



2018

**CHEMILUMINESCENCE
IMMUNOASSAY
FOCUSED MANUFACTURER**

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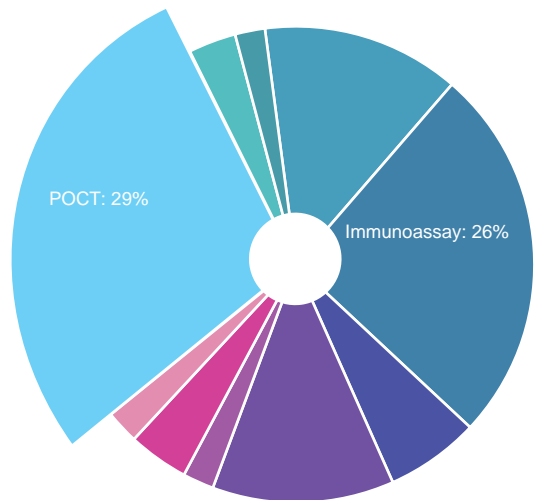
In-Vitro Diagnostics

In-Vitro Diagnostic Market Size

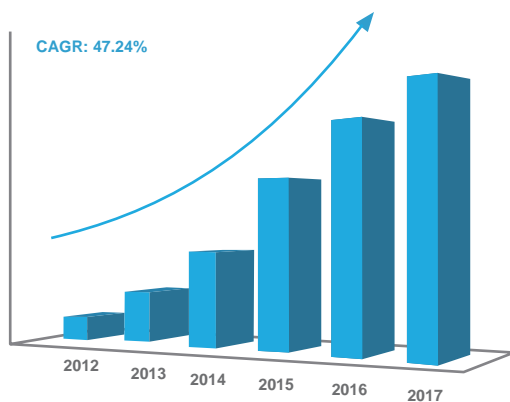
Compound Annual Growth Rate(CAGR) of over 5%

Rank

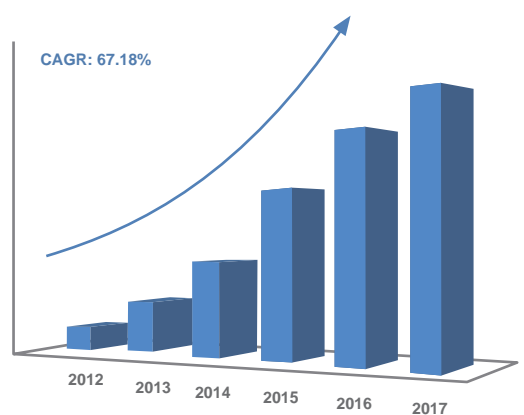
- POCT: 29%
- Immunoassay: 26%
- Clinical Chemistry: 14%
- Microbiology: 12%
- Hematology: 6%
- Histology/Cytology: 4%
- Blood Test: 3%
- Nucleic Acid Assays: 2%
- Flow Cytometry: 2%
- Coagulation: 2%



Snibe International Business Growth



Annual New Installation Unit



Snibe's core products were put into batch production in 2010 and since then, the company has experienced rapid growth and development.

Company Profile



Shenzhen New Industries Biomedical Engineering Co., Ltd (Snibe) is located in the Hi-Tech Industrial Park of the Nanshan District in Shenzhen, China.

Founded in December 1995, Snibe is a professional bio-medical company that specializes in the research, production and sale of clinical laboratory instruments and in vitro reagents.

Since 1995, Snibe has been focusing on the R&D of immunoassay products and has developed the key technique of utilising magnetic microbeads. After decades of effort, in 2008, Snibe became the first company in China to successfully develop and release a fully automated Chemiluminescence Immunoassay (CLIA) System.

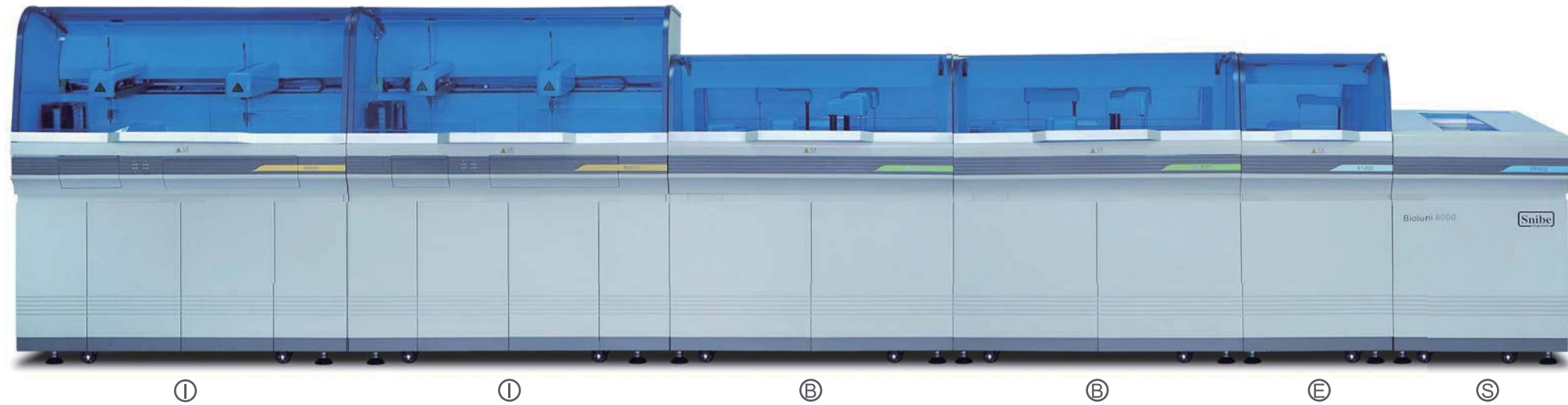
As a leading brand in China, Snibe is characterized by the following features:

- Application of advanced magnetic microbeads as the key separation material for its CLIA system
- Application of advanced synthesized small-molecule organic compounds as markers
- Developing and producing automated Chemiluminescence Immunoassay Systems

1995	Founded in Shenzhen, China
1997	Developed enzyme-linked immunoassay system-Magimuzyme
2002	Received "Shenzhen High-tech Enterprise" award
2005	Developed semi-auto CLIA analyzer and dedicated reagent kits. Received "Shenzhen Science and Technology Progress Award"
2007	ISO 9001, ISO 13485 certified by TUV Joined "National High-tech Industrialization Demonstration Project"
2008	Developed China's first automated CLIA analyzer and dedicated kits
2009	Received "National High-tech Enterprise" award
2010	Launched automated CLIA analyzer and dedicated kits
2012	Developed China's first Integrated System
2013	Launched high throughput CLIA analyzer MAGLUMI™ 4000
2014	New Production Center and Headquarters put into use
2015	The new headquarters in Pingshan starts construction
2016	Launched CLIA analyzer MAGLUMI™ 4000 Plus
2017	1 st CLIA manufacturer in China who gets FDA cleared

Integrated System

Biolumi™ 8000



Flexible combination of different module

B+S



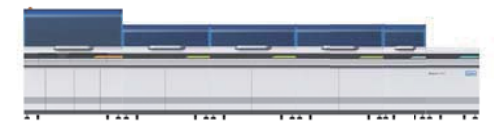
I+B+S



I+I+B+S



I+B+B+B+E+S



Specificity

IMMUNOASSAY MODULE (I)

- » Magnetic separation, flash CLIA technology
- » More than 120 parameters(Tumor marker, Fertility,) Hepatic Fibrosis, Inflammation Monitoring, Cardiac Markers etc.)
- » **25** reagents on board
- » **280** tests/hour
- » Clot detection,liquid level detection

BIOCHEMISTRY MODULE (B)

- » **1600** tests/hour
- » Continuous loading reagent during operation
- » Clot detection, liquid level detection
- » Wavelength range 340nm - 800nm, detect 16 different wavelengths simultaneously

ELECTROLYTE MODULE(E)

- » **1000** tests/hour
- » Continuous loading reagent during operation
- » Clot detection, liquid level detection

SAMPLE PROCESSNG MODULE(S)

- » Loading **280** samples at one time
- » Recognize the barcode of primary tube
- » Continuous loading and unloading samples during operation
- » Specific STAT channel

Immunoassay



MAGLUMI™ 600

SPECIFICATION

- » Throughput:
Maximum **180** tests/hour
- » Sample and reagent continuous loading
- » On board capability: up to **16** samples
- » Reagent position: **4**
- » Random access or batch mode, STAT

TARGETED END-USER

- » Small labs
- » Back-up

TEST VOLUME PER DAY

- » Daily test: 10-35



MAGLUMI™ 800

SPECIFICATION

- » Throughput:
Maximum **180** tests/hour
- » Sample and reagent continuous loading
- » On board capability: up to **40** samples
- » Reagent position: **9**
- » Random access or batch mode, STAT

TARGETED END-USER

- » Small labs
- » Mid-size Labs

TEST VOLUME PER DAY

- » 5-10 parameters
- » Daily test: 40-80



MAGLUMI™ 1000

SPECIFICATION

- » Throughput:
Maximum **120** tests/hour
- » Sample and reagent continuous loading
- » On board capability: up to **144** samples
- » Reagent position: **15**
- » Random access or batch mode, STAT

TARGETED END-USER

- » Mid-size Labs
- » Hospitals

TEST VOLUME PER DAY

- » 10-20 parameters
- » Daily test: 50-100



MAGLUMI™ 2000

MAGLUMI™ 2000 Plus

MAGLUMI™ 4000 Plus

SPECIFICATION

- » Throughput:
Maximum **180** tests/hour
- » Sample and reagent continuous loading
- » On board capability: up to **144** samples
- » Reagent position: **15**
- » Random access or batch mode, STAT

SPECIFICATION

- » Throughput:
Maximum **180** tests/hour
- » Sample and reagent continuous loading
- » On board capability: up to **144** samples
- » Reagent position: **25**
- » Random access or batch mode, STAT
- » Refrigerated sample and reagent area

SPECIFICATION

- » Throughput:
Maximum **280** tests/hour
- » Sample and reagent continuous loading
- » On board capability: up to **144** samples
- » Reagent position: **25**
- » Random access or batch mode, STAT
- » Refrigerated sample and reagent area

TARGETED END-USER

- » Mid or large size labs
- » Hospitals

TARGETED END-USER

- » Large labs
- » Hospitals
- » Chain labs

TARGETED END-USER

- » Large labs
- » Hospitals
- » Chain labs

TEST VOLUME PER DAY

- » > 20 parameters
- » Daily test: 100-300

TEST VOLUME PER DAY

- » > 20 parameters
- » Daily test: 100-300

TEST VOLUME PER DAY

- » > 20 parameters
- » Daily test: 200-500

MAGLUMI™

Immunoassay



Thyroid

TSH (3rd Generation)
T₄
T₃
FT₄
FT₃
Tg (Thyroglobulin)
TGA (Anti-Tg)
TRAb
TMA
Anti-TPO
Rev T₃
Intact PTH



Fertility

FSH
LH
HCG/ β -HCG
PRL
Estradiol
Progesterone
Testosterone
DHEA-S
free Testosterone
free Estriol
17-OH Progesterone
AMH
*SHBG
*Androstenedione
*PLGF
*sFLT-1



Tumor Markers

Ferritin
AFP
CEA
Total PSA
f-PSA
CA 125
CA 15-3
CA 19-9
HCG/ β -HCG
Tg (Thyroglobulin)
PAP
CA 50
CYFRA 21-1
CA 242
CA 72-4
NSE
S-100
SCCA
TPA-snibe
Pepsinogen I
Pepsinogen II
Gastrin-17
H.pylori IgG
 β 2-MG
Calcitonin
Proinsulin
*H.pylori IgA
*H.pylori IgM
*proGRP
*AFP-L3
*HE4
*PIVKA-II
*HER-2



Autoimmune

TGA(Anti-Tg)
TRAb
TMA
Anti-TPO
ICA
IAA(Anti Insulin)
GAD 65
Anti-IA2
*Anti-CCP
*Anti-dsDNA
*ANA
*ENA
*Anti-Sm
*Anti-Ribosomal-P
*Anti-Scl-70
*Anti-CENP-B
*Anti-Jo-1
*Anti-M2
*Anti-Histone
*Anti-RNP
*Anti-SSB
*Anti-SSA



Glyco Metabolism

C-Peptide
Insulin
ICA
IAA (Anti Insulin)
Proinsulin
GAD 65
Anti-IA2



Bone Metabolism

Calcitonin
Osteocalcin
25-OH Vitamin D
Intact PTH
* β -CTX
*PINP



Kidney Function

β ₂-MG
Albumin



Cardiac

CK-MB
Troponin I
Myoglobin
NT-proBNP
Aldosterone
Angiotensin I
Angiotensin II
D-Dimer
LP-PLA2
hs-cTnl
hs-CRP
Direct Renin
*H-FABP
*BNP



Prenatal Screening

AFP (Prenatal Screening)
free β -HCG
PAPP-A
HCG/ β -HCG
free Estriol



Immunoglobulin

IgM
IgA
IgE
IgG



Inflammation Monitoring

hs-CRP
PCT (Procalcitonin)
*IL- 6



TORCH

Toxo IgG
Toxo IgM
Rubella IgG
Rubella IgM
CMV IgG
CMV IgM
HSV-1/2 IgG
HSV-1/2 IgM
HSV-2 IgG
*HSV-2 IgM
*HSV-1 IgG
*HSV-1 IgM



Infectious Disease

HBsAg
Anti-HBs
HBeAg
Anti-HBe
Anti-HBc
Anti-HCV
Syphilis
Chagas
HTLV I/II
Anti-HAV
HAV IgM
HIV p24 Ag
HIV Ab/Ag combi
H.pylori IgG
*H.pylori IgA
*H.pylori IgM
*Anti-HBc IgM



EBV

EBV EA IgG
EBV EA IgA
EBV VCA IgG
EBV VCA IgM
EBV VCA IgA
EBV NA IgG
*EBV NA IgA



Anemia

Vitamin B₁₂
Ferritin
Folate (FA)



Hepatic Fibrosis

HA
PIIIP N-P
C IV
Laminin
Cholyglycine



Drug Monitoring

CSA (Cyclosporine A)
FK 506 (Tacrolimus)
Digoxin



Others

GH (hGH)
IGF-I
Cortisol
ACTH
*IGFBP-3

Special assays

Routine assays

* Available soon

Product availability subject to required regulatory approval

Key Techniques

Chemiluminescence Immunoassay (CLIA) System

CLIA uses two important technologies, one is the labelling technology which determines the reaction mode, and the other is a separation technology which determines the sensitivity, accuracy and precision of the reagents.

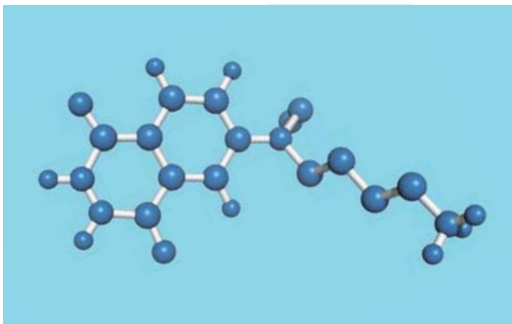
LABELLING TECHNOLOGY

Two types of labelling technologies are commonly used. One is an enzyme label and another is a non-enzyme small molecule. Enzyme label reagents are not very stable and are easily affected by the change of storage conditions.

The MAGLUMI™ system applies ABEI labels. ABEI is a non-enzyme small molecule with special molecular formula to enhance stability in acid and alkaline buffer. Using fast Chemiluminescence, ABEI's chemical reaction with sodium hydroxide (NaOH) and Hydroperoxide (H_2O_2) finishes the process in 3 seconds.

Key technology

Luminescence label -- ABEI



SEPARATION TECHNOLOGY

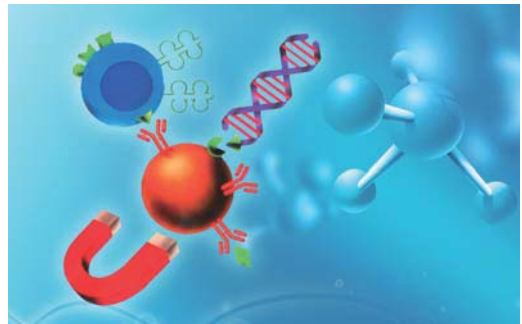
MAGLUMI™ uses Nano Magnetic Microbeads. As separation technology, it has been widely used in the field of CLIA.

Compared with traditional separation technology, it has the following advantages:

- » Shortening the reaction time by enlarging the reaction area of antigens and antibodies.
- » Enhancing the sensitivity by better and faster capture of antigens and antibodies,
- » Reducing inter or intra-assay discrepancies significantly by mixing the reagents thoroughly in a liquid separation platform.
- » Enhancing the accuracy by absorbing antigens and antibodies through chemical reaction.

Key technology

Magnetic microbeads



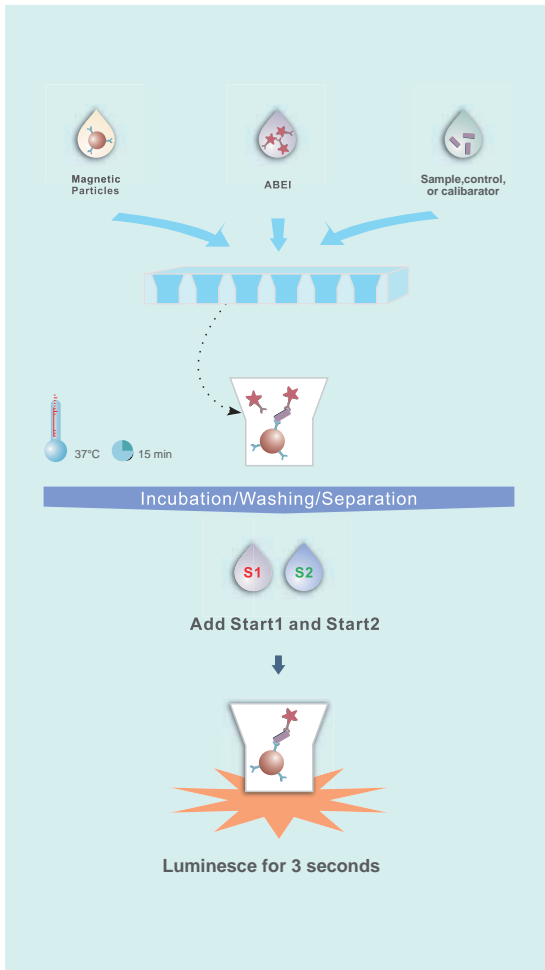
Product Advantages:

- » Comprehensive test menu, over 154 parameters
- » High throughput, up to 280 tests/hour
- » Reliable performance, lower breakdown rate
- » Same reagent package available for series instruments
- » Integrated reagent kit, internal control and calibrators FOC
- » Easy to maintain and has worldwide service

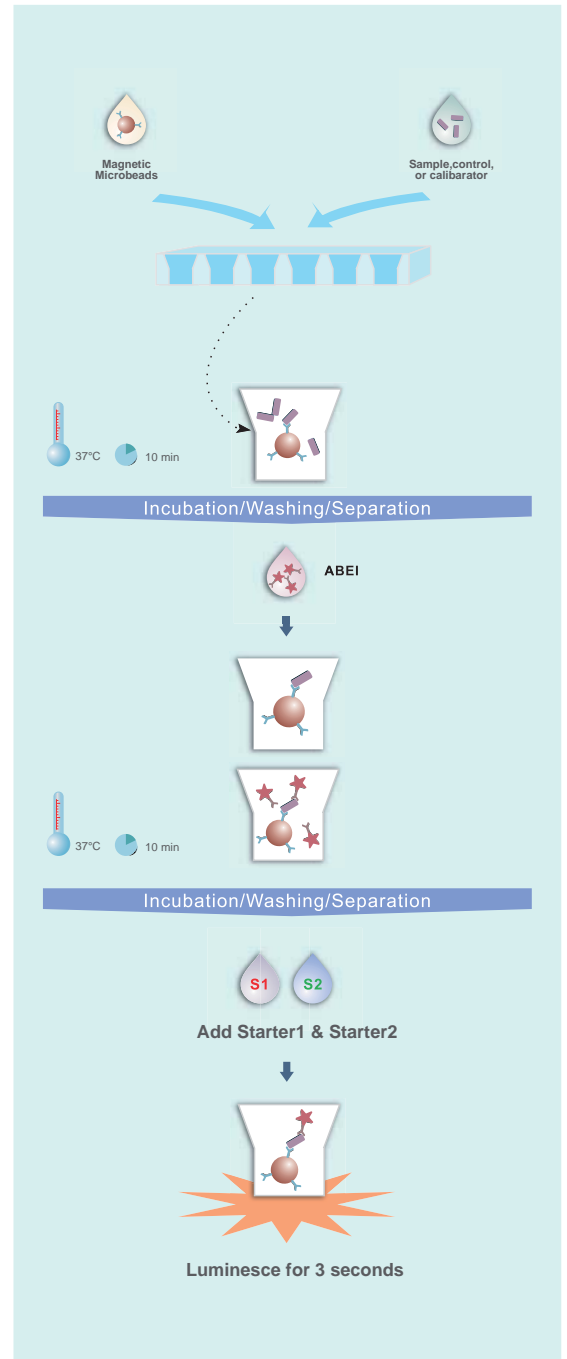


Principle

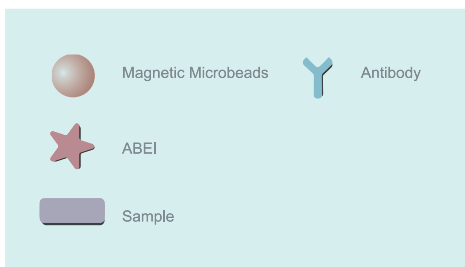
ONE STEP ASSAY



TWO STEP ASSAY



NOTE



Biochemistry Test Menu



Cardiac

CK
CK-MB
α-HBDH
LDH
*LDH1



Hepatic

TBA
ALT (SGPT)
AST (SGOT)
ALP
GGT
TBIL
DBIL
TP
ALB
*Ammonia
*PA
*CHE
*AFU



Lipids

HDL-C
LDL-C
TC
TG
ApoE
Lp(a)
Hcy
*ApoA1
*ApoB



Special Protein

*ASO
*RF
*CRP (Full Range)
*UIBC
*Urine/CSF Protein
*G6PD
*IgM
*IgA
*IgG
*C3
*C4
*ACP
*Transferrin



ISE

Na
K
Cl
Ca
pH



Pancreatic

α-AMY
*LIP



Diabetes

GLU
*LAC
*HbA1c



Renal

Cr(CREA)
Uric Acid
Urea
*Cysc
*mALB
*α1-MG
*β2-MG



Inorganic Ion

*Fe (Iron)
*Ca
*P (phos)
*Mg

* Available soon



Biochemistry Analyzer

SPECIFICATION



Biossays™ 240

- » Throughput: **240** tests/hour
- » Sample Handling: up to **90** sample positions, STAT
- » Reagent Handling: up to **90** reagent positions, with refrigeration
- » Reaction cuvette: **80**, optical diameter is **5** mm
- » ISE: optional



Biossays™ 240 Plus

- » Throughput: **240** tests/hour
- » Sample Handling: up to **90** sample positions, STAT
- » Reagent Handling: up to **90** reagent positions, with refrigeration
- » Reaction cuvette: **80**, optical diameter is **5** mm
- » ISE: optional
- » Washing Station: Available



Biossays™ BC1200

- » Throughput: **600** tests/hour
- » Sample Handling: **115** sample positions, STAT
- » Reagent Handling: **2** trays, **90** reagent positions, with refrigeration
- » Reaction cuvette: **120**, optical diameter is **6** mm
- » ISE: optional



Biossays™ BC2200

- » Throughput: **1600** tests/hour
- » Sample Handling: **280** sample positions, STAT
- » Reagent Handling: **2** trays, **90** reagent positions, with refrigeration
- » Reaction cuvette: **330**, optical diameter is **6** mm