
Dengue NS1	SMFP-44	CFPC-62
Ferritin	SMFP-23	CFPC-32
Ferritin Plus	-	CFPC-67
FSH	SMFP-5	CFPC-35
FSH Plus	-	CFPC-70
HbA1c	SMFP-28	CFPC-38
HBsAg	SMFP-15	CFPC-29
hCG	-	CFPC-40
HIV Ag/Ab	SMFP-39	CFPC-58
hsCRP	-	CFPC-6
H. pylori SA	-	CFPC-81
iFOB	-	CFPC-15
iFOB/Calp. Combo	-	CFPC-84
Influenza/RSV	-	CFPC-80
Influenza A+B	-	CFPC-61
LH	SMFP-6	13010
LH Plus	-	CFPC-69
Microalbumin	SMFP-30	i-CHROMA MAU-25
Myoglobin	SMFP-34	CFPC-37
NORO	SMFP-26	CFPC-76
NT-proBNP	SMFP-36	CFPC-49
PCT	SMFP-7	CFPC-23
PCT Plus	SMFP-32	CFPC-64
PRL	SMFP-8	CFPC-27
PRL Plus	-	CFPC-68
Progesterone	-	CFPC-21
PSA	SMFP-9	i-CHROMA PSA-25
PSA Plus	-	CFPC-71
RF IgM	-	CFPC-39
ROTA	SMFP-25	CFPC-75
Rota/Adeno	SMFP-43	CFPC-79
Strep A	-	CFPC-74
T3	SMFP-18	CFPC-44
T4	SMFP-19	CFPC-26
Testosterone	SMFP-29	13012

Test items	Catalog No.	
	AFIAS	ichroma™
Tn-I	-	13011
Tn-I Plus	SMFP-35	CFPC-65
Total βhCG	SMFP-3	-
TSH	SMFP-20	CFPC-22
TSH Plus	-	CFPC-45
Vitamin D	-	CFPC-47
Zika IgG/IgM	SMFP-40	CFPC-59

Control items	Catalog No.
ichroma™ MAU Control	CFPO-4
ichroma™ iFOB Control	CFPO-14
hemochroma Plus Control	CFPO-29
ichroma™ Vitamin D Control	CFPO-79
Boditech Tumor marker Control	CFPO-94
Boditech Hormone Control	CFPO-95
Boditech HbA1c Control	CFPO-96
Boditech PCT Control	CFPO-97
Boditech Cardiac Control	CFPO-98
Boditech Ferritin Control	CFPO-99
Boditech CRP Control	CFPO-100
Boditech D-Dimer Control	CFPO-101
Boditech Vitamin D Control	CFPO-102
Boditech RF IgM Control	CFPO-103
Boditech Anti-CCP Control	CFPO-125
Boditech HBsAg Control	CFPO-142
Boditech Anti-HCV Control	CFPO-143
Boditech Anti-HBs Control	CFPO-144

Calibrator items	Catalog No.
Boditech Tumor marker Calibrator	CFPO-106
Boditech Hormone Calibrator	CFPO-107
Boditech HbA1c Calibrator	CFPO-108
Boditech PCT Calibrator	CFPO-109
Boditech Cardiac Calibrator	CFPO-110
Boditech Ferritin Calibrator	CFPO-111
Boditech CRP Calibrator	CFPO-112
Boditech D-Dimer Calibrator	CFPO-113

Analyzer	Catalog No.
ichroma™ II	FPRR021
AFIAS-6	FPRR020
AFIAS-1	FPRR019
ichroma™-50	FPRR022
ichroma™	FR203
ichroma™ M	FPRR026
hemochroma PLUS	FPRR005
i-chamber	FPRR009
HandyRay	LMT-300





Respect for life

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