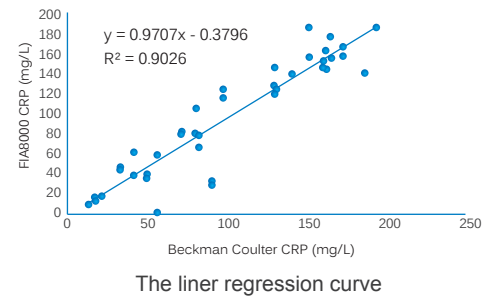# hs-CRP+CRP

The sensitive indicator for diagnosis and identification of virus infection or bacterial infection | One Step Test for hs-CRP+CRP

## Clinical Applications

- Diagnosis and identification of virus infection or bacterial infection
- Detection of severity of conventional inflammation
- Monitoring of postoperative infection and complication
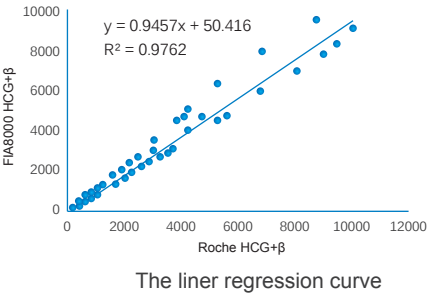- Prediction of cardiovascular event risk probability



$y = 0.9707x - 0.3796$
$R^2 = 0.9026$

The liner regression curve

# HCG+β

As an aid diagnosis of early pregnancy | One Step Test for HCG+β

## Clinical Applications

- Diagnosis of early pregnancy
- Diagnose and monitor the status of the embryonic development
- Diagnosis of ectopic pregnancy
- Observation of threatened abortion and incomplete abortion
- To assist the diagnosis of Down's syndrome (DS) with AFP and FE3
- Diagnosis of trophoblastic disease, therapeutic effect and prognosis
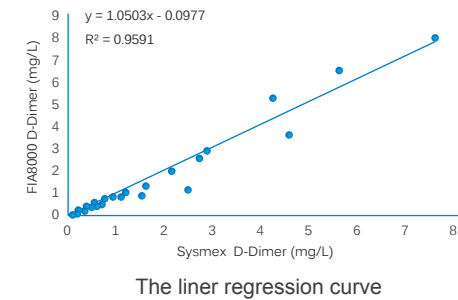


$y = 0.9457x + 50.416$
$R^2 = 0.9762$

The liner regression curve

# D-Dimer

The specific indicator for the exclusion of venous thromboembolism (VTE) | One Step Test for D-Dimer

## Clinical Applications

- Aid in the exclusion of venous thromboembolism (VTE)
- Aid in the exclusion of pulmonary embolism (PE)
- Aid in the diagnosis of disseminated intravascular coagulation (DIC)
- Aid in the diagnosis of acute coronary syndrome (ACS)
- Aid in the evaluation of coagulation status of pregnancy-induced hypertension
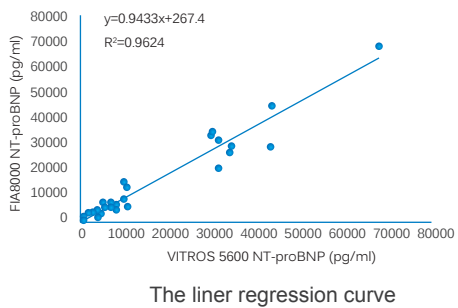- Aid in the diagnosis and prognosis of patients with surgery; monitor the thrombolytic therapy.



$y = 1.0503x - 0.0977$
$R^2 = 0.9591$

The liner regression curve

# NT-proBNP

The ideal biomarker for the evaluation of the heart function | One Step Test for NT-proBNP

## Clinical Applications

- Early detection for patients with heart failure
- Diagnosis and risk stratification of heart failure
- Distinguishing dyspnea caused by heart failure from other disease
- Monitoring and prognostic assessment of heart failure treatment
- Screening and diagnosis for non-cardiac heart failure patients
- As an aid in the risk stratification for ACS



$y = 0.9433x + 267.4$
$R^2 = 0.9624$

The liner regression curve

# FIA8000  Test Items

| Cat.# | Test Item | Disease | Measuring Range | Sample | Cut-off Value | Reaction Time | Qualification |
|---|---|---|---|---|---|---|---|
| CG 1001 | cTnI | Myocardial infarction | 0.5~50.0 ng/ml | S/P/W.B. | 0.5 ng/ml | 15 min | CE CFDA |
| CG 1002 | NT-proBNP | Heart failure | 100~35000 pg/ml | S/P/W.B. | 300 pg/ml | 15 min | CE CFDA |
| CG 1003 | hs-CRP+CRP | Cardiovascular inflammatory diseases; Inflammatory disorders | 0.5~200 mg/L | S/P/W.B./ Fingertip blood | 3 mg/L 10 mg/L | 90 s | CE CFDA |
| CG 1004 | NT-proBNP /cTnI | Heart failure; Acute coronary syndrome | 100~12000 pg/ml 0.5~50.0 ng/ml | S/P/W.B. | 300 pg/ml 0.5 ng/ml | 18 min | CE CFDA |
| CG 1005 | CK-MB /cTnI /Myo | Myocardial injury | 2.5~80.0 ng/ml 0.5~50.0 ng/ml 30~1000 ng/ml | S/P/W.B. | 5 ng/ml 0.5 ng/ml 70 ng/ml | 15 min | CE CFDA |
| CG 1006 | D-Dimer | Venous thromboembolism; Pulmonary embolism | 0.1~10.0 mg/L | P/W.B. | 0.5 mg/L | 7 min | CE CFDA |
| CG 1007 | PCT | Sepsis; Septic shock | 0.1~50.0 ng/ml | S/P/W.B. | 0.1ng/ml | 15min | CE CFDA |
| CG 1008 | CysC | Early diagnosis of kidney disease; Detection of kidney damage for surgery patients | 0.5~10.0 mg/L | S/P/W.B. | 0.51~1.09 mg/L | 3 min | CE CFDA |
| CG 1009 | mAlb | Early diagnosis and evaluation of diabetic nephropathy | 10~200 mg/L | Urine | 20 mg/L | 3 min | CE CFDA |
| CG 1010 | NGAL | The best indicator of early renal injury | 50~5000 ng/ml | S/Urine | Serum:200 ng/ml Urine:100 ng/ml | 3 min | CE CFDA |
| CG 1011 | β2 - MG | Kidney damage for diabetic & hypertensive patients | 0.5~20.0 mg/L | S/P/W.B. | 0.8~3.0 mg/L | 3 min | CE CFDA |
| CG 1012 | CK-MB /cTnI | Myocardial injury | 2.5~80.0 ng/ml 0.5~50.0 ng/ml | S/P/W.B. | 5 ng/ml 0.5 ng/ml | 15 min | CE |
| CG 1013 | HCG+β | Pregnancy early test | 5~100000 mIU/ml | S/P | 5.1 mIU/ml | 10min | CE CFDA |
| CG 1017 | HbA1c | Diabetes mellitus | 2%~14% | W.B. | 3.8%~5.8% | 3 min | CE CFDA NGSP |
| CG 1018 | CK-MB | Myocardial injury | 2.5~80.0 ng/ml | S/P/W.B. | 5 ng/ml | 15 min | CE |
| CG 1024 | TSH | Thyroid diseases | 0.1-50.00 µIU/ml | S/P | 0.27-4.2 µIU/ml | 15 min | CE |

GP Getein Biotech, Inc.

**IVD Industry**
**POCT Leading Brand**

IVD  CE

# FIA8000

Quantitative Immunoassay Analyzer

## PREMIUM POINT-OF-CARE SOLUTION



**Getein Biotech, Inc.**

## Flexible Operation Modes

### Inside mode (Automatic Timing)



Sample Dispense → Test Card Insert → Press "ENT" Button → Result Printed Automatically after reaction

### Outside mode (Manual Timing)



Sample Dispense → Timing the Reaction Manually → Test card insert → Result Printed Automatically in 5~8 s

## Technical Data

| Assay Method | Lateral Flow Chromatography (Colloidal Gold) |
|---|---|
| Test Result | Quantitative |
| Language | English/Chinese/German/Spanish/Serbian (French, Russian, Arabic, Vietnamese etc. are under developing) |
| Display | 5.6 Inch Touch Screen; Resolution 640×480 |
| Printer | Internal Thermal Printer |
| Working Environment | Temperature: +15 ˚C ~35 ˚C  Relative humidity: 10%~85%  Air pressure: 70.0 kPa~106.0 kPa |
| Power Supply | AC100 V~AC240 V, 50 Hz~60 Hz |
| Storage Capacity | 10,000 results can be saved |
| Dimensions | 250 mm×250 mm×120 mm (D×W×H) |
| Weight | 1.8 kg |

---

## FIA8000

**Quantitative Immunoassay Analyzer**



▷ **Portable Design**
Small in size (250×250×120 mm);
Light in weight (1.8 kg)

▷ **Easy to Use**
Ready-to-use cassette, One-step test,
automatic print, quantitative result

▷ **Multiple Test Items**
Cardiac; Inflammation monitoring;
Diabetes mellitus; Renal Function ect.

▷ **Reliable Performance**
CV≤1%; r≥0.990

▷ **LIS and HIS Connectivity**

## Test Items

| | |
|---|---|
| Cardiac | cTnI  NT-proBNP  CK-MB  CK-MB/cTnI  NT-proBNP/cTnI  CK-MB/cTnI/Myo  H-FABP  CK-MB/cTnI/H-FABP* |
| Venous Thromboembolism | D-Dimer |
| Inflammation Monitoring | hs-CRP+CRP  PCT |
| Diabetes Care | HbA1c |
| Renal Function | mAlb  $\beta_2$-MG  CysC  NGAL |
| Fertility | HCG+β |
| Hormone | TSH |

*Under developing
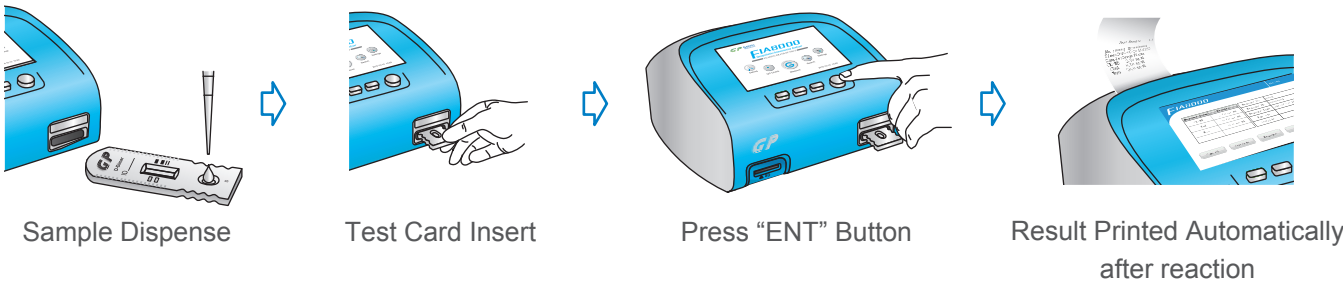
## Application Departments

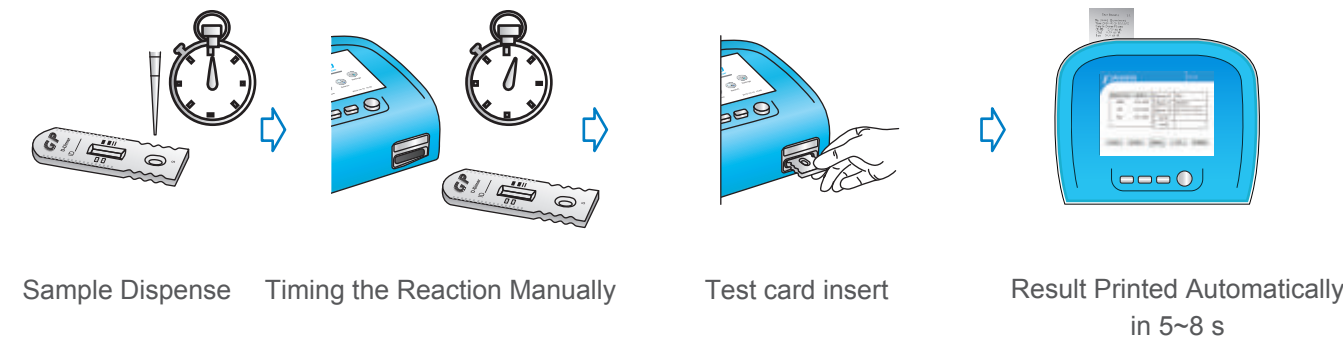The analyzer can be widely applied to many clinical departments as follows:

- Cardiology Dept.
- Oncology Dept.
- Gynecology Dept.
- Clinical Laboratory.
- Nephrology Dept.
- Respiratory Dept.
- Emergency Dept.
- Pediatrics Dept.
- Gastroenterology Dept.
- ICU
- Endocrinology Dept.
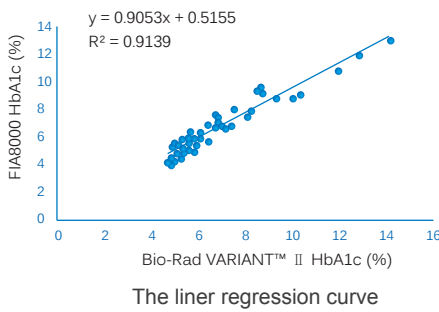- Urology Dept.

---

## HbA1c

The golden standard in the evaluation of Glycemic control

NGSP Certificated   One Step Test for HbA1c

### Clinical Applications

- Early screening and diagnosis of diabetes
- Evaluation of Glycemic control
- Prediction of chronic diabetic complications
- Identification of stress hyperglycemia and diabetes
- Diagnosis and treatment of GDM, etc.



$y = 0.9053x + 0.5155$
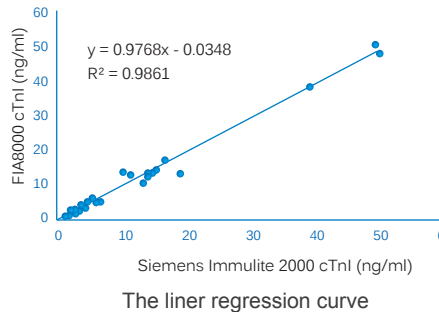$R^2 = 0.9139$

The liner regression curve

## cTnI

The golden standard in the diagnosis of Acute Myocardial Infarction (AMI)

One Step Test for cTnI

### Clinical Applications

- As an aid in the early diagnosis of acute myocardial infarction (AMI)
- Acute myocarditis, unstable angina, acute coronary syndrome(ACS)
- Evaluate the severity of myocardial damage
- As an aid in the prognosis of ACS



$y = 0.9768x - 0.0348$
$R^2 = 0.9861$

The liner regression curve

## CK-MB/cTnI/Myo

Combining the advantages of three biomarkers, higher sensitivity and specificity, lower rate of missed diagnosis and misdiagnosis

One Step Test for CK-MB/cTnI/Myo

### Clinical Applications

- Identification and diagnosis of ACS patients suspected
- Evaluating the efficacy of Myocardial-Reperfusion
- Aid in the detection and assessment of AMI to the chest pain
- Monitoring the clinical curative effect of therapeutic drug

### Product Advantages

- Combined advantages of three biomarkers with higher sensitivity and specificity
- Three biomarkers in one cartridge simplified test operation
- As an aid in clinic to lower the rate of missed diagnosis and misdiagnosis to guarantee early diagnosis and prevention



Cardiac Marker Release Patterns