

MAGLUMI® 800

Chemiluminescence Immunoassay (CLIA) System



Outstanding Technology Power of MAGLUMI[®]

Chemiluminescence Immunoassay (CLIA) System

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

ABEI Labelling Technology

Two types of labelling 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 solutions. The chemical reaction process of ABEI with sodium hydroxide (NaOH) and hyperoxide (H₂O₂) finishes in 3 seconds.

Magnetic Microbeads Separation Technology

MAGLUMI[®] uses magnetic microbeads. As a separation technology, it has been widely used in the field of CLIA. Compared with traditional separation technologies, 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 capturing of antigens and antibodies.
- Reducing inter or intra-assay discrepancies significantly by mixing the reagents thoroughly in a liquid separation platform.



Advantage of MAGLUMI[®] 800

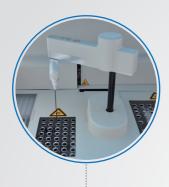


- For small and middle size labs or hospitals
- Simple, Smart, Humanization designed model
- More than enough test menu to meet the different needs and it will be extended according to your requirement
- Free quality control and calibrator helps to reduce the cost per of test
- Quality guarantee by the third party quality control and external quality assessment (EQA)
- Key technology ABEI and magnetic microbead enhances stability and sensitivity of MAGLUMI[®] reagents



MAGLUMI® 800

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



Pipettor

- Aspirate reagent / sample with high speed
- Titanium needle with crush-proof function
- Clot detection & liquid level detection
- Coated with TEFLON to prevent carry-over
- Internal & external washing



Automated cuvette loader

- Up to 40 modules of 240 tests
- Continuous loading



Sample area

- Up to 40 samples on board with barcode
- Continuous loading & cooling function
- Random, batch, and STAT mode



Incubator

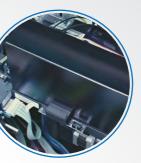
• 13 Incubate slots (78 tests at the same time)

Snibe

MAGLUMI 800

• The temperature is 36.8 °C ±0.5 °C





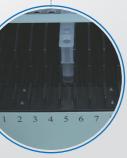
Chamber

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



Washer

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



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

Operation Software

Start SystemTe	st 📔 Pat&Rea	Process	Definitions	System	Report	
		Snib				
		MAGLUMI 80	00 V2.00			
	Current Time/Date	Random Access Mode / Nor 14:25:06 / 2016-03-18	rmal Mode			
	Remaining Time	00:00				
		Patients&I	Reagents			
		MAGLUN 800	MI Snibe			G



Comprehensive Software

- User-friendly interface
- Real-time status monitoring for each test
- Monitoring reagent and consumable status
- Intelligent alarm function
- Multilingual support, 10 languages available by request



Quality Control

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



Maintenance Guide

- Smart Maintenance with step by step guide, ensure performance reliability and reduce unnecessary service calls
- Daily, weekly and monthly maintenance guide for analyzer



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- and post- dilution available for the case of high concentration sample



Bidirectional LIS Connection

• Bidirectional LIS connection by TCP/IP and COM

Test Menu

Thyroid

TSH (3rd Generation) T4 T3 FT4 FT3 Tg (Thyroglobulin) TGA (Anti-Tg) Anti-TPO TRAb TMA Rev T3 *T-Uptake

Hepatic Fibrosis

HA PIIIP N-P C IV Laminin Cholyglycine

TORCH

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

Inflammation Monitoring

hs-CRP PCT (Procalcitonin) IL-6 (Interleukin 6) SAA(Serum Amyloid A)

Fertility

FSH LH

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

Hypertension

Direct Renin Aldosterone Angiotensin I Angiotensin II Cortisol ACTH

Autoimmune

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-Histones IgG Anti-nRNP/Sm lgG Anti-SS-B IgG Anti-SS-A IgG TGA(Anti-Tg) Anti-TPO TRAb TMA ICA IAA(Anti Insulin) GAD 65 Anti-IA2 *Anti-Cardiolipin IgG *Anti-Cardiolipin IgM *Anti-MPO

Immunoglobulin

lgM IgA IgE IgG

Tumor Markers

AFP CEA Total PSA f-PSA CA 125 CA 15-3 CA 19-9 PAP CA 50 CYFRA 21-1 CA 242 CA 72-4 NSE S-100 SCCA TPA-snibe ProGRP HE4 HER-2 PIVKA-II

Infectious Disease

HBsAa Anti-HBs HBeAg Anti-HBe Anti-HBc Anti-HCV Syphilis Anti-HAV HAV IgM HIV Ab/Ag Combi Chagas HTLV I+II H.pylori IgG H.pylori IgA H.pylori IgM 2019-nCoV IgG 2019-nCoV IgM SARS-CoV-2 S-RBD IgG SARS-CoV-2 Neutralizing Antibody SARS-CoV-2 Ag *Anti-HBc IgM

Drug Monitoring

Digoxin CSA (Cyclosporine A) FK 506 (Tacrolimus)

Kidney Function

β₂-MG Albumin

*NGAL

Cardiac

CK-MB Troponin I Myoglobin hs-cTnl H-FABP NT-proBNP BNP D-Dimer Lp-PLA2 *MPO

Metabolism

Pepsinogen I Pepsinogen II Gastrin-17 GH (hGH) IGF-I IGFBP-3

Prenatal Screening

 $\begin{array}{l} \mbox{AFP(Prenatal Screening)} \\ \mbox{Free } \beta\mbox{-HCG} \\ \mbox{PAPP-A} \\ \mbox{free Estriol} \end{array}$

Anemia Vitamin B12

Ferritin Folate (FA) *RBC Folate *EPO

Glyco Metabolism

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

Bone Metabolism

Calcitonin Osteocalcin 25-OH Vitamin D Intact PTH *β-CrossLaps (β-CTx) *total P1NP

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Technical Specifications

Reagent Feature	 Flash chemiluminescence label-ABEI, with high sensitivity and long stability Superpara magnetic microbeads separation technology, 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 automatic numbered LIS connection, automatic read sample infomation 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 Automatic and optional ratio for high concentration sample dilution Constant 36.8 ± 0.5°C incubation 	
Operation System	 Windows 7, Windows 10 Color touch screen 	
Interconnection	Bidirectional LIS connection by TCP/IP and COM	
Dimensions Weight	 Input: AC 110/230 Vac, 50/60 Hz, Max 630W Dimension and Weight: 102*72*56cm 73kg 	



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