Finecare™

Fluorescence Immunoassay Rapid Quantitative Test

Wondfo

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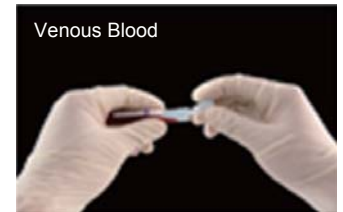E-mail: customerservice@wondfo.com.cn

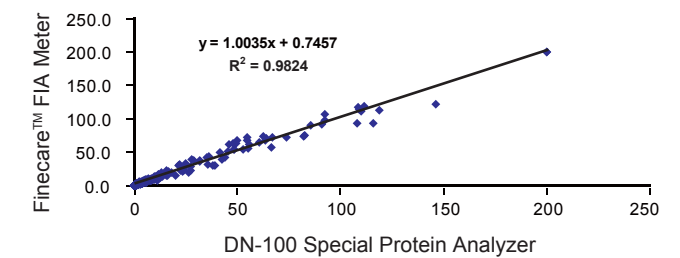**Guangzhou Wondfo Biotech Co., Ltd.**

Wondfo

CONTENTS

- **Infection Markers:** CRP, PCT

- **Cardiac Markers:** NT-proBNP, cTnI, Myo, CK-MB, H-FABP, 3 in 1

- **Coagulation Marker:** D-Dimer

- **Renal Injury Marker:** MAU

- **Diabetes Marker:** HbA1c
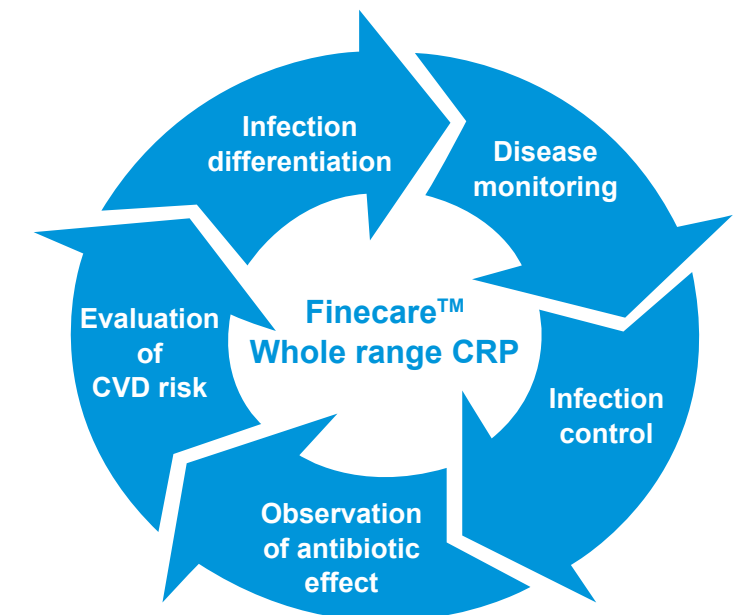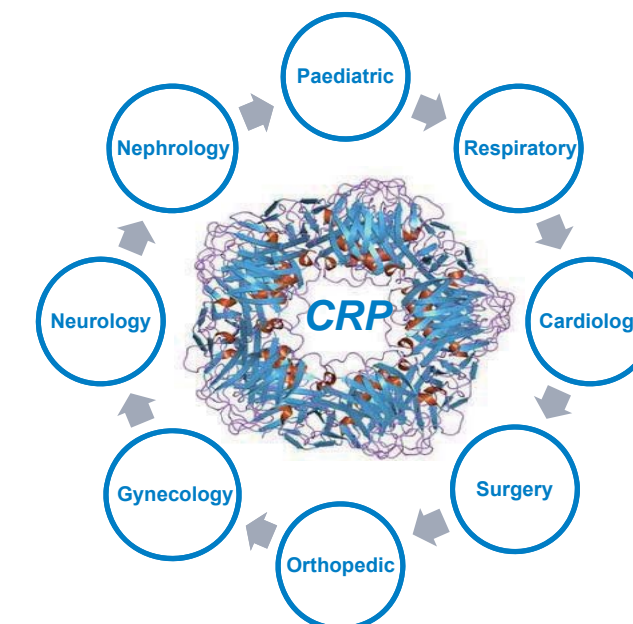
- **Tumor Markers:** AFP, PSA

CRP (C-reactive Protein) Rapid Quantitative Test

CRP

CRP is a protein found in the blood, the rise of CRP levels response to inflammation. Combination of CRP and blood routine test increases diagnosis accuracy.

Characteristic:

- Rapid (Reaction time = 3min. TAT≤10min)
- Fluorescence signaling, higher sensitivity and specificity
- Whole range (hsCRP+CRP)
- Both venous blood and capillary blood are applicable
- CRP control

Venous Blood

Capillary Blood

Performance:

Reaction time	3 minutes
Test time	10 seconds
Linear range	0.5 – 200 mg/L
Reference value	hsCRP＜1.0, CRP＜10

$y = 1.0035x + 0.7457$
$R^2 = 0.9824$

Finecare™ FIA Meter

DN-100 Special Protein Analyzer

Application:

Paediatric
Respiratory
Cardiology
Surgery
Orthopedic
Gynecology
Neurology
Nephrology

CRP

Infection differentiation
Disease monitoring
Finecare™ Whole range CRP
Infection control
Observation of antibiotic effect
Evaluation of CVD risk

PCT

PCT (Procalcitonin) Rapid Quantitative Test

PCT is a peptide precursor of the hormone calcitonin. Measurement of PCT can be used as a marker of severe sepsis caused by bacteria and generally grades well with the degree of sepsis.
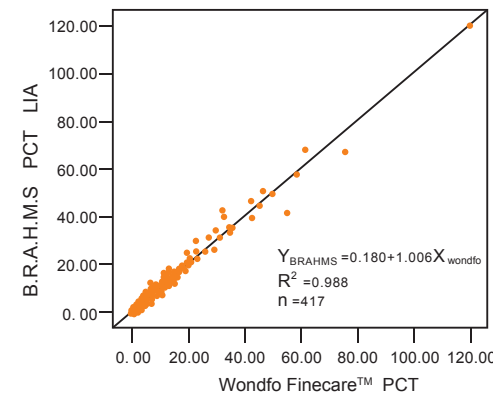
Characteristic:

- Rapid (Reaction time =15min)
- Fluorescence signaling, higher sensitivity and specificity
- Preferred indicator of bacterial infection and sepsis
- PCT control
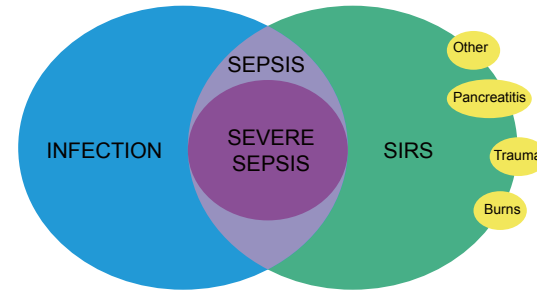
Performance:

Reaction time	15 minutes
Test time	10 seconds
Linear range	0.1 – 100ng/mL
Specimen type	Whole blood/Serum/Plasma
Precision	CV≤15%

$$Y_{BRAHMS} = 0.180 + 1.006 X_{wondfo}$$
$$R^2 = 0.988$$
$$n = 417$$

B.R.A.H.M.S PCT LIA vs Wondfo Finecare™ PCT

Application:

- Early diagnosis of severe infection
- Differentiating infection of bacteria from virus

Differential diagnosis

- Accurately guiding medication time and dosage of antibotics
- Effectively avoiding antibiotic abuse

Medication guiding

- Sepsis indication, MODS prognosis
- Clinical observation of antibiotic treatment

Prognosis evaluation

Dynamic monitoring

- Severity monitoring of servious patient
- Monitoring of postoperative infection

Application mainly in Emergency, ICU, Pediatric, Respiratory, Surgical department etc.
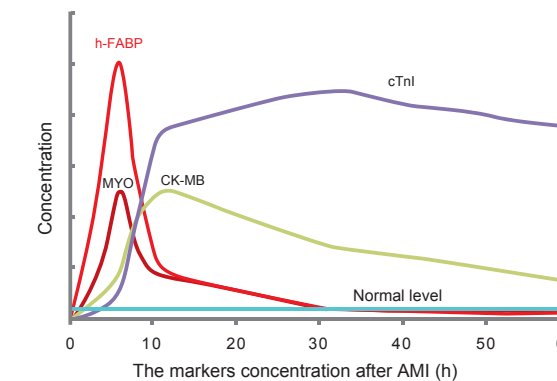

Cardiac Markers

NT-proBNP / H-FABP / CK-MB / cTnI / Myo / 3 in 1

Cardiac markers are used in the diagnosis and risk stratification of patients with chest pain, suspected acute coronary syndrome (ACS) and heart failure (HF). In Wondfo cardiac markers platforms, whole blood / serum / plasma tests can quantitatively detect multiple analytics on immunofluorescence meter, the detection sensitivity is up to pg / ml level.

Clinical application:

| Disease	Test item
HF	NT-proBNP
ACS	cTnI, Myo, CK-MB
Chest pain	H-FABP, cTnI, Myo, CK-MB, hsCRP
Dyspnea	D-Dimer, NT-proBNP, H-FABP, cTnI, Myo,CK-MB,hsCRP

Signification of combine diagnosis:

The markers concentration after AMI (h)

Diagnosis suggestion of myocardial injury markers

$<$2h	H-FABP+Myo
2-6h	H-FABP+Myo+cTnI+CK-MB
4-8h	cTnI+CK-MB
$>$8h	cTnI

- Early diagnosis of AMI
- Prognosis of ACS risk assessment and stratification
- Myocardial infarct size estimates
- ACS early judgment
- Detect myocardial damage degree after surgery
- Indicator after AMI thrombolytic and treatment

Test Procedure & Interpretation:

Collect specimen → Mix → Add sample → Insert sample card and read result
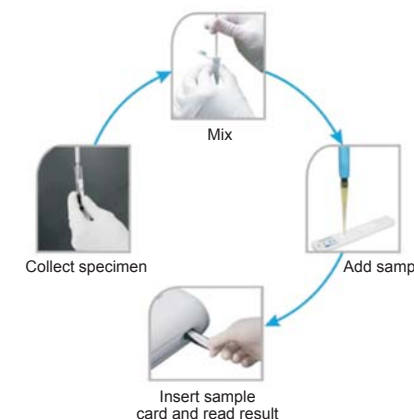
15min

- Multi-channel can test multi-cardiac markers at the same time.
- Results display on the screen automatically.

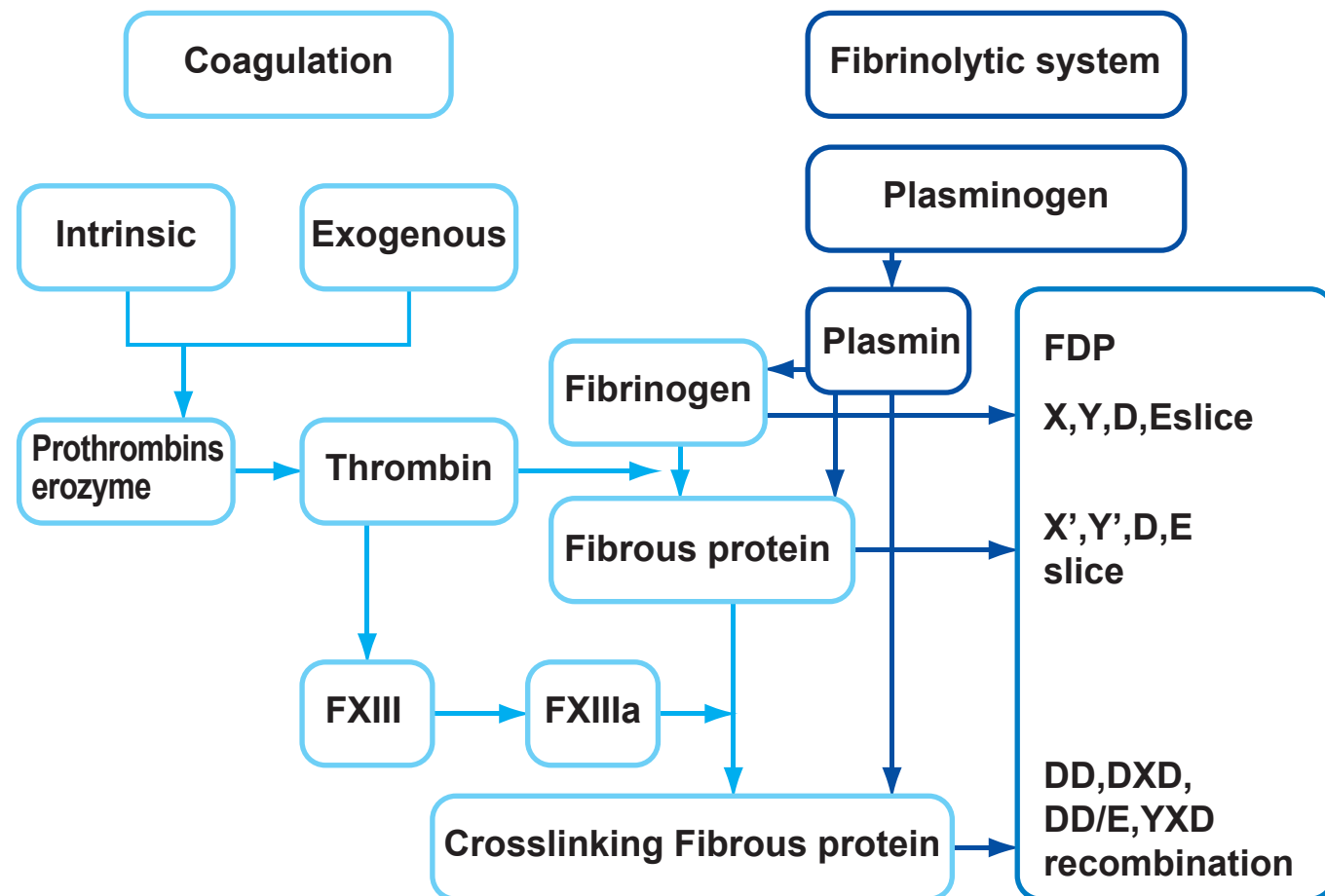D-Dimer is a fibrin degradation product, a small protein fragment present in the blood after a blood clot is degraded by fibrinolysis. In early diagnosis of diseases (chest pain, dizziness, dyspnea such as pulmonary embolism, myocardial infarction and cerebral infarction), D-Dimer can improve efficiency and optimize process diagnosis.

Characteristic:

- Rapid (Reaction time = 3min)
- Quantitative detection
- High accuracy and sensitivity
- Convenient and simple operation
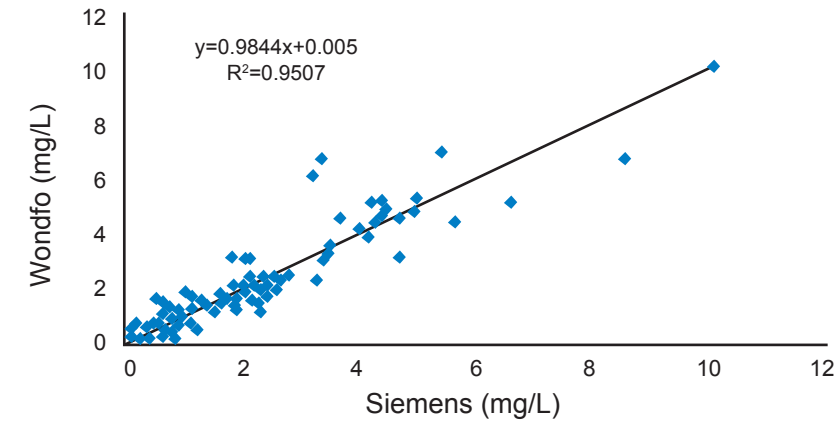
Mechanism of D-Dimer:

Coagulation

Fibrinolytic system

Intrinsic   Exogenous

Plasminogen

Prothrombins erozyme → Thrombin

Fibrinogen

Plasmin

FDP
X,Y,D,Eslice

Fibrous protein

X',Y',D,E slice

FXIII → FXIIIa

Crosslinking Fibrous protein

DD,DXD, DD/E,YXD recombination

Performance:

D-Dimer comparison test of whole blood specimen between Wondfo and Siemens

$$y=0.9844x+0.005$$
$$R^2=0.9507$$

(Wondfo (mg/L) vs Siemens (mg/L))

Compared with 356 test results of D-Dimer specimens conducted by Siemens, Wondfo Finecare™ FIA System has high accuracy in D-Dimer test (5-35 ng/ml), the correlation $R^2=0.951$, positive coincidence rate is 96.3%, negative coincidence rate is 88.4%, total coincidence rate is 92.8%, which can satisfy the clinical requirement.

Linear range	0.1~10mg/L
Reference value	<0.5mg/L
Reaction time	3min
Plasma	18uL
Whole blood	15uL

Application:

Vascular srugery   Obstetrics   Orthopedics

General surgery   Traumatology

Neurosurgery   Pulmonary embolism (PE)   Oncology

Myocardial infarction

Urinary surgery   Cerebral infarction   Pneumology

Monitoring in preoperative   Neurology

ICU

Prognosis in neoplasm staging   Cardiology

Cardiothoracic surgery   Endocrine

pediatrics   Agedness   Hematology   Nephrology

MAU — MAU (Microalbumin) Rapid Quantitative test

MAU (Urine albumin) occurs when the kidney leaks small amounts of albumin into the urine, when there is an abnormally high permeability for albumin in the renal glomerulus. In a properly functioning body, albumin is not normally present in urine because it is retained in the blood stream by the kidneys.
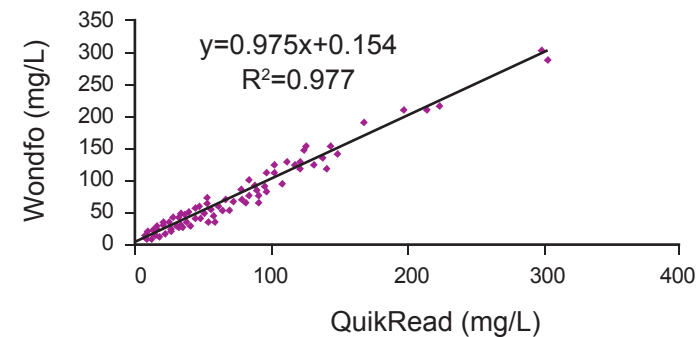
Characteristic:

- Rapid (Test time =10min)
- Fluorescence signaling, higher sensitivity and specificity
- Most sensitive and reliable indicator of Nephropathy
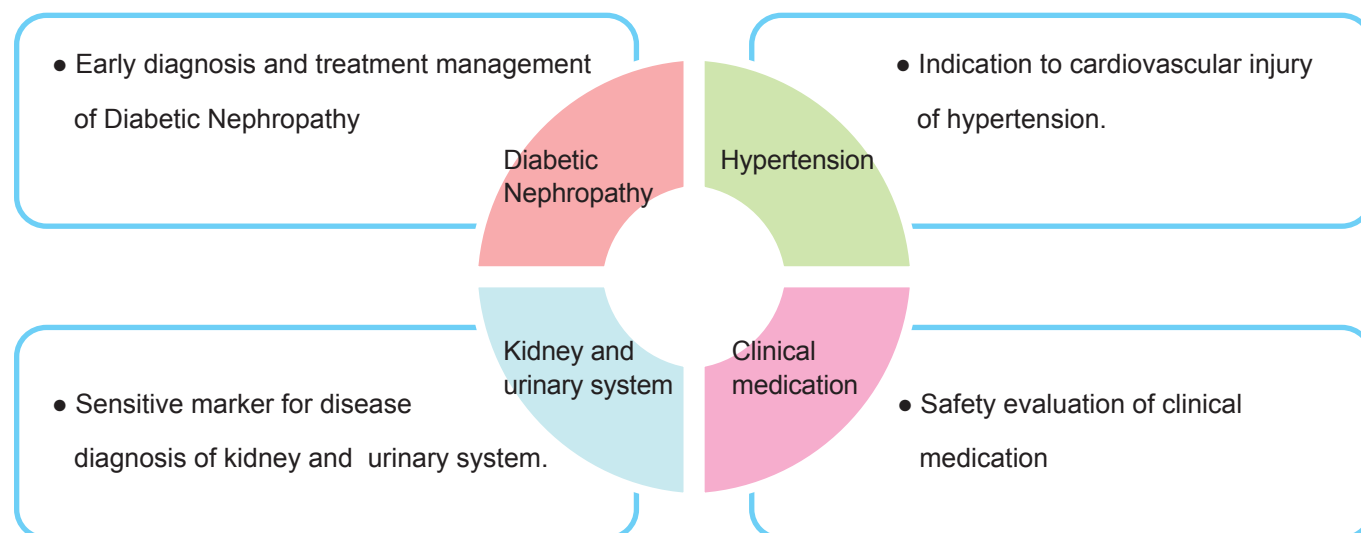- MAU control

Diabetes Affects the Kidney
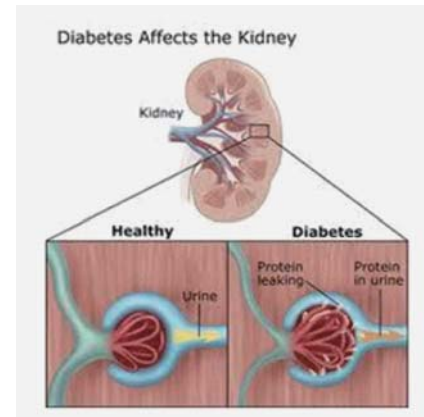
Performance:

Reaction time	10 minutes
Specimen volume	10 uL
Linear range	5 – 300mg/L
Specimen	Urine
Precision	CV≤15%

$y=0.975x+0.154$
$R^2=0.977$

Wondfo (mg/L) vs QuikRead (mg/L)

Application:

- Early diagnosis and treatment management of Diabetic Nephropathy
- Indication to cardiovascular injury of hypertension.
- Sensitive marker for disease diagnosis of kidney and urinary system.
- Safety evaluation of clinical medication

Diabetic Nephropathy / Hypertension / Kidney and urinary system / Clinical medication


HbA1c — HbA1c Rapid Quantitative Test

HbA1c is the product of the hemoglobin combining with blood glucose in red blood cells, which can reflect the average blood glucose level 2 ~ 3 months prior to the measurement. HbA1c is the "gold standard" of evaluation for long-term blood glucose controls. Wondfo HbA1c Rapid Quantitative Test applying sandwich fluorescence immunoassay technology can achieve high sensitivity and specificity.

Characteristic:

- Simpler: Immunofluorescence technology—rapid and convenient operation procedure
- Higher sensitive: Fluorescence signaling cascade enhancement technology
  —accurate detection for low concentration of analyte.
- More accurate: IQC/EQC- double quality control technology—Minimizing system/random errors
- Better time fault tolerance—no remarkable difference in 5-30min test results
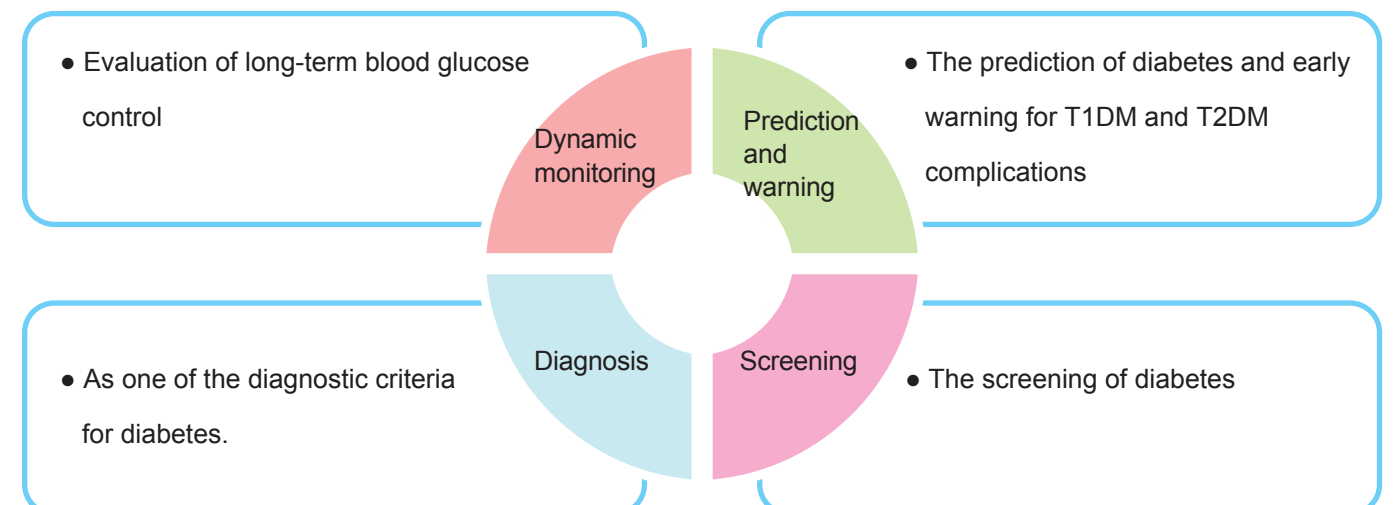
Performance:

Performance	Technical Specifications
Reaction time	5 minutes
Test time	10 seconds
Linear range	4.5 ~ 14.5%
Cutoff value	6%
Precision	CV＜10%

$y=0.9888x+0.1215$
$R^2=0.9702$
$n=183$

Bio-Rad D10 vs Wondfo
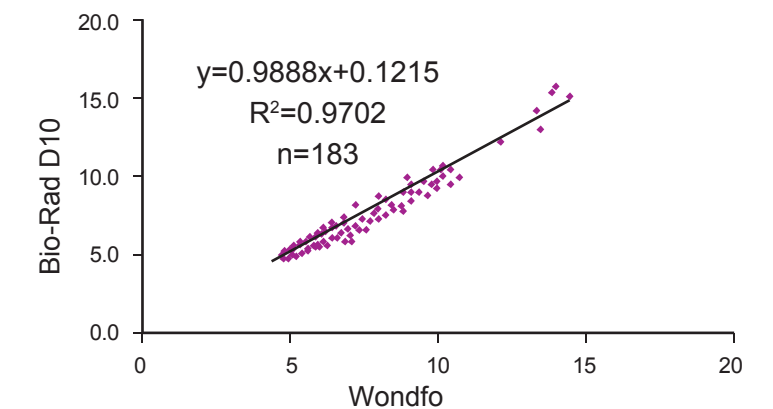
Compared with 183 test results of HbA1c specimens (whole blood)conducted by Bio-Rad D10 automatic analyzer, Wondfo Finecare™ FIA System has high accuracy in HbA1c test (4.5~14.5%), the correlation $R^2>$ 0.97, which can satisfy the clinical requirement.

Application:

- Evaluation of long-term blood glucose control
- The prediction of diabetes and early warning for T1DM and T2DM complications
- As one of the diagnostic criteria for diabetes.
- The screening of diabetes

Dynamic monitoring / Prediction and warning / Diagnosis / Screening

AFP

## AFP (Alpha Fetal Protein) Rapid Quantitative Test

AFP is a glycoprotein, mainly coming from embryo liver cells. AFP is the most sensitive and specific indicator for primary liver cancer diagnosis. Wondfo AFP Rapid Quantitative Test applying sandwich fluorescence immunoassay technology can achieve high sensitivity and specificity.

Characteristic:

- Accurate quantification
- Rapid test, result in 15 minutes
- The most sensitive and specific indicator for primary liver cancer
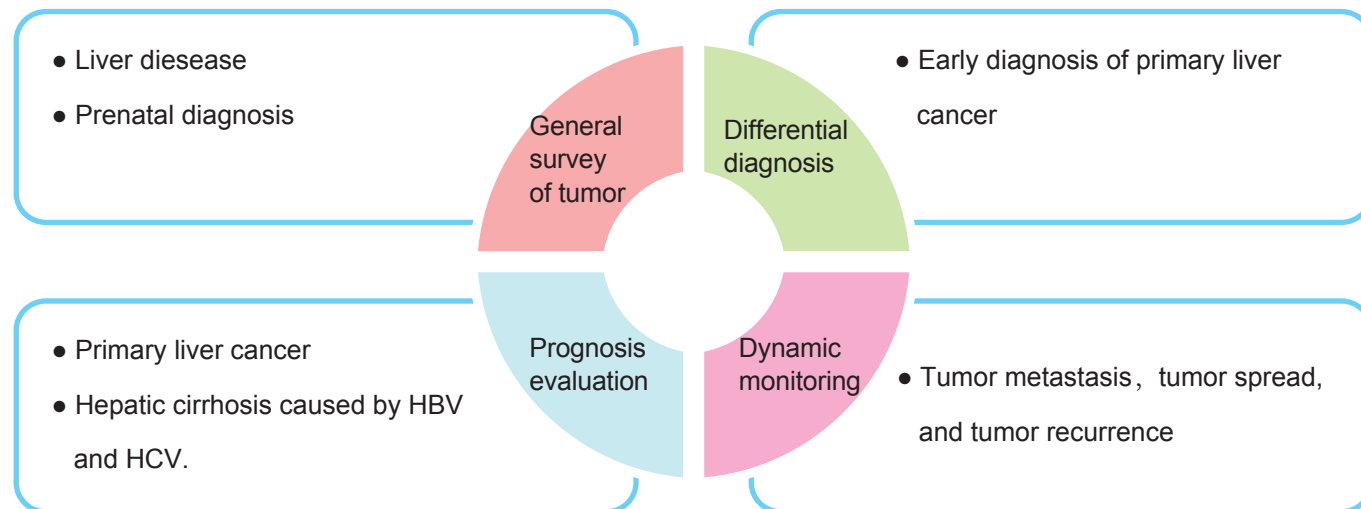- AFP control

Performance:

Reaction time	15 minutes
Test time	10 seconds
Linear range	5 – 350 ng/mL
Cutoff value	20 ng/mL

$y=1.0004x+1.8538$
$R^2=0.9945$

(Wondfo-AFP vs Roche-AFP scatter plot)
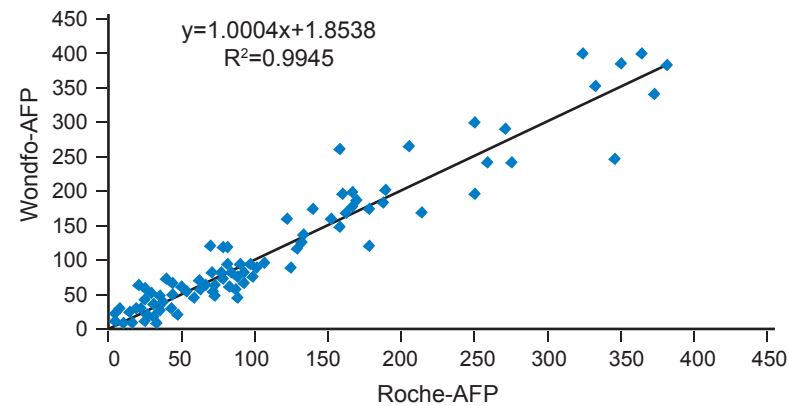
Compared with 629 test results of AFP specimens conducted by Roche, Wondfo Finecare™ FIA System has high accuracy in AFP test (5-350 ng/ml), the correlation $R^2=0.9945$, which can satisfy the clinical requirement.

Application:

- Liver diesease
- Prenatal diagnosis

- Early diagnosis of primary liver cancer

- Primary liver cancer
- Hepatic cirrhosis caused by HBV and HCV.

- Tumor metastasis，tumor spread, and tumor recurrence

General survey of tumor | Differential diagnosis | Prognosis evaluation | Dynamic monitoring

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PSA

## PSA (Prostate Specific Antigen) Rapid Quantitative Test

PSA is a glycoprotein, secreted by the prostate epithelium. The normal value of PSA in serum is lower than 4ng/mL. Wondfo PSA rapid quantitative test applying sandwich fluorescence immunoassay technology can achieve high sensitivity and specificity.

Characteristic:

- Accurate quantification
- Rapid test, result in 15 min
- PSA control

Performance:

Reaction time	15 minutes
Test time	10 seconds
Linear range	2– 100 ng/mL
Cutoff value	4 ng/mL
Precision	CV≤ 15%

$y=0.9997x+0.2523$
$R^2=0.994$

(Wondfo-PSA vs Roche-PSA scatter plot)
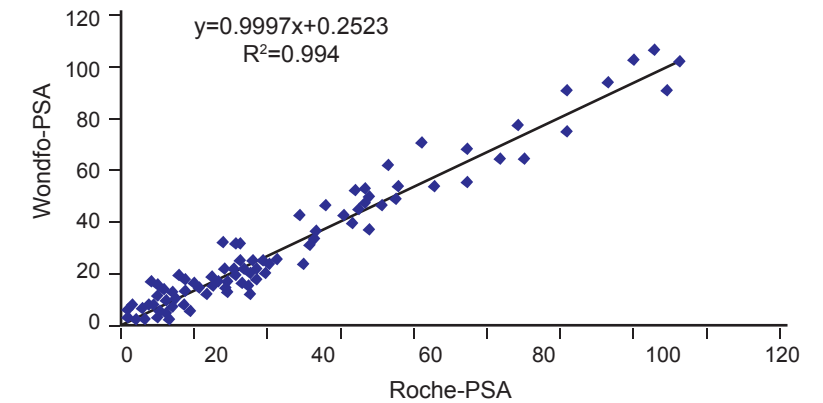
Compared with 829 test results of PSA specimens conducted by Roche, Wondfo Finecare™ FIA System has high accuracy in PSA test (2-100 ng/ml), the correlation $R^2=0.994$, which can satisfy the clinical requirement.

Application:

- Prostate disease
- Male>50 years old

- Early diagnosis of prostatic cancer

- Prostatic cancer

- Tumor metastasis，tumor spread, and tumor recurrence

General survey of tumor | Differential diagnosis | Prognosis evaluation | Dynamic monitoring