



Fluorescence Immunoassay Product Catalogue

Q8 Pro and Test Menu



POCT



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About Zyblio

Zybio Inc. (referred to as "Zybio") is a national high tech enterprise founded in 2008, one of the leading Chinese medical companies dedicated in a comprehensive line of IVD reagents and equipment, including Hematology, Chemistry, CLIA, POCT, Molecule, Microbiology.

Since the beginning, Zybio has implemented high standard in all aspects in terms of research & development, production, marketing, sales and technical services, to satisfy the needs of our users.

Now, there are over 3000 employees totally and one-third of them are engaged in R&D, of which more than 50% have a master's degree or above.

We have built 8 R&D centers in China, including Chongqing R&D center, Shanghai R&D center, Guangzhou R&D center, Shenzhen R&D center, Beijing R&D center, Xiamen R&D center, Changchun R&D center and Nanjing R&D center. Strong R&D team guarantees more diverse and high-quality product, which drives us forward. In addition, we have an independent service center allocating more than 100 service or application engineers to serve our clients throughout the world.

Based on the ideology of “plan together, create together, share together”, we have set up a network of operations throughout China and keep expanding globally.





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Fluorescence Immunoassay Analyzer (Q8 Pro)

Q8 Pro is a quantitative POCT analyzer based on dry immunoassay fluorescence technology that integrates operation, analysis, and result display. It can automatically complete a series of operations including test card loading, item identification, incubation, detection, card discarding and results print within 15 minutes.



• Features



User-friendly

- 15-inch touch screen, intuitive software interface
- 25 channels, up to 25 different items in one time
- External solid waste container, easy to maintain and environment friendly



Intelligent

- Maintenance free
- Real-time monitoring
- Power-off protection, and ready to store test result
- Temperature stable incubator



Accurate

- Automatically recognize item information
- Stable photoelectric signal
- Advanced rare earth element fluorescent microsphere labeling technology, higher sensitivity
- Online software update



Convenient

- Multi-sample types, including serum, plasma, urine
- Time to result within 10 minutes
- Free calibration system
- Result transmission by LIS



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• Technical Advantages

Q8 Pro labels antigen or antibody with rare earth element, which effectively eliminates non-specific fluorescence interference and improves analysis sensitivity.

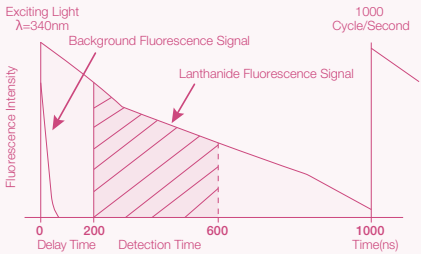


Figure 1: Fluorescence signal decay time comparison

• Parameters

Principle	Fluorescence Immunochromatography
Channel	25
Test Time	3-15 min
Sample Type	Whole blood, capillary blood, serum, plasma
Incubation Temperature	37.0°C±1.5°C
Data Transmission	LIS
Operation System	Windows 10
Display	15-inch

Storage Capacity	100,000 tests
Software Update	By USB or internet
Power Supply	100-240V~, 50/60 Hz, 150 VA
Temperature	10~30°C
Relative Humidity	30%~85%
Air Pressure	70~106 KPa
Altitude	≤ 3000 m
Dimension	416 mm × 395 mm × 404 mm (W*D*H)
Weight	18 Kg

• Test menu

Panel	Test Items
Inflammation	CRP, SAA, PCT, IL-6
Cardiac Markers	D-Dimer, NT-proBNP, cTnT, 3 in 1(cTnT/CK-MB/Myo), cTnl
Bone metabolic	25-OH Vitamin D*
Thyroid	TSH*, T3*, T4*
DM	HbA1c
SARS-CoV-2	SARS-CoV-2 Neutralizing Antibody, SARS-CoV-2 Antibody

* Coming soon

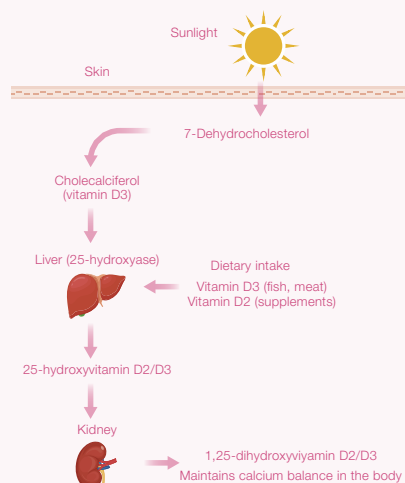
25-OH-VD

- Bone metabolic

Vitamin D is a kind of fat-soluble vitamins, is a multi-functional hormone can maintain a healthy body, which plays an important role on the control of calcium phosphate levels in the body and bone calcification. In addition, vitamin D plays an important role in the function of many systemic systems, including cardiovascular system, immune system, nervous system, glucose metabolism, cell proliferation and differentiation, etc.

Total vitamin D can be converted to 25-hydroxyvitamin D in the liver and further hydroxylated to the active 1, 25-dihydroxyvitamin D in the kidney.

The 25-hydroxy vitamin D test is the most accurate way to measure how much vitamin D is in your body.



- Parameter

Panel	Test Item	Reaction Time	Sample Type and Volume	Mixture Loading Volume	Measuring Range	Reference Range	Qualification
Vitamin	25-OH-VD	15 min	WB/Plasma/ Serum: 70µL	70uL	5.0–120.0 ng/mL	≥30 ng/mL	CE, NMPA

- Order Information

Test Item	Catalog No.	Test/kit	Unit	Quantity	Available Systems
25-OH-VD	2014101	25 T/Kit	Kit	1	Q8 Pro



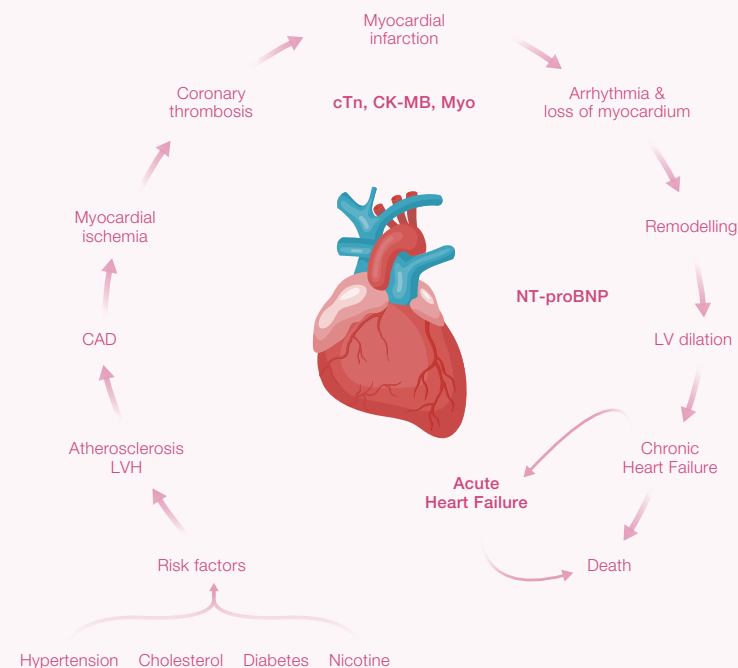
NT-proBNP, D-Dimer, cTnT, cTnI, 3 in 1 (cTnT/CK-MB/Myo)

- Cardiac Markers

Acute myocardial infarction (AMI) is a major cause of morbidity and mortality worldwide. The highest risk of fatality occurs within the initial hours of onset of AMI. Thus, early diagnosis of cardiac ischemia is critical for the effective management of patients with AMI. Myo is a preferred early indicator for the diagnosis of acute myocardial infarction (AMI). CTnl is a highly specific indicator for the diagnosis of AMI. Ck-mb is less sensitive than Myo or cTnl, but it is of certain value in the diagnosis of early post-AMI reinfarction. Clinical evidence shows that any single test result has the possibility of misdiagnosis and missed diagnosis, and combined test is more conducive to the early and accurate diagnosis of AMI.

NT-proBNP is measured as a simple blood test to help diagnose and monitor heart failure. It's released in response to changes in pressure inside the heart. These changes can be related to heart failure and other cardiac problems. Levels goes up when heart failure develops or gets worse, and levels goes down when heart failure is stable.

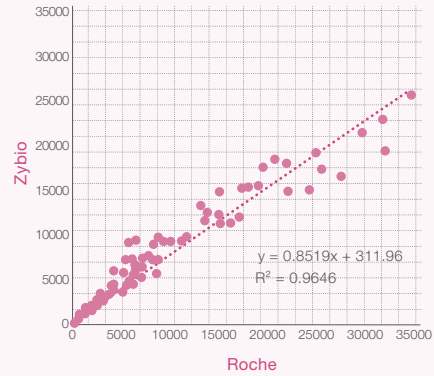
A NT-proBNP test is most often used to diagnose or rule out heart failure. The test is particularly useful in hospital emergencies to help distinguish heart failure from severe lung damage, which often has the same symptoms. In an outpatient setting, the test is useful for monitoring disease progression and the effects of treatment.



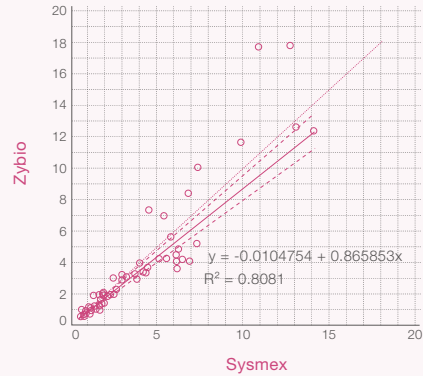
• Parameter

Panel	Test Item	Reaction Time	Sample Type and Volume	Mixture Loading Volume	Measuring Range	Reference Range	Qualification
Cardiac Markers	NT-proBNP	10 min	WB:100µL Plasma/Serum: 70µL	/	30-35000 pg/mL	under 75 years old <125 pg/mL Over 75 years old <450 pg/mL	CE, NMPA
	D-Dimer	5 min	WB:100µL Plasma: 70µL	/	0.2-20 µg/mL	D-Dimer < 0.5 •g/mL	CE, NMPA
	cTnT	10 min	WB:100µL Plasma/Serum: 70µL	/	0.01-10.00 ng/mL	cTnT < 0.04 ng/mL	CE, NMPA
	cTnI	15 min	WB:100µL Plasma/Serum: 70µL	/	0.10~50.00ng/mL	0-0.3 ng/mL	CE, NMPA
	3 in 1 (cTnT/CK-MB/Myo)	10 min	WB:100µL Plasma/Serum: 70µL	/	cTnT: 0.01-10.00 ng/mL CK-MB: 1-80 ng/mL Myo: 5-500 ng/mL	cTnT < 0.04 ng/mL CK-MB < 5 ng/mL Myo < 72 ng/mL	CE, NMPA

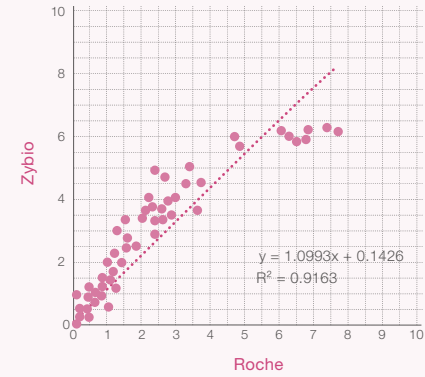
• Performance



NT- pro BNP comparison test between Zybion and Roche




D-Dimer comparison test between Zybion and Sysmex



cTnT comparison test between Zybion and Roche

• Order Information

Test Item	Catalog No.	Test/kit	Unit	Quantity	Available Systems
NT-proBNP	2012701	25 T/Kit	Kit	1	Q8 Pro
D-Dimer	2012601	25 T/Kit	Kit	1	Q8 Pro
cTnT	2012801	25 T/Kit	Kit	1	Q8 Pro
cTnI	2014001	25 T/Kit	Kit	1	Q8 Pro
3 in 1 (cTnT/CK-MB/Myo)	2012901	25 T/Kit	Kit	1	Q8 Pro



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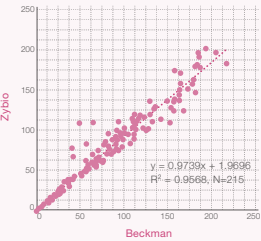
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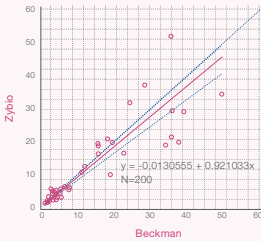
Parameter

Panel	Test Item	Reaction Time	Sample Type and Volume	Mixture Loading Volume	Measuring Range	Reference Range	Qualification
Infection Marker	CRP	3 min	WB/Plasma/ Serum: 5µL	70µL	0.5-200 µg/mL	hs-CRP < 1 µg/mL, CRP < 10 µg/mL	CE, NMPA
	SAA	3 min	WB/Plasma/ Serum: 5µL	70µL	3-200 µg/mL	SAA <10 ug/mL	CE, NMPA
	PCT	10 min	WB:100µL Plasma/Serum: 70µL	/	0.1-100.0 ng/mL	PCT < 0.5 ng/mL	CE, NMPA
	IL-6	15 min	WB:100µL Plasma/Serum: 70µL	/	5~4000 pg/mL	< 7pg/mL	CE, NMPA

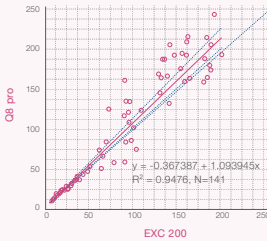
Performance



CRP comparison test between Zybto and Beckman



PCT comparison test between Zybto Q8 pro and Roche cobas e 411



SAA comparison test between Q8 pro and EXC200 (Chemistry analyzer)

Order Information

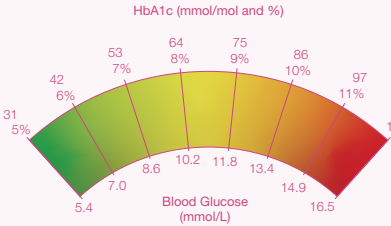
Test Item	Catalog No.	Test/kit	Unit	Quantity	Available Systems
CRP	2012501	25 T/Kit	Kit	1	Q8 Pro
SAA	2013101	25 T/Kit	Kit	1	Q8 Pro
IL-6	2013901	25 T/Kit	Kit	1	Q8 Pro
PCT	2013001	25 T/Kit	Kit	1	Q8 Pro

HbA1c

Diabetic Markers

A hemoglobin A1c (HbA1c) test measures the amount of blood sugar (glucose) attached to hemoglobin. Hemoglobin is the part of your red blood cells that carries oxygen from your lungs to the rest of your body. An HbA1c test shows what the average amount of glucose attached to hemoglobin has been over the past three months. It's a three-month average because that's typically how long a red blood cell lives.

If your HbA1c levels are high, it may be a sign of diabetes, a chronic condition that can cause serious health problems, including heart disease, kidney disease, and nerve damage.



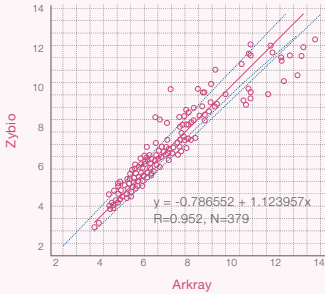
HbA1c as an indicator of diabetes control

Parameter

Panel	Diabetic
Test Item	HbA1c
Reaction Time	5 min
Specimen Type and Volume	Whole blood: 5µL
Mixture Loading Volume	Diluted sample: 70uL
Measuring Range	4.0 - 14.0%
Reference Range	4.0%-6.0%
Qualification	CE, IFCC, *NGSP

NGSP certification is on process

Performance



HbA1c comparison test between Zybto and Arkray

Order Information

Test Item	Catalog No.	Test/kit	Unit	Quantity	Available Systems
HbA1c	2013501	25 T/Kit	Kit	1	Q8 Pro



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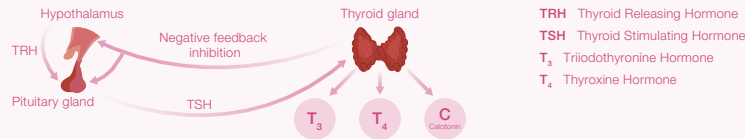
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T3, T4, TSH

Serological tests of thyroid function include total thyroxine (T4), total triiodothyronin (T3), free thyroxine (FT4), free triiodothyronin (FT3), thyroid stimulating hormone (TSH), etc. It is an important part of diagnosing and treating thyroid disorders. While some conclusions can be drawn from a single test, a combination of test results are usually needed to establish the full nature of your thyroid health. By comparing the values of thyroid tests, a doctor can determine whether a person has hypothyroidism (people with low thyroid function), hyperthyroidism (people with overactive thyroid), or an autoimmune thyroid disease such as Graves' disease or Hashimoto's thyroiditis.



- Interpretation for Thyroid Function Test

	High T3/T4	Normal T3/T4	Low T3/T4
High TSH	Pituitary hyperthyroidism Thyroid hormone resistance	Subclinical hypothyroidism	Primary hypothyroidism
Normal TSH	Sampling within 6 h of thyroxine dose	Normal	Pituitary or hypothalamic hypothyroidism Severe non-thyroidal illness ^v
Low TSH	Hyperthyroidism	Subclinical hyperthyroidism Subtle thyroxine overreplacement Autonomous functioning thyroid nodule Non-thyroidal illness	Pituitary or hypothalamic hypothyroidism Severe non-thyroidal illness

- Parameter

Panel	Test Item	Reaction Time	Sample Type and Volume	Mixture Loading Volume	Measuring Range	Reference Range	Qualification
Thyroid Function	TSH	15 min	WB:100μL Plasma/Serum: 70μL	/	0.1-100.0 mIU/L	0.3 mIU/L-4.2 mIU/L	CE, NMPA
	T3	15 min	WB/Plasma/ Serum: 70μL	70μL	0.5-10.0 nmol/L	1.23 nmol/L-3.07 nmol/L	CE, NMPA
	T4	15 min	WB/Plasma/ Serum: 70μL	70μL	12.87-310.0 nmol/L	66-181 nmol/L	CE, NMPA

- Order Information

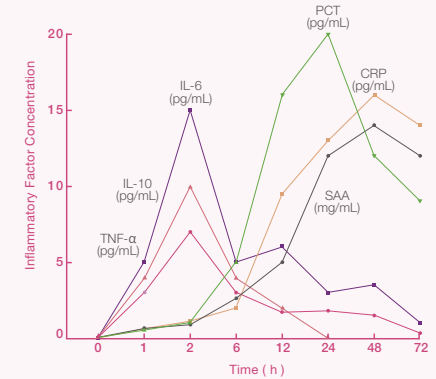
Test Item	Catalog No.	Test/kit	Unit	Quantity	Available Systems
TSH	2013801	25 T/Kit	Kit	1	Q8 Pro
T3	2013601	25 T/Kit	Kit	1	Q8 Pro
T4	2013701	25 T/Kit	Kit	1	Q8 Pro

CRP, SAA, IL-6, PCT

- Infection Marker

Infectious diseases are one of the most common clinical diseases. Due to the diversity of routes of infection, the variety of pathogens, and individual differences in symptoms and signs, delayed diagnosis and treatment may occur. Therefore, it is particularly important to distinguish the infection type of patients when infectious diseases occur.

The four inflammatory tests (PCT/IL-6/SAA/CRP) can help quickly and effectively identify the types of infection in patients, which can not only alleviate the lack of diagnosis speed, but also classify the diagnosis, avoiding the misuse of antibiotics and the waste of scarce medical resources during the critical period.



	CRP	SAA	PCT	IL-6*
Clinical Features	Bacterial infections increased, and some viral infections increased	Virus infection increased significantly, bacterial infection increased greatly, decreased greatly when infection is cured	The most specific markers of bacterial infection and sepsis can be used to monitor antibiotic use	Bacterial and viral infections, mycoplasma infections, malignant tumors, severe tissue damage, autoimmune diseases, etc.
Dynamic Characteristics	Rising stage: 6-12 h Platform stage: 24-48 h	Rising stage: 8 h Platform stage: 5-6 h	Rising stage: 2-4 h Platform stage: 12-48 h	Rising stage: 0-1 h Platform stage: 2 h
Local Inflammation	↑	↑	↑	↑
Bacterial Infection	↑ ↑	↑ ↑	↑ ↑	↑ ↑
Viral Infection	↑	↑ ↑	—	↑ ↑
Fungal Infection	—	—	↑	↑ ↑
Clinical Value	Most commonly used	Virus infection preference	Most specific	Most sensitive
Application Scenarios	CS panel: Outpatient service, etc. (Upper respiratory tract or gastrointestinal tract infection)		IP panel: Multi-department and multi-scene (Inpatient and emergency department, Different disease states)	



SARS-CoV-2 Nab, SARS-CoV-2 Total antibody

• COVID-19

The pandemic (i.e. COVID-19) and mutated variants continuously threatens throughout the world.

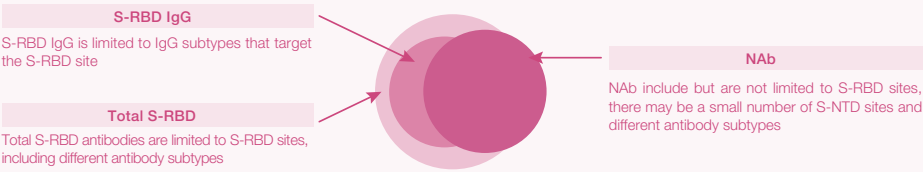
RT-PCR (fluorescent probe) method remains as golden standard for COVID-19 diagnosis, though due to lack of proficient sampling operation, as well as stage of patient's infection, there are false negatives occurred at a minor possibility.

SARS-CoV-2 antibody tests could be a supplementary detection for suspected cases with negative test of SARS-CoV-2 nucleic acid tests or in conjunction with nucleic acid assay in the diagnosis of suspected cases.

As COVID-19 vaccination continues to deepen, SARS-CoV-2 neutralizing antibody detection comes into being.

SARS-CoV-2 Neutralizing Antibody detection is a valuable tool in measuring the effectiveness of vaccines and help detection of neutralizing antibody in human with infected or suspected SARS-CoV-2.

What's the differences between SARS-CoV-2 antibody and neutralizing antibody?



• Parameter

Panel	Test Item	Reaction Time	Sample Type and Volume	Mixture Loading Volume	Target Protein	Measuring Range	Reference Range	Qualification
COVID-19	SARS-CoV-2 Neutralizing Antibody	10 min	Whole blood / plasma / serum	100 μL for whole blood 60 μL for serum/plasma	S-RBD	0.03-10 U/mL	< 0.3 U/mL	CE
	SARS-CoV-2 Antibody	10 min	Whole blood / plasma / serum	100 μL for whole blood 60 μL for serum/plasma	S-RBD	Qualitative	Negative	CE

• Order Information

Test Item	Catalog No.	Test/kit	Unit	Quantity	Available Systems
SARS-CoV-2 Neutralizing Antibody	2110201	25 T/Kit	Kit	1	Q8 Pro
SARS-CoV-2 Antibody	2100201	25 T/Kit	Kit	1	Q8 Pro



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