Fluorescence Immunoassay Rapid Quantitative Test
CRP (C-reactive Protein) Rapid Quantitative Test

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.

Characteristics:
- 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

Performance:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reaction time</td>
<td>3 minutes</td>
</tr>
<tr>
<td>Test time</td>
<td>10 seconds</td>
</tr>
<tr>
<td>Linear range</td>
<td>0.5 – 200 mg/L</td>
</tr>
<tr>
<td>Reference value</td>
<td>hsCRP &lt; 1.0, CRP &lt; 10</td>
</tr>
</tbody>
</table>

Application:
- Neurology
- Gynecology
- Neurology
- Paediatric
- Respiratory
- Nephrology
- Cardiology
- Surgery
- Gynaecology
- Orthopedic
- Cardiology
- CVD risk
- Infection control
- Observation of antibiotic effect
- Infection differentiation
- Disease monitoring
- Finecare™ whole range CRP

y = 1.0035x + 0.7457
R² = 0.9824
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%

**Application:**
- Early diagnosis of severe infection
- Differentiating infection of bacteria from virus
- Sepsis indication, MODS prognosis
- Clinical observation of antibiotic treatment
- Accurately guiding medication time and dosage of antibiotics
- Effectively avoiding antibiotic abuse
- Severity monitoring of serious patient
- Monitoring of postoperative infection
- Early diagnosis of AMI
- Prognosis of ACS risk assessment and stratification
- Myocardial infarct size estimates
- Severe sepsis indication
- MODS prognosis
- Clinical observation of antibiotic treatment
- ACS early judgment
- Detect myocardial damage degree after surgery
- Indicator after AMI thrombolytic and treatment

**Test Procedure & Interpretation:**
- Multi-channel can test multi-cardiac markers at the same time.
- Results display on the screen automatically.

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**
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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

**Significance of combined diagnosis:**

**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
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

- Intrinsic
- Exogenous

Prothrombins

- Thrombin
- Fibrinogen

Fibrinolytic system

- Plasminogen
- Plasmin
- FDP
- X,Y,D,Eslice
- X',Y',D,E slice
- DD,DXD, DD/E,YXD recombination

Crosslinking Fibrous protein

**Application:**

- Vascular surgery
- Obstetrics
- Orthopedics
- Traumatology
- General surgery
- Pulmonary embolism (PE)
- Cardiac surgery
- Myocardial infarction
- Neurosurgery
- Cerebral infarction
- Urinary surgery
- Monitoring in preoperative
- ICU
- Prognosis in neoplasm staging
- Pediatrics
- Agedness
- Hematology
- Nephrology
- Endocrine
- Oncology
- Pneumology
- Neurology
- Cardiology

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

**Performance:**

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

![Graph showing linear range and correlation](image)

(y=0.9844x+0.005
R²=0.9507)

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 R²=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.
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 = 10 min)
- Fluorescence signaling, higher sensitivity and specificity
- Most sensitive and reliable indicator of Nephropathy
- MAU control

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

**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

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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 5-30 min test results

**Performance:**
- Reaction time: 5 minutes
- Test time: 10 seconds
- Linear range: 4.5 ~ 14.5%
- Cutoff value: 6%
- Precision: CV ≤ 10%

**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

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**Graphs and Equations:**
- MAU QuikRead and Bio-Rad D10 comparison
- HbA1c Bio-Rad D10 and Wondfo Finecare™ FIA System comparison

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**Note:** The graphs and equations represent the comparison of test results and accuracy between different systems, indicating the reliability and effectiveness of the tests.
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

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 R²=0.9945, which can satisfy the clinical requirement.

**Application:**

- Liver disease
- Prenatal diagnosis
- Primary liver cancer
- Hepatic cirrhosis caused by HBV and HCV.

- Early diagnosis of primary liver cancer
- Differential diagnosis
- Dynamic monitoring
- Tumor metastasis, tumor spread, and tumor recurrence

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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: CVs 15%

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 R²=0.994, which can satisfy the clinical requirement.

**Application:**

- Prostate disease
- Male>50 years old
- Prostatic cancer
- Tumor metastasis, tumor spread, and tumor recurrence