



# **PRODUCT CATALOGUE**

## **2022**

**BEIJING O&D BIOTECH CO., LTD.**

## O&D BIOTECH PROFILE

Founded in 2004 and located in Zhongguancun Shunyi Park, Beijing O&D Biotech Co., Ltd. is a fast-growing high-tech enterprise with strong expertise in production, supply and development of in-vitro diagnostic instruments and reagents. As a pioneer dedicated to POCT, we have expanded our product portfolio into CyPath® TCT systems and RUNP® diagnostic test kits for Covid-19 and other infectious diseases, cardiac abnormalities, diabetes, infection, hormone, cerebral injuries, gastrointestinal diseases and renal injuries on Fluorescence Immunoassay and Chemiluminescence Immunoassay platforms.

O&D Biotech has been certified by ISO 13485 since 2012, and owns over 70 CFDA (NMPA) certificates and multiple CE certificates. RUNP® diagnostic test kits for cardiac markers have been awarded the certificate of conformity of inter-room quality assessment by the clinical examination center of the National Health Commission of China; Our Fluorescence Immunoassay Analyzers are the recommended medical instruments for the construction of chest pain centers. Utilizing special technologies such as Semi-Liquid Phase Reaction, Immunochromatographic Assay and Red Nanofluorescent Microsphere, fluorescence immunoassay reagents have been widely used and won high reputation from customers.

During the Covid-19 epidemic, KS-002 Fluorescent Immunoassay Analyzer was recommended by the China Association of Medical Equipment among the first emergency medical supplies for Covid-19 prevention and control. Our Covid-19 test kits have been approved by the Ministry of Commerce into the "White List" for exporters.

Throughout the development and expansion process, Beijing O&D Biotech has built an ever-expanding, talented workforce from home and abroad and woven diligence, passion, resilience, and a can-do attitude into our cultural fabric, driving us to pursue the mission of "winning time for saving lives".



## CERTIFICATES



ISO 13485



CE



Manufacturing License

## RUNP® Reagents

### Qualitative Rapid Test-Colloidal Gold

- COVID-19 Antigen Rapid Test
- COVID-19 IgM/IgG Rapid Test
- Influenza A and B (FLU A&B) Test Kit

### Quantitative Test Kits-Fluorescence Immunoassay

COVID-19	COVID-19 Antigen
Cardiac	CK-MB, D-Dimer, CRP, Myo, 3 in 1 (cTnI/Myo/CK-MB), NT-proBNP, cTnI, *Lp-PLA2, H-FABP, *MPO
Diabetes	HbA1c, *Cys-C, *C-Peptide, Insulin
Hormone	β-HCG
Infection	PCT, SAA, *SAA/CRP, IL-6
Others	S100-β, *NGAL, *2 in 1 (PGI/PGII), *MAU, *AMH

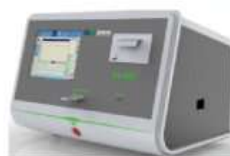
*Products with \* are under R&D.*

## INSTRUMENTS

### Fluorescence Immunoassay



KS-001



KS-002

### Chemiluminescence Immunoassay *(Only available in China)*



ACT99\*



K1000\*



K2000\*

### TCT System



CyPath®

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# COVID-19 Antigen Rapid Test

## Colloidal Gold

### For Professional Use



- Instant results in 15 minutes
- Easy to use, no equipment required
- Room temperature storage (2-30°C)
- Non-invasive sampling
- Cost-effective solution for large-scale testing
- High sensitivity and specificity

### Product Components



Test cassette



Extraction tube



Nasal swab

### Order Information

Catalog No.	00013C
Product Name	COVID-19 Antigen Rapid Test
Packing Size	25T/KIT
Sample Type	Nasal/oropharyngeal swab
Storage Condition	2-30°C
Shelf Life	18 months
Contents	25x Test cassettes (individually packed) 25x Extraction tubes with extraction buffer inside 25x Swabs 1x Instruction for use
Qualification	CE, Germany BfArM&PEI, France Approval, EU Common List

# COVID-19 Antigen Rapid Test

## Colloidal Gold

### For Self Test



- Instant results in 15 minutes
- Easy to use, no equipment required
- Room temperature storage (2-30°C)
- Non-invasive sampling
- High sensitivity and specificity

### Product Components



Test cassette



Extraction tube



Nasal swab

### Order Information

Catalog No.	00013CG/00014CH/00013CB
Product Name	COVID-19 Antigen Rapid Test
Packing Size	1T/KIT; 2T/KIT; 5T/KIT (25T/KIT; 50T/KIT)
Sample Type	Nasal swab
Storage Condition	2-30°C
Shelf Life	18 months
Contents	Test cassettes (individually packed) Extraction tubes with extraction buffer inside Nasal swabs 1x Instruction for use
Qualification	CE

# COVID-19 IgM/IgG Rapid Test

## Colloidal Gold



- Easy to use, no equipment required
- Instant results in 5-15 minutes
- Room temperature storage (2-30°C)
- Compatible with whole blood/serum/plasma
- Simultaneous monitoring of IgM and IgG
- CE marked

### Product Components



Test cassette



Extraction buffer

### Order Information

Catalog No.	00011C
Product Name	COVID-19 IgM/IgG Rapid Test
Packing Size	20T
Sample Type	whole blood/serum/plasma
Storage Condition	2-30°C
Shelf Life	18 months
Contents	Cassette: Cassette individually sealed in the aluminum foiled pouch with a desiccant. b. Drop bottle with sample diluent buffer. c. One copy of instruction for use.
Qualification	CE



## KS-001 Dry Fluorescent Immunoassay Analyzer

- ❖ Get results in 5-15 minutes
- ❖ QC & system check
- ❖ Built-in thermal printer
- ❖ LIS connectivity
- ❖ CE marked

7" Touch Screen

Built-in Thermal Printer

Test Cartridge Port

ID Card Reader

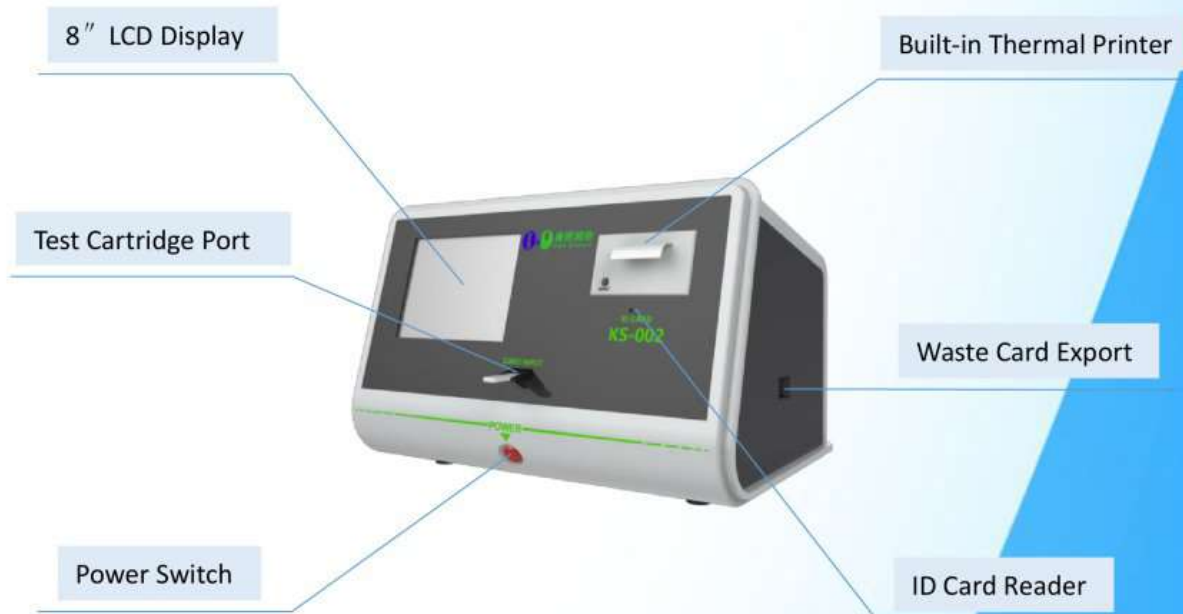


## KS-001 Specification

Catalogue Number	00014C
Number of channels	1
Product Name	KS-001 Dry Fluorescent Immunoassay Analyzer
Testing Modes	Auto-test/Queuing/Instant test
Testing Speed	120 T/h under the Queuing Mode
CV	CV ≤ 10%
Screen	7" LCD touch screen
Software	Result query and QC function are available.
Calibration Information Reading	ID card reader reads and saves the information of multiple batches of test items
Barcode scanning	The instrument has a built-in barcode scanner to identify the barcode of the test cartridge and can be connected externally to a barcode scanner to scan patient information.
Sample Type	Whole blood, plasma, serum or other sample types (varies by test item, PCT, CRP, β-HCG can be used directly with peripheral blood)
Printer	Built-in thermal printer
Interface	USB, RS232, NI and other interfaces
Data processing	Data can be exported or uploaded to the LIS system
Power	AC 220V, 50Hz; Input power 38VA
Dimension	265(L) x 212(W) x 128(H) mm
Packaging Size	370(L) x 320(W) x 230(H) mm
Net Weight	2.5kg
Storage Condition	The environment temperature is recommended from -20°C to 55°C. Relative humidity should less than 93%. Harmful gas, flammable and explosive substances and corrosive gases are prohibited.
Shelf Life	5 years

# KS-002 Dry Fluorescent Immunoassay Analyzer

- ❖ Each channel has independent timing, detecting multiple items simultaneously without interference
- ❖ Incubation function ensures 23-28 °C of testing temperature
- ❖ Various sample types including whole blood, plasma, serum, urine and peripheral blood.



## KS-002 Specification

Catalog No.	00026C
Number of Channels	12
Product Name	KS-002 Dry Fluorescent Immunoassay Analyzer
Testing Mode	Automatic testing: the instrument automatically completes test cartridge incubation, testing and discarding of waste cards
Testing Speed	up to 120 T/h (Testing speed depends on incubation time)
CV	CV ≤ 10%
Screen	8" LCD screen. The instrument can be connected to a monitor by VGA interface.
Software	WINDOWS operating system; Result query and QC function are available.
Calibration Information Reading	ID card reader reads and saves the information of multiple batches of test items
Barcode Scanning	The instrument has a built-in barcode scanner to identify the barcode of the test cartridge and can be connected externally to a barcode scanner to scan patient information.
Sample Type	Whole blood, plasma, serum or other sample types (varies by test item, PCT, CRP, β-HCG can be used directly with peripheral blood)
Printer	Built-in thermal printer
Interface	USB, VGA, NI and other interfaces
Data Processing	Data can be exported or uploaded to the LIS system
Power	AC 220V, 50Hz; Input power 250VA
Packaging Size	600(L)x 465(W) x 470(H)mm
Dimension	490(L)x 328(W) x 336(H)mm
Net weight	16kg
Storage Condition	The environment temperature is recommended from -20°C to 55°C. Relative humidity should less than 93%. Harmful gas, flammable and explosive substances and corrosive gases are prohibited.
Shelf Life	5 years

## O&D Biotech Fluorescent Immunoassay Parameters

Category	Test Item	Sample Type	Sample Volume	Assay Time	Working Range	Clinical Reference	Shelf Life	Certification
Cardiac	CK-MB	WB/S/P	75μL	12min	0.32-80ng/mL	<8.4ng/mL	18 months	CE, NMPA (CFDA)
	D-Dimer	WB/P	15μL	10min	0.1-10mg/L	0-0.5mg/L	18 months	CE, NMPA
	CRP (full range)	WB/S/P	5μL	5min	0.5-200mg/L	<10mg/L	18 months	CE, NMPA
	Myo	WB/S/P	75μL	11min	2.4-400ng/mL	<99.3ng/mL	18 months	CE, NMPA
	NT-proBNP	WB/S/P	75μL	15min	18-25000pg/mL	< age 75: <125pg/mL ≥age 75: <450pg/mL	18 months	CE, NMPA
	cTnl	WB/S/P	75μL	15min	0.03-32ng/mL	<0.16ng/mL	18 months	CE, NMPA
	3 in 1 (cTnl/Myo/CK-MB )	WB/S/P	75μL	15min	cTnl: 0.03-32ng/mL Myo: 2.4-400ng/mL CK-MB: 0.32-80ng/mL	cTnl: <0.16ng/mL Myo: <99.3ng/mL CK-MB: <8.4ng/mL	18 months	CE, NMPA
	H-FABP	WB/S/P	75μL	15min	1-100ng/mL	<10ng/mL	18 months	CE, NMPA
	Lp-PLA2	WB/S/P	75μL	15min	5-1000ng/mL	0-175ng/mL	12 months	CE, NMPA
	MPO	WB/S/P	75μL	15min	10-1000ng/mL	0~80ng/mL	12 months	CE, NMPA
Diabetes	HbA1c	WB	5μL	15min	3-15%	4-6 %	12 months	CE, NMPA
	Cys-C	WB/S/P	5μL	5min	0.5-10mg/L	0.5mg/L-1.1mg/L	18 months	CE, NMPA
	C-Peptide	WB/S/P	75μL	15min	0.1-30ng/mL	0.80-5.20ng/mL	18 months	CE, NMPA
	Insulin	WB/S/P	75μL	15min	1-300mIU/L	5-20mIU/L	18 months	CE, NMPA
Hormone	β-HCG	WB/S/P	5μL	15min	25-10000mIU/mL	0-25mIU/mL	18 months	CE, NMPA
Infection	PCT	WB/S/P	75μL	15min	0.1-100ng/mL	0-0.5ng/mL	18 months	CE, NMPA
	SAA	WB/S/P	5μL	5min	5-300mg/L	<10mg /L	18 months	CE, NMPA
	SAA/CRP	WB/S/P	5μL	5min	5-300mg/L	SAA: 0-10mg/L CRP: 0-10mg/L	18 months	CE, NMPA
	IL-6	WB/S/P	75μL	15min	4-4000pg/mL	0-7pg/mL	18 months	CE, NMPA
Others	S100-β	WB/S/P	75μL	15min	0.08-10ng/mL	0-0.18ng/mL	12 months	CE, NMPA
	NGAL	Urine/WB/S/P	75μL	15min	10-1500ng/mL	Urine: 0-100ng/mL WB/Serum/Plasma: 0-106ng/mL	12 months	CE, NMPA
	2 in 1 (PG I/PG II)	WB/S/P	75μL	15min	PGI: 10-200ng/mL PGII: 5-100ng/mL	70-200ng/mL	18 months	CE, NMPA
	MAU	Urine	75μL	5min	5-200mg/L	<20mg/L	18 months	CE, NMPA
	AMH	WB/S/P	75μL	15min	0.1-25ng/ml	0.7~6.8 ng/ml.	18 months	CE, NMPA

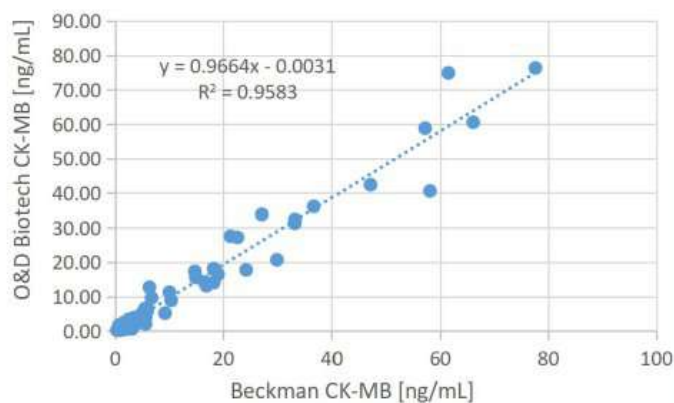
## Creatine Kinase MB (CK-MB)

Creatine kinase-MB (CK-MB) is a form of an enzyme found primarily in heart muscle cells. This test measures CK-MB in the blood. CK-MB is one of three forms (isoenzymes) of the enzyme creatine kinase (CK). CK is released from muscle cells and is detectable in the blood whenever there is muscle damage. When there is an increased amount of CK present in the blood, the CK-MB test can be used to determine whether it is due to heart damage or is more likely to be related to skeletal muscle injury.

### Specification

Sample type	WB/S/P
Sample vol.	75µL
Assay time	12 min
Working range	0.32-80ng/mL
Performance	CV ≤ 15%
Storage	2-30°C
Shelf Life	18 months

### Performance



### Ordering Information

Item	Cat #	Packing	Instruments
Creatine Kinase MB (CK-MB) Test Kit	00003C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

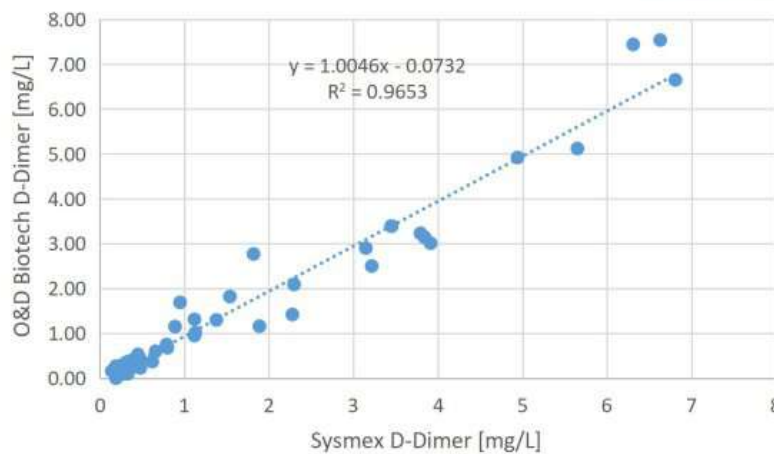
## D-Dimer

D-Dimer is one of the protein fragments produced when a blood clot gets dissolved in the body. It is normally undetectable or detectable at a very low level unless the body is forming and breaking down blood clots. Then, its level in the blood can significantly rise. This test detects D-Dimer in the blood.

### Specification

Sample type	WB/P
Sample vol.	15µL
Assay time	10 min
Working range	0.1-10 mg/L
Performance	CV $\leq$ 15%
Storage	2-30°C
Shelf Life	18 months

### Performance



### Ordering Information

Item	Cat #	Packing	Instruments
D-Dimer Test Kit	00007C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

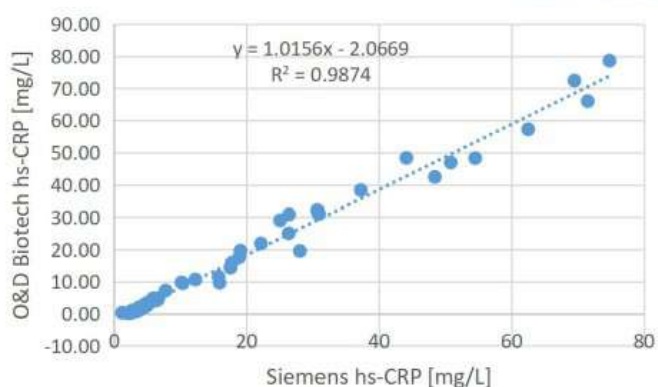
## Full Range C-reactive Protein (CRP)

C-reactive protein (CRP) is a protein that increases in the blood with inflammation and infection as well as following a heart attack, surgery, or trauma. Studies have suggested that a persistent low level of inflammation plays a major role in atherosclerosis, the narrowing of blood vessels due to build-up of cholesterol and other lipids, which is often associated with cardiovascular disease (CVD).

### Specification

Sample type	WB/S/P
Sample vol.	5µL
Assay time	5 min
Working range	0.5-200 mg/L
Performance	CV ≤ 15%
Storage	2-30°C
Shelf Life	18 months

### Performance



### Ordering Information

Item	Cat #	Packing	Instruments
Full Range C-Reactive Protein (CRP) Test Kit	00006C	25 tests/box; 20 boxes/ctn	KS-001, KS-002



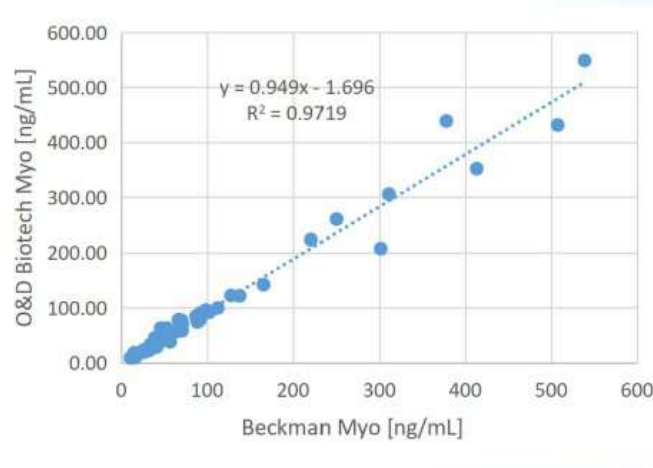
## Myoglobin (Myo)

Myoglobin is a small protein found in heart and skeletal muscles that binds oxygen. It traps oxygen within muscle cells, allowing the cells to produce the energy required for muscles to contract. When heart or skeletal muscle is injured, myoglobin is released into the blood. Elevated levels can be measured within a few hours following an injury.

### Specification

Sample type	WB/S/P
Sample vol.	75µL
Assay time	11 min
Working range	2.4-400 ng/mL
Performance	CV ≤ 15%
Storage	2-30°C
Shelf Life	18 months

### Performance



### Ordering Information

Item	Cat #	Packing	Instruments
Myoglobin Test Kit	00002C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

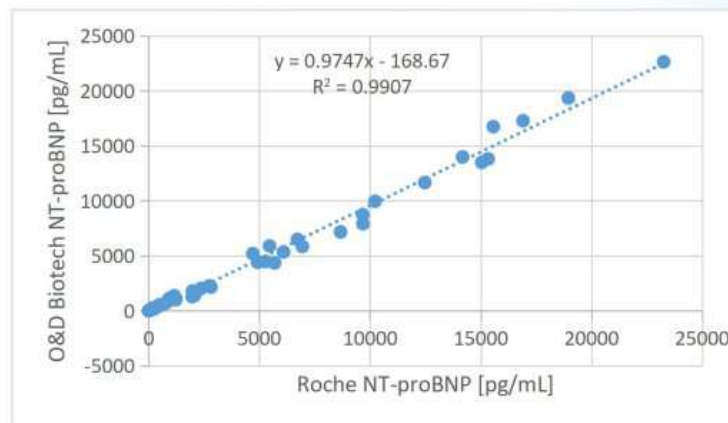
## NT-proBNP

N-terminal pro b-type natriuretic peptide (NT-proBNP) is peptide (small proteins) continually produced in small quantities in the heart and released in larger quantities when the heart senses that it needs to work harder. This supports fluid retention and volume expansion in the arteries and veins. Subsequently, the heart muscle is stretched and works hard to pump blood under normal resting condition. Tests for BNP and NT-proBNP measure their levels in the blood in order to detect and evaluate heart failure.

### Specification

Sample type	WB/S/P
Sample vol.	75µL
Assay time	15 min
Working range	18-25000 pg/mL
Performance	CV ≤ 15%
Storage	2-30°C
Shelf Life	18 months

### Performance



### Ordering Information

Item	Cat #	Packing	Instruments
N-terminal Pro-brain Natriuretic Peptide (NT-proBNP) Test Kit	00004C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

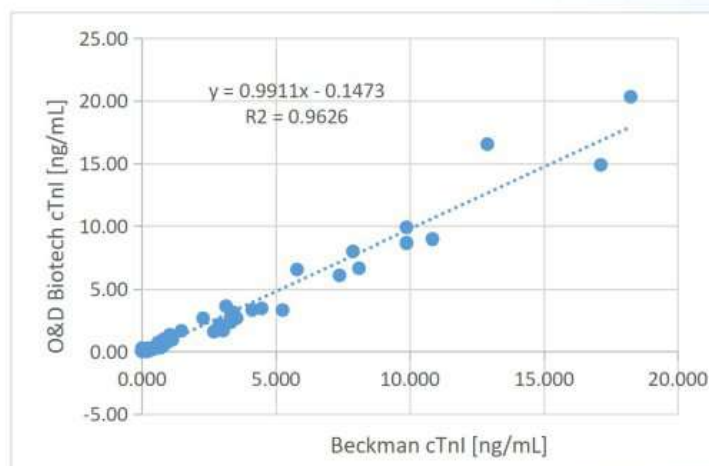
## Cardiac Troponin I (cTnI)

Measurements of cardiac troponin I are used in the diagnosis and treatment of myocardial infarction and as an aid in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

### Specification

Sample type	WB/S/P
Sample vol.	75µL
Assay time	15 min
Working range	0.03-32 ng/mL
Performance	CV ≤ 15%
Storage	2-30°C
Shelf Life	18 months

### Performance



### Ordering Information

Item	Cat #	Packing	Instruments
Cardiac troponin I (cTnI) Test Kit	00001C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

## 3 in 1 (cTnI/Myo/CK-MB)

Cardiac biomarkers show up in the blood after a heart has been under severe stress and becomes injured because it isn't getting enough oxygen. The levels of biomarkers are often used to quickly find out the size of a heart attack and how seriously the heart was affected. Cardiac troponin is by far the most commonly used biomarker, which has the highest known sensitivity. It enters into the bloodstream soon after a heart attack and stays in the bloodstream days after all other biomarkers go back to normal levels. CK-MB is a subtype of CK. It is more sensitive for finding heart damage from a heart attack. CK-MB rises 4 to 6 hours after a heart attack but is generally back to normal in a day or two. Myoglobin is a small protein that stores oxygen. Myoglobin is sometimes measured in addition to troponin to help diagnose a heart attack.

### Specification

Sample type	WB/S/P
Sample vol.	75µL
Assay time	15 min
Working range	cTnI: 0.03-32 ng/mL Myo: 2.4-400 ng/mL CK-MB: 0.32-80 ng/mL
Performance	CV ≤ 15%
Storage	2-30°C
Shelf Life	18 months

### Ordering Information

Item	Cat #	Packing	Instruments
3 in 1 (cTnI/Myo/CK-MB) Test Kit	00009C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

## Heart fatty-acid binding protein (H-FABP)

Heart fatty-acid binding protein (H-FABP) is one of the most abundant proteins in cardiomyocytes. Upon acute myocardial infarction (AMI) the blood and urine levels of H-FABP rise rapidly within 1-3 hours, reach their peak values at 6 hours, and return to baseline concentration within 24 hours. Characteristics of H-FABP appear to be similar to those of myoglobin. However, H-FABP concentrations are almost 10-fold higher in the heart than in the skeletal muscle. In contrast, myoglobin concentrations are 2-fold lower in cardiac cells than skeletal cells. Thus, the greater cardiospecificity of H-FABP account for its greater value in diagnostics of AMI.

### Specification

Sample type	WB/S/P
Sample vol.	75 $\mu$ L
Assay time	15 min
Working range	1-100 ng/mL
Performance	CV $\leq$ 15%
Storage	2-30 $^{\circ}$ C
Shelf Life	18 months

### Ordering Information

Item	Cat #	Packing	Instruments
Heart fatty-acid binding protein Test Kit	00008C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

## Lipoprotein-associated phospholipase A2 (Lp-PLA2)

Lipoprotein-associated phospholipase A2 (Lp-PLA2) is an enzyme that appears to play a role in the inflammation of blood vessels and is thought to help promote atherosclerosis. This test measures the amount or activity of Lp-PLA2 in the blood. Some recent studies have shown that Lp-PLA2 is an independent risk marker for cardiovascular disease (CVD), including coronary heart disease (CHD), and ischemic stroke. In these studies, increased concentrations of Lp-PLA2 were seen in many people who were diagnosed with CHD and ischemic stroke, regardless of other risk factors. These findings make this relatively new test potentially useful as one of a growing number of cardiac risk markers that are used to help determine a person's risk of developing CVD.

### Specification

Sample type	WB/S/P
Sample vol.	75µL
Assay time	15 min
Working range	5-1000 ng/mL
Performance	CV ≤ 15%
Storage	2-30°C
Shelf Life	12 months

### Ordering Information

Item	Cat #	Packing	Instruments
Lipoprotein-Associated Phospholipase A2 Test Kit	00019C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

## Myeloperoxidase (MPO)

Myeloperoxidase (MPO) enzyme is found in neutrophil primary granules and monocyte lysosomes. MPO catalyzes the conversion of hydrogen peroxide to hypochlorite and hypochlorous acid. MPO is encoded by a single gene that undergoes posttranslational modification to produce the active enzyme found in leukocytes. Autoantibodies to MPO (MPO antineutrophil cytoplasmic antibodies: ANCA) occur in several diseases and may be involved in the pathogenesis of vascular inflammation in patients with microscopic polyangiitis (MPA). Patients with MPA often develop MPO ANCA and may present with azotemia secondary to glomerulonephritis (pauci-immune necrotizing glomerulonephritis). MPO ANCA are not specific for MPA, and also may be detected in patients with systemic lupus erythematosus with or without lupus nephritis, Goodpasture syndrome and Churg-Strauss syndrome. Lupus nephritis and Goodpasture syndrome, as well as Wegener granulomatosis may present with azotemia and progressive renal failure. It is not possible to distinguish among these diseases on the basis of clinical signs and symptoms; autoantibody testing may be helpful.

### Specification

Sample type	WB/S/P
Sample vol.	75 $\mu$ L
Assay time	15min
Working range	10-1000 ng/mL
Performance	CV $\leq$ 15%
Storage	2-30 $^{\circ}$ C
Shelf Life	12 months

### Ordering Information

Item	Cat #	Packing	Instruments
Myeloperoxidase (MPO) Test Kit	00027C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

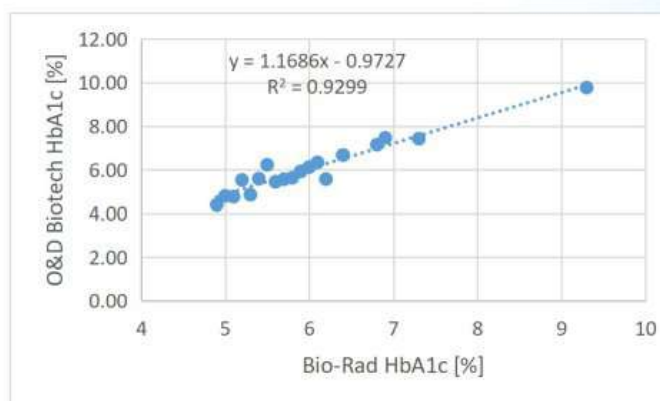
## Hemoglobin A1c (HbA1c)

Hemoglobin A1c is a minor component of hemoglobin to which glucose binds. Hemoglobin A1c levels depend on blood glucose concentrations. The higher the sugar concentration in the blood, the higher the detectable hemoglobin A1c levels. At any point in time, hemoglobin A1c levels represent the average blood sugar concentrations in the person with diabetes for approximately the preceding 3 months.

### Specification

Sample type	WB
Sample vol.	5 $\mu$ L
Assay time	15 min
Working range	3-15 % (NGSP)
Performance	CV $\leq$ 15%
Storage	2-30 $^{\circ}$ C
Shelf Life	12 months

### Performance



### Ordering Information

Item	Cat #	Packing	Instruments
Glycosylated Hemoglobin A1c (HbA1c) Test Kit	00021C	25 tests/box; 20 boxes/ctn	KS-001, KS-002



## Cystatin C (Cys-C)

Cystatin C is a relatively small protein that is produced throughout the body by all cells that contain a nucleus and is found in a variety of body fluids, including the blood. It is produced, filtered from the blood by the kidneys, and broken down at a constant rate. This test measures the amount of cystatin C in blood to help evaluate kidney function.

Cystatin C is filtered out of the blood by the glomeruli, clusters of tiny blood vessels in the kidneys that allow water, dissolved substances, and wastes to pass through their walls while retaining blood cells and larger proteins. What passes through the walls of the glomeruli forms a filtrate fluid. From this fluid, the kidneys reabsorb cystatin C, glucose, and other substances. The remaining fluid and wastes are carried to the bladder and excreted as urine. The reabsorbed cystatin C is then broken down and is not returned to the blood.

### Specification

Sample type	WB/S/P
Sample vol.	5 $\mu$ L
Assay time	5min
Working range	[0.5, 10]mg/L
Performance	CV $\leq$ 15%
Storage	2-30 $^{\circ}$ C
Shelf Life	18 months

### Ordering Information

Item	Cat #	Packing	Instruments
Cystatin C (Cys-C) Test Kit	00031C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

## C-Peptide

C-peptide is a substance, a short chain of amino acids, that is released into the blood as a byproduct of the formation of insulin by the pancreas. This test measures the amount of C-peptide in a blood or sometimes a urine sample.

In the pancreas, within specialized cells called beta cells, proinsulin, a biologically inactive molecule, is split apart to form one molecule of C-peptide and one molecule of insulin. Insulin is vital for the transport of glucose into the body's cells and is required on a daily basis. When insulin is released from the beta cells into the blood in response to increased levels of glucose, equal amounts of C-peptide are also released. Since C-peptide is produced at the same rate as insulin, it is useful as a marker of insulin production.

### Specification

Sample type	WB/S/P
Sample vol.	75µL
Assay time	15min
Working range	0.1-30ng/mL
Performance	CV $\leq$ 15%
Storage	2-30°C
Shelf Life	18 months

### Ordering Information

Item	Cat #	Packing	Instruments
C-Peptide Test Kit	00033C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

## Insulin (INS)

Insulin is a hormone that is produced and stored in the beta cells of the pancreas. It is secreted in response to elevated blood glucose following a meal and is vital for the transportation and storage of glucose, the body's main source of energy. Insulin helps transport glucose from the blood to within cells, thus helping regulate blood glucose levels, and has a role in lipid metabolism. This test measures the amount of insulin in the blood.

Insulin and glucose blood levels must be in balance. After a meal, carbohydrates usually are broken down into glucose and other simple sugars. These are absorbed into the blood, causing the blood glucose level to rise, which in turn stimulates the pancreas to release insulin into the blood. As glucose moves into cells, the level in the blood decreases and release of insulin by the pancreas decreases.

### Specification

Sample type	WB/S/P
Sample vol.	75µL
Assay time	15min
Working range	1-300mIU/L
Performance	CV ≤ 15%
Storage	2-30°C
Shelf Life	18 months

### Ordering Information

Item	Cat #	Packing	Instruments
Insulin (INS) Test Kit	00034C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

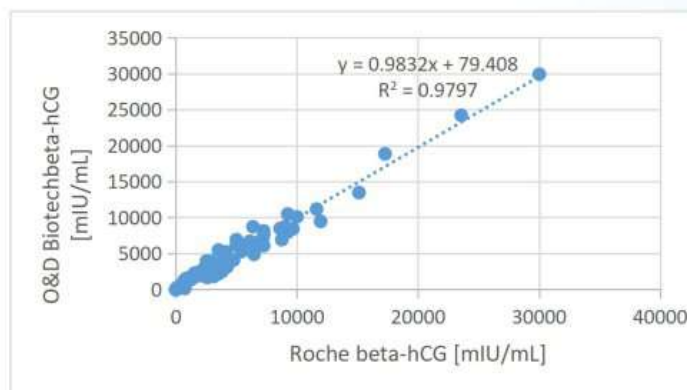
## $\beta$ -human Chorionic Gonadotropin ( $\beta$ -hCG)

Beta-hCG (bHCG or  $\beta$ -hCG) is a sex hormone found in the mother's blood serum that can be used to help interpret obstetric ultrasound findings. Beta-hCG levels may be used in three ways in the clinical setting of pregnancy: qualitatively, for presence/absence of fetal tissue; quantitatively, for assessing if a pregnancy is meeting appropriate cut-off values for its age; quantitatively, for trending the growth rate of fetal tissue. Outside the pregnancy setting, it may also be used quantitatively as a tumor marker, to aid in diagnosing a potentially beta-hCG secreting mass (e.g. choriocarcinoma).

### Specification

Sample type	WB/S/P
Sample vol.	5 $\mu$ L
Assay time	15 min
Working range	25-10000 mIU/mL
Performance	CV $\leq$ 15%
Storage	2-30 $^{\circ}$ C
Shelf Life	18 months

### Performance



### Ordering Information

Item	Cat #	Packing	Instruments
$\beta$ -human Chorionic Gonadotropin ( $\beta$ -hCG) Test Kit	00017C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

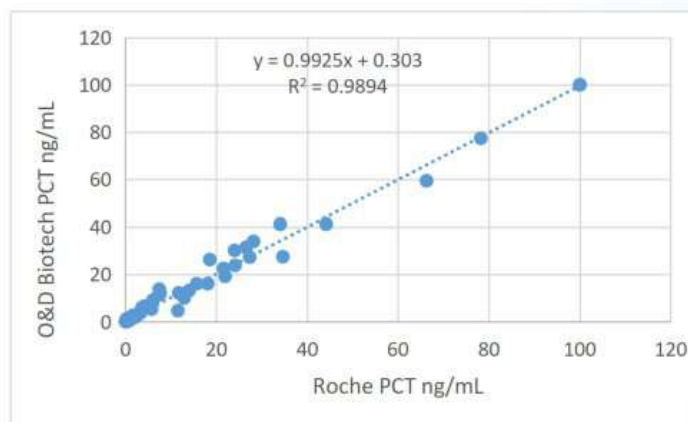
## Procalcitonin (PCT)

Procalcitonin is a substance produced by many types of cells in the body, often in response to bacterial infections but also in response to tissue injury. The level of procalcitonin in the blood can increase significantly in systemic bacterial infections and sepsis. This test measures the level of procalcitonin in the blood.

### Specification

Sample type	WB/S/P
Sample vol.	75 $\mu$ L
Assay time	15 min
Working range	0.1-100 ng/mL
Performance	CV $\leq$ 15%
Storage	2-30 $^{\circ}$ C
Shelf Life	18 months

### Performance



### Ordering Information

Item	Cat #	Packing	Instruments
Procalcitonin (PCT) Test Kit	00005C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

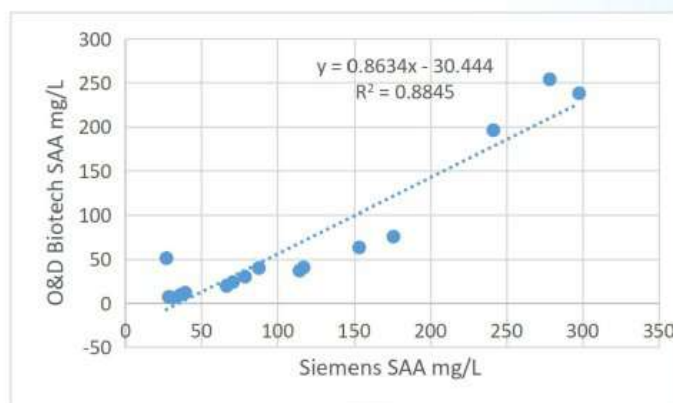
## Serum Amyloid A (SAA)

Serum amyloid A (SAA) is an early and sensitive blood biomarker for tissue injury and inflammation and has been indicated in many inflammatory diseases. The level of SAA circulating in the blood is known to increase dramatically in response to tissue damage or inflammation, classifying it as an acute phase protein. Circulating SAA concentrations may increase up to 1000-fold following inflammation, infection, tissue injury and cell necrosis and decline rapidly following recovery.

### Specification

Sample type	WB/S/P
Sample vol.	5 µL
Assay time	5min
Working range	5-300mg/L
Performance	CV ≤ 15%
Storage	2-30°C
Shelf Life	18 months

### Performance



### Ordering Information

Item	Cat #	Packing	Instruments
Serum Amyloid A (SAA) Test Kit	00022C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

## Influenza A+B (Colloidal Gold)

Influenza (the flu) is a common viral respiratory infection that causes an illness ranging from mild to severe, and sometimes can be fatal. Influenza testing detects the presence of the virus in a sample of respiratory secretions. Two types of influenza virus, A and B, cause annual flu pandemics and most epidemics. Influenza testing can help rule out other illnesses and reduce the chances of people using unnecessary antibiotics, while increasing the chances that they will receive anti-viral therapy early in the illness, when it is most effective.

### Specification

Sample type	nasal swab/nasopharyngeal swab
Assay time	20 min
Working range	qualitative
Performance	CV $\leq$ 15%
Storage	2-30°C
Shelf Life	18 months

### Performance

Sensitivity	Specificity
A: 80.3% B: 58.3%	A: 96.6% B: 98.0%

### Ordering Information

Item	Cat #	Packing
Influenza A and B (FLU A&B) Test Kit	00015C	20 tests/box; 20 boxes/ctn

## 2 in 1 (SAA/CRP)

Serum amyloid A (SAA) is an early and sensitive blood biomarker for tissue injury and inflammation and has been indicated in many inflammatory diseases. The level of SAA circulating in the blood is known to increase dramatically in response to tissue damage or inflammation, classifying it as an acute phase protein. Circulating SAA concentrations may increase up to 1000-fold following inflammation, infection, tissue injury and cell necrosis and decline rapidly following recovery. C-reactive protein (CRP) is a protein that increases in the blood with inflammation and infection as well as following a heart attack, surgery, or trauma. Studies have suggested that a persistent low level of inflammation plays a major role in atherosclerosis, the narrowing of blood vessels due to build-up of cholesterol and other lipids, which is often associated with cardiovascular disease (CVD).

### Specification

Sample type	WB/S/P
Sample vol.	5 µL
Assay time	5min
Working range	5-300mg/L
Performance	CV ≅ 15%
Storage	2-30°C
Shelf Life	18 months

### Ordering Information

Item	Cat #	Packing	Instruments
2 in 1 (SAA/CRP) Test Kit	00023C	25 tests/box; 20 boxes/ctn	KS-001, KS-002



## Interleukin-6 (IL-6)

Interleukin-6 (IL-6) is a protein produced by various cells. It helps regulate immune responses, which makes the IL-6 test potentially useful as a marker of immune system activation. IL-6 can be elevated with inflammation, infection, autoimmune disorders, cardiovascular diseases, and some cancers. The test measures the amount of IL-6 in the blood. Interleukin-6 is one of a large group of molecules called cytokines. Cytokines have multiple roles to play within the body and act especially within the immune system to help direct the body's immune response. They are a part of the "inflammatory cascade" that involves the coordinated, sequential activation of immune response pathways. IL-6 acts on a variety of cells and tissues. It promotes differentiation of B-cells (white blood cells that produce antibodies), promotes cell growth in some cells, and inhibits growth in others. It stimulates the production of acute phase proteins. IL-6 also plays a role in body temperature regulation, bone maintenance, and brain function. It is primarily pro-inflammatory but can also have anti-inflammatory effects.

### Specification

Sample type	WB/S/P
Sample vol.	75 $\mu$ L
Assay time	15min
Working range	4-4000pg/mL
Performance	CV $\leq$ 15%
Storage	2-30°C
Shelf Life	18 months

### Ordering Information

Item	Cat #	Packing	Instruments
Interleukin-6 (IL-6) Test Kit	00024C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

## S100- $\beta$ Protein

S100B is a calcium-binding peptide and is used as a parameter of glial activation and/or death in many disorders of the central nervous system (CNS). It plays important roles in normal CNS development and recovery after injury. Although S100B is mainly found in astroglial and Schwann cells, it also has extracerebral sources. S100B is a useful neurobiochemical marker of brain damage such as in circulatory arrest, stroke and traumatic brain injury. S100B is also associated with neurodegenerative diseases like Alzheimer's disease or other chronic neurological diseases. Moreover, S100B may have a potential in predicting the efficiency of treatment and prognosis.

### Specification

Sample type	WB/S/P
Sample vol.	75 $\mu$ L
Assay time	15 min
Working range	0.08-10 ng/mL
Performance	CV $\leq$ 15%
Storage	2-30 $^{\circ}$ C
Shelf Life	12 months

### Ordering Information

Item	Cat #	Packing	Instruments
S100- $\beta$ Protein Test Kit	00018C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

## Neutrophil Gelatinase-Associated Lipocalin (NGAL)

Neutrophil gelatinase-associated lipocalin (NGAL) is an emerging biomarker for earlier identification of acute kidney injury (AKI). Using similar methodology, a reference interval for urine NGAL in adults was determined to be <113 ng/mL. Age- and sex-specific ranges have not been established, but there is evidence that urine NGAL concentrations increase with age and are higher in females than in males.

### Specification

Sample type	Urine/WB/S/P
Sample vol.	75 $\mu$ L
Assay time	15 min
Working range	10-1500 ng/mL
Performance	CV $\leq$ 15%
Storage	2-30 $^{\circ}$ C
Shelf Life	12 months

### Ordering Information

Item	Cat #	Packing	Instruments
Neutrophil Gelatinase-Associated Lipocalin (NGAL) Test Kit	00020C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

## Pepsinogen I/Pepsinogen II (PGI/PGII)

Pepsinogen I and II, the precursors of pepsin, are produced by the gastric mucosa and released into the gastric lumen and peripheral circulation (Samloff and Liebman, 1973). Severe inflammation of gastric mucosa and its progression toward atrophic gastritis (AG) is correlated with a change in serum biomarkers pepsinogen I and II. It has been previously reported that pepsinogen II is a good marker for the diagnosis of any type of gastritis as it can differentiate between subjects with gastritis from those with normal mucosa. The progression of gastritis to acute and pangastritis is associated with a continual increase in serum pepsinogen II levels, whereas the levels of pepsinogen I in the early stage of acute gastritis remain unchanged and in the normal range.

### Specification

Sample type	WB/S/P
Sample vol.	75 $\mu$ L
Assay time	15 min
Working range	PGI: 10-200ng/mL PGII: 5-100ng/mL
Performance	CV $\leq$ 15%
Storage	2-30 $^{\circ}$ C
Shelf Life	18 months

### Ordering Information

Item	Cat #	Packing	Instruments
Pepsinogen I/Pepsinogen II (PGI/PGII) Test Kit	00032C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

## Urinary Microalbumin (MAU)

A urine microalbumin test is a test to detect very small levels of a blood protein (albumin) in urine. In healthy individuals, the kidney filters waste from the blood and retain healthy components, such as albumin. However, microalbumin may be detected in the urine in the early stages of kidney disease. This is frequently seen in chronic diseases, such as diabetes or high blood pressure. Kidney damage can cause proteins to leak through kidneys and exit the body in urine. MicroAlbumin in Urine (MAU) is one of the first clinically identifiable markers for risk of kidney damage. Identifying kidney disease at an early stage can help prevent serious complications.

### Specification

Sample type	Urine
Sample vol.	75 $\mu$ L
Assay time	5 min
Working range	5-200mg/L
Performance	CV $\leq$ 15%
Storage	2-30 $^{\circ}$ C
Shelf Life	18 months

### Ordering Information

Item	Cat #	Packing	Instruments
Urinary Microalbumin (MAU) Test Kit	00035C	25 tests/box; 20 boxes/ctn	KS-001, KS-002

## Anti-Müllerian Hormone (AMH)

In women, to assess ovarian function and menopausal status; in the evaluation of polycystic ovary syndrome (PCOS) or to evaluate the effectiveness of ovarian cancer treatment; in an infant, to evaluate the presence of external sex organs that are not clearly male or female (ambiguous genitalia) and/or function of the testicles in an infant boy. When a health care practitioner wants to evaluate a woman's fertility, predict onset of menopause, suspects PCOS, or wants to evaluate the cause of male characteristics in a female (virilization); sometimes prior to some assisted reproductive procedures; periodically when a woman is undergoing treatment for an AMH-producing ovarian cancer; when it is suspected that the testicles of an infant boy are absent, hidden, or not functioning properly.

### Specification

Sample type	WB/S/P
Sample vol.	75 µL
Assay time	15 min
Working range	0.1-25ng/ml
Performance	CV ≤ 15%
Storage	2-30°C
Shelf Life	18 months

### Ordering Information

Item	Cat #	Packing	Instruments
AMH Test Kit	00025C	25 tests/box; 20 boxes/ctn	KS-001, KS-002