

INCLIX

QUANTITATIVE IMMUNOASSAY ANALYZER



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Multi-parameter Quantitative Immunoassay for Point-Of-Care Testing (POCT)

INCLIX™ is an immunochromatographic analyzer providing Point-Of-Care Testing (POCT) at patient care settings or clinical laboratories. It facilitates automatic detection of various biomarkers for cardiovascular disease, infectious disease, cancer, diabetes, allergy, and etc. with high accuracy and sensitivity.

INCLIX™ analyzer is a compact, easy-to-use and multi-parameters instrument. Its unique user friendly software provides an efficient data management system. Test results can be printed out using the built-in thermal printer or the connected local & network printer. Measurement data can be exported to PC, USB Flash Memory or LIS.

Features

- Both Qualitative and Quantitative Testing
 - Dual Assay Modes: Standard Mode/Quick Mode
 - Stores more than 10,000 test results
 - Instrument Check by Reference Kit
 - Internal Barcode Scanner to import Test Device, Lot and Exp. Date
- Built In Thermal Printer
 - Data Export to PC, LIS or USB Flash Memory
 - Options
 - External keyboard, External barcode scanner

Specifications

Operating System	Embedded Linux
Display	7" Color LCD (Resolution 800 x 480)
I/O Interface	4 x USB 2.0 / 1 x RJ-45 LAN Connector
Control	Touch Screen
Supported Accessories	Thermal printer (Built-in), Barcode scanner, Keyboard, and Mouse (Optional)
Patient Records	10,000 Patients
Rating	12 VDC, 5A
Power Consumption	30W
Dimensions (L x W x H)	Approx. 230 x 250 x 250 mm (9.0 x 9.84 x 9.84 in.)
Weight	Approx. 1.93 kg (68.1oz)
Operating Temperature	Between 10°C(50°F) and 40°(104°F)
Storage Temperature	Between -10°C(14°F) and 50°C(122°F)
Features	- High sensitivity & repeatability - Management of Patient records
Environmental	- For indoor use only - Main supply voltage fluctuations should not exceed ±10% - Transient over-voltages according to installation category II - Pollution degree 2

Quantitative Assay

Category	Catalog No.	Item	Sample Type	Sample Volume	Measuring Time	Measuring Range	Reference Value	Certification
Infection	CRPT025E	CRP	WB,serum,plasma	5 µL	5 minutes	2.5 - 300 mg/L	< 5 mg/L	CE
	DCRT025E	dual CRP	WB,serum,plasma	5 µL	5 minutes	0.5 - 200 mg/L	< 5 mg/L	CE
	PCTT025E	PCT	Serum,plasma	100 µL	15 minutes	0.25 - 40 ng/mL	< 0.5 ng/mL	CE
Cardiac	HCRT025E	hsCRP	WB,serum,plasma	5 µL	5 minutes	0.1 - 10 mg/L	< 1 mg/L	CE
	TPIT025E	Troponin I	WB,serum,plasma	100 µL	15 minutes	0.2 - 50 ng/mL	< 0.3 ng/mL	CE
	DIMT025E	D-dimer	Available with CE mark soon					
Diabetes	HBAT025E	HbA1c	WB	5 µL	3 minutes	4 - 14%		CE/NGSP
Pregnancy	BCGT025E	β-hCG	WB,serum,plasma	100 µL	10 minutes	5 - 1500 mIU/mL	> 10 mIU/mL	CE
Allergy	IGET025E	Total IgE	Serum,plasma	20 µL	10 minutes	5 - 2000 IU/mL	Adult general population (non-atopic): <100 IU/mL	CE
Vitamin-D	VIDT025E	Vitamin D	Available with CE mark soon					
Thyroid	TSHT025E	TSH	Available with CE mark soon					
	TRIT025E	T3	Available with CE mark soon					
	TETT025E	T4	Available with CE mark soon					
Cancer	PSAT025E	PSA	Available with CE mark soon					
Other	-	Other Test Parameters	Other test parameters will be available step by step					

Qualitative Assay

Category	Catalog No.	Item	Sample Type	Sample Volume	Measuring Time	Certification
Influenza	IFNT025E	SGT i-flex Influenza A&B	Nasopharyngeal swab	4 drops	3~10 minutes	CE
Zika	ZIKT025E	SGT i-flex Zika IgM/IgG	Serum,plasma	5 µL	15~20 minutes	CE



CRP / hsCRP / dual CRP

• **Intended Use**

INCLIX™ CRP / hsCRP / dualCRP quantitatively measures C-reactive protein (CRP) concentration in whole blood, serum or plasma using the INCLIX™ analyzer. For *in-vitro* diagnostic use only.

• **Specifications**

Sample Type	Whole blood, serum, or plasma
Sample Volume	5 µL
Measuring Range	
CRP	2.5 - 300 mg/L (Cutoff 10 mg/L)
hsCRP	0.1 – 10 mg/L (Cutoff 1 mg/L)
dual CRP	0.5 – 200 mg/L (Inflammation cutoff 10mg/L, cardiovascular disease cutoff 1 mg/L)
Reference Value	CRP<10 mg/L, hsCRP<1.0 mg/L
Precision	<10% CV in working range
Measuring Time	5 minutes
Package	25 tests/box
Diluent Buffer	Diluent Buffer(1 ml/tube) is provided
Storage Temp.	2-30°C (36-86°F)
Shelf Life	24 months

PCT

• **Intended Use**

INCLIX™ PCT quantitatively measures Procalcitonin (PCT) concentration in serum and plasma using the INCLIX™ analyzer. For *in-vitro* diagnostic use only.

• **Specifications**

Sample Type	Serum or Plasma
Sample Volume	100uL
Measuring Range	0.25- 40 ng/mL (Cutoff 0.5 ng/mL)
Reference Value	<0.5ng/mL
Precision	<15% CV in working range
Measuring Time	15 minutes
Package	25 tests/box
Diluent Buffer	Diluent Buffer is not necessary to perform test
Storage Temp.	2-30°C (36-86°F)
Shelf Life	24 months



Troponin I

• **Intended Use**

INCLIX™ Troponin I quantitatively measures Troponin I concentration in whole blood, serum or plasma using the INCLIX™ analyzer. For *in-vitro* diagnostic use only.

• **Specifications**

Sample Type	Whole blood, serum, or plasma
Sample Volume	100 µL
Measuring Range	0.2 – 50 ng/mL
Reference Value	< 0.3 ng/mL
Precision	<10% CV in working range
Measuring Time	15 minutes
Package	25 tests/box
Diluent Buffer	Diluent Buffer(0.1 ml/tube) is provided
Storage Temp.	2-30°C (36-86°F)
Shelf Life	24 months

HbA1c

• **Intended Use**

INCLIX™ HbA1c quantitatively measures HemoglobinA1c(HbA1c) concentration in whole blood using the INCLIX™ analyzer. For *in-vitro* diagnostic use only.

• **Specifications**

Sample Type	Whole blood
Sample Volume	5 µL
Measuring Range	4 – 14%
Precision	<5% CV in working range
Measuring Time	3 minutes
Package	25 tests/box
Diluent Buffer	Diluent Buffer(1 ml/tube) is provided
Storage Temp.	2-30°C (36-86°F)
Shelf Life	24 months

β-hCG

• Intended Use

INCLIX™ β-hCG quantitatively measures human Chorionic Gonadotropin (hCG) concentration in serum, plasma and whole blood. The test is used as an aid to diagnose early pregnancy. For *in-vitro* diagnostic use only.

• Specifications

Sample Type	Serum, plasma or whole blood
Sample Volume	100 µL
Measuring Range	5 - 1500 mIU/mL
Precision	<15% CV in working range
Measuring Time	10 minutes
Package	25 tests/box
Diluent Buffer	Diluent Buffer(0.1 mL/tube) is provided
Storage Temperature	2-30°C (36-86°F)
Shelf Life	24 months

Total IgE

• Intended Use

INCLIX™ Total IgE quantitatively measures total immunoglobulin E (IgE) concentration in serum or plasma. The test is used as an aid in the diagnosis of IgE mediated allergic disorders. For *in-vitro* diagnostic use only.

• Specifications

Sample Type	Serum or plasma
Sample Volume	20 µL
Measuring Range	5-2000 IU/mL (The reference value in the adult general population (non-atopic) is <100 IU/mL, if IgE concentration is >100 IU/mL, allergic disease is suspected.
Precision	<10% CV in working range
Measuring Time	10 minutes
Package	25 tests/box
Diluent Buffer	Diluent Buffer(200 µL/tube) is provided
Storage Temperature	2-30°C (36-86°F)
Shelf Life	24 months

SGT i-flex Rapid Test Series

» SGT i-flex Influenza A&B

- For both Qualitative Reading by INCLIX™ Analyzer and Rapid Test

• Intended Use

SGT i-flex Influenza A&B is an immunoassay for qualitative detection of Influenza virus type A or type B antigens directly from nasopharyngeal swab specimens. The test is used as an aid to detect the influenza viruses by simultaneously distinguishing between A and B, which are human-infected subtypes. For *in-vitro* diagnostic use only.

Note: SGT i-flex Influenza A&B could be used along with INCLIX™ Analyzer. In this case, INCLIX Analyzer shows the result of test by qualitative reading (positive, negative).

• Specifications

Sample Type	Nasopharyngeal swab
Extracted Sample Loading Volume	4 drops
Reaction Time	3~10 minutes after loading the sample
Storage Temperature	2-30°C (36-86°F)
Shelf Life	24 months

» SGT i-flex Zika IgM/IgG

• Intended Use

SGT i-flex Zika IgM/IgG is an immunoassay for qualitative detection of IgM and IgG antibodies to Zika virus in human Serum/Plasma. The test is useful as a screening test for Zika viral infection. For *in-vitro* diagnostic use only.

• Specifications

Sample Type	Serum or plasma
Sample Volume	5 µL
Reaction Time	15~20 minutes
Storage Temperature	2-30°C (36-86°F)
Shelf Life	24 months