

**BIOTIME**<sup>®</sup>

**PRODUCT  
CATALOG  
2023**


# **PRODUCT CATALOG**



# COMPANY PROFILE

Established in April, 2008, Xiamen Biotime is a hi-tech enterprise that specializes in R&D, production and sales of POCT in vitro diagnostic devices and reagents. Biotime has always been carrying the faith of "Quality Comes From Professionalism And Service Makes The Future". Committed to "Being Unique From Our Competitors", we have successfully established our mature medical marketing channels during the past years. With our leading technologies, Biotime aims to develop superior IVD products which provide better solutions for health care and benefit people all over the world.

 **200,000+**  
Square Meters of Manufacturing

 **2000+**  
Dedicated Employees

 **800+**  
Global Distributors

 **200+**  
Researchers

 **80+**  
Countries

 **5+**  
R&D Centers

# CORPORATE HONOR



## Trademarks

**40+** Registered in China  
**30+** Registered Overseas  
**30+** countries



## Patents

**110+**



## Certifications

**213+** CE  
**230+** NMPA  
**2+** NGSP  
**2+** IFCC  
**1** US FDA

# BIOTIME HISTORY



# MILESTONE

## Fluorescence Immunoassay (FIA) 07/12

### 01

- Device** BIOT-YG-I (Single Channel)
- FLI-100 (Single Channel)
- FLI-600 (6 Channels)
- FLI-4000 (Fully Automated)

- Test Item** Cardiac
- Brain Injury
- Tumor
- Inflammation
- Hormones
- Diabetes & Renal Injury
- Thyroid
- Gastrointestinal
- Infectious Disease
- Others

## Chemiluminescence Immunoassay (CLIA) 13/16

### 02

- Device** CLi-1600 (16 Channels)

- Test Item** Cardiac
- Inflammation
- Thyroid
- Hormones
- Diabetes
- Brain Injury
- Tumor
- Thrombotic
- Health Check
- Infectious diseases
- Pre-eclampsia
- Growth and development

## High-Performance Liquid Chromatography(HPLC) 17/19

### 03

- Device** HLC-100 (12 Channels)
- Test Item** HbA1c Reagent

## Electrochemistry 20/24

### 04

- Device** BL-100 (Single Channel)
- Test Item** Blood Lead Strips
- Device** Blood Glucose Meter (GDH-FAD)
- Test Item** Blood Glucose Strips
- Device** Blood Ketone Meter
- Test Item** Blood Ketone Strips
- Device** Uric Acid Meter
- Test Item** Uric Acid Strips

## Lateral Flow Immunoassay 25/26

### 05

- Test Item** Covid-19 & Additional Respiratory Tract Infection
- Vector Borne Infection

## Clinical Chemistry (Urinalysis) 27/28

### 06

- Test Item** URS-14 Strips



01

# FLUORESCENCE IMMUNOASSAY (FIA) PRODUCT LINE

Advanced Solutions for Rapid Diagnostics

## POINT OF CARE FIA SOLUTIONS FOR YOUR LAB SETTINGS



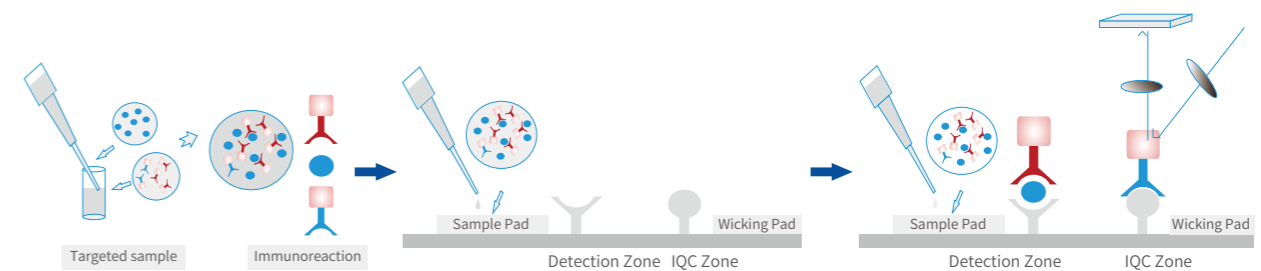
**FLI-100**  
Single Channel

**FLI-4000**  
Fully - Automated

**FLI-600**  
6 Channels

**BIOT-YG-I**  
Single Channel

## FLUORESCENT IMMUNOCHROMATOGRAPHY PRINCIPLE



## APPLICATION



Hospital



Laboratory



Health Center



Ambulance



Clinic

## COVERING ALL LEVELS OF YOUR LAB SETTINGS



**BIOT-YG-I**



**FLI-100**



**FLI-600**



**FLI-4000**

Method	Fluorescent immunochromatography	
User Experience	Semi-Automated	
Sample Types	Whole Blood/ Serum/ Plasma/ Urine	
Capacity	Single Channel	
Test Results	3-20 min	
Connectivity	RS232, USB, Ethernet (Direct connection to LIS / HIS)	
Battery Options	No	Yes
History Tracking	Yes	
Dimension (H x W x D)	225×220×113mm	200 x 240 x 152mm
Weight	2.5kg	2.9kg
User Site	Primary hospitals and clinics	
Certification	CE/NMPA/NGSP/IFCC	CE/NMPA

Method	Fluorescent immunochromatography	
User Experience	Semi-Automated	Fully - Automated
Sample Types	Whole Blood/ Serum/ Plasma/ Urine	
Capacity	6 Channels	13 Sample Positions
Test Results	3-20 min	
Connectivity	RS232, USB, Ethernet (Direct connection to LIS / HIS)	
Battery Options	No	
History Tracking	Yes	
Dimension (H x W x D)	408×282×376mm	470×594×472mm
Weight	14kg	53.8 kg
User Site	Primary and Secondary hospitals and clinics	Tertiary hospitals and clinics
Certification	CE/NMPA	



Test Item	Qualification	Specimen	Sampling	Reaction Time	Detection Range
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### Cardiac

cTnI	CE/NMPA	Whole Blood/Plasma	Whole Blood:80µL/Plasma:50µL	15min	0.05-50ng/mL
Myo	CE/NMPA	Serum/Plasma	Serum:10µL/Plasma:10µL	15min	2.5-400ng/mL
CK-MB	CE/NMPA	Serum/Plasma	Serum:40µL/Plasma:40µL	15min	1-80ng/mL
cTnI/Myo/CK-MB (3 in 1)	CE/NMPA	Whole Blood/Plasma	Whole Blood:80µL/Plasma:50µL	15min	Refer to individual item
D-Dimer	CE/NMPA	Whole Blood/Plasma	Whole Blood:80µL/Plasma:50µL	3min	0.1-10mg/L
NT-proBNP	CE/NMPA	Whole Blood/Serum/Plasma	Whole Blood:80µL/Serum:50µL/Plasma:50µL	15min	15-35000pg/mL
cTnI/Myo/CK-MB/D-Dimer/NT-proBNP (5 in 1)	CE/NMPA	Whole Blood	Whole Blood:100µL	15min	Refer to individual item
hFABP	CE/NMPA	Serum/Plasma	Serum:10µL/Plasma:10µL	15min	2-120ng/mL
BNP	CE/NMPA	Whole Blood/Plasma	Whole Blood:80µL/Plasma:50µL	10min	10-5000pg/mL
LP-PLA2	CE/NMPA	Whole Blood/Plasma	Whole Blood:30µL/Plasma:20µL	10min	5-800ng/mL
Hcy*	CE/NMPA	Plasma	Plasma:40µL	15min	2.50µmol/L
hscTnI	CE/NMPA	Whole Blood/Serum/Plasma	Whole Blood:60µL/Serum:40µL/Plasma:40µL	15min	20-40000pg/mL
cTnI/Myo/BNP*	CE/NMPA	Whole Blood/Plasma	Whole Blood:80µL/Plasma:50µL	15min	Refer to individual item

### Brain Injury

s100-β	CE/NMPA	Whole Blood/Serum/Plasma	Whole Blood:60µL/Serum:40µL/Plasma:40µL	10 min	0.05-10.0ug/L
NSE*	/	/	/	/	/

### Tumor

AFP	CE/NMPA	Serum/Plasma	Serum:20µL/Plasma:20µL	10min	3-2000ng/mL
CEA	CE/NMPA	Serum/Plasma	Serum:20µL/Plasma:20µL	10min	0.5-500ng/mL
CEA/AFP(2 in 1)	CE	Serum/Plasma	Serum:20µL/Plasma:20µL	10min	Refer to individual item
tPSA	CE	Serum	Serum:20µL	15min	0.5-200ng/mL
fPSA	CE	Serum	Serum:20µL	15min	0.2-30ng/mL

Test Item	Qualification	Specimen	Sampling	Reaction Time	Detection Range
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### Inflammation

CRP	CE/NMPA	Whole Blood/Serum/Plasma	Whole Blood:5µL/Serum:3µL/Plasma:3µL	3min	0.5-200mg/L
PCT	CE/NMPA	Whole Blood/Serum/Plasma	Whole Blood:80µL/Serum:50µL/Plasma:50µL	15min	0.1-100ng/mL
SAA	CE/NMPA	Whole Blood/Serum/Plasma	Whole Blood:5µL/Serum:3µL/Plasma:3µL	3min	1-200mg/L
CRP/SAA(2 in 1)	CE/NMPA	Whole Blood/Serum/Plasma	Whole Blood:5µL/Serum:3µL/Plasma:3µL	3min	Refer to individual item
IL-6	CE/NMPA	Serum	Serum:50µL	15min	5-1000pg/mL

### Hormones

β-HCG	CE/NMPA	Serum/Plasma	Serum:20µL/Plasma:20µL	10min	5-200000mIU/mL
PROG	CE/NMPA	Serum	Serum:40µL	10min	0.3-80ng/mL
FSH	CE/NMPA	Serum	Serum:20µL	20min	0.3-200mIU/mL
LH	CE/NMPA	Serum	Serum:20µL	20min	1-200mIU/mL
PRL	CE/NMPA	Serum	Serum:20µL	20min	1.0-4000.0µIU/mL
FSH/LH/PRL(3 in 1)	CE/NMPA	Serum	Serum:20µL	20min	Refer to individual item
TES(Testosterone)	CE/NMPA	Serum	Serum:20µL	10min	0.2-20ng/mL
E2	CE/NMPA	Serum	Serum:40µL(incubation10min)	10min	10-3000pg/mL
AMH	CE	Serum	Serum:50µL	10min	0.1-25ng/mL

### Diabetes and Renal Injury

HbA1c	CE/NMPA/NGSP	Whole Blood	Whole Blood:5µL	5min	4-15%
MAU	CE/NMPA	Urine	Urine:10µL	10min	2-300mg/L
Cys-C	CE/NMPA	Whole Blood/Plasma	Whole Blood:15µL/Plasma:10µL	5min	0.2-8mg/L

### Thyroid

TSH	CE/NMPA	Serum/Plasma	Serum:40µL/Plasma:40µL	20min	0.4-100uIU/mL
TT4	CE/NMPA	Serum/Plasma	Serum:40µL/Plasma:40µL	15min	10-320nmol/L
TT3	CE/NMPA	Serum	Serum:40µL	15min	0.5-10nmol/L
FT3	CE	Serum	Serum:40µL	15min	0.4-50pmol/L
FT4	CE	Serum	Serum:40µL	15min	0.3-100pmol/L

### Gastrointestinal

2 in 1 (PG I/Pg II)	CE/NMPA	Serum	Serum:10µL	15min	PG I:1-200ng/mL PG II:0.5-100ng/mL
PG I/Pg II/G17	CE/NMPA	Whole Blood/Serum/Plasma	Whole Blood:60µL/Serum:40µL/Plasma:40µL	15min	PG I:1-200ng/mL PG II:1-100ng/mL G17:1-50pmol/L
Pepsin*	/	/	/	/	/

### Infectious Disease

HBsAg	/	Serum/Plasma	Serum:80µL/Plasma:80µL	10min	Negative: <1.0 IU/mL Positive: ≥1.0 IU/mL
HCV	/	Serum/Plasma	Serum:80µL/Plasma:80µL	10min	Negative: COI <1.0 Positive: COI ≥1.0

### Others

Ferritin	CE/NMPA	Serum	Serum:10µL	15min	1-1000ng/mL
25(OH)-D	CE/NMPA	Plasma	Plasma:20µL(incubation 10 min)	10min	5.0-120.0ng/mL
Total IgE	CE	Whole Blood/Serum/Plasma	Whole Blood:30µL/Serum:20µL/Plasma:20µL	12min	1-1000IU/mL

\*\*\* Coming Soon



02

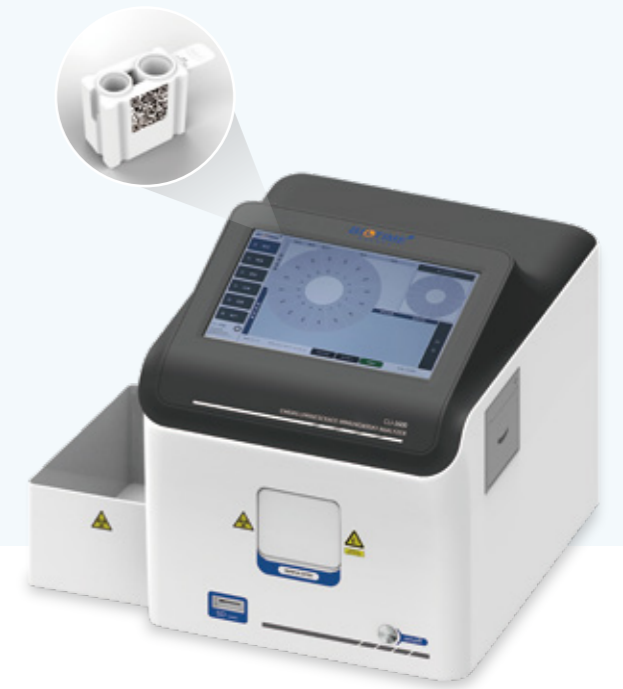
# CHEMILUMINESCENCE IMMUNOASSAY (CLIA) PRODUCT

Innovative Point-of-Care Solution

## CLi-1600

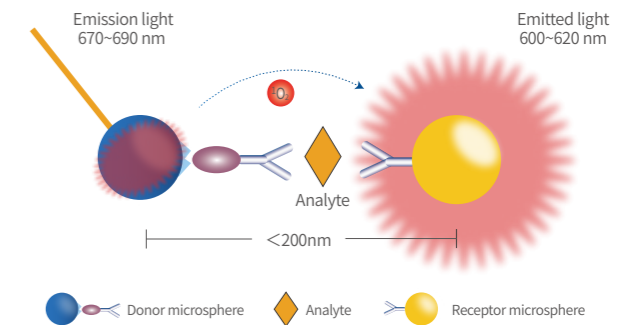
The right size Chemiluminescence Immunoassay System for your lab

16 Channels



### LIGHT-INITIATED CHEMILUMINESCENCE PRINCIPLE

Analyzer emits a laser at about 670~690 nm to irradiate the reaction well and excite the donor microsphere to generate singlet oxygen. Then the singlet oxygen contacts the receptor microsphere to generate emitted light at about 600~620 nm. Due to its very short half-life period, singlet oxygen can only diffuse over a distance of several hundred nanometers. Only the receptor and donor microspheres that form the antigen and antibody compound can generate emitted light at 600-620 nm.



### APPLICATION



Hospital



Laboratory



Health Center



Clinic





## ADVANTAGES

- Principle's Input**  
 Homogeneous mixture  
 Washing steps are not required  
 Whole blood sample option  
 Fastest results are in 5 minutes  
 Minimal sample consumption  
 Room temperature storage
- Analyzer's Input**  
 Multiple items simultaneously recognition  
 Small & light size

Model	CLi-1600
Principle	Light-initiated chemiluminescence
User Experience	Semi-Automated
Sample Types	Whole Blood/ Serum/ Plasma
Capacity	16 Channels
Fastest Results	5 min
Throughput	60 Tests/hour
Quality Control System	Yes
Connectivity	USB×2/RS232×2/Internet RJ45, LIS / HIS
Transport Storage	2-30°C
History Tracking	Yes
Data Storage	50000 pcs
Dimension (H x W x D)	312mm × 382mm × 345mm
Weight	10.5 kg

### Cardiac

MYO	NT-proBNP	hFABP*
BNP	CK-MB	ST2*
hs-cTnI	D-Dimer	HCY*
hs-cTnT	Lp-PLA2	

### Inflammation

SAA	PCT	HBP
CRP	IL-6	

### Thyroid

TSH	ft3	Anti TG*
TT3	ft4	Anti TPO*
TT4	TG*	

### Fertility/Infertility

β-hCG	LH	E2
PROG	PRL	AMH
FSH	TESTO	

### Diabetes

HbA1c	INS	C-P
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### Brain injury

S-100β*	NSE*	
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### Tumor

PGI	CA50*	Ferr*
PGII	CA125*	G17*
AFP*	Cyfra21-1*	Pro GRP
CEA*	SCC*	
Total-PSA*	Free-PSA*	

### Thrombotic

TAT*	TM*	FDP*
PIC*	T-PAIC*	

### Health check

VD	Ferr	Folate
VB12*		

### Infectious disease

HBsAg*	HBeAb*	Anti-HCV*
HBsAb*	HBcAb*	Anti-TP*
HBeAg*	HIV Ag/Ab*	

### Pre-eclampsia

sFLT-1*	PLGF*	FDP*
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\*\*\* Coming Soon

03

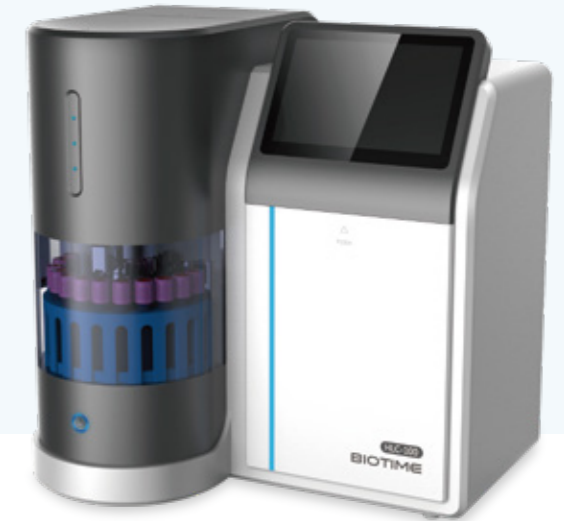
# HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC)

Gold - Standard for Diabetes Solution

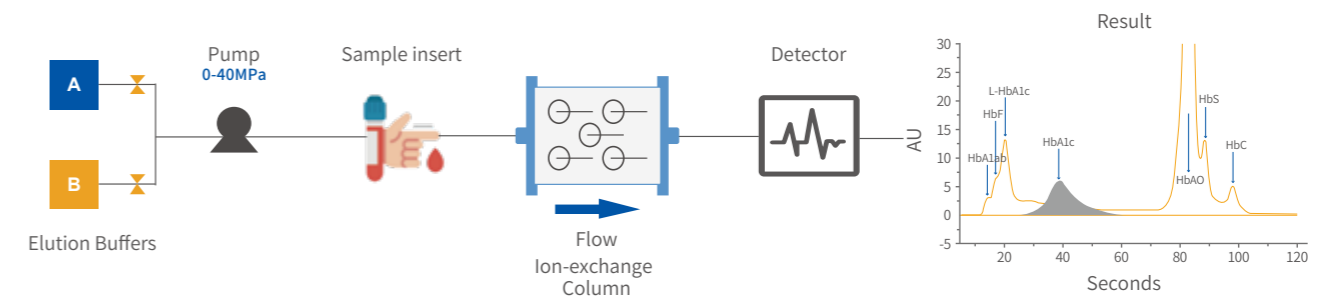
# HLC-100

HbA1c Testing Method

12 Channels



## ION-EXCHANGE HPLC PRINCIPLE



## APPLICATION



Hospital



The Diabetes Centre



Clinic



Gestational Diabetes Screening

## ADVANTAGES



CV  $\leq$  1.5%



Rapid test results



Longer detection range



Gold Standard for HbA1c detection



Room Temperature storage

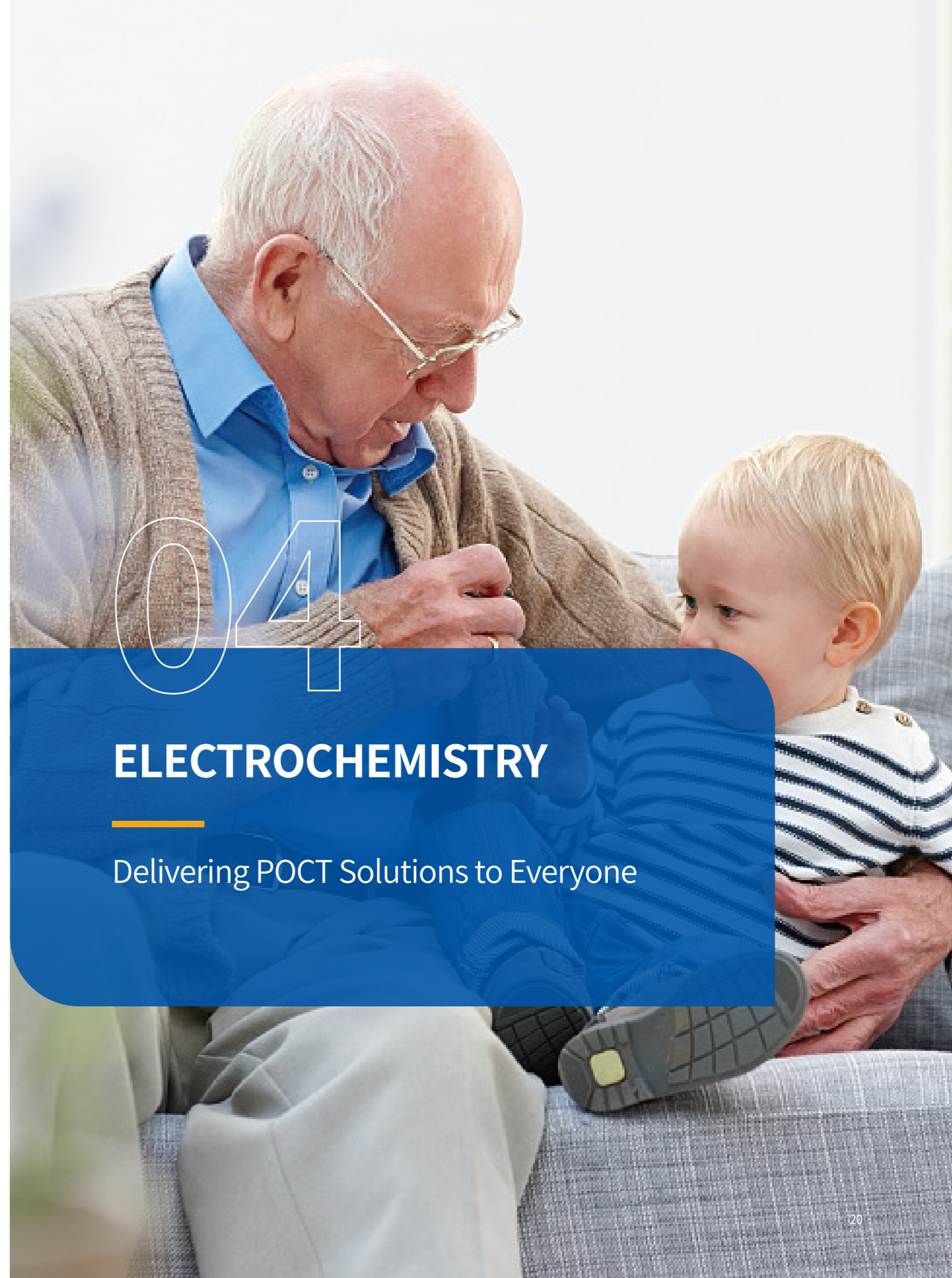


Extended life-cycle of HPLC column



Two Emergency Detection Channels

Model	HLC-100
Principle	Ion-exchange HPLC
User Experience	Fully-Automated
Sample Types	Whole blood
Capacity	10 Channels with extra 2 emergency
HbA1c Assay Range	3.5% - 20%
CV	$\leq$ 1.5%
Fastest Results	2 min
Throughput	20 Tests/h
HPLC Column Life	1000
Sample Volume	4 $\mu$ L
Quality Control System	Yes
Connectivity	LIS / HIS
Storage	2-30°C
History Tracking	Yes
Dimension (H x W x D)	350mm $\times$ 415mm $\times$ 420mm
Weight	24 kg
Certification	CE/IFCC/NGSP/NMPA



## ELECTROCHEMISTRY

Delivering POCT Solutions to Everyone

# BL-100

Blood Lead Testing

Single Channel



## ADVANTAGES



Rapid test results



Shorter T-A-T



Convenient Sampling

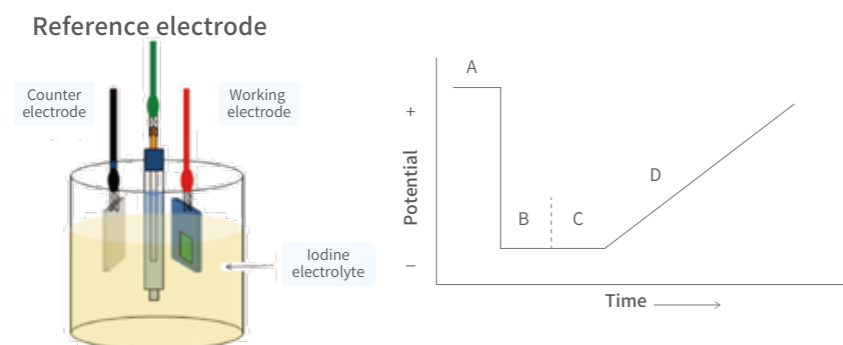


Small & Light Analyzer Size



Unique Technology principle

## ANODIC STRIPPING VOLTAMMETRY (ASV) PRINCIPLE



A: cleaning step  
 B: electroplating step  
 C: equilibrium step  
 D: stripping step

## APPLICATION



Hospital



Clinic



Laboratory



Pediatric Centre

Model	BL-100
Principle	Portable Anodic stripping voltammetry (ASV)
User Experience	Semi-Automated
Capacity	Single Channel
Fastest Results	7 min
Accuracy	$r \geq 0.995$
Detection Range	20 - 650 $\mu$ g/L
Sample Volume	50 $\mu$ L
Sample Types	Whole blood, fingertip blood
Connectivity	LIS / HIS
Storage	2-30°C
History Tracking	Yes
Dimension (H x W x D)	160mm x 180mm x 250mm
Weight	2.5 kg

# YOUR COMPLETE GUIDE



01 BGM-202 Blood Glucose Meter (GDH-FAD)

02 BKM-02 Blood Ketone Meter

03 UAM-02 Uric Acid Meter

## APPLICATION



Clinic



Ambulance



Physician Office



Pharmacy Store

## BGM-202 Blood Glucose Monitoring System

Method	GDH-FAD (Minimizing risk of interference)
Specimen type	Fingertip blood samples
Sample volume	0.8µL
Measuring range	1.1-33.3 mmol/L
Measuring time	5s
Test system	Fully automatic code-free
Test kit storage temperature	2-30°C
Quality Control	Provided
Shelf life	24 months
Certification	CE



## UAM-02 Uric Acid Monitoring System



Method	Electrochemical
Specimen type	Clean-catch urine
Sample volume	1.5µL
Measuring range	0.18-1.19mmol/L
Measuring time	13s
Test system	Fully automatic code-free
Data storage	250pcs
Test kit storage temperature	2-30°C
Quality Control	24 months
Certification	CE

## BKM-02 Blood Ketone Monitoring System

Method	Electrochemical
Specimen type	Whole blood
Sample volume	1.5µL
Measuring range	0.0-8.0mmol/L
Measuring time	10s
Test system	Fully automatic code-free
Data storage	250pcs
Test kit storage temperature	2-30°C
Quality Control	24 months
Certification	CE



# 05

## LATERAL FLOW IMMUNOASSAY

Speedy Diagnostics Elevating Everyone's Well-being

# COVID-19 SOLUTIONS

## SARS-COV-2 IGG/IGM RAPID TEST

### Advantages

- US FDA and CE approved
- High specificity and sensitivity
- Test result within 10 min
- Serum, plasma and whole blood available
- Without instrument, suitable for field screening



CE FDA

## SARS-COV-2 ANTIGEN RAPID TEST

### Advantages

- High accuracy, specificity and sensitivity
- Test results within 20-30 min
- 24 months shelf life
- Room temperature storage
- QR code and APP to track patient's information

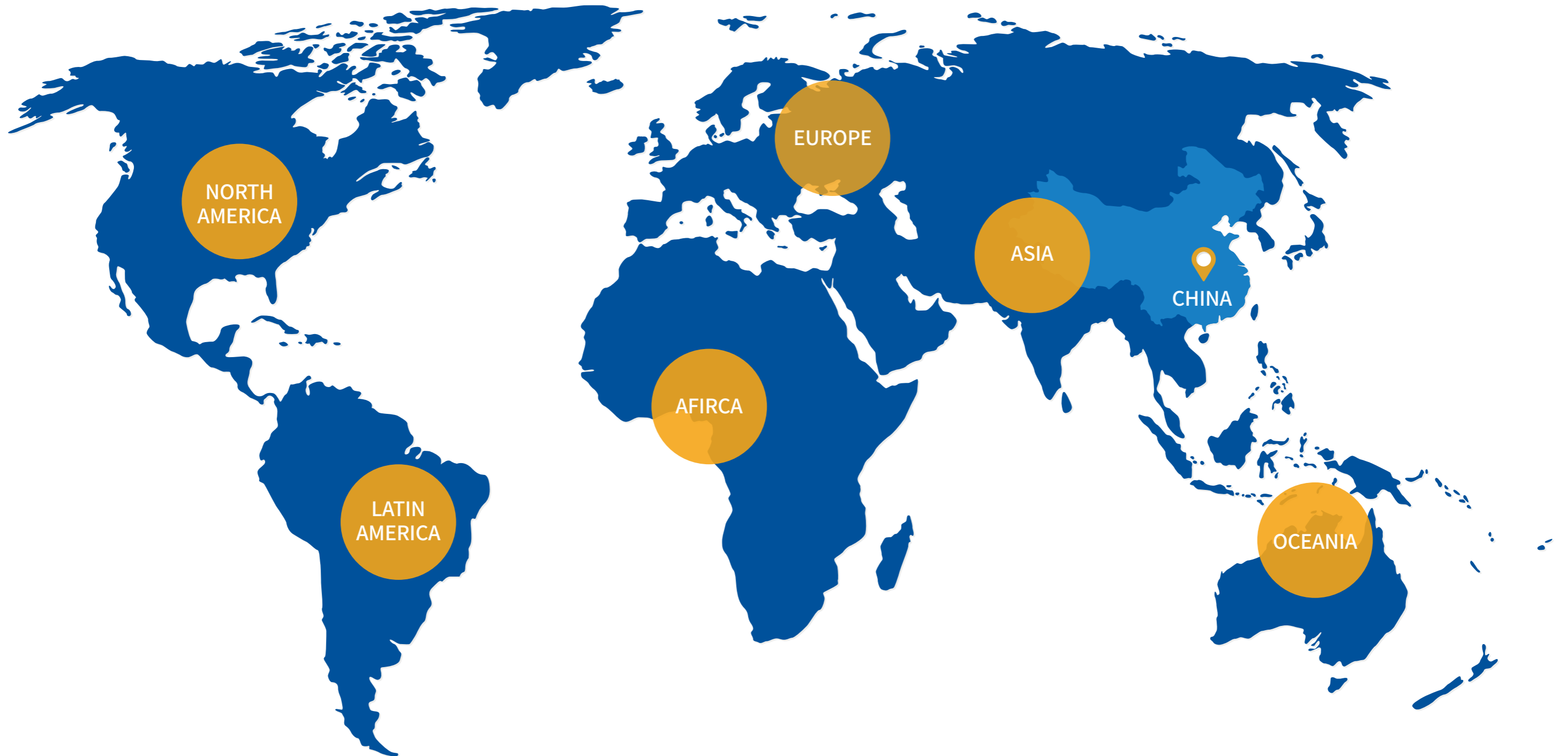


CE

Test Item	Specimen	Sensitivity/Specificity	Detection Time	Pack	Qualification
<b>• Respiratory Tract Infection</b>					
Flu A Ag	Nasal / Throat / Nasopharyngeal	99.1% / 99.7%	15 min	25T	CE
Flu B Ag	Nasal / Throat / Nasopharyngeal	99.3% / 99.7%	15 min	25T	CE
Flu A/B Ag Combo Test	Nasal / Throat / Nasopharyngeal	Relevant to individual item	15 min	25T	CE
ADV Ag	Nasal / Throat / Nasopharyngeal	99.0% / 99.0%	15 min	25T	CE
RSV Ag	Nasal / Throat / Nasopharyngeal	99.2% / 99.6%	15 min	25T	CE
ADV/RSV/Flu A&B Ag Combo Test	Nasal / Throat / Nasopharyngeal	Relevant to individual item	15 min	25T	CE
SARS-CoV-2 Ag	Nasal / Throat / Sputum	90.9% / 99.9%	20-30 min	10/15T	NMPA/CE
COVID-19/Flu A/B Ag Combo Test	Nasal	Relevant to individual item	15-30 min	1T	CE2934
SARS-CoV-2 IgG/IgM Ab	Serum/Plasma/Whole Blood	96.7% / 97.5% (IgG) 100% / 98.8% (IgM)	20 min	25T	CE
<b>• Vector borne diseases</b>					
Malaria P.v Ag	Whole Blood	98.3% / 99.4%	20-30 min	25T	CE
Malaria P.f Ag	Whole Blood	98.5% / 99.4%	20-30 min	25T	CE
Malaria P.f/P.v Ag Combo Test	Whole Blood	Relevant to individual item	20-30 min	25T	CE
Malaria P.f/Pan Ag Combo Test	Whole Blood	Relevant to individual item	20-30 min	25T	CE
Dengue NS1 Ag	Serum/Plasma/Whole Blood	99.1% / 99.3%	15 min	25T	CE
Dengue IgG/IgM Ab	Serum/Plasma/Whole Blood	99.1% / 99.0% (IgG) 97.3% / 98.6% (IgM)	15 min	25T	CE
Dengue Ag/Ab Combo Test	Serum/Plasma/Whole Blood	Relevant to individual item	15 min	25T	CE



# BIOTIME FOOTPRINT



Rapid, beyond imagination