

IVD Industry  
POCT Leading Brand

# FIA8000

*Quantitative Immunoassay Analyzer*

PREMIUM POINT OF CARE SOLUTION



# FIA8000 *Quantitative Immunoassay Analyzer*



## ► Highlights

- ◆ **Portable Design** Small in size (250 x 250 x 120mm); Light in weight (1.8kg)
- ◆ **Multiplex Test Items** Cardiac; Inflammation monitoring; Diabetes mellitus; Fertility; Renal function etc.
- ◆ **Easy to Use** Ready-to-use cassette, one-step test, automatic print, quantitative result
- ◆ **Reliable Performance**  $CV \leq 1\%$ ;  $r \geq 0.990$
- ◆ **LIS and HIS Connectivity**

## ► Test Items

|                                |        |                    |                |                |
|--------------------------------|--------|--------------------|----------------|----------------|
| <b>CARDIAC</b>                 | cTnI   | NT-proBNP          | NT-proBNP/cTnI | CK-MB/cTnI/Myo |
|                                | H-FABP | CK-MB/cTnI/H-FABP  |                |                |
| <b>VENOUS THROMBOEMBOLISM</b>  |        | D-Dimer            |                |                |
| <b>INFLAMMATION MONITORING</b> |        | hs-CRP             | PCT            |                |
| <b>DIABETES CARE</b>           |        | HbA1c              |                |                |
| <b>FERTILITY</b>               |        | HCG+β              |                |                |
| <b>RENAL FUNCTION</b>          |        | β <sub>2</sub> -MG | mAlb           | CysC           |
|                                |        |                    |                | NGAL           |

## ► Application Department

The analyzer can be widely applied to clinical departments including Cardiology Dept., Clinical Laboratory, Emergency Dept., ICU, Oncology Dept., Nephrology Dept., Pediatrics Dept., Endocrinology Dept., Gynecology Dept., Respiratory Dept., Gastroenterology Dept., Urology Dept. etc.

## 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 5-8s*

## Technical Data

|                     |                                                                                                        |                    |
|---------------------|--------------------------------------------------------------------------------------------------------|--------------------|
| Assay Method        | Lateral Flow Chromatography (Colloidal Gold)                                                           |                    |
| Test Result         | Quantitative                                                                                           |                    |
| Language            | Chinese/English/German/Spanish/Serbian<br>(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℃ - 35℃         |
|                     | Relative humidity                                                                                      | 10% - 85%          |
|                     | Air pressure                                                                                           | 70.0kPa - 106.0kPa |
| Power Supply        | AC 100~240V, 50~60 Hz                                                                                  |                    |
| Data Storage        | 10,000 results can be saved                                                                            |                    |
| Dimensions          | Height                                                                                                 | 120mm              |
|                     | Width                                                                                                  | 250mm              |
|                     | Length                                                                                                 | 250mm              |
| Weight              | 1.8kg                                                                                                  |                    |

# FIA8000 Parameters

| Cat.#   | Test Item          | Disease                                                                               | Measuring Range | Sample                      | Cut-off Value   | Reaction Time |
|---------|--------------------|---------------------------------------------------------------------------------------|-----------------|-----------------------------|-----------------|---------------|
| CG 1001 | cTnI               | Myocardial infarction                                                                 | 0.5~50.0ng/ml   | S/P/W.B                     | 0.5ng/ml        | 15min         |
| CG 1002 | NT-proBNP          | Heart failure                                                                         | 100~35000pg/ml  | S/P/W.B                     | 300pg/ml        | 15min         |
| CG 1003 | hs-CRP             | Cardiovascular inflammatory diseases;<br>Inflammatory disorders                       | 0.5~200mg/L     | S/P/W.B/<br>Fingertip blood | 3mg/L<br>10mg/L | 90s           |
| CG 1004 | NT-proBNP<br>/cTnI | Heart failure;<br>Acute coronary syndrome                                             | 100~12000pg/ml  | S/P/W.B                     | 300pg/ml        | 18min         |
|         |                    |                                                                                       | 0.5~50.0ng/ml   |                             | 0.5ng/ml        |               |
| CG 1005 | CK-MB              | Myocardial injury                                                                     | 2.5~80.0ng/ml   | S/P/W.B                     | 5ng/ml          | 15min         |
|         | /cTnI              |                                                                                       | 0.5~50.0ng/ml   |                             | 0.5ng/ml        |               |
|         | /Myo               |                                                                                       | 30~1000ng/ml    |                             | 70ng/ml         |               |
| CG 1006 | D-Dimer            | Venous thromboembolism;<br>Pulmonary embolism                                         | 0.1~10.0mg/L    | P/W.B                       | 0.5mg/L         | 7min          |
| CG 1007 | PCT                | Sepsis;<br>Septic shock                                                               | 0.1~50ng/ml     | S/P/W.B                     | 0.1ng/ml        | 15min         |
| CG 1008 | CysC               | Early diagnosis of kidney disease;<br>Detection of kidney damage for surgery patients | 0.5~10.0mg/L    | S/P/W.B                     | 0.51~1.09 mg/L  | 3min          |
| CG 1009 | mAlb               | Early diagnosis and evaluation of diabetic nephropathy                                | 10~200mg/L      | Urine                       | 20mg/L          | 3min          |
| CG 1010 | NGAL               | The best indicator of early renal injury                                              | 50~5000ng/ml    | S/Urine                     | Serum:200ng/ml  | 3min          |
|         |                    |                                                                                       |                 |                             | Urine:100ng/ml  |               |
| CG 1011 | $\beta_2$ -MG      | Kidney damage for diabetic & hypertensive patients                                    | 0.5~20.0mg/L    | S/P/W.B                     | 0.8~3.0 mg/L    | 3min          |
| CG 1012 | CK-MB<br>/cTnI     | Myocardial injury                                                                     | 2.5~80.0ng/ml   | S/P/W.B                     | 5ng/ml          | 15min         |
|         |                    |                                                                                       | 0.5~50.0ng/ml   |                             | 0.5ng/ml        |               |
| CG 1013 | HCG+ $\beta$       | Pregnancy early test                                                                  | 5~10000mIU/ml   | S/P/W.B                     | 5.1mIU/ml       | 10min         |
| CG 1017 | HbA1c              | Diabetes mellitus                                                                     | 2%~14%          | W.B                         | 3.8%~5.8%       | 3min          |
| CG 1018 | CK-MB              | Myocardial injury                                                                     | 2.5~80.0ng/ml   | S/P/W.B                     | 5ng/ml          | 15min         |

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