Snibe Diagnostic

Distributed by:

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CHEMILUMINESCENCE IMMUNOASSAY 2020

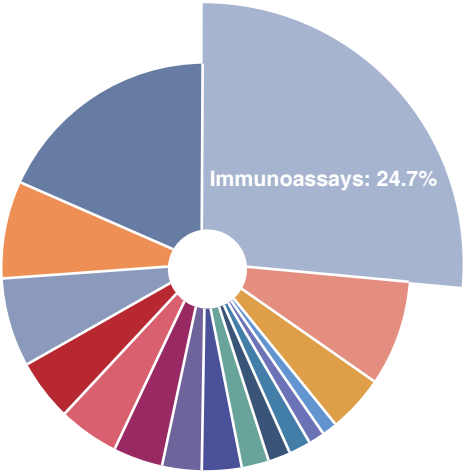
In-Vitro Diagnostics

In-Vitro Diagnostic Market Size

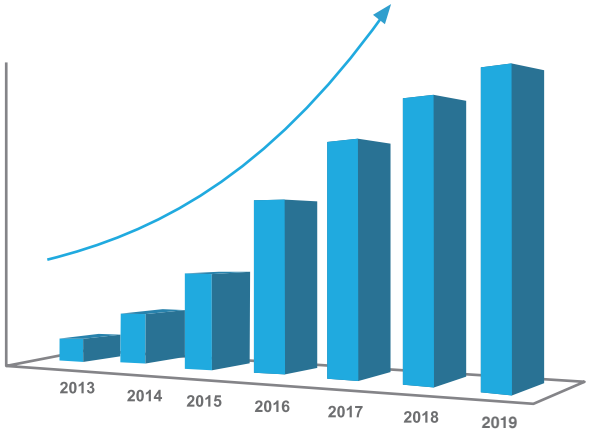
Compound Annual Growth Rate(CAGR) of over 5%

Rank

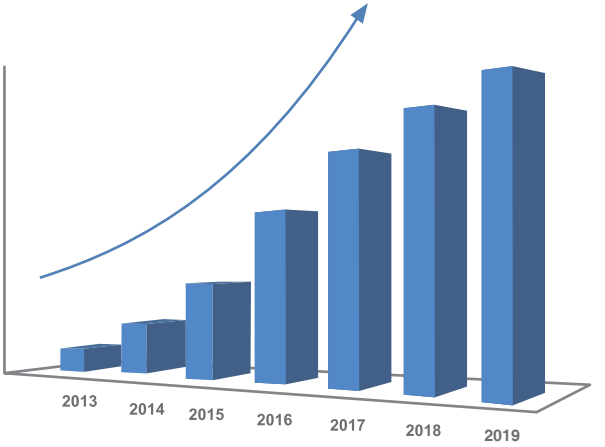
- Immunoassays: 24.7%
- Whole Blood Glucose Monitoring: 13.4%
- Clinical Chemistry: 10.6%
- POC/POL: 10.6%
- Clinical Molecular: 9.9%
- Microbiology: 5.2%
- Anatomic Pathology: 5.1%
- Hematology: 5.0%
- Coagulation: 3.4%
- Immunohematology: 2.7%
- Blood Screening Immunoassays: 2.5%
- Central Lab Critical Care: 1.4%
- Blood Screening Molecular: 1.4%
- Clinical Flow Cytometry: 1.1%
- Urinalysis: 1.0%
- Other Products: 1.9%



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.

Contents

Company Profile

Snibe is a leading brand of Chemiluminescence immunoassay solution from Shenzhen, China. Also, Snibe is the first company who got FDA cleared on Chemiluminescence immunoassay product in China.

With more than 1700 staffs, Snibe has been focusing on Chemiluminescence immunoassay solution for 25 years. At present, Snibe's products have been widely exported to more than 145 countries with more than 12000 installations globally.

Best Quality, Best Service is our target. Snibe would like to be the pioneer in global diagnosis field.

1995
Founded in Shenzhen, China

1997
Developed enzyme-linked immunoassay system-Magimuzyme

2002
Received "Shenzhen High-tech Enterprise"

2005
Developed semi-auto CLIA analyzer and dedicated reagent kits.
Received "Shenzhen science and technology innovation 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

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
1st CLIA manufacturer in China who got FDA cleared

2018
Launched the fastest CLIA analyzer MAGLUMI X8

2019
The New Headquarters put into use

As a leading IVD 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

Total Laboratory Automation Solutions

SATLAS-TCA

Decapper Flex Module

Centrifuge Module

Recapper Module

ES Flex Module

Fully-Automatic Biochemistry Analyzer

Bypass Module

MAGLUMI® X8 Fully-Automatic CLIA Analyzer

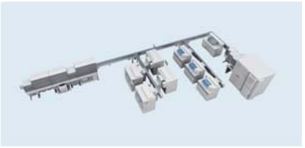
Aliquoter & Labeler Module

Conveyors

Third-Party Board

Cold Storage Module

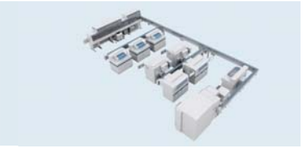
Recapper Module



F model

I model

T model



U model

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 160 parameters (Tumor marker, Fertility, Hepatic Fibrosis, Inflammation Monitoring, Cardiac Markers, Infectious Disease, Autoimmune 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 PROCESSING 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
- 5-10 parameters
- 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 2000

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
- **Inpeco Automation Track Connectable**

TARGETED END-USER
- Mid or large size labs
- Hospitals

TEST VOLUME PER DAY
- > 20 parameters
- Daily test: 100-300

MAGLUMI 2000 Plus

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
- **Inpeco Automation Track Connectable**

TARGETED END-USER

- Large labs
- Hospitals
- Chain labs

TEST VOLUME PER DAY

- > 20 parameters
- Daily test: 100-300

MAGLUMI 4000 Plus

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
- **Inpeco Automation Track Connectable**

TARGETED END-USER

- Large labs
- Hospitals
- Chain labs

TEST VOLUME PER DAY

- > 20 parameters
- Daily test: > 300

MAGLUMI X8

SPECIFICATION

- Throughput: Maximum **600** tests/ hour
- Up to 2400 tests/hour (Four modules combined)
- Sample and reagent continuous loading
- On board capability: up to **300** samples
- Reagent position: **42**
- Random access or batch mode, STAT
- Refrigerated reagent
- **Capable to link Laboratory Automation system (TLA/LAS)**

TARGETED END-USER

- Large labs
- Hospitals
- Chain labs

TEST VOLUME PER DAY

- > 20 parameters
- Daily test: > 500

MAGLUMI Test Menu

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
H.pylori IgA
H.pylori IgM
β2-MG
Calcitonin
Proinsulin
ProGRP
HE4
HER-2
*PIVKA-II

Cardiac

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

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

Thyroid

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

Infectious Disease

HBsAg
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
*Anti-HBc IgM

Drug Monitoring

Digoxin
CSA (Cyclosporine A)
FK 506 (Tacrolimus)

Anemia

Vitamin B12
Ferritin
Folate (FA)
*RBC Folate

Prenatal Screening

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

Broadest CLIA Test Menu

Glyco Metabolism

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

Hepatic Fibrosis

HA
PIIIP N-P
C IV
Laminin
Cholyglycine

EBV

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

Fertility

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

Inflammation Monitoring

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

Autoimmune

TGA(Anti-Tg)
Anti-TPO
TRAb
TMA
ICA
IAA(Anti Insulin)
GAD 65
Anti-IA2
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 IgG
Anti-SS-B IgG
Anti-SS-A IgG
Anti-CCP
*Anti-Cardiolipin IgG
*Anti-Cardiolipin IgM
*Anti-MPO

Bone Metabolism

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

Kidney Function

β_2-MG
Albumin
*NGAL

Immunoglobulin

IgM
IgA
IgE
IgG

Others

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

*Available Soon

MAGLUMI Special Assays

Autoimmune (Anti-dsDNA, ANA Screen, ENA Screen, Anti-Sm, Anti-Rib-P, Anti-Centromeres, Anti-Jo-1, Anti-M2-3E, Anti-Histones, Anti-nRNP/Sm, Anti-SS-B, Anti-SS-A, Anti-CCP)

Antinuclear antibodies (ANA) are autoantibodies of different specificity directed against antigens of the cell nucleus. Systemic autoimmune diseases are characterized by the presence of antinuclear antibodies. The presence of antinuclear antibodies occurs with high frequency in systemic autoimmune diseases such as Systemic Lupus Erythematosus (SLE), Mixed Connective Tissue Disease (MCTD), Sjogren's Syndrome (SS), Systemic Sclerosis (SSc), Poly/Dermatomyositis (PM/DM) and Primary Biliary Cirrhosis (PBC).

Anti-TPO

Thyroid peroxidase (TPO) is a key enzyme in the synthesis of thyroid hormones. Disorders of the thyroid gland are frequently caused by autoimmune mechanisms Anti-TPO activate the complement. The increase of Anti-TPO is often seen in autoimmune thyroid diseases such as: Hashimoto thyroiditis, Graves' disease and Hypothyroidism.

TRAb

TSH receptor antibodies (TRAbs) are the auto- antibodies of the thyroid membrane TSH receptor (TSHR). TRAbs are grouped depending on their effects on receptor signalling: activating antibodies (associated with hyperthyroidism), blocking antibodies (associated with thyroiditis) and neutral antibodies.

25-OH Vitamin D

25-OH Vitamin D (25-hydroxylation of Vitamin D also known as Calcifediol) is a prehormone that is produce in the liver by hydroxylation of Vitamin D by the enzyme cholecalciferol 25-hydroxylase. Concentration of 25-OH Vitamin D is considered the best indicator of Vitamin D status.

ProGRP

Gastrin-releasing peptide (GRP) is an important regulatory molecule. Studies have confirmed that small cell lung cancer (SCLC) patients with tumor cells produced GRP and ProGRP was positively correlated, therefore, the detection of ProGRP in serum is a general method.

H.pylori IgG & IgA & IgM

After contact with H.pylori, patients may exhibit antibodies of classes IgA, IgG and IgM against H.pylori in the serum. IgM antibodies are formed a few days after contact with H.pylori. After a few weeks specific IgM is no longer detectable. IgA antibodies usually form after a few weeks and remain detectable over a long time period.

HER-2

Numerous reports have revealed that the Human Epidermal Growth Factor Receptor 2 (HER-2) gene and its protein products play an important role in the occurrence, development and metastasis of breast cancer. The overexpression of HER-2 usually indicates that breast cancer is highly malignant and prone to relapse and metastasis with poor prognosis.

SCCA

The SCC-Ag is a serological tumor marker and it is a subfractions of the tumor-associated antigen TA-4, characterized as glycoprotein. Serum concentration of SCC-Ag correlate with stage of disease, the presence or absence of risk factors, the effect of treatment and the oncological outcome.

HE4

The human epididymal protein 4 (HE4) belongs to the family of whey acidic four-disulfide core (WFDC) proteins with suspected trypsin inhibitor properties. HE4 can detect 67% sensitivity to ovarian cancer with a specific level of 96% and shows the highest sensitivity of any single marker, especially in early stage disease.

Gastrin-17

Gastrin-17 has the strongest biological activity in the Gastrin family, which can be used for the diagnosis of Zollinger-Ellison Tumor (Gastrinoma) and Peptic Ulcer Disease, early screening and prognosis of Gastric Carcinoma and differential diagnosis of Chronic Atrophic Gastritis (CAG).

CA 50

Cancer antigen 50 (CA 50) is a non-specific tumor marker for a variety of cancers, which may elevate in most cases of pancreatic cancer. CA 50 has been used to diagnose different types of cancers in combination with other markers. It has also been used to evaluate treatment response and monitor cancer recurrence.

CA 72-4

Elevated CA 72-4 has been found in patients with epithelial ovarian cancer but not those with benign ovary diseases. Therefore, CA 72-4 is a valuable marker for distinguishing patients with ovary malignant diseases between those with benign diseases. Combination test of CA 72-4, CEA and CA 199 could increase the sensitivity for diagnosis of gastric cancer.

PG I/PG II

Pepsinogen (PG) is a kind of aspartate protease secreted by digestive gland. According to the immunogenicity it can be divided into two types: PG I and PG II. PG can be used to reflect the status and function of gastric mucosa. PG I/PG II < 3 as diagnostic cut- off value.

CA242

CA 242 has been used in the diagnosis of pancreatic cancer and colorectal cancer. In combination with other markers such as CA 19-9 and CEA, increased sensitivity and specificity may give some values for cancer diagnosis. CA 242 is also used to monitor patients with pancreatic cancer and colorectal cancer after surgery.

NSE

Neuron specific enolase (NSE) is a kind of enolase that involved in glycolysis pathway. The study of NSE shows that it excessively exist in the tumors which origin from neuroendocrine tissue, especially in small cell lung cancer (SCLC), results in the obvious increase of serum NSE level.

CYFRA 21-1

As the high specificity and sensitivity, CYFRA 21-1, a fragment of cytokeratin 19, has become the most valuable serum tumor marker for squamous cell carcinoma, especially for the non-small cell lung cancer (NSCLC) and becoming the first choice of NSCLC diagnosis.

MAGLUMI Special Assays

f-PSA/Total PSA

The level of Prostate-specific antigen (PSA) is very low in the blood of healthy men, most PSA is often bound to serum proteins while few of the PSA which are not bound with serum proteins, is defined as “free PSA (f-PSA)”. A lower ratio of f-PSA/total PSA is an indicator of prostate cancer occurrence or recurrence.

Androstenedione

Androstenedione is a C19 steroid hormone, and its overproduction is due to ovarian dysfunction or may be of adrenal origin. High circulating levels are found in women with polycystic ovaries and 21-hydroxylase deficiency. Significant lower levels are found in postmenopausal osteoporosis.

SHBG

Sex hormone-binding globulin (SHBG) is a glycoprotein responsible for blood transport of testosterone and estradiol. Blood SHBG concentrations are affected by a number of different diseases, such as hyperthyroidism, hypogonadism, hirsutism, virilism, polycystic ovarian syndrome (PCOS).

17-OH Progesterone

17-OH Progesterone is mainly converted by Progesterone in Adrenal cortex, and partly in gonad. 17-OH Progesterone can be used for the evaluation of patients with suspected congenital adrenal hyperplasia (CAH), primarily for newborns and adolescent girls. 17α-hydroxylase deficiency may lead to very low or undetectable levels of 17-OH Progesterone.

free Testosterone

Only measurement of free testosterone permits the estimating of the hormone biological activity. Free testosterone determinations are recommended to overcome the influences caused by variations of transport proteins on the total testosterone concentration.

AMH

The Anti-Mullerian Hormone (AMH), a peptide homodimer of molecular weight 140 kDa, plays an important role in sexual determination and differentiation during embryonic development. AMH is correlated with ovarian pathophysiology and can be used for the diagnosis of abnormal sex development in children.

H-FABP, hs-cTnI

For early diagnosis of acute myocardial infarction (AMI), Heart-type Fatty Acid Binding Protein (H-FABP) and hs-cTnI show better detection sensitivity. H-FABP is an ideal diagnostic marker of AMI recurrence and an important mortality predication marker of acute coronary syndrome (ACS). The hs-cTnI assays will improve both early diagnosis and short and long-term risk stratification.

NT-proBNP

NT-proBNP is a marker of hemodynamic stress on the heart, denoting the neurohumoral activation of the myocardium. NT-proBNP is mainly secreted by myocardial cells of ventricular wall, which can used for diagnosis of congestive heart failure (CHF), grade and prognosis of heart failure and risk stratification of patients with acute coronary syndrome (ACS) and CHF.

Lp-PLA2

Lp-PLA2, a member of phospholipase A2 superfamily, is associated with circulating atherogenic lipoproteins, and is highly expressed in the diseased vessel. Lp-PLA2 has predictive value for CHD or cardiovascular complications in healthy individuals and for recurrent events in patients with known atherosclerosis.

Direct Renin

Renin, also known as an angiotensinogenase, is a kind of proteolytic enzyme secreted by the juxtaglomerular cells of kidney. Direct Renin can be used for the diagnosis of hypertension, the guidance for hypertension treatment and the diagnosis of renin-producing tumors in the kidney. The ratio between Direct Renin and Aldoterones can be used for the diagnosis of Primary Aldosteronism (PA).

Aldosterone

Aldosterone (ALD) is a hormone synthesized by the adrenal glands, which plays an important role in maintaining normal sodium and potassium concentrations in blood. Testing ALD can be used for diagnosis of the primary hyperaldosteronism (Conn's syndrome) and secondary hyperaldosteronism.

Hepatic Fibrosis (HA, PIIIP N-P, C IV, Laminin, Cholyglycine)

Hyaluronic acid (HA) can sensitively reflect the fiber amount generated in liver and show the condition of liver damage accurately. In chronic liver diseases and fibrosis, Laminin (LN) is progressively deposited along Disse's space accompanying sinusoid capillarization and its serum values have been related to the degree of portal hypertension. P Ⅲ P N-P serum can reflect the stage of liver fibrosis in chronic liver disease. Type IV collagen (C IV) is one of the earliest synthesized during experimental injury, and the serum level of C IV is a useful biomarker in the research of hepatic injury and fibrosis. When liver cells are damaged, the capacity of CG absorption reduced, CG concentration in the blood increased.

PCT, IL-6

Procalcitonin (PCT) and Interleukin-6 (IL-6) can be released as an acute-phase reactant in response to inflammatory stimuli, especially those of bacterial origin. PCT will be increased in bacterial infections, reflecting the activity of systemic inflammatory response. IL-6 reaches peak concentrations several hours before the rise in CRP and PCT concentration occurs, therefore, IL-6 and PCT can be used for the inflammation monitoring with combined detection.

CSA

Cyclosporin A (CSA) is used in medicinal transplantation and cure of autoimmune diseases as a available immunosuppressive drug. The safety margin of cyclosporine is narrow. Therefore, the application of cyclosporin requires drug monitoring.

FK506

FK506 (tacrolimus) is an immunosuppressive drug that is used mainly for organ transplant to reduce the activity of the patient's immune system. Monitoring the levels of FK506 in blood can promptly adjust medication of FK506 via drug interactions and reduce the incidence of renal toxicity and rejection.

Cortisol

Cortisol is synthesized from cholesterol and its production is stimulated by pituitary adrenocorticotropic hormone (ACTH) which is regulated by corticotropin releasing factor (CRF). Increased cortisol levels may indicate: Cushing's syndrome or Adrenal tumors in patients. Decreased cortisol levels may indicate: Underactive or damaged adrenal glands (adrenal insufficiency).

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

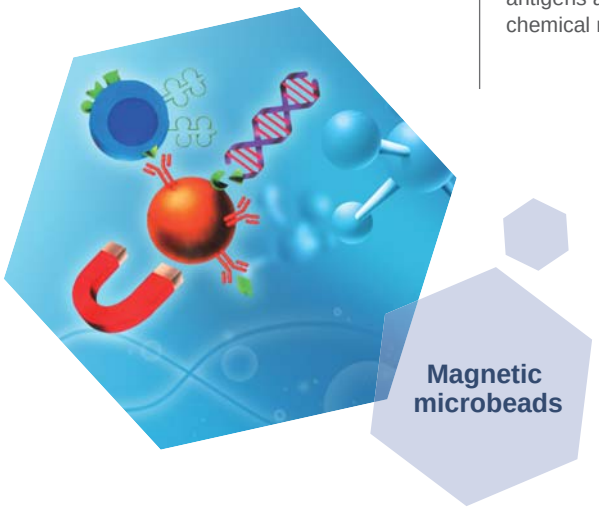
- Two types of labelling technologies are commonly used. One is an enzyme label and another is a non-enzyme small molecule.Enzyme label reagents are not very stable and easily affected by the change of storage conditions.
- The MAGLUMI system applies ABEI labels. ABEI is a non-enzyme small molecule with special molecular formula to enhance stability in acid and alkaline buffer.Using fast Chemiluminescence, ABEI's chemical reaction with sodium hydroxide (NaOH) and Hyperoxide (H_2O_2) finishes the process in 3 seconds.

SEPARATION TECHNOLOGY

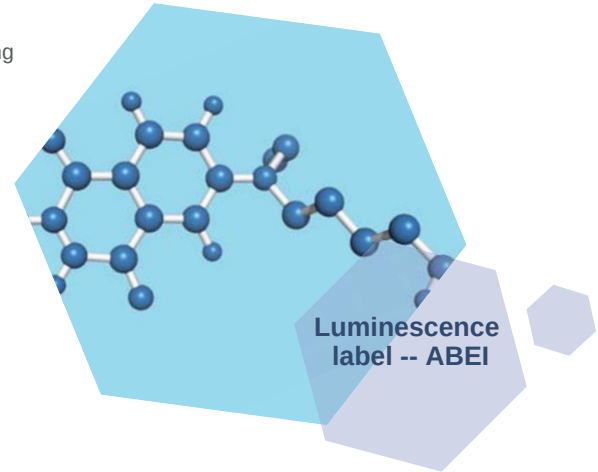
- MAGLUMI uses Magnetic Microbeads. As separation technology, it has been widely used in the field of CLIA.
- Compared with traditional separation technology, it has the following advantages:
- Shortening the reaction time by enlarging the reaction area of antigens and antibodies.
- Enhancing the sensitivity 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.

PRODUCT ADVANTAGES

- Comprehensive test menu, over 160 parameters
- High throughput, up to 600 tests/hour
- Reliable performance, lower breakdown rate
- Same reagent package available for series instruments
- Integrated reagent kit, internal control and calibrators FOC



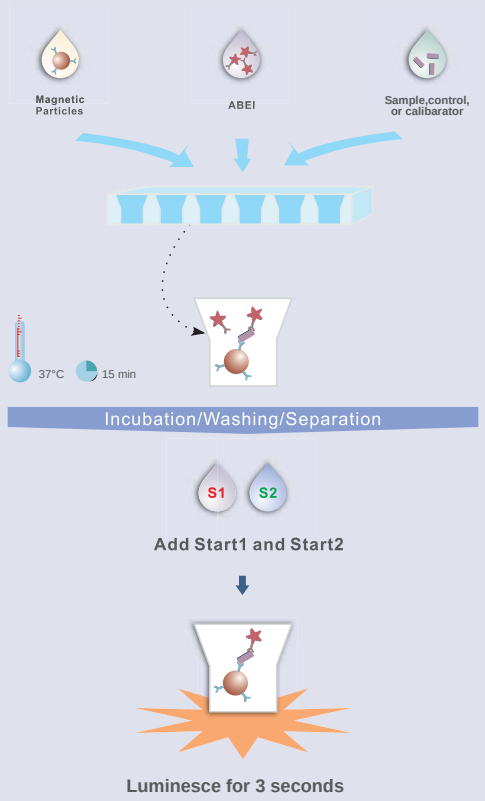
Magnetic microbeads



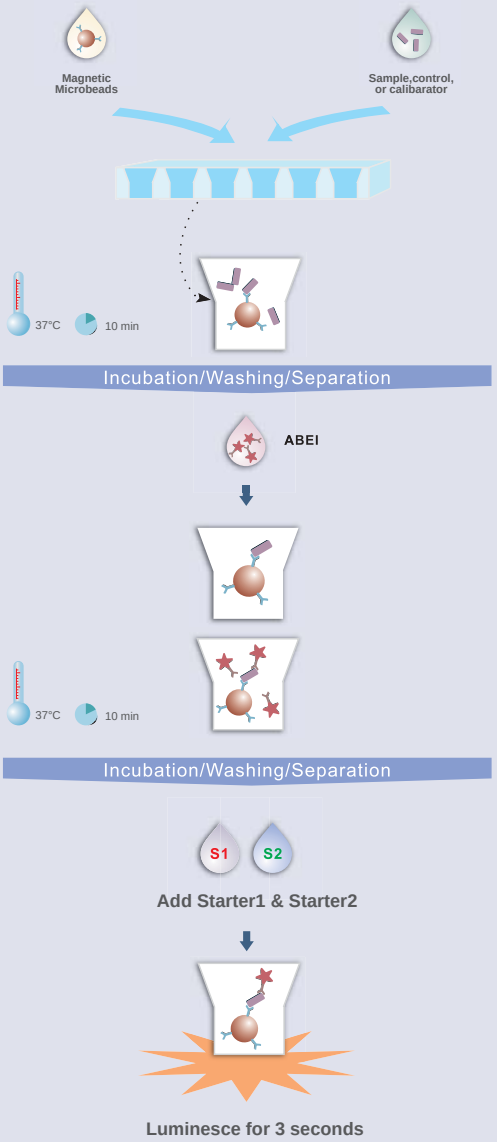
Luminescence label -- ABEI

Principle

ONE STEP ASSAY



TWO STEP ASSAY



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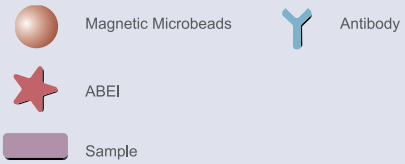
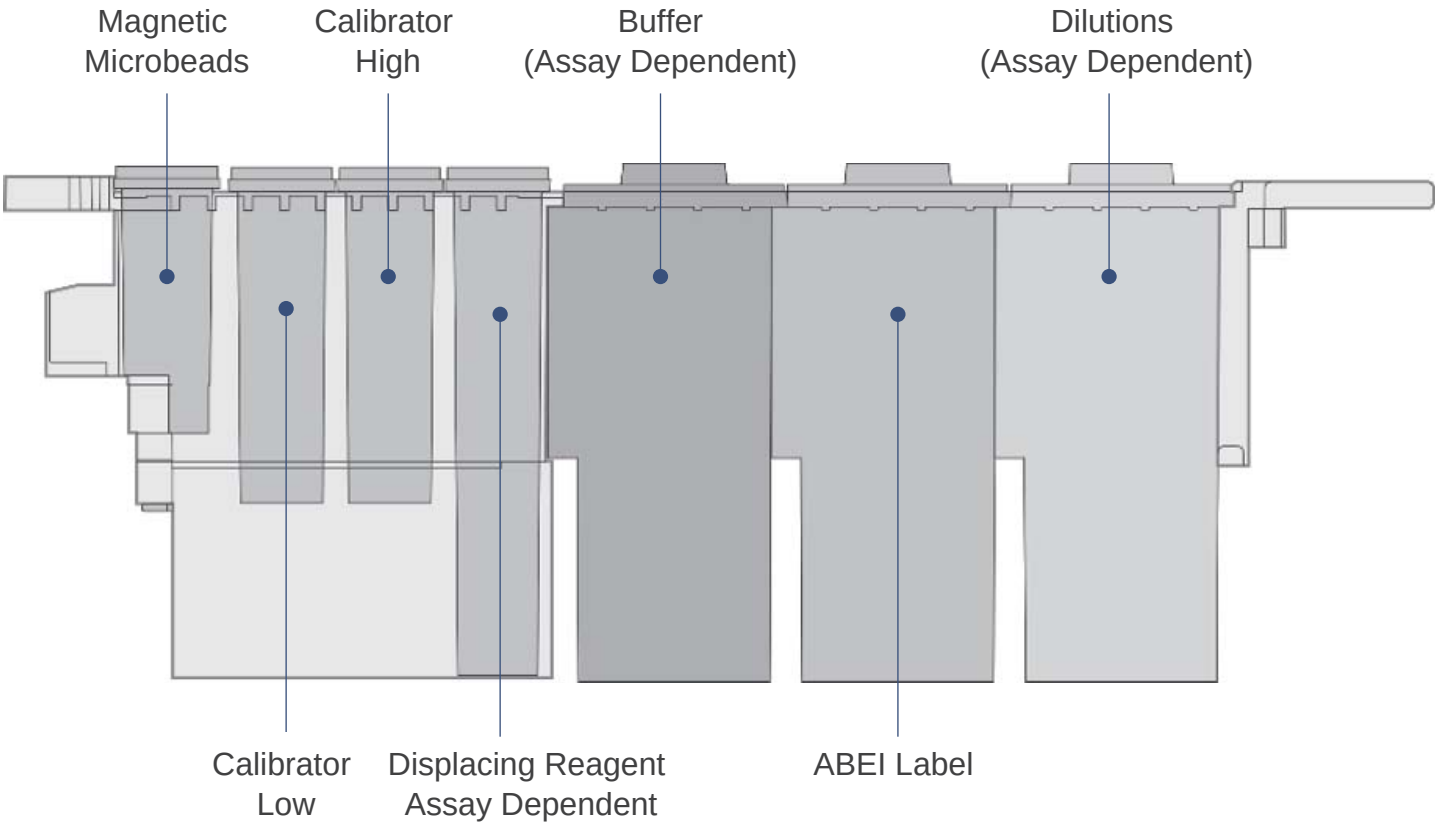


Reagent Component



Reagent (50T/100T)

Consumables

Reaction Module

Light Check

Wash Concentrate

Starter 1+2

Tubing Cleaning Solution

Reagent Storage Box

Biochemistry Analyzer

Biossays 240

SPECIFICATION

- Throughput: **240** tests/hour
- Sample Handling: up to **90** sample positions, STAT
- Reagent Handling: up to **90** reagent positions, with refrigeration
- Reaction cuvette: **80** (Disposable)
- ISE: optional

Biossays 240 Plus

SPECIFICATION

- Throughput: **240** tests/hour
- Sample Handling: up to **90** sample positions, STAT
- Reagent Handling: up to **90** reagent positions, with refrigeration
- Reaction cuvette: **80** (Reusable)
- ISE: optional
- Washing Station: Available

Biossays BC1200

SPECIFICATION

- Throughput: **600** T/H (Photometric), **600** T/H (ISE Module)
- Sample Handling: **115** sample positions, STAT
- Reagent Handling: **2** trays, **90** reagent positions, with refrigeration
- Reaction cuvette: **120**
- ISE:optional

Biossays BC2200

SPECIFICATION

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

Biochemistry Test Menu

Cardiac

CK
CK-MB
α-HBDH
LDH
*LDH1

Diabetes

GLU
LAC
*HbA1c
*GSP
*D3-HB
*GA
*NAG

Hepatic

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

ISE

Na
K
Cl
Ca
pH

Inorganic Ion

Fe (Iron)
Ca
P (phos)
*Mg

Special Protein

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

Lipids

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

Renal

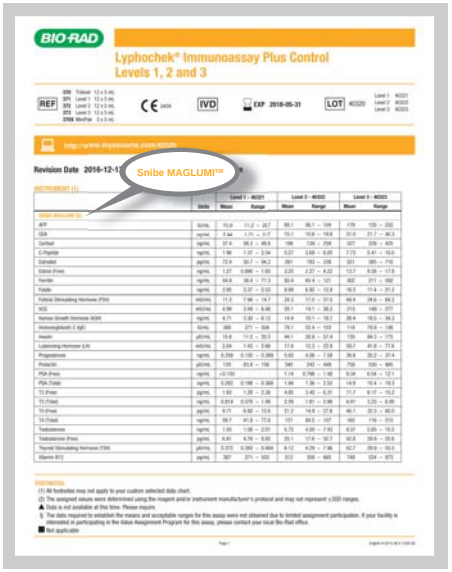
Cr (CREA)
Uric Acid
Urea
*Cysc
*mALB
*α1-MG
*β2-MG
*Urine/CSF Protein
*RBP

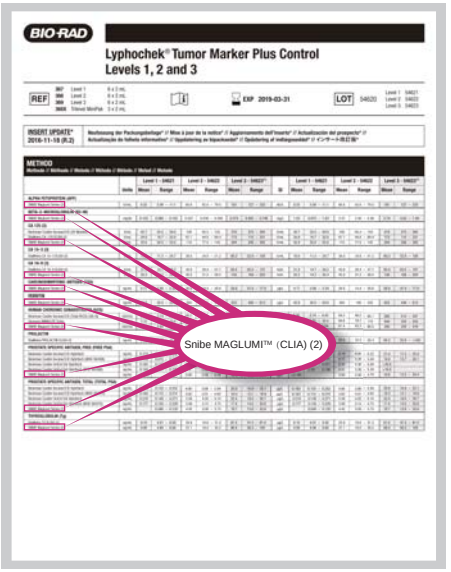
Pancreatic

α-AMY
*LIP

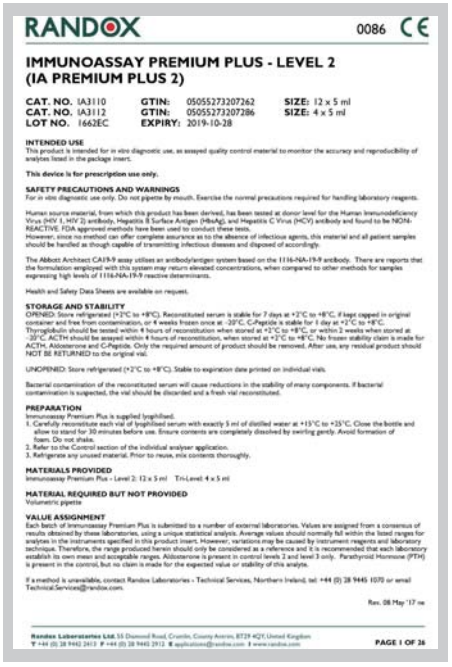
* Available soon

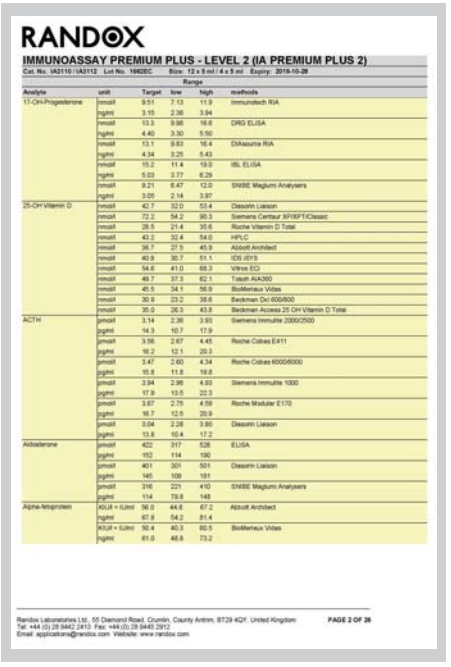
Third-Party Quality Control





From 2014, Snibe becomes the first Chinese CLIA manufacturer which BIO-RAD's QC information is available.





From 2017, Snibe becomes the first Chinese CLIA manufacturer which RANDOX's QC information is available.

As one of the most popular and reliable third party quality control provider, BIO-RAD & RANDOX's quality control could be an excellent tool to monitor the performance of immunoassay system in the lab.

External Quality Assessment

Snibe participates various EQA program every year

COLLEGE of AMERICAN PATHOLOGISTS

The College of American Pathologists recognizes

Snibe Co Ltd

9392207-01

As a laboratory demonstrating continuous improvement in quality through participation in the 2017 CAP Surveys, and/or Anatomic Pathology Education Programs.

R. Bruce Williams, MD, FCAP
CAP President

CAP Proficiency Test

RCPAQAP

Enrolment Certificate

CHEMICAL PATHOLOGY
2019

This is to certify that

Participant no. 11259

Snibe QC Lab

No.16, Jinhui Road Pingshan New District Shenzhen 518122 China

is enrolled in the following program(s)

Anti-Mullerian Hormone - Full Program
Endocrine - Full Program
Prostate Specific Antigen - Full Program
Steroids - Full Program
Tumour Markers - Full Program

Enrolment Date: 12 March 2019

Page 1 of 1

BIO-RAD

Certificate of Achievement

EQAS External Quality Assurance Services

THE SHENZHEN COMPANY OF SNIBE

BIO-RAD External Quality Assurance Services (EQAS)

RIQAS

Certificate of Participation

RIQAS

Randox International Quality Assessment Scheme (RIQAS)

2013 - 2014 Certificate of Proficiency

2014 - 2015 Certificate of Proficiency

2015 - 2016 Certificate of Proficiency

2016 - 2017 Certificate of Proficiency

2017 - 2018 Certificate of Proficiency

2018 - 2019 Certificate of Proficiency

This is to certify that

Shenzhen New Industries Biomedical Engineering Co., Ltd (SNIBE)
16 Jinhui Road
Pingshan New District
Shenzhen 518122

has participated in the international
25 Hydroxyvitamin D EQAS
and has met the performance target*
set by the DEQAS Advisory Panel

* 75% or more results fell within ±25% of the Target Value

Advisory Panel

Glenville Jones • Jacqueline Berry • Etienne Cavalier
Ramon Durazo-Arvizu • Elaine Gunter
Karen Phinney • Christopher Sempos • Patrick Twomey

Dr Emma Walker FRCPath
DEQAS Organiser

DEQAS

Snibe participated in the international 25 OH Vitamin D EQAS and gained the certificate for 6 consecutive years.

New Headquarters

R&D Production Center

Analyzer Production

- High precision Instrument Production, over 9000 m²
- Auto-Immunoassay Analyzer: 3000 units/year.
- Auto-Chemistry Analyzer: 1500 units/year.

Reagent Production

- Modern kits production facility, over 12000 m²
- 8 production lines
- With annual productivity of 4 milion reagent kits

Analyzer Comparison

High workload system

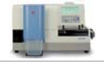
Manufacturer	Comparison	Specification	Principle	Throughput	Time to First Result	Sample Positions	Clot Detection	Reagent Positions	On-board Refrigeration	Loading Number of cuvettes in One Time		Operation Mode	Reagent Kit	On-board Shelf Life Reagent kit	Stability of Recalibration	Lumination Label	Substrate	Solid Phase
Snibe		**MAGLUMI X8**	**Flash CLIA**	**600 tests/hour**	**15 mins**	**300**	**available**	**42**	**available**	**2912**		**random access, batch, STAT**	**control and calibrators included**	**4 weeks**	**1-4 weeks**	**ABEI**	**NaOH, H_2O_2**	**Superpara magnetic microbeads**
Snibe		**MAGLUMI 4000Plus**	**Flash CLIA**	**280 tests/hour**	**16 mins**	**144**	**available**	**25**	**available**	**960**		**random access, batch, STAT**	**control and calibrators included**	**4 weeks**	**1-4 weeks**	**ABEI**	**NaOH, H_2O_2**	**Superpara magnetic microbeads**
SIEMENS		Immulite 2000	Glow CLIA	200 tests/hour	35 mins	90	available	24	available	1000		random access, batch, STAT	calibrators and QC extra charged	90 days	2 weeks	ALP	AMPPD	Plastic balls, centrifuging needed
SIEMENS		Centaur XP	Flash CLIA	240 tests/hour	18 mins	180	available	30	available	1000		random access, batch, STAT	calibrators and QC extra charged	4-28 days	1-4 weeks	Acridinium ester	NaOH, H2O2	Superpara magnetic particles
ABBOTT		Architect i2000 SR	Flash CLIA	200 tests/hour	15 mins	135	available	25	available	1200		random access, batch, STAT	calibrators and QC extra charged	4-28 days	14 days	Acridinium ester	NaOH, H_2O_2	Superpara magnetic particles
ROCHE		Cobas E601	ECLIA	170 tests/hour	17 mins	150	available	25	available	1006		random access, batch, STAT	calibrators and QC extra charged	4-28 days	2-4 weeks	$[Ru(bpy)^3]^{2+}$ruthenium	TPA	Superpara magnetic particles
BECKMAN		DxI 600	Glow CLIA	200 tests/hour	12 mins	60	available	50	available	2200		random access, batch, STAT	calibrators and QC extra charged	56 days	56 days	ALP	AMPPD	Superpara magnetic particles
DIASORIN		Liaison XL	Flash CLIA	180 tests/hour	17mins	120	available	25	available	1000		random access, batch, STAT	QC extra charged	4 weeks	2-4 weeks	ABEI	NaOH, H_2O_2	Superpara magnetic particles
ORTHO		VITROS 3600	Glow CLIA	189 tests/hour	16 mins	90	available	31	N/A	N/A		random access, batch, STAT	QC extra charged	4 weeks	28 days	HRP	luminogenic substrates	Micro Well

Analyzer Comparison

Medium workload system

Manufacturer	Comparison	Specification	Principle	Throughput	Time to First Result	Sample Positions	Clot Detection	Reagent Positions	On-board Refrigeration	Loading Number of cuvettes in One Time		Operation Mode	Reagent Kit	On-board Shelf Life Reagent kit	Stability of Recalibration	Lumination Label	Substrate	Solid Phase
Snibe		**MAGLUMI 2000**	**Flash CLIA**	**180 tests/hour**	**17 mins**	**144**	**available**	**15**	**available**	**720**		**random access, batch, STAT**	**calibrators and quality control included**	**4 weeks**	**1-4 weeks**	**ABEI**	**NaOH, H_2O_2**	**Superpara magnetic microbeads**
ROCHE		Cobas e411	ECLIA	88 tests/hour	18 mins	30/75	available	18	available	180		random access, batch, STAT	calibrators and QC extra charged	14-56 days	4 weeks	$[Ru(bpy)^3]^{2+}$ruthenium	TPA	Superpara magnetic particles
BECKMAN		Access 2	Glow CLIA	100 tests/hour	12 mins	60	not available	24	available	294		random access, batch, STAT	calibrators and QC extra charged	56 days	56 days	ALP	AMPPD	Magnetic particles
TOSOH		AIA900	Flourescence EIA	90 tests/hour	20 mins	100	available	Max 100 cups	not available	120		random access, batch, STAT	calibrators and QC extra charged	N/A	90 days	ALP	4-MUP	Magnetic beads
ABBOTT		Architect i1000 SR	Flash CLIA	100 tests/hour	15 mins	65	available	25	available	360		random access, batch, STAT	calibrators and QC extra charged	4-28 days	2 weeks	Acridine Ester	/	Superpara magnetic particles
DIASORIN		LIAISON® XS	Flash CLIA	85 tests/hour	17 mins	48	available	10	available	172		random access, batch, STAT	QC extra charged	4 weeks	2 weeks	ABEI	NaOH, H2O2	Superpara magnetic particles

Low workload system

Manufacturer	Comparison	Specification	Principle	Throughput	Time to First Result	Sample Positions	Clot Detection	Reagent Positions	On-board Refrigeration	Loading Number of cuvettes in One Time		Operation Mode	Reagent Kit	On-board Shelf Life Reagent kit	Stability of Recalibration	Lumination Label	Substrate	Solid Phase
Snibe		**MAGLUMI 600**	**Flash CLIA**	**180 tests/hour**	**17 mins**	**16**	**available**	**4**	**available**	**60**		**random access, batch, STAT**	**calibrators and quality control included**	**4 weeks**	**1-4 weeks**	**ABEI**	**NaOH, H_2O_2**	**Superpara magnetic microbeads**
Snibe		**MAGLUMI 800**	**Flash CLIA**	**180 tests/hour**	**17 mins**	**40**	**available**	**9**	**available**	**240**		**random access, batch, STAT**	**calibrators and quality control included**	**4 weeks**	**1-4 weeks**	**ABEI**	**NaOH, H_2O_2**	**Superpara magnetic microbeads**
BIOMERIEUX		VIDAS	Flourescence EIA	30 tests/hour	45 mins	30	not available	30	not available	30		random access, batch, STAT	calibrators and quality control included	N/A	2-4 weeks	ALP	4-MUP	Coated pipetting tips
TOSOH		AIA 600 II	Flourescence EIA	60 tests/hour	18 mins	52 test cups	available	52	not available	52		random access, batch, STAT	calibrators and QC extra charged	N/A	90 days	ALP	4-MUP	Magnetic particles in cups
TOSOH		AIA 360	Flourescence EIA	36 tests/hour	20 mins	25 test cups	available	25	not available	25		random access, batch, STAT	calibrators and QC extra charged	N/A	90 days	ALP	4-MUP	Magnetic particles in cups

Parameter Comparison

TEST MENU		Snibe MAGLUMI	ROCHE ELECSYS	ABBOTT ARCHITECT	ABBOTT ALINITY	SIEMENS ATELLICA	SIEMENS ADVIA CENTAUR	SIEMENS IMMULITE	BECKMAN UNICELL	BIOMERIEUX VIDAS	DIASORIN LIASION
Applicable Analyzers		All MAGLUMI Analyzers	Cobas e601/e411 Modular E170	ARCHITECT i1000/2000 SR	Alinity i/ii	Atellica IM 1300/ IM 1600	CENTAUR CP/XP	Immulite 2000	Dxl 600/800	Mini vidas/Vidas3	LIASION XL
Product Name											
Thyroid	TSH (3rd Generation)	○	○	○	○	○	○	○	○	○	○
	T4	○	○	○	○	○	○	○	○	○	○
	T3	○	○	○	○	○	○	○	○	○	○
	FT4	○	○	○	○	○	○	○	○	○	○
	FT3	○	○	○	○	○	○	○	○	○	○
	Tg (Thyroglobulin)	○	○			✲		○	○		○
	TGA (Anti-Tg)	○	○	○	○	○	○	○	○	○	○
	Anti-TPO	○	○	○	○	○	○	○	○	○	○
	TRAb	○	○		✲			○			
	TMA	○									
	Rev T3	○									
	●T-Uptake	✲	○		○	○	○	○			
Fertility	FSH	○	○	○	○	○	○	○	○	○	○
	LH	○	○	○	✲	○	○	○	○	○	○
	HCG/β–HCG	○	○	○	○	○	○	○	○	○	○
	PRL	○	○	○	○	○	○	○	○	○	○
	Estradiol	○	○	○	○	○	○	○	○	○	○
	DHEA-S	○	○	○	○	○	○	○	○	○	○
	Progesterone	○	○	○	✲	○	○	○	○	○	○
	Testosterone	○	○	○	○	○	○	○	○	○	○
	free Testosterone	○									
	free Estriol	○						○	○		
	17-OH Progesterone	○									
	AMH	○	○			✲			○	○	
	SHBG	○	○	○	○	○	○	○	○		○
	Androstenedione	○				✲		○			○
	●PlGF	✲	○			✲	✲				
	●sFlt-1	✲	○			✲	✲				
Prenatal Screening	AFP (Prenatal Screening)	○	○				○	○	○		
	free β–HCG	○	○			○	○	○			
	PAPP-A	○	○			○	✲	○			
	HCG/β–HCG	○	○	○	○	○	○	○	○	○	○
	Free Estriol	○						○	○		
Tumor Markers	Ferritin	○	○	○	○	○	○	○	○	○	○
	AFP	○	○	○	○	○	○	○	○	○	○
	CEA	○	○	○	○	○	○	○	○	○	○
	Total PSA	○	○	○	○	○	○	○	○	○	○
	f-PSA	○	○	○	○	○	○	○	○	○	○

Special parameters in orange ●Available soon

Parameter Comparison

TEST MENU		Snibe MAGLUMI	ROCHE ELECSYS	ABBOTT ARCHITECT	ABBOTT ALINITY	SIEMENS ATELLICA	SIEMENS ADVIA CENTAUR	SIEMENS IMMULITE	BECKMAN UNICELL	BIOMERIEUX VIDAS	DIASORIN LIASION
Applicable Analyzers		All MAGLUMI Analyzers	Cobas e601/e411 Modular E170	ARCHITECT i1000/2000 SR	Alinity i/ii	Atellica IM 1300/ IM 1600	CENTAUR CP/XP	Immulite 2000	Dxl 600/800	Mini vidas/Vidas3	LIASION XL
Product Name											
Tumor Markers	CA 125	○	○	○	○	○	○	○	○	○	○
	CA 15-3	○	○	○	○	○	○	○	○	○	○
	CA 19-9	○	○	○	○	○	○	○	○	○	○
	HCG/β-HCG	○	○	○	○	○	○	○	○	○	
	Tg (Thyroglobulin)	○	○			✲		○	○		○
	Pepsinogen I	○		○	✲						
	Pepsinogen II	○		○	✲						
	Gastrin-17	○						○			
	H.pylori IgG	○					✲	○		○	○
	H.pylori IgA	○									
	H.pylori IgM	○									
	CA 50	○									
	PAP	○						○			
	CYFRA 21-1	○	○	○	○						
	CA 242	○									
	CA 72-4	○	○		○						
	NSE	○	○		○						○
	S-100	○	○								○
	SCCA	○	○	○	○						
	TPA-snibe	○									
	β_2-MG	○									○
	Calcitonin	○	○			○		○			○
	HE4	○	○	○	○						
	Proinsulin	○									
	ProGRP	○	○	○	○						
	HER-2	○				○	○				
	●PIVKA - II	✲		○	○						
Bone Metabolism	Intact PTH	○	○	○	○	○	○	○	○		○
	Calcitonin	○	○			○		○			○
	Osteocalcin	○	○					○			○
	25-OH Vitamin D	○	○	○	○	○	○		○	○	○
	●β-CrossLaps (β-CTx)	✲	○								
	●total P1NP	✲	○								

Special parameters in orange ●Available soon

Parameter Comparison

TEST MENU		Snibe MAGLUMI	ROCHE ELECSYS	ABBOTT ARCHITECT	ABBOTT ALINITY	SIEMENS ATELLICA	SIEMENS ADVIA CENTAUR	SIEMENS IMMULITE	BECKMAN UNICELL	BIOMERIEUX VIDAS	DIASORIN LIASION
Applicable Analyzers		All MAGLUMI Analyzers	Cobas e601/e411 Modular E170	ARCHITECT i1000/2000 SR	Alinity i/ii	Atellica IM 1300/ IM 1600	CENTAUR CP/XP	Immulite 2000	Dxl 600/800	Mini vidas/Vidas3	LIASION XL
Product Name											
Inflammation Monitoring	hs-CRP	○						○			
	PCT (Procalcitonin)	○	○	○	✲	○	○			○	○
	IL-6	○	○			✲	✲	○	○		
	•SAA (Serum Amyloid A)	✲									
Cardiac	CK-MB	○	○	○	○	○	○	○	○	○	
	Troponin I	○	○	○	○	○	○	○	○	○	
	Myoglobin	○	○	○		○	○	○	○	○	
	hs-cTnI	○		○	○	○	○			○	
	H-FABP	○									
	NT-proBNP	○	○		○	○	○	○			
	BNP	○		○	○	○	○		○		
	Aldosterone	○									○
	Angiotensin I	○									
	Angiotensin II	○									
	Direct Renin	○									○
	D-Dimer	○	○					○		○	
	Lp-PLA2	○									
	hs-CRP	○						○			
	•MPO	✲									
Hepatic Fibrosis	HA	○				○	○				
	PIIIP N-P	○				○	○				
	C IV	○									
	Laminin	○									
	Cholyglycine	○									
Immunoglobulin	IgM	○									
	IgA	○									
	IgE	○	○			○	○	○	○	○	
	IgG	○								○	
Drug Monitoring	CSA (Cyclosporine A)	○	○	○	✲	○	○				
	FK 506 (Tacrolimus)	○	○	○	✲		○			○	
	Digoxin	○	○	○		○	○	○		○	
Infectious Disease	HBsAg	○	○	○	○	○	○	○		○	○
	Anti-HBs	○	○	○	○	○	○	○		○	○
	HBeAg	○	○	○	○	○	○				○
	Anti-HBe	○	○	○	○	○	○			○	○
	Anti-HBc	○	○	○	○		○	○		○	○
	Anti-HCV	○	○	○	○		○			○	○
	Syphilis	○	○	○	○	○	○	○			

Special parameters in orange ●Available soon

Parameter Comparison

TEST MENU		Snibe MAGLUMI	ROCHE ELECSYS	ABBOTT ARCHITECT	ABBOTT ALINITY	SIEMENS ATELLICA	SIEMENS ADVIA CENTAUR	SIEMENS IMMULITE	BECKMAN UNICELL	BIOMERIEUX VIDAS	DIASORIN LIASION
Applicable Analyzers		All MAGLUMI Analyzers	Cobas e601/e411 Modular E170	ARCHITECT i1000/2000 SR	Alinity i/ii	Atellica IM 1300/ IM 1600	CENTAUR CP/XP	Immulite 2000	Dxl 600/800	Mini vidas/Vidas3	LIASION XL
Product Name											
Infectious Disease	Anti-HAV	○	○	○	○		○			○	○
	HAV IgM	○	○			○	○			○	○
	HIV Ab/Ag combi	○	○	○	○	○	○				○
	Chagas	○	○	○	○						○
	HTLV I+II	○	○	○	○						○
	H.pylori IgG	○					✲	○		○	○
	H.pylori IgA	○									
	H.pylori IgM	○									
	●Anti-HBc IgM	✲	○	○				○		○	
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	○									
Glyco Metabolism	C-Peptide	○	○	○	○	○	○	○			○
	Insulin	○	○	○	○	○	○	○			○
	ICA	○	○								
	IAA (Anti Insulin)	○	○								
	Proinsulin	○	○								
	GAD 65	○	○								
	Anti-IA2	○	○								

Special parameters in orange ●Available soon

Parameter Comparison

TEST MENU		Snibe MAGLUMI	ROCHE ELECSYS	ABBOTT ARCHITECT	ABBOTT ALINITY	SIEMENS ATELLICA	SIEMENS ADVIA CENTAUR	SIEMENS IMMULITE	BECKMAN UNICELL	BIOMERIEUX VIDAS	DIASORIN LIASION
Applicable Analyzers		All MAGLUMI Analyzers	Cobas e601/e411 Modular E170	ARCHITECT i1000/2000 SR	Alinity i/ii	Atellica IM 1300/ IM 1600	CENTAUR CP/XP	Immulite 2000	Dxl 600/800	Mini vidas/Vidas3	LIASION XL
Product Name											
Anemia	Vitamin B12	○	○	○		○	○	○	○	○	*
	Ferritin	○	○	○	○	○	○	○	○	○	○
	Folate (FA)	○	○	○	○	○	○	○	○		*
	•RBC Folate	○	○		○	○	○	○	○		
Autoimmune	TGA (Anti-Tg)	○	○	○	○	○	○	○	○	○	○
	Anti-TPO	○	○	○	○	○	○	○	○	○	○
	TRAb	○	○		*			○			
	TMA	○									
	ICA	○									
	IAA (Anti Insulin)	○									
	GAD 65	○									
	Anti-IA2	○									
	ANA Screen	○									○
	ENA Screen	○									○
	Anti-dsDNA IgG	○									○
	Anti-Sm IgG	○									
	Anti-Rib-P IgG	○									
	Anti-Scl-70 IgG	○									
	Anti-Centromeres IgG	○									
	Anti-Jo-1 IgG	○									
	Anti-M2-3E IgG (AMA-M2)	○									
	Anti-Histones IgG	○									
	Anti-nRNP/Sm IgG	○									
	Anti-SS-B IgG	○									
	Anti-SS-A IgG	○									
	•Anti-CCP	○	○	○	○	○	○	○			
	•Anti-Cardiolipin IgG	*									○
	•Anti-Cardiolipin IgM	*									○
	•Anti-MPO	*									
Kidney Function	β_2-MG	○						○		○	
	Albumin	○						○			
	•NAGL	*		○	*						
Others	Cortisol	○	○	○	○	○	○	○	○	○	○
	GH (hGH)	○	○			*		○	○		○
	IGF-I	○	○			*		○			○
	ACTH	○	○			*		○			○
	IGFBP-3	○				*		○			

Special parameters in orange ●Available soon

Evaluation Poster

Preference of joint detection for liver fibrosis

Li W[a]. Luo C[a]
Snibe Reagent Research & Development Center., Shenzhen, China

1 Background

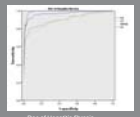
Liver repairs injury through the deposition of new collagen and other extracellular matrix. based on the level of these components, the liver fibrosis can be diagnosed. Direct serum markers hyaluronic acid (HA), laminin (LN), procollagen type III amino-terminal peptide (PIIINP),type IV collagen(CIV) are proved to effective use for liver fibrosis diagnosis on Maglumi fully-auto chemiluminescence immunoassay (CLIA) system. As joint detection can improve the sensitivity and specificity to some extent and ensure the reliability, a method to evaluate the joint effort of these four biomarkers is introduced.

2 Methods

Herein, presenting results of 120 pathological samples (including 11 liver cancers, 87 cirrhosis and 21 liver fibrosis) and 100 Volunteers from Maglumi Hepatic fibrosis Quad marker test for CLIA on the Maglumi 4000. SNIBE (Shenzhen New Industries Biomedical Engineering) fully autoanalyzer. The results of four reagents (HA, LN, PIIIP N-P, CIV) are analyzed by ROC, determining the optimum cut-off values and compare the clinical performance of these biomarkers, which are shown in Youden's Index and AUC. HA>LN> PIIIP N-P >CIV. The AUC of the first three reagent are all over 0.9, and that of HA is over 0.99(0.991), even for PIIIP N-P, the AUC is 0.891 as well, making these biomarkers a promising method for the diagnosis of liver fibrosis.

3 Results:

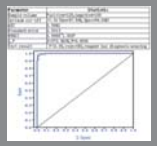
As the result shown, the AUC of Maglumi Hepatic fibrosis reagents (HA, LN, PIIIP N-P, CIV) are 0.991(Sen97.50%, spec96.00%), 0.969(Sen90.83%, spec96.00%), 0.891(Sen70.83%, spec98.00%) and 0.907(sen79.17%, spec95.00%) respectively, with cut-off value of 97.81, 46.46, 29.02 and 26.57 ng/ml. The clinical performance of the reagents is HA>LN> PIIIP N-P >CIV.



Roc of Hepatitis fibrosis

Performance of assay

Assay	AUC	Se*	AUC 95% Limits of Agreement Sig*	Low limit	Upper limit
HA	0.991	0.004	0	0.983	1.000
CIV	0.907	0.02	0	0.867	0.946
PIIIP N-P	0.891	0.022	0	0.847	0.934
LN	0.969	0.012	0	0.947	0.992



Dual-reagent measurement (HA and LN)

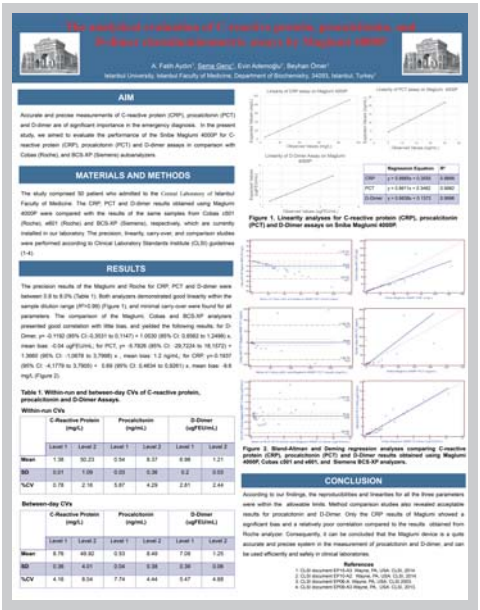
Tetra-reagent measurement (HA、LN、PIIIP N-P、CIV)

4 Conclusions

As illustrated above, HA and LN of Snibe reagent kit perform optimum for the liver fibrosis, with AUC of 0.991 and 0.969 respectively. PIIIP N-P and C IV do less well, during the liver fibrosis process, C IV trends to be a marker of synthesis than deposition , while these reagents can use to differentiate alcoholic liver disease and different stage of chronic liver disease to meet various demands.
The results of joint detection show better clinical diagnosis ability than any single reagent, AUC for Dual-reagent measurement and Tetra-reagent measurement are 0.9981 and 0.995 respectively, the distinction between dual-reagent and tetra-reagent measurement is not significant, Z=1.P>0.05.
Maglumi Hepatic fibrosis Quad marker tests are effective for the liver fibrosis diagnosis, especially for the late stage. Owing to the limit sample, the diagnosis on early stage and the prediction of different liver fibrosis stages have not done completely, which is the forthcoming work.

5 References

Chen J, Liu C, Chen H, et al. Study on noninvasive laboratory tests for fibrosis in chronic HBV infection and their evaluation[J]. J Clin Lab Anal, 2013, 27:5-11.
Gressner AM, Weiskirchen R. Modern pathogenetic concepts of liver fibrosis suggest stellate cells and TGF-be-ta as major players and therapeutic targets [J]. J Cell Mol Med, 2006, 10:76-99.



The analytical evaluation of C-reactive protein, procalcitonin and D-dimer immunoassays on the Maglumi 4000

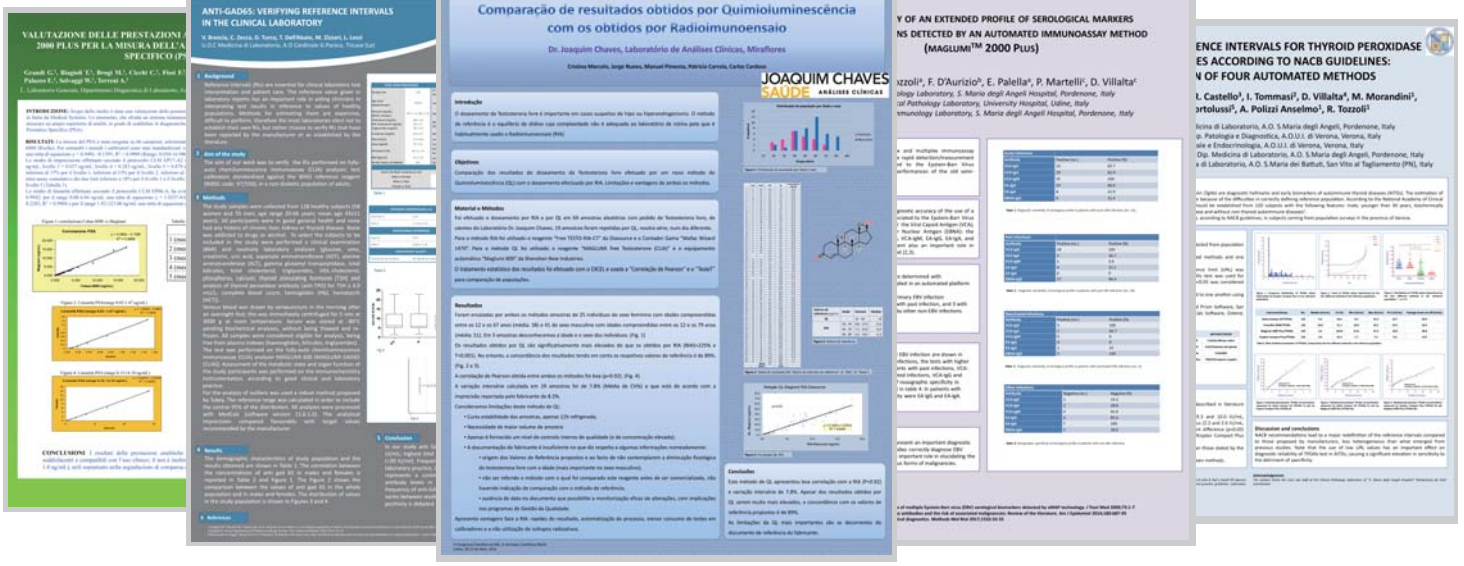
A. Fatih Aydın[1], Berna Genç[1], Evin Ademoğlu[1], Beyhan Öner[1]
[1]Istanbul University, Istanbul Faculty of Medicine, Department of Biochemistry, 34093, Istanbul, Turkey

AIM

MATERIALS AND METHODS

RESULTS

CONCLUSION



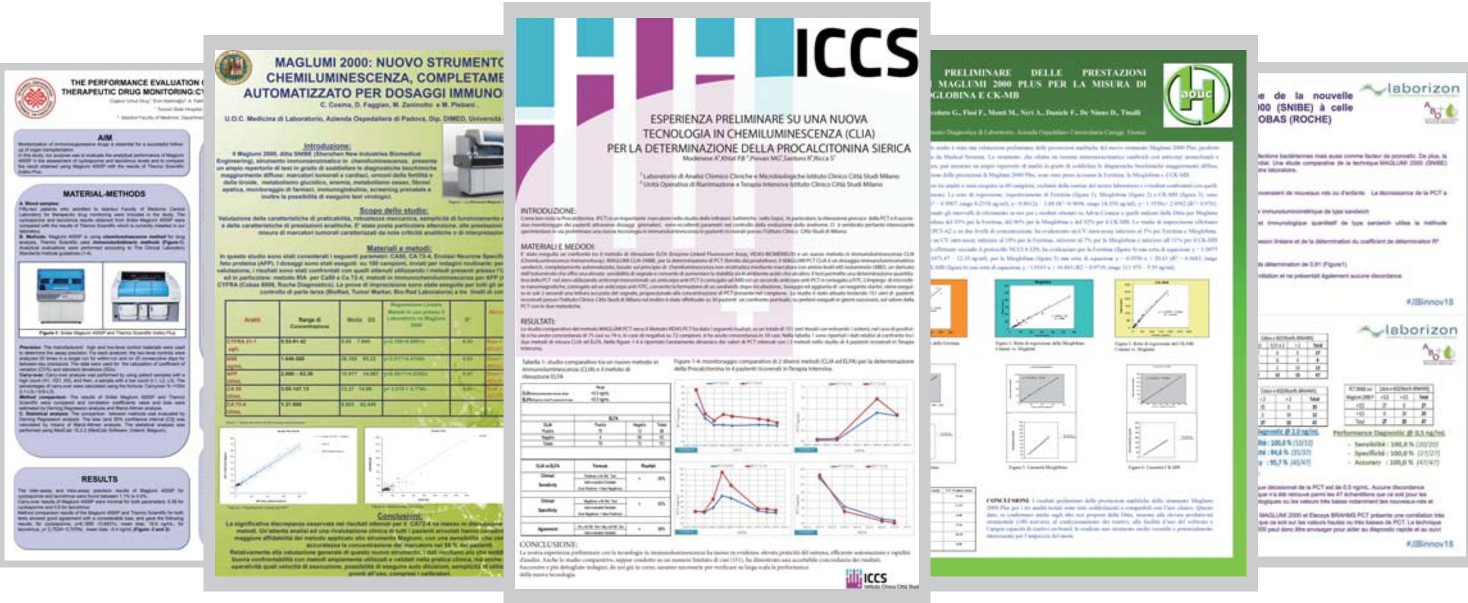
VALUTAZIONE DELLE PRESTAZIONI … 2000 PLUS PER LA MISURA DELL'A… SPECIFICO (P…

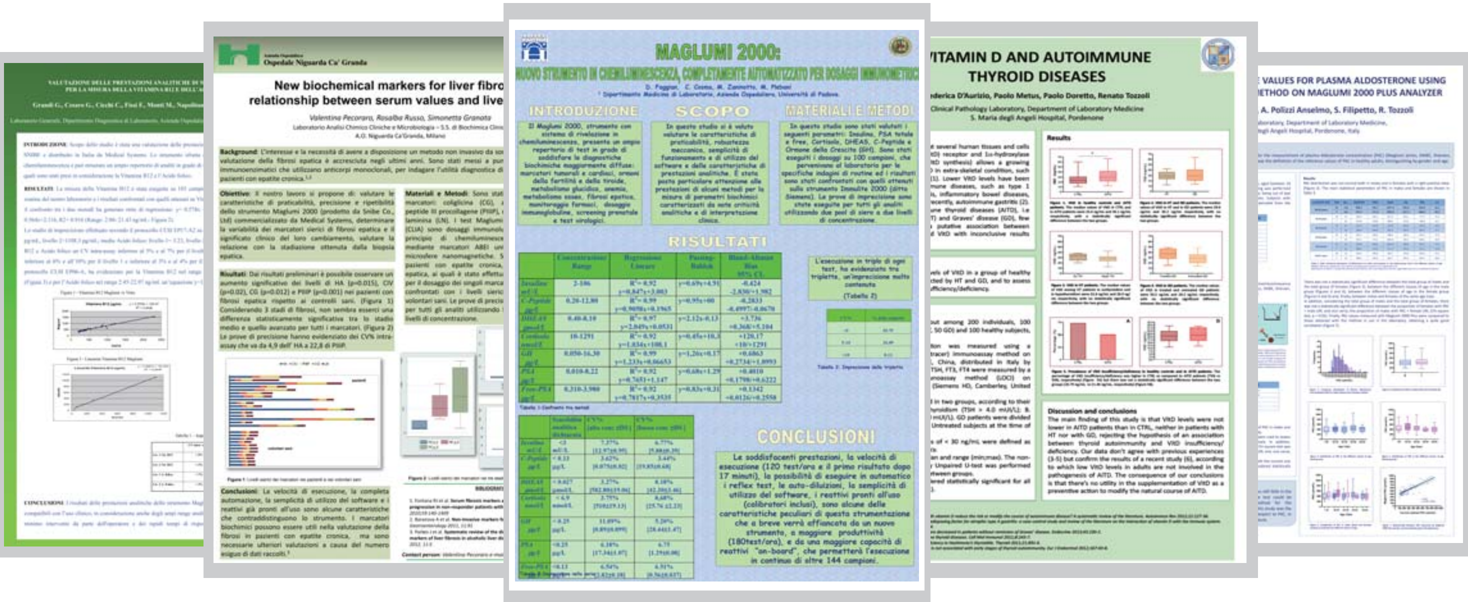
ANTI-GAD65: VERIFYING REFERENCE INTERVALS IN THE CLINICAL LABORATORY

TESTOSTERONA LIVRE
Comparação de resultados obtidos por Quimioluminescência com os obtidos por Radioimunoensaio
Dr. Joaquim Chaves, Laboratório de Análises Clínicas, Miraflores
JOAQUIM CHAVES SAÚDE ANÁLISES CLÍNICAS

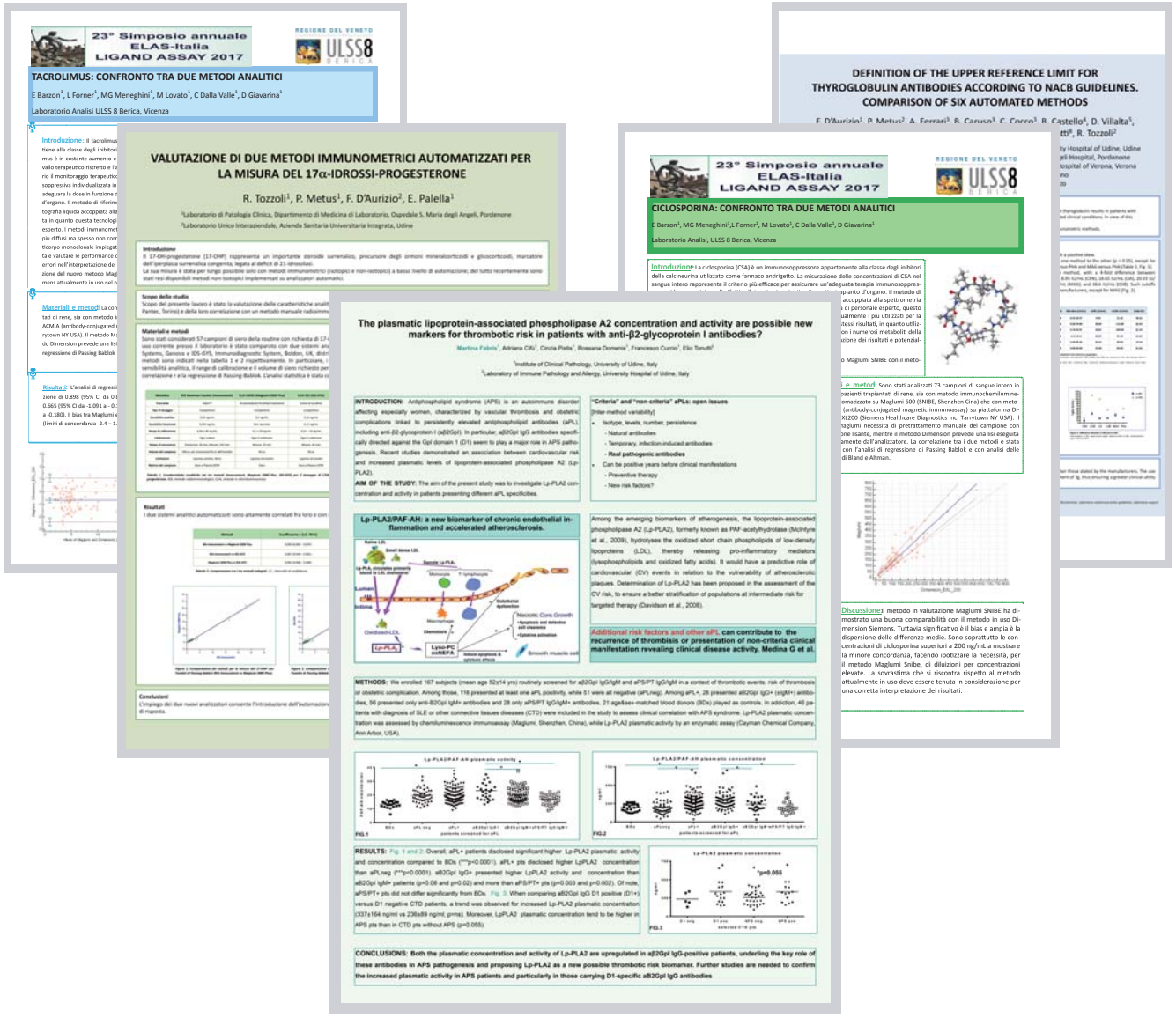
…Y OF AN EXTENDED PROFILE OF SEROLOGICAL MARKERS …NS DETECTED BY AN AUTOMATED IMMUNOASSAY METHOD (MAGLUMI™ 2000 PLUS)

…ENCE INTERVALS FOR THYROID PEROXIDASE …ES ACCORDING TO NACB GUIDELINES: …N OF FOUR AUTOMATED METHODS


THE PERFORMANCE EVALUATION
MAGLUMI 2000: NUOVO STRUMENTO
CHEMILUMINESCENZA, COMPLETAME
AUTOMATIZZATO PER DOSAGGI IMMUNO
ICCS
ESPERIENZA PRELIMINARE SU UNA NUOVA
TECNOLOGIA IN CHEMILUMINESCENZA (CLIA)
PER LA DETERMINAZIONE DELLA PROCALCITONINA SIERICA
laborizon
#JBinnov18


New biochemical markers for liver fibro
relationship between serum values and live
MAGLUMI 2000:
INTRODUZIONE
SCOPO
MATERIALI E METODI
RISULTATI
CONCLUSIONI
VITAMIN D AND AUTOIMMUNE
THYROID DISEASES
VALUES FOR PLASMA ALDOSTERONE USING
METHOD ON MAGLUMI 2000 PLUS ANALYZER

Evaluation Poster



Letter of Recommendation

DIPARTIMENTO DI MEDICINA - DIMED
Department of Medicine - Dimed
Direttore: Prof. Fabrizio Fabris

1222-2022 800 ANNI — UNIVERSITÀ DEGLI STUDI DI PADOVA

University-Hospital of Padova
Via Giustiniani, 2
35128Padova
Italy

To whom it may concern:

It is with great pleasure that I submit this letter of recommendation on behalf of University-Hospital of Padova, Italy.

As the Director of the Department of Laboratory Medicine of the University-Hospital of Padova, I am writing to you and make a recommendation for Snibe CLIA systems.

First of all, I would like to make a brief introduction of the University-Hospital of Padova: The University of Padua is built in 1222 and it's one of the oldest top universities in Europe. The University-Hospital of Padova is one of the biggest hospitals in Italy.

We have been using Snibe MAGLUMI CLIA system for 7 years. The reagent parameters currently in use or evaluated in cooperation are as follows: Cholyglycine, CA50, CA72-4, GAD 65, Anti-IA2, Insulin, C-Peptide, SHBG, GH, IGF-1, ACTH, DHEA-S, TRAb, IL-6), 25-OH Vitamin D and Free Testosterone. We are satisfied with it both because the analytical performances are quite good and because of the a broad test menu available for Maglumi. We have been working with the MAGLUMI 2000 Plus and this analyzer brought us high efficiency and accurate results.

For the next steps, we are planning to try more new tests such as Gastric Cancer Markers (H. pylori IgG, Gastrin-17, Pepsinogen I, Pepsinogen II), IGFBP-3, PIGF, sFlt-1 and 17-OH Progesterone on SNIBE MAGLUMI platform based on the past 7 years' good experience.

Should you have any further questions on the performance of the above mentioned SNIBE MAGLUMI system, do not hesitate to contact me.

Best Regards,

Padova, October 22th, 2019

Mario Plebani
Full Professor of Clinical Biochemistry and Clinical Molecular Biology
Director
Department of Laboratory Medicine
University-Hospital of Padova
Dean
School of Medicine University of Padova

Mario Plebani

- Full Professor of Clinical Biochemistry and Clinical Molecular Biology
- Dean of School of Medicine University of Padova
- Director of Department of Laboratory Medicine University-Hospital of Padova
- Italy Editor in Chief of the Journal CCLM and Diagnosis (Dx), Italy

Exhibition

Euromedab - Barcelona, 2019
Gold Sponsor

AACC - USA, 2019

Medlab Africa - Morroco, 2019
Diamond Sponsor

AACC Middle East - Dubai, 2019
Platinum Sponsor

Colabiocli - Panama, 2019
Diamond Sponsor

Medlab Middle East - Dubai, 2019

APFCB - Taiwan, China, 2016

Medica - Germany, 2018

Feb.

MEDLAB Middle East

Feb. 03-06, 2020

Dubai, UAE

May

IFCC WorldLab SEOUL

May 24-28, 2020

Seoul, Korea

Jun.

37th Nordic Congress

Jun. 09-12, 2020

Trondheim, Norway

Jul.

AACC

Jul. 26-30, 2020

Chicago,USA

Nov.

MEDICA

Nov. 16-19, 2020

Dusseldorf, Germany

Publication

- Autoimmune diagnostics: the technology, the strategy and the clinical governance -- *Immunol Res*
- Alteration in levels of Serum calcium, phosphorous and magnesium in patients of Hypothyroidism -- *Int.J.Med.Res*
- A rapid and sensitive chemiluminescence immunoassay based on magnetic particles for squamous cell carcinoma antigen in human serum -- *Clinica Chimica Acta*
- Assessment of thyroid function in multi-transfused children of β Thalassemia major with iron overload -- *WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES*
- Determining the concentration of procacitonin using a magnetic particles-based chemiluminescence assay for the clinical diagnosis of sepsis -- *Analytical Sciences*
- Stocking Densities and Chronic Zero Culture Water Exchange Stress' Effects on Biological Performances, Hematological and Serum Biochemical Indices of GIFT Tilapia Juveniles (Oreochromis niloticus) -- *J Aquac Res Development*
- Low Vitamin D Status is Associated with Increased Titers of Thyroid Stimulating Hormone Receptor Antibodies in Graves' Disease -- *ENDOCRINE PRACTICE*
- Study of serum vitamin D, calcium in hypothyroidism- a case-control study -- *J Clin Sci Res*
- Effect of dietary vitamin C on non-specific immunity and mRNA expression of three heat shock proteins(HSPs) in juvenile Megalobrama amblycephala under pH stress -- *Aquaculture*
- Increased Prolactin Levels Are Associated with Impaired Processing Speed in Subjects with Early Psychosis -- *PLOS one*

- Increased Frequency of Follicular Helper T Cells in Patients with Autoimmune Thyroid Disease -- *J Clin Endocrinol Metab*
- Establishment of a liver fibrosis model in cynomolgus monkeys -- *EXP TOXICOL PATHOL*
- Effect of spironolactone combined with angiotensin-converting enzyme inhibitors and/or angiotensin ll receptor blockers on chronic glomerular disease -- *Exp.Ther.Med*
- Utility of Lipoprotein (a) as a Marker of Cardiovascular Disease Risk in Hypothyroid Patients -- *International Journal of Biochemistry Research & Review*
- Free thyroxine levels are associated with cognitive changes in individuals with a first episode of psychosis: A prospective 1-year follow-up study -- *Schizophrenia Research*
- Evaluation of predictive value of pleural CEA in patients with pleural effusions and histological findings: A prospective study and literature review -- *Clinical Biochemistry*
- Study of Insulin Resistance in Polycystic Ovarian Syndrome -- *International Journal of Biochemistry Research & Review*
- Bone turnover markers in women with early stage breast cancer who developed bone metastases. A prospective study with multivariate logistic regression analysis of accuracy -- *Clinica Chimica Acta*
- Establishment of a liver fibrosis model in cynomolgus monkeys -- *Experimental and Toxicologic Pathology*
- Interleukin 10 (−1082 G/A) and (−819 C/T) gene polymorphisms in Egyptian women with polycystic ovary syndrome (PCOS) -- *Meta Gene*

Publication


Research

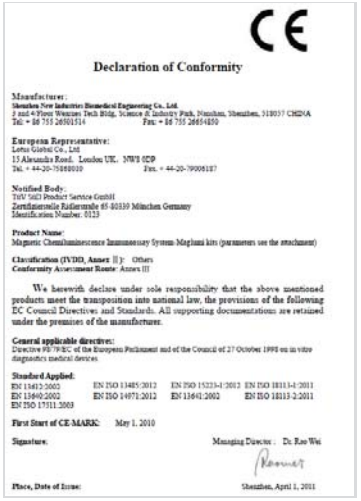
Original Investigation

Efficacy of Folic Acid Therapy in Primary Prevention of Stroke Among Adults With Hypertension in China
The CSPPT Randomized Clinical Trial

JAMA

- Efficacy of folic acid therapy for the primary prevention of stroke
- Use of Prostate-Specific Antigen (PSA) Isoforms For The Detection of Prostate Cancer in Men With a PSA Level Of 3-10 ng/ml: A Zimbabwean Perspectivel -- *IJSR*
- The impacts of thyroid function on the diagnostic accuracy of Cystatin C to detect acute kidney injury in ICU patients: a prospective, observational study *Care* -- *Crit*
- T cell-derived leptin contributes to increased frequency of Th17 cells in female patients with Hashimoto's thyroiditis -- *Clin Exp Immunol*
- Simpler score of routine laboratory tests predicts liver fibrosis in patients with chronic hepatitis *B* -- *J.of Gastroenterology and Hepatology*
- Serum Carcinoembryonic Antigen (CEA), Carbohydrate Antigen (CA) 19-9, Cytokeratin-19 Fragment (CYFRA 21-1) and Matrix Metalloproteinase-7 (MMP-7) Measurement for Detecting Cholangiocarcinoma A Preliminary Case-control Study -- *European Society for Medical Oncology 37th Congress*
- Relationship between thyroid function and ICU mortality: a prospective observation study -- *Crit Care*
- measurement of Serum Carcinoembryonic Antigen, Carbohydrate Antigen 19-9, Cytokeratin-19 Fragment and Matrix Metalloproteinase-7 for Detecting Cholangiocarcinoma: A Preliminary Case-Control Study -- *Anticancer Research*
- Is vitamin D a player or not in the pathophysiology of autoimmune thyroid diseases? -- *Autoimmunity Reviews*

Certificates



Declaration of Conformity

Manufacturer:
Shenzhen New Industries Biomedical Engineering Co., Ltd.
2 and 4/Floor Wenmen Tech Bldg, Science & Industry Park, Nanshan, Shenzhen, 518057 CHINA
Tel: + 86 755 26501514 Fax: + 86 755 26854850

European Representative:
Lotus Global Co., Ltd.
15 Alexandra Road. London UK. NW8 0DP
Tel. + 44-20-75080010 Fax. + 44-20-79008187

Notified Body:
TuV SüD Product Service GmbH
Zertifizierstelle Ridlerstraße 65 80339 München Germany
Identification Number: 0123

Product Name:
Magnetic Chemiluminescence Immunoassay System-Maglumi kits (parameters see the attachment)

Classification (IVDD, Annex II): Others
Conformity Assessment Route: Annex III

We herewith declare under sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:
Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostics medical devices

Standard Applied:
EN 13483:2003 EN ISO 13485:2012 EN ISO 15223-1:2012 EN ISO 18113-1:2011
EN 13640:2002 EN ISO 14971:2012 EN 13641:2002 EN ISO 18113-2:2011
EN ISO 17511:2003

First Start of CE-MARK: May 1, 2010

Signature: Managing Director : Dr. Rao Wei

Place, Date of Issue: Shenzhen, April 1, 2011

CE Instrument

SHENZHEN HUATONGWEI INTERNATIONAL INSPECTION Co., Ltd.

Declaration of Conformity

Certification number: CTE10110044
Issue date: Nov 22, 2010

In accordance with the following Applicable Directives

2004/108/EC
Electromagnetic Compatibility

The equipment, as described herewith, was tested pursuant to applicable test procedure and complies with the requirements of

EN 61326-1: 2006
EN 61326-2-6: 2006

The test results are traceable to the international or national standards.

Applicant: Shenzhen New Industries Biomedical Engineering Co., Ltd
4F, Wearnes Tech Bldg, Science & Industry Park, Nanshan, Shenzhen, China 518057

Manufacturer: Shenzhen New Industries Biomedical Engineering Co., Ltd
4F, Wearnes Tech Bldg, Science & Industry Park, Nanshan, Shenzhen, China 518057

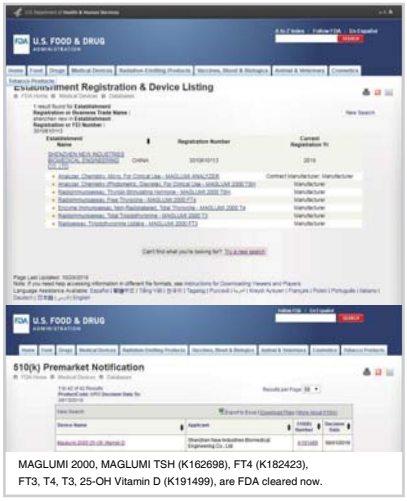
Equipment under test: Fully Automatic Chemiluminescence Immunoassay Analyzer
Model/Type reference : Maglumi 2000(representative model for test)
Listed Models: Maglumi 1000, Maglumi 2000 Plus
Laboratory Name: Shenzhen Huatongwei International Inspection Co., Ltd
Add: No.12 Road, Hi-tech Park, Shenzhen, China
Tel: 86-755-26748058 Fax: 86-755-26748085
http://www.szhtw.com.cn E-mail: master@szhtw.com.cn

Note:
The certification is only valid for the equipment and configuration described, in conjunction with the test data detailed above.
The CE mark as shown beside can be used, under the responsibility of the manufacturer, after completion of an EC Directive of Conformity and compliance with all relevant EC Directive.

For and on behalf of Shenzhen Huatongwei International Inspection Co., Ltd.

Authorized by:

CE Instrument EMC / Safety



U.S. FOOD & DRUG

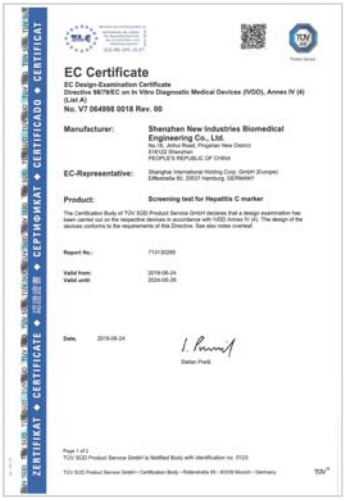
Establishment Registration & Device Listing

U.S. FOOD & DRUG

510(k) Premarket Notification

MAGLUMI 2000, MAGLUMI TSH (K162698), FT4 (K182423), FT3, T4, T3, 25-OH Vitamin D (K191499), are FDA cleared now.

FDA 510(K) CLEARED



EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)
No. V7 064098 0018 Rev. 00

Manufacturer: Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.16, Jinhui Road, Pingshan New District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product: Screening test for Hepatitis C marker

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. See also notes overleaf.

Report No.: 71313029S
Valid from: 2019-06-24
Valid until: 2024-06-24
Date: 2019-06-24
Stefan Preiß

Page 1 of 2
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

CE List A

CERTIFICATE

The Certification Body of TÜV SÜD Management Service GmbH certifies that

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.16, Jinhui Road, Pingshan New District
Shenzhen, P.R. China
Post Code: 518122

Unified social credit code / Organization code: 91440300192366852D

has established and applies a Quality Management System for

including the sites and scope of application see enclosure.

An audit was performed, Report No. 7484078496.
Proof has been furnished that the requirements according to

ISO 9001:2015

are fulfilled.

The certificate is valid from 2018-01-05 until 2019-12-31.

The certified organization shall undergo and pass the regular surveillance audit to maintain the validity of this certificate.

Certificate Registration No.: 12 100 35580 TMS.

ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFICAT ◆ 認證證書 ◆ CEPTИФИКАТ

ISO 9001

CERTIFICATE

No. Q5 17 10 64998 015

Holder of Certificate: Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.16, Jinhui Road, Pingshan New District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: Design, Production, Distribution and Service of In-vitro Diagnostic Medical Device for Magnetic Chemiluminescence Immunoassay Kits and Matched Analyzers, Biochemical Reagents and Matched Analyzers

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: G21713001
Valid from: 2018-03-12
Valid until: 2019-12-31
Date: 2018-03-12
Stefan Preiß

Page 1 of 2

ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFICAT ◆ 認證證書 ◆ CEPTИФИКАТ

ISO 13485

医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号
Certificate No.: YS2018T0267

产品名称：见附件
Product(s): See Attachment

规格型号：见附件
Model: See Attachment

产品注册或备案凭证号
Registration certificate(s): 见附件 See Attachment

生产企业：深圳市新产业生物医学工程股份有限公司
Manufacturer: Shenzhen New Industries Biomedical Engineering Co.,Ltd.

生产企业住所：深圳市坪山新区金沙区汇通路 16 号
Address of manufacturer: No. 16, Jinhui Road, Pingshan New District, Shenzhen, P.R. China

生产许可或备案凭证号
Manufacturing license(s): 粤食药监械生产许 20000003 号

兹证明上述产品已准许出口至以下国家/地区。
This is to certify that the above products have been registered to be manufactured and sold in China.

(此证明书从发证时起有效期 2 年)
This certificate is valid for two years from the date of issuance)

FSC

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 5) (List A and B and devices for self-testing)
No. V1 16 01 64998 011

Manufacturer: Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.16, Jinhui Road, Pingshan New District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Lotus Medical Equipment Limited
268 Cameron Court, Cork Street
Dublin 8
IRELAND

Product Category(ies): Products for determination of tumor markers (PSA) and infection markers

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

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Date: 2018-03-02
Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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CE Reagent

Top 10 Reasons Why Choose Snibe

» No.1 CLIA manufacturer in China

» No.1 fast CLIA analyzer MAGLUMI X8

» 1st in China who received FDA Cleared on CLIA product

» 25 years focusing on immunoassay and IVD

» Reliable and stable ISO quality management system

» Over 12000 units of MAGLUMI installation in more than 145 countries and areas

» Fast responding to market feedback and timely launching of new assays

» Original manufacturer of core products including analyzers and reagents

» Advanced magnetic microbeads separation and ABEI labeling technology

» Quality guarantee by the third party quality control and External Quality Assessment (EQA)