

MAGLUMI™ 800

Chemiluminescence Immunoassay (CLIA) System



WWW.INSIGNIABIOMEDICAL.COM

OUTSTANDING TECHNOLOGY POWER OF MAGLUMI

WWW.INSIGNIABIOMEDICAL.COM

Chemiluminescence Immunoassay (CLIA) System

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

Labeling Technology

Two types of labeling technologies are commonly used. One is enzyme label and the other is non-enzyme small molecule label. Enzyme label reagents are not so stable and are easily affected by the change of storage conditions. Maglumi system applies ABEI labels. ABEI is a non-enzyme small molecule with special molecular formula to enhance stability in acid and alkaline solution. As fast chemiluminescence, ABEI chemical reaction with sodium hydroxide (NaOH) and Hydrogen peroxide (H_2O_2) finishes the process in 3 seconds.

Separation Technology

Maglumi uses 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.

WWW.INSIGNIABIOMEDICAL.COM



ADVANTAGE OF MAGLUMI™ 800

WWW.INSIGNIABIOMEDICAL.COM



- For small and middle size labs or hospitals
- Simple, Smart, Humanization designed model
- More than enough test menu to meet the different needs and it will be extended according to your requirement
- Free Quality Control and calibrator helps to reduce the Cost Per Test
- Quality guarantee by the Third party quality control and External Quality Assessment (EQA)
- Key technology ABEI and Nano magnetic microbead enhances stability and sensitivity of MAGLUMI reagents

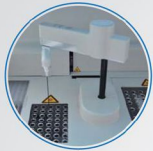


WWW.INSIGNIABIOMEDICAL.COM

MAGLUMI™ 800

- Integrated design and humanized appearance
- Simple and smart operation
- Compact size and weight

WWW.INSIGNIABIOMEDICAL.COM



Pipettor

- Aspirate reagent/sample with high speed
- Titanium needle for crushproof
- Clot detection & liquid level detection
- Coated with TEFLON to prevent carry-over
- Inner & external washing



Chamber

- High-sensitivity and low-noise PMT
- Cuvettes detection and anti-overflow



Automated cuvette loader

- Up to 40 modules of 240 tests
- Continuous loading



Washer

- Strong magnetic field helps better separation
- Three pairs of washing needles with anti-overflow function



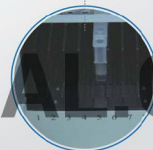
Sample area

- Up to 40 sample on board with barcode
- Continuous loading & cooling function



Incubator

- 13 incubate slots (78 tests at the same time)
- The temperature is 36.8 °C ± 0.5 °C



Reagent area

- Up to 9 reagents on board with RFID
- RFID label storing reagent information
- Easy and fast for adding and updating
- RFID tag, high reliability

WWW.INSIGNIABIOMEDICAL.COM

OPERATION SOFTWARE

WWW.INSIGNIABIOMEDICAL.COM



Comprehensive software

- User-friendly Interface
- Real-time status monitoring for each test
- Monitoring reagent and consumable status
- Intelligent alarm function



Maintenance Guide

- Daily, weekly and monthly maintenance guide for analytical unit
- Ensure performance reliability



Quality control

- Westgard rules and Levey-Jennings chart for both internal and external quality control



Test Summary Function

- Test summary including system test, calibration, QC, statistics of samples, valid tests and rerun tests
- Search and review test information conveniently



Pre or post defined dilution Function

- Pre or post defined dilution flexibly if high concentration is met



Connect to LIS (bidirection)

- Bidirection, Lis can connect by online and ASTM

WWW.INSIGNIABIOMEDICAL.COM

MAGLUMI™ 800

Chemiluminescence Immunoassay (CLIA) System

Technical Specifications

Reagent Feature

- Flash chemiluminescence label-ABEI with high sensitivity and long stability
- Nano magnetic microbeads separation, fast and efficient

Main Features

- Throughput: up to 180 tests/hour
- 24 hours ready to use
- Time to first result: 17 minutes

Modes of Operation

- Random, Batch and STAT

Sample Loading

- Up to 40 sample tubes
- Continuous loading, STAT available
- Barcode reader recognition or analyzer auto numbered
- LIS connection, auto read sample info
- Refrigerated sample area with independent power supply

Reagent Loading

- 9 reagents on board
- Continuous loading
- RFID reading all info of reagent
- Refrigerated reagent area

Reagent Integral

- Ready-to-use, no pretreatment required
- Including calibrators
- RFID tag storing all info of reagent
- RFID tag with built-in master curve
- 2-point calibration to adjust master curve
- Calibration stability: Max 4 weeks

Other Features

- Clot detection
- Liquid level detection
- Auto and optional ratio for high sample dilution
- Constant 37°C incubation

Operation System

- Windows 7
- DELL compatible (Dual-core CPU)
- Color touch screen

Interconnection

- Bi-communication with LIS via ASTM protocol

Dimensions Weight

- Input: AC 110-230V, 50/60 Hz, Max 630W
- Dimension and Weight: 102*72*56cm 73kg



Shenzhen New Industries Biomedical Engineering Co., Ltd.(Snibe)

21st Floor, Block A, Building 1, Shenzhen Software Industry Base,
No. 1008, Keyuan Road, Nanshan District, Shenzhen 518000 CHINA

Tel: +86 755 26501514

Fax: +86 755 26654850

Email: sales@snibe.com

Web: www.snibe.com



DISTRIBUTOR:



Thyroid

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



Fertility

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



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**



EBV

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



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**



Bone Metabolism

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



Glyco Metabolism

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



Autoimmune

TGA(Anti-Tg)
Anti-TPO
TRAb
TMA
ICA
IAA(Anti Insulin)
GAD 65
Anti-IA2
***Anti-CCP**
***Anti-dsDNA IgG**
***ANA Screen**
***ENA Screen**
***Anti-Sm IgG**
***Anti-Rib-P IgG**
***Anti-Scl-70 IgG**
***Anti-Centromeres IgG**
***Anti-Jo-1 IgG**
***Anti-M2-3E IgG**
***Anti-Histone IgG**
***Anti-nRNP/Sm IgG**
***Anti-SS-B IgG**
***Anti-SS-A IgG**



Infectious Disease

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



Prenatal Screening

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



Anemia

Vitamin B12
Ferritin
Folate (FA)



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**



Hepatic Fibrosis

HA
PIIIP N-P
C IV
Laminin
Cholyglycine



Drug Monitoring

Digoxin
CSA (Cyclosporine A)
FK 506 (Tacrolimus)



Inflammation Monitoring

hs-CRP
PCT(Procalcitonin)
***IL- 6**



Immunoglobulin

IgM
IgA
IgE
IgG



Kidney Function

β_2 -MG
Albumin



Others

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

In Blue Special Assay
*Available Soon

WWW.INSIGNIABIOMEDICAL.COM

WWW.INSIGNIABIOMEDICAL.COM

23

154

130+

8000+

Years Focus

Parameters

Countries Installed

Units Installed

WWW.INSIGNIABIOMEDICAL.COM

FDA
510(k)
Cleared



MAGLUMI™ 600



MAGLUMI™ 800



MAGLUMI™ 1000



MAGLUMI™ 2000

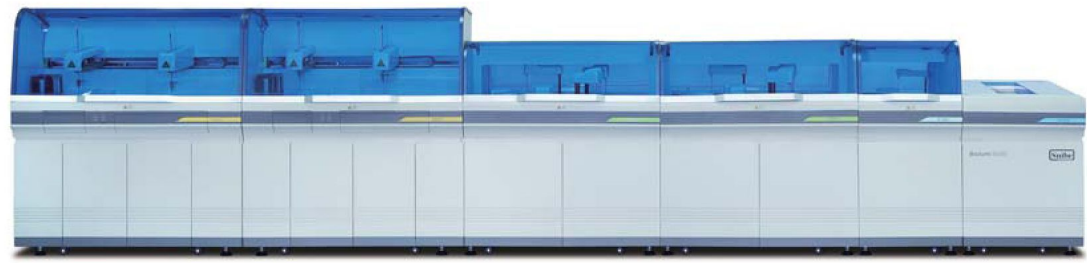


MAGLUMI™ 2000 Plus



MAGLUMI™ 4000 Plus

Integrated System-Biolumi™ 8000



Automated Biochemistry Analyzer



Biossays™ 240



Biossays™ 240 Plus



Biossays™ BC1200



Biossays™ BC2200

Hepatic

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

Special Protein

- *ASO
- *RF
- *hsCRP (Full Range)
- *UIBC
- *TP (Urine/CSF)
- *G6PD
- *IgA
- *IgM
- *IgG
- *C3
- *C4
- *ACP
- *Transferrin

ISE

- Na
- K
- Cl
- Ca
- pH

Inorganic Ion

- *Fe (Iron)
- *Ca
- *P (Phos)
- *Mg

Renal

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

Pancreatic

- α-AMY
- *LIP

Diabetes

- GLU
- *LAC
- *HbA1c

Cardiac

- CK
- CK-MB
- α-HBDH
- LDH
- *LDH1

Lipids

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

WWW.INSIGNIABIOMEDICAL.COM