

<p>AFP CEA PSA CA 125 CA 19.9 CA15.3 Anti TG Ab Anti TPO Ab HIV Hepatite virale Procalcitonina TORCH infecții (Maternal Care) Tip diluare automat; Program control al calității obligatoriu; Indicatori de avertizare obligatoriu; Toate softurile necesare instalate pentru buna funcționare a echipamentului obligatoriu Limba de comunicare rom/eng Interfață LIS bidirecțională Afișaj Ecran LCD/LED Printer - obligatoriu Cititor cod bare - obligatoriu Alimentarea 220 V, 50 Hz Să fie incluși toți reagenții, toate accesoriile, consumabile necesare (vase pentru deșeuri, tuburi pentru reagenți, tuburi pentru spălare) pentru efectuarea analizelor și buna funcționare a echipamentului - ≥ 50 analize (pentru testare/instruire).</p> <p>Investigatii pentru 2026, cantitati minime: Hbe Ag&Ab – 634t HBc IgM – 57t HCV Ab – 826t HBc Ab – 584t HbsAb – 799t HBsAg – 1113t Toxocara IgG – 744t</p>	<p>FT3 - da FT4 - da AFP - da CEA - da PSA - da CA 125 - da CA 19.9 - da CA15.3 - da Anti TG Ab - da Anti TPO Ab - da HIV - da Hepatite virale - da Procalcitonina - da TORCH infecții (Maternal Care) – da. Tip diluare automat – <i>da, Page 5-3 din Manual utilizare Maglumi X3.</i> Program control al calității – <i>da, Page 5-1 din Manual utilizare Maglumi X3.</i> Indicatori de avertizare obligatoriu – <i>da, pag. 5-50, cap.5.9.2 din Manual utilizare Maglumi X3.</i> Toate softurile necesare pentru buna funcționare a echipamentului sunt instalate - <i>da, pag. 2-12 din Manual utilizare Maglumi X3.</i> Limba de comunicare eng – da, Page 5-43 din Manual utilizare Maglumi X3. Interfață LIS bidirecțională – <i>da, pag. 8 din prospect MAGLUMI X3.</i> Afișaj Ecran LCD - <i>da, pag. 2-12 din Manual utilizare Maglumi X3.</i> Printer – <i>da, inclus.</i> Cititor cod bare – <i>da, pag. 8 din prospect MAGLUMI X3.</i> Alimentarea a.c.100 V-240 V, 50 Hz/60 Hz, <i>da, pag. 2-2 din User Manual MAGLUMI X3.</i> Sunt incluși toți reagenții, toate accesoriile, consumabile necesare (vase pentru deșeuri, tuburi pentru reagenți, tuburi pentru spălare) pentru efectuarea analizelor și buna funcționare a echipamentului - 50 analize (pentru testare/instruire).</p> <p>Investigatii pentru 2026, cantitati minime: Hbe Ag&Ab – 634t HBc IgM – 57t</p>
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<p>IgE Total – 721t CMV IgG – 503t. HSV IgG – 486t. H.pylori IgG – 356t. PSA Total – 1027t. fT3 – 600t. fT4 – 600t; Vitamina D – 800t; TSH – 1000t. anti TPO – 400t. CEA – 300t. CA 19-9 – 300t. CA 125 – 200t. PSA liber – 200t. Feritin – 250t Acid folic – 150t. Vit B12 – 150t AFP – 200t Procalcitonin – 200t.</p>	<p>HCV Ab – 826t HBc Ab – 584t HbsAb – 799t HBsAg – 1113t Toxocara IgG – 744t IgE Total – 721t CMV IgG – 503t. HSV IgG – 486t. H.pylori IgG – 356t. PSA Total – 1027t. fT3 – 600t. fT4 – 600t; Vitamina D – 800t; TSH – 1000t. anti TPO – 400t. CEA – 300t. CA 19-9 – 300t. CA 125 – 200t. PSA liber – 200t. Feritin – 250t Acid folic – 150t. Vit B12 – 150t AFP – 200t Procalcitonin – 200t.</p>
<p>Note: Oferta de preț trebuie să includă reactivii necesari pentru testele indicate, soluțiile QC și calibrare. Cantitatea soluțiilor propuse trebuie să asigure efectuarea procedurilor de control al calității și calibrare, ori de câte ori este necesar.</p>	<p>Nota: Oferta de preț include reactivii necesari pentru testele indicate, soluțiile QC și calibrare. Cantitatea soluțiilor propuse va asigura efectuarea procedurilor de control al calității și calibrare, ori de câte ori este necesar.</p>
<p>Furnizorul va asigura: Transmiterea către spital documentația completă privind conectarea analizatorului la sistemul informatic (H3 SIA AMS/AMP) și să asigure suportul tehnic necesar echipei desemnate de spital sau firmei de software care realizează efectiv conectarea. Instruirea personalului. Mentenanța preventivă și corectivă gratuită pe toată durata contractului atât pentru analizator cât și pentru dispozitivele auxiliare livrate (ex. Calculator, UPS, sistem filtrare).</p>	<p>GBG-MLD va asigura: Transmiterea către spital documentația completă privind conectarea analizatorului la sistemul informatic (H3 SIA AMS/AMP) și va asigura suportul tehnic necesar echipei desemnate de spital sau firmei de software care realizează efectiv conectarea. Instruirea personalului. Mentenanța preventivă și corectivă gratuită pe toată durata contractului atât pentru analizator cât și pentru dispozitivele auxiliare livrate (ex. Calculator, UPS, sistem filtrare).</p>

<p>Seturile de mentenanță și piesele de schimb gratuite pe toată durata contractului atât pentru analizator cât și pentru dispozitivele auxiliare livrate (ex. Calculator, UPS, sistem filtrare apă).</p> <p>Toate consumabilele necesare gratuite pe toată durata contractului atât pentru analizator cât și pentru dispozitivele auxiliare livrate (ex. Calculator, UPS, sistem filtrare apă), dacă acestea nu au fost incluse în oferta inițială.</p> <p>Timpul de intervenție în caz de defect: maxim 24 ore de la solicitarea telefonică.</p> <p>Preț pentru reactivi nemodificat pentru toată perioada contractului.</p> <p>Perioada de valabilitate pentru reagenții livrați: La momentul livrării: Minim 6 luni, dar nu mai puțin de 80% din termenul total de valabilitate.</p> <p>Să se indice timpul de stabilitate a reactivilor după deschidere. Termenele mai mari vor fi considerate un avantaj.</p>	<p>Seturile de mentenanță și piesele de schimb gratuite pe toată durata contractului atât pentru analizator cât și pentru dispozitivele auxiliare livrate (ex. Calculator, UPS, sistem filtrare apă).</p> <p>Toate consumabilele necesare gratuite pe toată durata contractului atât pentru analizator cât și pentru dispozitivele auxiliare livrate (ex. Calculator, UPS, sistem filtrare apă), dacă acestea nu au fost incluse în oferta inițială.</p> <p>Timpul de intervenție în caz de defect: maxim 24 ore de la solicitarea telefonică.</p> <p>Preț pentru reactivi nemodificat pentru toată perioada contractului.</p> <p>Perioada de valabilitate pentru reagenții livrați: la momentul livrării minim 6 luni, dar nu mai puțin de 80% din termenul total de valabilitate.</p> <p>Timpul de stabilitate a reactivilor după deschidere: 4 săptămâni.</p>
<p>Operatorul Economic va include în prețul dispozitivului medical și prețurile pentru fiecare test considerând:</p> <p>Efectuarea controlului calității pentru fiecare test în fiecare zi lucrătoare.</p> <p>Efectuarea calibrării ori de câte ori va fi necesar (în baza rezultatului controlului calității).</p> <p>Toate piesele și kiturile de mentenanță necesare bunei funcționării pe întreaga perioadă contractului.</p> <p>Sistemul de filtrare (stație purificare apă) și toate filtrele necesare pentru funcționarea stației de purificare al apei pe toată perioada contractului.</p> <p>UPS (Sursa neîntreruptibilă de alimentare) și costurile acumulatorilor necesare pe toată perioada contractului.</p> <p>Calculator (PC), monitor, tastatura, mouse cu garanție deplină și înlocuire în caz de defectare.</p> <p>Toate consumabilele, inclusiv: soluții de spălare, soluții de buffer, electrozi/modul ISE, cuve/rotor pentru reacție, lămpi și tot spectrul de consumabile necesare bunei funcționări pentru efectuarea tuturor testelor solicitate de IMSP.</p> <p>Toate serviciile de mentenanță preventivă și corectivă necesare bunei funcționări pe perioada contractului.</p> <p>Respectiv, se vor lua în calculul toate cheltuielile care ar putea apărea în întreaga perioadă contractului.</p>	<p>GBG-MLD a inclus în prețul dispozitivului medical prețurile pentru fiecare test considerând:</p> <p>Efectuarea controlului calității pentru fiecare test în fiecare zi lucrătoare.</p> <p>Efectuarea calibrării ori de câte ori va fi necesar (în baza rezultatului controlului calității).</p> <p>Toate piesele și kiturile de mentenanță necesare bunei funcționării pe întreaga perioadă contractului.</p> <p>Sistemul de filtrare (stație purificare apă) și toate filtrele necesare pentru funcționarea stației de purificare al apei pe toată perioada contractului – N/A.</p> <p>UPS (Sursa neîntreruptibilă de alimentare) și costurile acumulatorilor necesare pe toată perioada contractului.</p> <p>Calculator (PC), monitor, tastatura, mouse cu garanție deplină și înlocuire în caz de defectare.</p> <p>Toate consumabilele, inclusive tot spectrul de consumabile necesare bunei funcționări pentru efectuarea tuturor testelor solicitate de IMSP.</p> <p>Toate serviciile de mentenanță preventivă și corectivă necesare bunei funcționări pe perioada contractului.</p> <p>Respectiv, se vor lua în calculul toate cheltuielile aferente funcționării dispozitivului, care ar putea apărea în întreaga perioadă contractului.</p>

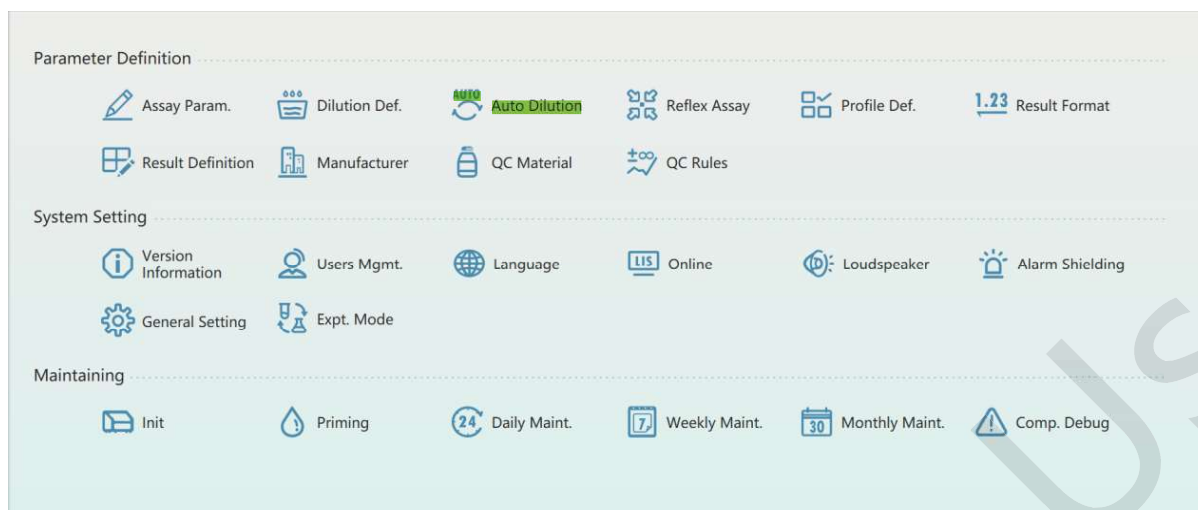





Figure 5.1-4 [Set] menu

5.1.4 Operation bar

The action bar includes multiple shortcut buttons and status displays.

1. A shortcut button is used to quickly run a certain function.

- : <Warning Message> button. After the analyzer gives an alarm, this button alerts the user of the nature of the error. The details can be viewed by clicking this button.
- : <Start> button. After sample registration, calibration registration and QC registration are completed, click this button and the software will start to send test command to the analyzer to start tests.
- : <Pause Cycle> button. If you need to pause a test during the analyzer's test process, click the button and the analyzer will pause the action.



Note:

Do not keep the system in the cycle paused status for long, otherwise it may affect the result of some tests.



Fully-auto chemiluminescence
immunoassay analyzer

MAGLUMI®
XE

Operating Instructions

Chapter 2 Analyzer overview

2.1 Overview

The MAGLUMI X3 Fully-auto chemiluminescence immunoassay analyzer and the supporting diagnostic reagent series constitute a magnetic separation, ABEI-labeled, and accurate direct chemiluminescence micro immunoassay system. The system is used for qualitative or quantitative analysis of the analytes in human samples. The analyzer performs automatic sample pipetting, reagent loading, incubation, washing, measurements, and result calculations, which reduces test errors and improves the accuracy and precision of test results.

2.2 Specifications of analyzer

Table 2.2-1 Specifications of analyzer

Item		Specifications
Basic characteristics	Test speed	200 tests/hour
	Sample type	Serum, plasma, urine, whole blood
	Barcode type	Code128, Code39, Code93, Codabar, 2/5 Interleaved
	QC	Monthly QC analysis
Analyzer characteristics	Sample volume	10–200 μ L
	Sample reagent area	A total of 72 sample positions and 20 reagent positions on six sample racks
	SampleArm	Liquid level detection, tracking with liquid level, clot detection, anti-bubble interference, collision detection, automatic washing
	Reagent volume	10–450 μ L
	Temperature of sample reagent area	Reagent area temperature is $10^{\circ}\text{C} \pm 3^{\circ}\text{C}$.
	Cuvette quantity	A total of 364 cuvettes can be loaded.
	Reaction temperature	$37.0^{\circ}\text{C} \pm 0.3^{\circ}\text{C}$, with the fluctuation not greater than 0.2°C .
Mixing Method	Mechanical oscillation	
External interfaces	Interface	Ethernet

Operation Environment	Temperature	10°C-30°C
	Relative humidity	≤70%
	Altitude	Not more than 2,000 metres
	Other	Keep away from electromagnetic field interference sources
Storage Environment	Temperature	-20°C-55°C
	Relative humidity	≤93%
	Atmospheric pressure	50.0 kPa–106.0 kPa
	Other	Room free of strong sunlight and corrosive gas, with good ventilation
Safety category	Anti-electric shock grade	Type I
	Overvoltage type	Type II
	Pollution grade	Grade 2
Whole analyzer	REF	010101003301
	Weight	132kg
	Outer dimensions Length * width * height	90 cm*75 cm*78 cm
	Packing dimensions Length * width * height	105.3cm*88.3cm*97.7cm
	Power supply	a.c.100 V-240 V, 50 Hz/60 Hz
	Power consumption (VA)	600 VA
	Noise	< 70dB

2.3 Overall composition of analyzer

The analyzer is composed of the main machine, accessories and software, wherein the main machine is composed of the material provision module, the liquid path module, the temperature control module, the mechanical drive module, the optical path detection module and the circuit control module; and the accessories include a desktop computer suite and cables.

- The material preparation module includes the cuvette storage module, the sample reagent area module, the starter module, and the cuvette dustbin module.
- The liquid module includes the SampleArm liquid path module, the washer liquid path module, the chamber liquid path module, the system liquid / waste liquid tank module, the sample/reagent area cooling liquid path module, and the sample/reagent area

5.9.1 Test statuses

The central part of Home is the status display area. From top to bottom sequentially: analyzer status, remaining time for current testing, samples and tests.

1. Analyzer status:

Analyzer statuses include "Connecting", "Init", "Standby", "Testing", "Maintaining", "Pause Cycle", "Continue", "Stop", "Analyzer Fault", and "System Test".

2. Remaining time:

The software updates the remaining time for the current test in real time. If a new test is loaded when a test is still in progress, the remaining time indicates the remaining time before all the tests are completed.

3. Samples:

Progress bar for samples: (number of samples finished / total number of samples)

4. Tests:

Progress bar for tests: (number of tests finished / total number of tests)

5.9.2 Remaining statuses and indicator lights

Each analyzer status and indicator light is displayed on both sides of Home. The status on the left is consumables and waste. When the status value is normal, the icon is displayed in green; when the status reaches the prompt value, the icon is displayed in yellow; when the status is warning, the icon is displayed in red. To view the specific situation, click the corresponding icon to enter the corresponding detailed interface to view.

From top to bottom, the right side displays: temperature, voltage, pending calibration, last BGW testing time, and the last maintenance time.

1. Temperature and voltage

When the temperature and voltage values are in the normal range, the corresponding icon is displayed in green; when the temperature and voltage values are outside the normal range, the corresponding icon is displayed in red.

2. Pending calibration

When there is no new calibration to be processed, the icon is displayed in green; when there is a new calibration needing to be processed, the icon is displayed in red and the reagent assay to have its calibration confirmed is displayed below.

3. Last BGW Time

Shows the time of the most recent BGW test. When a BGW test has finished that day, the icon is displayed in green; when a BGW test has not finished on the day, the icon is displayed in red.

4. Last maintenance time

Displays the last maintenance action time.

5.8.2.3 Language

Click the **<Language>** button to go to the **[Language]** interface, as shown in the following figure. After the language is selected, the software will display text in the corresponding language.

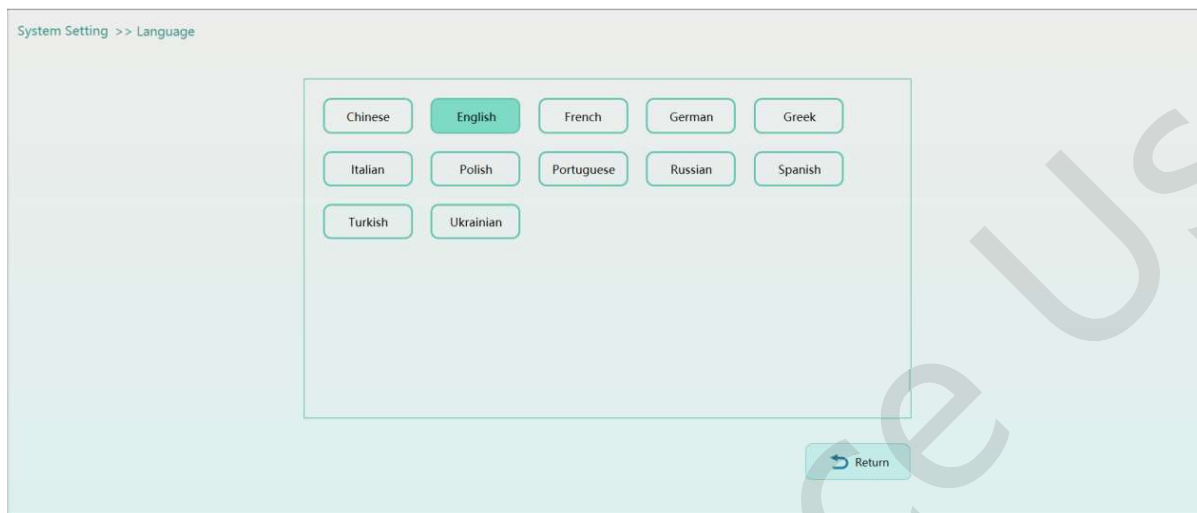


Figure 5.8-17 Language

5.8.2.4 Online

In the [System Setting] area, click the **<Online>** button to go to the [Online] interface, as shown in the following figure.

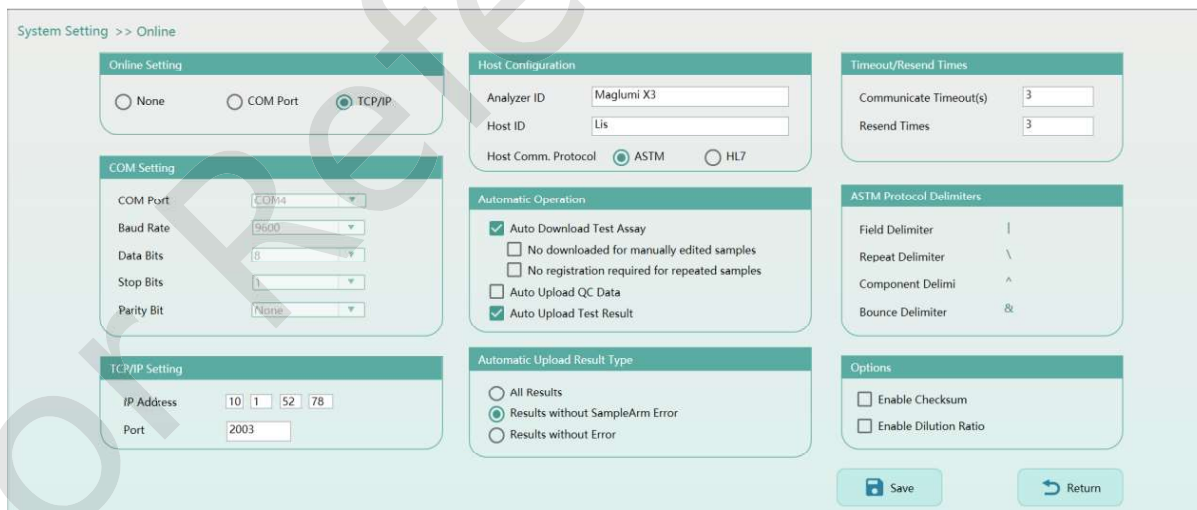


Figure 5.8-18 Online

The software provides two-way communication with a hospital LIS server. You can obtain the test assay information for a sample from the hospital LIS server by manually entering the sample ID or using a barcode, and send test results to the hospital LIS server.

1. Online settings:

MAGLUMI® X3

Fully-auto Chemiluminescence Immunoassay (CLIA) System

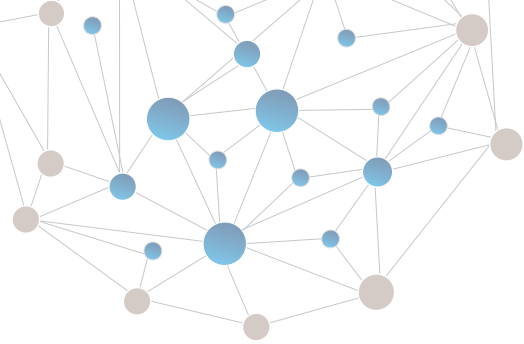
**FDA 510(K)
Cleared**



Save Your Space Without Compromise

Powerful Performance and Compact Design

Compatible with Small and Medium-sized Hospitals and Labs

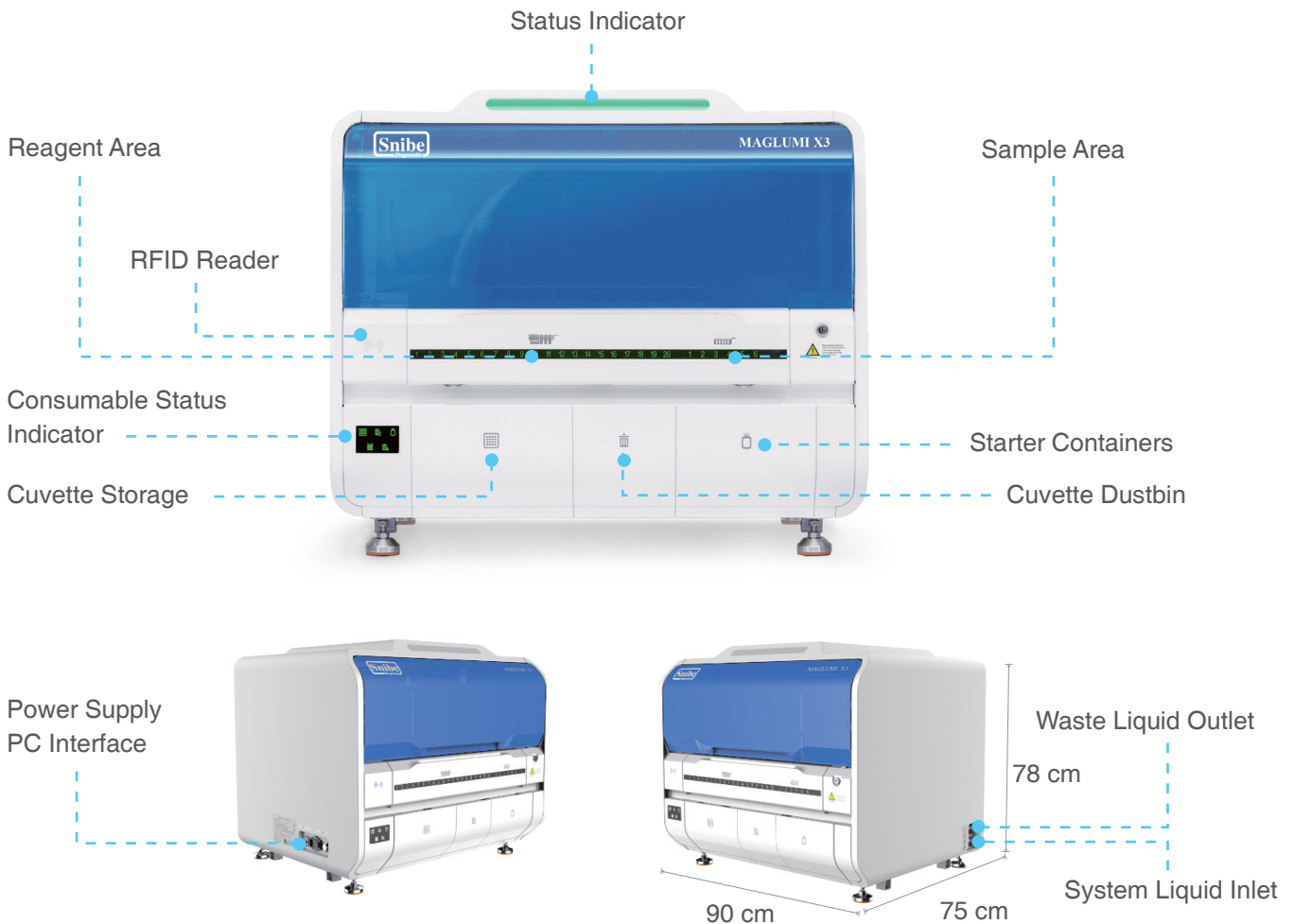


MAGLUMI® X3

Features & Benefits

- Small but powerful, **the throughput is up to 200 tests/hour**, and throughput per unit area is 296 T/h/m².
- Compatible with all MAGLUMI® reagents, one of the broadest automated CLIA test menus in the world (260 parameters).
- The latest intelligent washing technology and bidirectional temperature control measurement guarantee accurate and reliable results. The comprehensive advanced design of MAGLUMI® X3 ensures excellent performance.
- Single reaction cup can avoid light pollution and increase cuvette utilization, its integrated packaging can avoid the stuck of the cuvette and destroying the cuvette wall.
- No-pause loading/unloading of reagents/samples/reaction cups without waiting or interrupting tests.

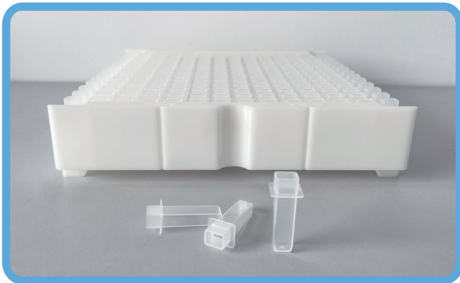
Functional Modules





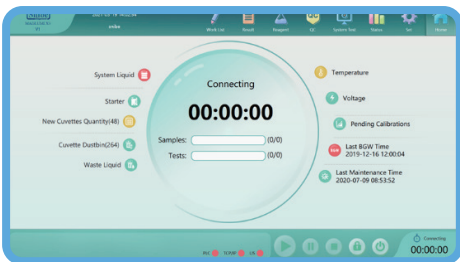
Reagent and Sample Loading

- 72 sample positions with barcode reader
- Sample in each position can be defined as STAT
- 20 reagent positions with RFID reader, 24h refrigerated at 10°C ($\pm 3^{\circ}\text{C}$)
- No-pause loading/unloading of reagents/samples/reaction cups without waiting or interrupting tests
- Reagent and sample indicator light available, real-time status monitoring, no need to check on the computer monitor



Single Reaction Cup with Integrated Packaging

- Single reaction cup can avoid light pollution and increase the cuvette utilization
- Single reaction cup with integrated packaging can avoid the stuck of the cuvette and destroying the cuvette wall



Intelligent UI Design

- New user-friendly UI design (Support multiple languages)
- Real-time display for monitoring each test procedure, reagent, and consumable quantities, makes it convenient for the management
- Intelligent error recovery



Convenient Management of Analyzer Status

- Intuitive indicator light of reagent, sample, and consumable. No need to focus on the monitor, the status can be known by looking at the analyzer from a distance



All Balanced and Strong

Accurate Pipetting Technology

- Single needle coated with TEFLON to avoid carry-over
- Independent washing unit for the needle, with different washing modes depending on different assays
- Pipetting detection technologies include liquid level, clot, and crash detection to ensure accurate pipetting



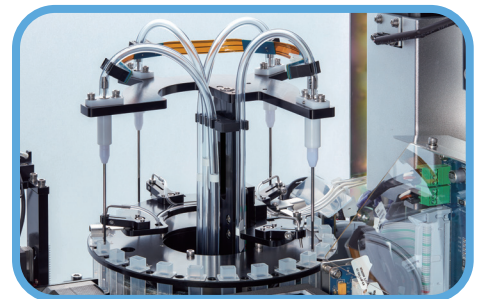
Accurate Incubation Technology

- Single reaction cup with five-sided heating at 37.0°C ($\pm 0.3^\circ\text{C}$), ensuring accurate, quick and uniform incubation
- Incubating 80 cuvettes simultaneously
- Non-contact mixing with different modes before incubation, ensuring sufficient reaction



High-Efficiency Washing Technology

- Magnetic separation washing with 4-step independent units and non-contact vortex mixing can reduce non-specific binding
- Different mixing modes depending on different assays, ensuring a sufficient washing to improve sensitivity



Stable and Accurate Measuring Chamber

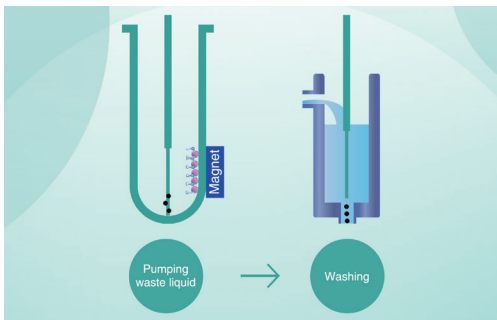
- ABEI-label exclusive proprietary technology
- PMT with heating and cooling function, ensuring the detection precision
- Independent measuring room, avoiding light cross-contamination





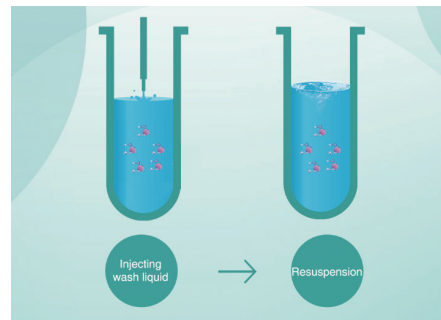
Exclusive Intelligent Washing Technology

Independent washing units for waste liquid needles



In the wash station, four waste liquid needles are equipped with four independent washing units to avoid the carry-over.

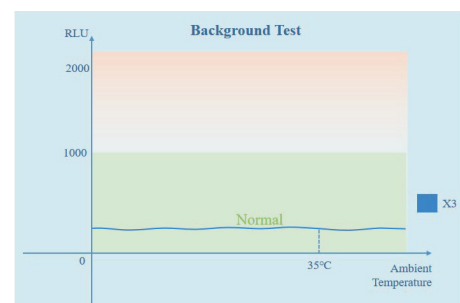
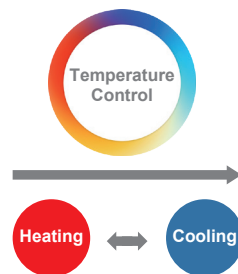
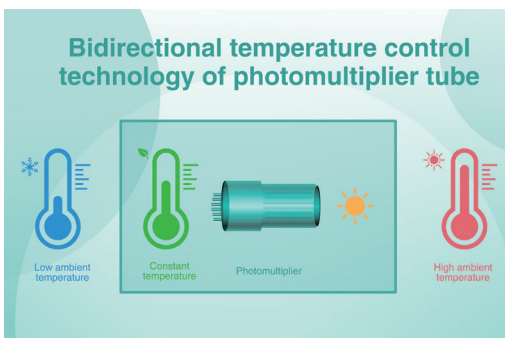
Magnetic separation washing and non-contact vortex mixing



Magnetic separation washing and non-contact vortex mixing units, with different mixing modes depending on different assays, ensure a sufficient washing to reduce the non-specific binding.

Stable and Accurate Measuring Chamber

Bidirectional temperature control technology of photomultiplier tube



Automatic temperature control in the measuring chamber can keep a stable background value, not affected by the ambient temperature, ensuring the accuracy of measurement results.



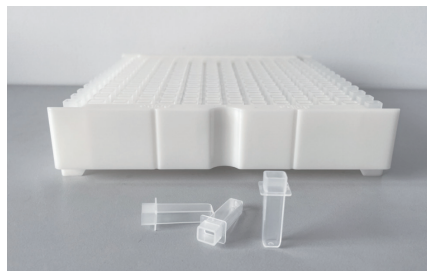
Top 10 Highlights of MAGLUMI® X3

- 1 One of the highest space efficiency CLIA analyzers combines one of the broadest automated CLIA test menus.
- 2 The throughput is up to 200 tests/hour (Throughput per unit area is 296 T/h/m²). No worry about the lack of laboratory space.
- 3 MAGLUMI® reagent kits (260 parameters) and consumables are compatible with MAGLUMI® X3.
- 4 The comprehensive advanced design of MAGLUMI® X3 ensures excellent performance.
- 5 Single reaction cup can avoid light pollution and increase cuvette utilization, its integrated packaging can avoid the stuck of the cuvette or destroying the cuvette wall.
- 6 No-pause loading/unloading of reagents/samples/reaction cups without waiting or interrupting tests.
- 7 Pipetting detection technologies include liquid level, clot, and crash detection to ensure accurate pipetting.
- 8 The latest intelligent washing technology and bidirectional temperature control measurement guarantee accurate and reliable results.
- 9 Intelligent UI design, user-friendly, easy, and convenient to operate.
- 10 Intuitive indicator lights reduce the frequency of manual reagent and consumable checks.

MAGLUMI® X3 Reagent and Consumables



Reagent Kit



Reaction Cup



Starter 1+2



Light Check



Wash Concentrate



System Tubing Cleaning Solution

Broad CLIA Test Menu with 260 Assays



Thyroid

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

Fertility

FSH
 LH
Total β -HCG **FDA**
 PRL (Prolactin)
 Estradiol
 Testosterone
 free Testosterone
 DHEA-S
 Progesterone
 Unconjugated Estriol
 17 α -OH Progesterone
 AMH
 SHBG
 Androstenedione
 PIGF
 sFit-1
 *Inhibin A
 *Inhibin B

Prenatal Screening

AFP (Prenatal Screening)
 free β -HCG
 PAPP-A
 Unconjugated Estriol
 *Inhibin A

TORCH

Toxo IgG
 Toxo IgM
 Rubella IgG
 Rubella IgM
 CMV IgG
 CMV IgM
 HSV-1/2 IgG
 HSV-1/2 IgM
 HSV-1 IgG
 HSV-2 IgG
 HSV-1 IgM
 HSV-2 IgM
 *Toxo IgG Avidity
 *CMV IgG Avidity
 *Parvovirus B19 IgG
 *Parvovirus B19 IgM

Metabolism

GH (hGH)
 IGF-I
 IGFBP-3

Infectious Disease

Hepatitis
 HBsAg
 Anti-HBs
 HBeAg
 Anti-HBe
 Anti-HBc
 Anti-HBc IgM
 Anti-HCV
 Anti-HAV
 HAV IgM
 HEV IgG
 HEV IgM
 *HBV Pre-S1 Ag
 *HDV IgG
 *HDV IgM
 *Anti-HDV

Respiratory
 2019-nCoV IgG
 2019-nCoV IgM
 SARS-CoV-2 S-RBD IgG
 SARS-CoV-2 Neutralizing Antibody
 SARS-CoV-2 Ag
Mycoplasma pneumoniae IgG
Mycoplasma pneumoniae IgM
Chlamydia pneumoniae IgG
Chlamydia pneumoniae IgM
 Respiratory Syncytial Virus IgM
 Coxsackievirus B IgM
 Adenovirus IgM
 Influenza A Virus IgM
 Influenza B Virus IgM
Legionella pneumophila IgM
 Human Parainfluenza Virus IgM

Others
 HIV Ab/Ag Combi
 Syphilis
 Chagas
 HTLV I+II
H. pylori IgG
H. pylori IgA
H. pylori IgM
 **H. pylori* Ag
 Dengue Virus IgG
 Dengue Virus NS1
 Dengue Virus IgM
 Monkeypox Virus Ag
 *TB-IGRAs
 *Zika Virus IgG
 *Zika Virus IgM
 *Zika Virus NS1
 **Chlamydia trachomatis* IgA
 **Chlamydia trachomatis* IgG

Bone Metabolism

Calcitonin β -CTx
 Osteocalcin total P1NP
 25-OH Vitamin D **FDA** PTH (1-84)
 Intact PTH *BAP

EBV

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

Autoimmune

Connective Tissue Disease
 ANA Screen
 ENA Screen
 Anti-dsDNA IgG
 Anti-Sm IgG
 Anti-Rib-P IgG
 Anti-SS-B IgG
 Anti-SS-A/Ro IgG (Ro60)
 Anti-Jo-1 IgG
 Anti-Scl-70 IgG
 Anti-Centromeres IgG
 Anti-Histones IgG
 Anti-Sm/RNP IgG
 Anti-Ro-52 IgG
 Anti-PM-Scl IgG
 *Anti-Nucleosome IgG

Rheumatoid Arthritis
 Anti-CCP
 *RF IgM
 *RF IgG
 *RF IgA
 *RF Screen

Celiac Disease
 tTG IgA
 tTG IgG
 DGP IgA
 DGP IgG

Autoimmune Liver Disease
 AMA-M2 IgG

Endocrinology
 Anti-TPO
 TGA (Anti-Tg)
 TRAb
 TMA
 Anti-GAD (GAD65)
 Anti-IA2
 ICA
 IAA (Anti Insulin)
 Anti-ZnT8

Vasculitis
 Anti-MPO IgG
 Anti-PR3 IgG
 Anti-GBM IgG

Antiphospholipid Syndrome
 Anti- β 2-Glycoprotein I IgG
 Anti- β 2-Glycoprotein I IgM
 Anti- β 2-Glycoprotein I IgA
 Anti- β 2-Glycoprotein I
 Anti-Cardiolipin IgG
 Anti-Cardiolipin IgM
 *Anti-Cardiolipin IgA
 *Anti-Cardiolipin

Anemia

Vitamin B12
 Ferritin
 Folate (FA)
 EPO
 RBC Folate
 *Anti-Intrinsic Factor
 *Active B12

Tumor Markers

AFP
 CEA
 Total PSA
 free PSA
 CA 125
 CA 15-3
 CA 19-9
 PAP
 CA 50
 CA 242
 CYFRA 21-1
 CA 72-4
 NSE
 S-100
 SCCA
 TPA-snibe
 ProGRP
 HE4
 HER-2
 PIVKA-II
 Pepsinogen I
 Pepsinogen II
 Gastrin-17
 *AFP-L3%

Cardiac

CK-MB
 Troponin I
 Myoglobin
 hs-cTnI
 hs-CRP
 H-FABP
 NT-proBNP
 BNP
 D-Dimer
 Lp-PLA2
 MPO
 HCY (Homocysteine)
 *sST2
 *hs-cTnI **STAT^{EX}**
 *NT-proBNP **STAT^{EX}**
 *Myoglobin **STAT^{EX}**
 *D-Dimer **STAT^{EX}**

Inflammation Monitoring

CRP
PCT (Procalcitonin)
 IL-6 (Interleukin 6)
 SAA (Serum Amyloid A)
 TNF- α
 IgE
 *VEGF
 *PCT **STAT^{EX}**
 *CRP **STAT^{EX}**

Neurology

NSE
 S-100
 * β -Amyloid (1-40) CSF
 * β -Amyloid (1-42) CSF
 *Phospho-Tau (181P) CSF
 *Total-Tau CSF
 * β -Amyloid (1-40) Plasma
 * β -Amyloid (1-42) Plasma
 *Phospho-Tau (181P) Plasma
 *Phospho-Tau (217P) Plasma
 *NfL Plasma

Kidney Function

β_2 -Microglobulin
 Albumin
 *NGAL

Glyco Metabolism

C-Peptide
 Insulin
 Proinsulin
 Anti-IA2
 ICA
 IAA (Anti Insulin)
 Anti-GAD (GAD65)
 Anti-ZnT8
 *Glucagon
 *Adiponectin (ADPN)

Drug Monitoring

Digoxin
 CSA (Cyclosporine A)
 FK 506 (Tacrolimus)
 *Sirolimus
 *Everolimus
 *Mycophenolic Acid

Hypertension

Direct Renin
 Aldosterone
 Angiotensin I
Angiotensin II
Cortisol
 ACTH

Coagulation Markers

D-Dimer
 TAT
 TM
 PIC
 tPAIC
 *FDP

Hepatic Fibrosis

Hyaluronic Acid (HA)
 PIIIP N-P
 C IV
 Laminin
 Cholyglycine
 GP73

STAT^{EX}

*hs-cTnI **STAT^{EX}**
 *NT-proBNP **STAT^{EX}**
 *Myoglobin **STAT^{EX}**
 *D-Dimer **STAT^{EX}**
 *PCT **STAT^{EX}**
 *CRP **STAT^{EX}**

Veterinary Testing

cTSH
 cTT4
 cFT4
 cCortisol
 cACTH



* Available soon

Note: Product availability may vary by country and is subject to required regulatory approval

Technical Specifications

Chemiluminescence Principle

- **Direct chemiluminescence**
- Magnetic microbeads separation, fast and efficient
- Key technology of ABEI-label and magnetic microbead separating enhances stability and sensitivity of **MAGLUMI®** reagents

Main Features

- **Throughput: up to 200 tests/hour**
- Space occupied < 0.68 m², throughput of per unit area > 296 T/h/m²
- 24 hours ready to use

Reagent Loading

- 20 reagent positions on board with no-pause loading/unloading
- 24-hour refrigerated, constant at 10°C (±3°C) in reagent area
- RFID reading all information of reagent
- Indicator light available, real-time status monitoring

Sample Loading

- Up to 72 sample positions
- **No-pause loading/unloading, STAT available**
- Indicator light available, real-time status monitoring
- **Barcode recognition: barcode reader available**
- Types of sample tube: micro sample cup, blood collection tube, plastic test tube
- **Sample editing mode: LIS connection, barcode recognition, manual editing**

Reagent Features

- **MAGLUMI®** reagent kits are compatible with all **MAGLUMI®** analyzers
- Calibrators and internal controls included
- 10 points master curve, 2-points re-calibration
- RFID tag storing all informations of reagents
- Storage temperature: 2°C-8°C

Reaction System

- Single reaction cup with five-sided heating at 37.0°C (±0.3°C) incubation, ensuring accurate, quick and uniform incubation
- Incubating 80 cuvettes simultaneously
- Non-contact mixing with different modes before incubation, ensuring sufficient reaction

Sampling System

- Titanium needle for crushproof
- Teflon coated for carry-over prevention
- Liquid level detection, clot detection, collision detection, wash automatically

Consumable System

- Single cup design, no-pause loading/unloading
- Starters: 230 mL of Starter 1 and Starter 2
- System liquid: Up to load 10 L at one time
- Indicator light monitors real-time consumable quantity

Washer

- 4-step washing technology
- Intelligent magnetic field design ensures excellent separation
- Three independent non-contact magnetic microbeads vortex cleaning technology
- Resuspension washing mode efficiently reduces non-specific binding and improves sensitivity
- Independent washing unit for waste liquid needle can completely wash without residue

Measuring Chamber

- High-sensitivity and low-noise photomultiplier tube (PMT)
- Heating and cooling bidirectional temperature control function included
- Original light pollution isolation technology prevents light pollution and ensures accurate and reliable results

Software System

- Friendly software UI design, humanized instrument operation procedure
- Real-time status display for each test procedure
- Self-recovery function makes sure the analyzer running smoothly without unnecessary manual intervention
- Bidirectional **SnibeLis®** connection by TCP/IP and COM Port
- Supporting **SnibeLinker®** remote diagnosis system

Dimensions & Weight

- Dimensions: 78 (h) × 90 (w) × 75 (d) cm
- Weight: 127 kg

MAGLUMI®, STAT-X™, SnibeLis® and SnibeLinker® are trademarks of Snibe. All other product names and trademarks are the property of their respective owners.



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Chapter 5 Software functions

5.1 Introduction to software interface

Double-click on the user software icon on the desktop after you log in to the Windows operating system. A login dialog will pop up in the interface after the software starts up. Enter your username and password, then click the **<Login>** button to access the main interface of the user software. The structure of each part of the software interface is introduced below.

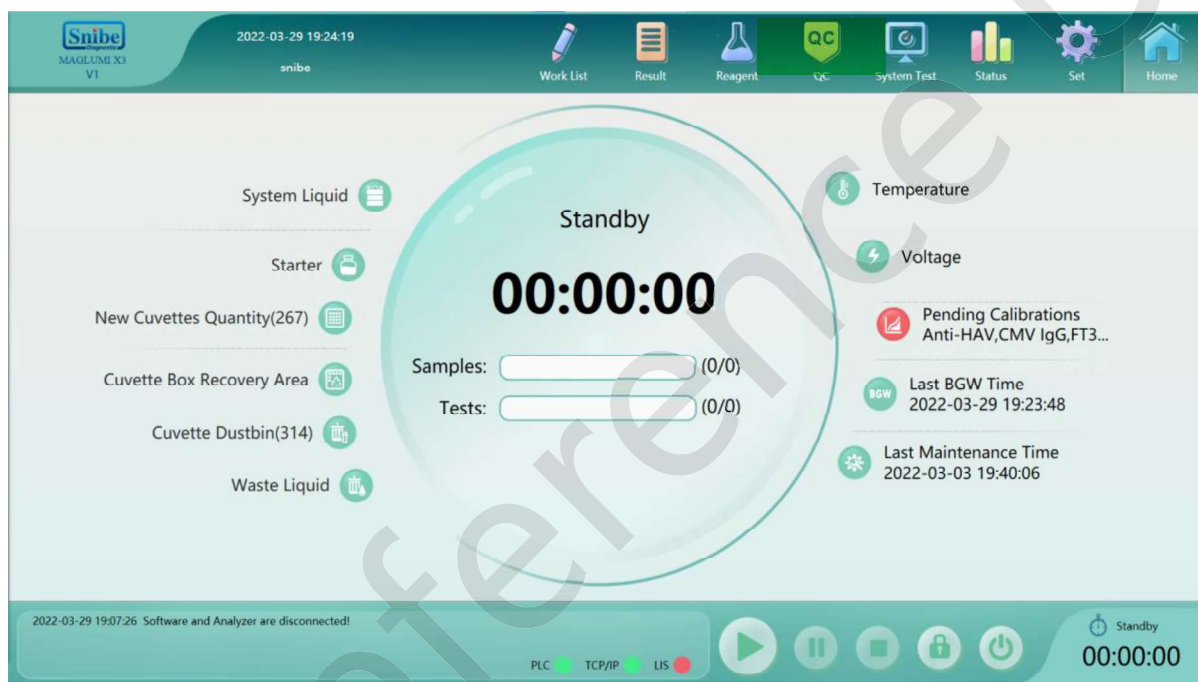


Figure 5.1-1 User software interface

5.1.1 Main menu

The main menu shows eight menu buttons.



Figure 5.1-2 Main menu of User Version software

Software functions

Descriptions of button functions are as follows.

Button	Function
Work List	Register samples and QC tests, run checks and other procedures.
Result	Check or delete sample test results, perform remeasuring or other actions.
Reagent	Check reagent information, register reagent calibration, check calibration results or perform other actions.
QC	View QC results, QC charts and perform other operations.
System Test	View system tests, system test results and perform other operations.
Status	Check analyzer temperature, voltage, consumables, etc.
Set	Set assay info, profile info, networking, language, etc.
Home	Display the status of the current part of the analyzer, test countdowns, etc.

5.1.2 Interfaces

The interfaces are used to show the details of each main function of the main menu and each interface is named after a main function of the main menu. The following figure shows the **[Work List]** interface.



Figure 5.1-3 [Work List] interface

5.1.3 Submenus

Click **<Menu>** on the main menu to access the submenu of this function. The submenu is named after the main menu button. The following figure shows the **[Set]** menu.



Parameter Basic Information

Panel	Assay	Sample Volume	Recommended Dilution Ratio	Measuring Range	Calibration Frequency	Reference Range	
Thyroid	TSH (3rd Generation) REF:130#03023M	100 µL	1:20	0.001-100 µIU/mL	28 days	0.3-4.5 µIU/mL	
	TT4 REF:130#53002M	40 µL	1:2	0.1-30 µg/dL	28 days	5.0-13 µg/dL	
	TT3 REF:130#53003M	40 µL	1:2	0.06-10 ng/mL	28 days	0.75-2.1 ng/mL	
	FT4 REF:130#53004M	40 µL	/	0.1-12 ng/dL	28 days	0.9 - 1.75 ng/dL	
	FT3 REF:130#53005M	40 µL	/	0.2-50 pg/mL	28 days	2-4.2 pg/mL	
	Tg (Thyroglobulin) REF:130#53006M	20 µL	1:10	0.02-500 ng/mL	28 days	3.5 - 77 ng/mL	
	TGA (Anti-Tg) REF:130#53007M	10 µL	1:10	0.5-2800 IU/mL	28 days	<95 IU/mL	
	Anti-TPO REF:130#53011M	10 µL	1:10	0.05-1000 IU/mL	28 days	<10 IU/mL	
	TRAb REF:130#53009M	10 µL	1:20	0.25-40 IU/L	7 days	<1.5 IU/L	
	TMA REF:130#53008M	10 µL	1:10	0.15-500 IU/mL	28 days	<10 IU/mL	
	Rev T3 REF:130#03010M	50 µL	/	0.05-10 ng/mL	7 days	0.31-0.95 ng/mL	
	T-Uptake REF:130#03014M	20 µL	/	0.1-2 TBI	28 days	0.8-1.3 TBI ; FT4I (free thyroxine index): 50-120 ng/mL	
	AFP REF:130#01033M	15 µL	1:50	0.500-1000 IU/mL	28 days	0-6.05 IU/mL	
	CEA REF:130#01032M	40 µL	1:50	0.200-1000 ng/mL	28 days	0-5.093 ng/mL	
	Total PSA REF:130#01034M	10 µL	1:19	0.002-400 ng/mL	28 days	≤4.0 ng/mL	
f-PSA REF:130#01035M	10 µL	1:5	0.010-50 ng/mL	28 days	fPSA/PSA<1/4		
CA 125 REF:130#01031M	15 µL	1:5	0.600-5000 U/mL	28 days	≤35 U/mL		
CA 15-3 REF:130#01038M	10 µL	1:10	1.000-1000 U/mL	28 days	95%: ≤28 U/mL 99%: ≤35 U/mL		
CA 19-9 REF:130#01037M	10 µL	1:10	0.600-1000 U/mL	28 days	95%: ≤28 U/mL 97.5%: ≤37 U/mL 99%: ≤41 U/mL		
PAP REF:130#51006M	40 µL	1:5	0.010-100 ng/mL	28 days	≤2.1 ng/mL		
CA 50 REF:130#01036M	10 µL	1:5	0.500-500 U/mL	28 days	≤25 U/mL		
CYFRA 21-1 REF:130#01040M	20 µL	1:5	0.100-1000 ng/mL	28 days	≤3.3 ng/mL		
CA 242 REF:130#01039M	15 µL	1:10	0.500-200 U/mL	28 days	≤10 U/mL		
CA 72-4 REF:130#01042M	40 µL	1:5	0.200-500 U/mL	28 days	95%: ≤6 U/mL 99%: ≤10 U/mL		
NSE REF:130#01030M	10 µL	1:5	0.050-500 ng/mL	28 days	95%: ≤15.7 ng/mL		
S-100 REF:130#51017M	100 µL	1:5	0.010-50 ng/mL	28 days	0-0.15ng/ml		
SCCA REF:130#01041M	80 µL	1:20	0.100-100 ng/mL	28 days	95%:≤2.5 ng/mL		
TPA REF:130#01043M	100 µL	1:10	3.00-6000 U/L	28 days	95%: ≤75 U/L		
ProGRP REF:130#01523M	100 µL	1:10	2.00-5000 pg/mL	7 days	95%: ≤69.2 pg/mL		
HE4 REF:130#01525M	15 µL	1:10	5.00-1500 pmol/L	7 days	98%: ≤140 pmol/L all women 95%: ≤70 pmol/L premenopausal women 95%: ≤140 pmol/L postmenopausal women		
HER-2 REF:130#01526M	20 µL	1:10	0.500-350 ng/mL	7 days	95%: ≤15.2 ng/mL		
PIVKA-II REF:130#01029M	100 µL	1:10	0.500-30000 mAU/mL	7 days	95%: ≤40 mAU/mL		
Fertility	FSH REF:130#52001M	40 µL	1:10	0.030-20 mIU/mL	28 days	Males: 1.4-12.6 mIU/mL Females: Follicular Phase: 3.3-12.9 mIU/mL Ovulation Phase: 4.5-22.1 mIU/mL Luteal Phase: 1.5-7.8 mIU/mL Postmenopause: 25.4-135.6 mIU/mL	
	LH REF:130#52002M	40 µL	1:10	0.030-250 mIU/mL	28 days	Males: 0.5-12.43 mIU/mL Females: Follicular Phase: 1.6-12.18 mIU/mL Mid-Cycle Peak: 7.31-92.53 mIU/mL Luteal Phase: 0.5-15.1 mIU/mL Postmenopause: 5.04-63.11 mIU/mL	
	HCG/β-HCG REF:130#52003M	15 µL	1:50	0.050-5000 mIU/mL	28 days	Comprehensive reference range, please refer to IFU	
	PRL(Prolactin) REF:130#52006M	15 µL	1:10	0.010-250 ng/mL	28 days	Males: 2.52-13.23 ng/mL Females: Premenopausal: 3.27-26.81 ng/mL Postmenopausal: 2.68-19.72 ng/mL	
	Estradiol REF:130#52007M	20 µL	1:10	1.000-4800 pg/mL	28 days	Male: 24.2-62.1 pg/mL Females: Follicular Phase: 11.2-225 pg/mL Ovulation Phase: 36.0-403 pg/mL Luteal Phase: 21.0-343 pg/mL Myoclasma Postmenopause: ≤136 pg/mL 1st Trimester: 152-3120 pg/mL 2nd Trimester: 1423-22032 pg/mL 3rd Trimester: ≤8413 pg/mL	
	Testosterone REF:130#52010M	20 µL	1:5	0.010-17 ng/mL	28 days	Males: 1.71-7.89 ng/mL Females: <0.92 ng/mL	
	Prenatal Screening	AFP(Prenatal Screening) REF:130#14001M	20 µL	/	1.130-500 IU/mL	14 days	Check the software for reference result
		free-β-HCG REF:130#14005M	40 µL	/	1.000-200 ng/mL	14 days	Check the software for reference result
		PAPP-A REF:130#64003M	20 µL	1:10	2.000-10000 mIU/L	28 days	Non-pregnant females: <8.13 mIU/L Median value during Pregnancy: 8 weeks: 548.797 mIU/L 9 weeks: 900.144 mIU/L 10 weeks: 1761.955 mIU/L 11 weeks: 2617.745 mIU/L 12 weeks: 4213.801 mIU/L 13 weeks: 6158.831 mIU/L
		free Estriol REF:130#02008M	80 µL	1:2	0.010-40.000 ng/mL	28 days	Week of gestation: 1-10: <0.01-0.85 ng/mL 11-14: <0.01-1.6 ng/mL 15-17: 0.11-2.7 ng/mL 18-20: 0.5-4.4 ng/mL 21-23: 0.8-5.6 ng/mL 24-26: 1.6-6.5 ng/mL 27-28: 2.2-7.2 ng/mL 31-32: 2.9-11.4 ng/mL 33-34: 3.1-13.8 ng/mL 35-36: 3.6-16.6 ng/mL 37-38: 3.6-16.6 ng/mL 39-40: 6.6-24.3 ng/mL
HbSAg REF:130#10009M		150 µL	1:99	0.020-250 IU/mL	14 days	Positive: ≥0.05 IU/mL Negative: <0.05 IU/mL	
Anti-HBs REF:130#10010M		40 µL	1:99	0.200-1000 mIU/mL	14 days	Positive: ≥10.0 mIU/mL Negative: <10.0 mIU/mL	
HBeAg REF:130#10011M		50 µL	1:999	0.010-200 IU/mL	14 days	Positive: ≥0.10 IU/mL Negative: <0.10 IU/mL	
Anti-HBe REF:130#10022M		20 µL	/	/	28 days	Positive: ≥1.00 AU/mL Negative: <1.00 AU/mL	
Anti-HBe REF:130#10023M		40 µL	/	/	14 days	Positive: ≥0.35 AU/mL Negative: <0.35 AU/mL	
Anti-HBc IgM REF:130#10014M		10 µL	/	/	14 days	Positive: ≥1.00 AU/mL Negative: <1.00 AU/mL	
Anti-HCV REF:130#10015M		50 µL	1:50	/	Every week	Positive: ≥1.00 AU/mL Negative: <1.00 AU/mL	
Syphilis REF:130#69003M		40 µL	/	/	14 days	Positive: ≥1.00 AU/mL Negative: <1.00 AU/mL	
Anti-HAV REF:130#10007M		20 µL	/	3.5-100.0 mIU/mL	Every week	Positive: ≥20mIU/mL Negative: <20 mIU/mL	
HAV IgM REF:130#10025M		10 µL	/	/	14 days	Positive: ≥1.00 AU/mL Negative: <1.00 AU/mL	
MIV Ag/Ab Combi REF:130#19008M		200 µL	/	/	2 weeks	Positive: ≥1.00 AU/mL Negative: <1.00 AU/mL	
Infectious Disease	Pneumoniae IgG REF:130#19009M	10 µL	/	/	14 days	Non-reactive: <1.00 AU/mL Reactive: ≥1.00 AU/mL	
	Mycoplasma Pneumoniae IgM REF:130#19011M	10 µL	/	/	14 days	Non-reactive: <1.00 AU/mL Reactive: ≥1.00 AU/mL	
	Chlamydia Pneumoniae IgG REF:130#19010M	10 µL	/	/	14 days	/	
	Chlamydia Pneumoniae IgM REF:130#19012M	10 µL	/	/	14 days	/	
	Dengue Virus IgM REF:130#19031M	10 µL	1:10	/	7 days	Non-reactive: <1.00 AU/mL Reactive: ≥1.00 AU/mL	
	Fertility	free Testosterone REF:130#52011M	40 µL	1:5	0.010-150 pg/mL	28 days	Males: 18-39years: 12.3-46.6 pg/mL 40-59years: 9.57-40.6 pg/mL ≥60 years: 7.72-31.4 pg/mL Females: 18-39years: ≤5.45 pg/mL ≥40years: ≤4.43 pg/mL
		DHEA-S REF:130#52012M	10 µL	1:10	0.100-1500 µg/dL	28 days	Comprehensive reference range, please refer to IFU
		Progesterone REF:130#52009M	10 µL	1:10	0.025-80 ng/mL	28 days	Males: 0.21-2.10 ng/mL Non-pregnant Females: Follicular Phase: 0.29-1.55 ng/mL Luteal Phase: 5.11-18.78 ng/mL Postmenopausal: ≤0.81 ng/mL Pregnancy: First Trimester: 4.89-51.31 ng/mL Second Trimester: 19.24-45.55 ng/mL
		free Estriol REF:130#52008M	80 µL	1:3	0.010-40ng/mL	28 days	Gestational Weeks: 1-10: 0.01-0.85 ng/mL 11-14: 0.01-1.6 ng/mL 15-17: 0.11-2.7 ng/mL 18-20: 0.5-4.4 ng/mL 21-23: 0.8-5.6 ng/mL 24-26: 1.6-6.5 ng/mL 27-28: 2.2-7.2 ng/mL 31-32: 2.9-11.4 ng/mL 33-34: 3.1-13.8 ng/mL 35-36: 3.6-16.6 ng/mL 37-38: 3.6-16.6 ng/mL 39-40: 6.6-24.3 ng/mL
		17-OH Progesterone REF:130#70004M	40 µL	1:10	0.035-30 ng/mL	28 days	Males: 0.29-2.06 ng/mL Females: Follicular Phases: 1.05 ng/mL Ovulation Phase: 0.13-1.46 ng/mL Luteal Phase: 0.27-4.21 ng/mL Postmenopause: ≤0.91 ng/mL Late Trimester: 2.24-9.30 ng/mL 1-13 years: 2.28 ng/mL 1month-1 year: 0.79-16.71 ng/mL
		AMH REF:130#52014M	40 µL	1:10	0.007-25 ng/mL	28 days	Males: 0.834-13.25 ng/mL Females: 20-24: 1.135-11.46 ng/mL 25-29: 0.775-9.752 ng/mL 30-34: 0.334-7.834 ng/mL 35-39: 0.133-6.653 ng/mL 40-44: 0.027-5.267 ng/mL 45-50: 0.040-2.824 ng/mL PCOS: 2.340-18.02 ng/mL
		SHBG REF:130#02515M	10 µL	1:10	0.200-250 nmol/L	14 days	Males: 20-49 years: 18.0-53.4 nmol/L ≥ 50 years: 18.7-74.2 nmol/L Females: 28.3-134 nmol/L
		Androstenedione REF:130#02516M	10 µL	1:5	0.020-10 nmol/L	7 days	Males: 0.602 - 3.10 ng/mL (2.10 - 10.8 nmol/L) Females: 0.303 - 3.32 ng/mL (1.06 - 11.6 nmol/L)
		PIGF REF:130#12010M	50 µL	/	2.00-10000 pg/mL	14 days	Gestational weeks: 10+0-14+6: 27.7-124 pg/mL 15+0-19+6: 66.9-295 pg/mL 20+0-23+6: 116-612 pg/mL 24+0-28+6: 171-1129 pg/mL 29+0-33+6: 111-1284 pg/mL 34+0-36+6: 74.6-1025 pg/mL 37+0-delivery: 53.2-904 pg/mL
		sFlt-1 REF:130#12011M	30 µL	/	6.0-85000 pg/mL	14 days	Gestational weeks: 10+0-14+6: 683-2625 pg/mL 15+0-19+6: 713-2822 pg/mL 20+0-23+6: 573-3035 pg/mL 24+0-28+6: 643-3293 pg/mL 29+0-33+6: 808-5279 pg/mL 34+0-36+6: 960-7543 pg/mL 37+0-delivery: 1478-9613 pg/mL
AFP(Ref) REF:130#14001M		20 µL	/	1.130-500 IU/mL	14 days	Check the software for reference result	
free-β-HCG(Ref) REF:130#14005M		40 µL	/	1.000-200 ng/mL	14 days	Check the software for reference result	
PAPP-A(Ref) REF:130#64003M		20 µL	1:10	2.000-10000 mIU/L	28 days	Non-pregnant females: <8.13 mIU/L Median value during Pregnancy: 8 weeks: 548.797 mIU/L 9 weeks: 900.144 mIU/L 10 weeks: 1761.955 mIU/L 11 weeks: 2617.745 mIU/L 12 weeks: 4213.801 mIU/L 13 weeks: 6158.831 mIU/L	
free Estriol(Ref) REF:130#02008M		80 µL	1:2	0.010-40.000 ng/mL	28 days	Week of gestation: 1-10: <0.01-0.85 ng/mL 11-14: <0.01-1.6 ng/mL 15-17: 0.11-2.7 ng/mL 18-20: 0.5-4.4 ng/mL 21-23: 0.8-5.6 ng/mL 24-26: 1.6-6.5 ng/mL 27-28: 2.2-7.2 ng/mL 31-32: 2.9-11.4 ng/mL 33-34: 3.1-13.8 ng/mL 35-36: 3.6-16.6 ng/mL 37-38: 3.6-16.6 ng/mL 39-40: 6.6-24.3 ng/mL	

Panel	Assay	Sample Volume	Recommended Dilution Ratio	Measuring Range	Calibration Frequency	Reference Range
Infectious Disease	Chagas REF:130#19001M	10 µL	/	/	2 weeks	Positive: ≥1.0 index/mL Negative: <1.0 index/mL
	HTLV I-II REF:130#19002M	50 µL	/	/	2 weeks	Positive: ≥1.0 index/mL Negative: <1.0 index/mL
	H.pylori IgG REF:130#01521M	10 µL	1:5	2.00-200 EIU	14 days	Positive: ≥30 EIU Negative: <30 EIU
	H.pylori IgA REF:130#51028M	10 µL	/	/	7 days	Positive: ≥1U/ml Negative: <1U/ml
	H.pylori IgM REF:130#51027M	10 µL	/	/	7 days	Positive: ≥1U/ml Negative: <1U/ml
	2019-nCoV IgG REF:130219015M	10 µL	1:9	/	Every week	Positive: ≥1.00 AU/mL Negative: <1.00 AU/mL
	2019-nCoV IgM REF:130219016M	10 µL	1:19	/	Every week	Positive: ≥1.00 AU/mL Negative: <1.00 AU/mL
	SARS-CoV-2 S-RBD IgG REF:130#19017M	10 µL	1:9	0.100-100 AU/mL	Every week	Positive: ≥1.00 AU/mL Negative: <1.00 AU/mL
	SARS-CoV-2 Neutralizing Antibody REF:130#19027M	40 µL	1:9	0.030-30 µg/mL	2 weeks	Positive: ≥200 µg/mL Negative: ≤0.050 µg/mL
	SARS-CoV-2 Ag REF:130#19026M	150 µL	/	4.00-10000 pg/mL	2 weeks	Negative: ≤ 25.0 pg/mL
	Monkeypox Virus Ag REF:130#19032M	100 µL	1:10	0.300-5000 pg/mL	7 days	Positive: ≥8.0 pg/mL Negative: <8.0 pg/mL
	Dengue Virus IgG REF:130#19030M	10 µL	1:10	0.500-200 AU/mL	7 days	Positive: ≥20.0 AU/mL Negative: <20.0 AU/mL
	Dengue virus NS1 REF:130#19029M	50 µL	1:20	0.500-400 AU/mL	7 days	Positive: ≥10.0 AU/mL Negative: <10.0 AU/mL
	Toxo IgG REF:130#12001M	10 µL	/	/	4 weeks	Positive: ≥2IU/ml Negative: <2IU/ml
	Toxo IgM REF:130#12002M	10 µL	/	/	4 weeks	Positive: ≥2.6AU/mL Equival: 25 x<2.6 AU/mL Negative: <2AU/mL
Rubella IgG REF:130#12003M	10 µL	/	/	4 weeks	Positive: ≥2IU/ml Negative: <2IU/ml	
Rubella IgM REF:130#12004M	10 µL	/	/	Every week	Positive: ≥3AU/mL Equival: 25 x<3 AU/mL Negative: <2AU/mL	
CMV IgG REF:130#12005M	10 µL	/	/	Every week	Positive: ≥2 AU/mL Negative: <2AU/mL	
CMV IgM REF:130#12006M	10 µL	/	/	4 weeks	Positive: ≥4.2 AU/mL Equival: 2<x<4.2 AU/mL Negative: <2 AU/mL	
HSV-12 IgG REF:130#62007M	10 µL	/	/	28 days	Negative: <2AU/mL Positive: ≥2AU/mL	
HSV-12 IgM REF:130#62009M	10 µL	/	/	28 days	Positive: ≥4AU/mL Equival: 2.00x<4.00 AU/mL Negative: <2AU/mL	
HSV-1 IgG REF:130#12012M	10 µL	/	0.020-30AU/mL	7 days	Positive: ≥1AU/mL Equival: 0.85x<1.00 AU/mL Negative: <0.8 AU/mL	
HSV-2 IgG REF:130#62008M	10 µL	/	/	28 days	Positive: ≥2AU/mL Negative: <2AU/mL	
HSV-1 IgM REF:130#12013M	10 µL	1:4	/	7 days	Non-reactive: <10.0 AU/mL Reactive: ≥10.0 AU/mL	
HSV-2 IgM REF:130#12014M	10 µL	1:4	/	7 days	Non-reactive: <10.0 AU/mL Reactive: ≥10.0 AU/mL	
EBV	EBV EA IgG REF:130#65001M	10 µL	/	/	28 days	Positive: ≥4.00 AU/mL Negative: <4.00 AU/mL
	EBV EA IgA REF:130#65002M	10 µL	/	/	28 days	Positive: ≥3.00 AU/mL Negative: <3.00 AU/mL
	EBV VCA IgG REF:130#65003M	10 µL	/	/	28 days	Positive: ≥4.00 AU/mL Negative: <4.00 AU/mL
	EBV VCA IgM REF:130#65004M	20 µL	/	/	28 days	Positive: ≥3.00 AU/mL Negative: <3.00 AU/mL
	EBV VCA IgA REF:130#65005M	10 µL	/	/	28 days	Positive: ≥4.00 AU/mL Negative: <4.00 AU/mL
	EBV NA IgG REF:130#65006M	10 µL	/	/	28 days	Positive: ≥4.00 AU/mL Negative: <4.00 AU/mL
	EBV NA IgA REF:130#15008M	10 µL	/	/	28 days	Positive: ≥1.00 AU/mL Negative: <1.00 AU/mL
	CK-MB REF:130#56001M	20 µL	1: 10	0.1-500ng/mL	28 days	Men: < 6.15 ng/mL Women: < 4.91 ng/mL
	Troponin I REF:130#56002M	100 µL	1: 10	0.006-50ng/mL	14 days	≤0.04 ng/mL
	Myoglobin REF:130#56003M	10 µL	1: 10	0.200-4000ng/mL	28 days	Men: 20.1-89.5 ng/mL Women: 16.2-58.7 ng/mL

Panel	Assay	Sample Volume	Recommended Dilution Ratio	Measuring Range	Calibration Frequency	Reference Range
Hypertension	Direct Renin REF:130#06511M	100 µL	1:10	0.500-1000 µIU/mL	14 days	Upright posture: 4.20-45.6 µIU/mL Supine posture: 3.11-41.2 µIU/mL
	Aldosterone REF:130#56007M	50 µL	1:50	5.000-2000pg/mL	28 days	Serum and plasma: Supine: 28-239 pg/mL Upright: 28-376 pg/mL Urine (24 hours) 1.1- 30.0 µg/day
	Angiotensin I REF:130#06005M	100 µL	1:10	0.100-24ng/mL	7 days	Normal Diet: Lying position: 0.15-2.33 ng/mL/hr; Standing position: 0.10-6.56 ng/mL/hr
	Angiotensin II REF:130#06006M	100 µL	1:10	5.000-1000pg/mL	7 days	Normal Diet: Lying position: 25-60pg/mL Standing position: 50-120pg/mL
	Cortisol REF:130#70002M	40µL	1:10	0.500-600 ng/mL	28 days	Serum: 6:00-10:00 : 45.5-208.2 ng/mL 16:00-20:00: 25.2-124.5 ng/mL Urine: 53-385 µg/24-hour
	ACTH REF:130#70003M	200 µL	1:10	1.00-2000pg/mL	28 days	7.2-63.5 pg/mL
Inflammation monitoring	CRP REF:130#66002M	10 µL	1: 5	0.0100-100mg/L	28 days	≤5 mg/L
	PCT REF:130#66001M	10 µL	1: 8	0.010-100ng/mL	28 days	≤0.05 ng/mL
	IL-6 REF:130#16504M	100 µL	1: 10	0.500-5000pg/mL	7 days	≤7 pg/mL
Glyco metabolism	SAA REF:130#16005M	10 µL	1: 5	0.100-300 µg/mL	14 days	≤10 µg/mL
	TNF-α REF:130#16006M	100 µL	1: 10	1.50 pg/mL-1000 pg/mL	28 days	≤8.00 pg/mL (95th percentile)
	C-Peptide REF:130#55001M	30 µL	1:10	0.005-40 ng/mL	28 days	Serum/plasma: 1.0-4.3 ng/mL Urine (24 hours): 16.9-187 µg/day
	Insulin REF:130#55002M	40 µL	1:10	0.05-300 µIU/mL	28 days	2.7-24.8 µIU/mL
	GAD 65 REF:130#55005M	50 µL	1:100	0.2-2000 IU/mL	28 days	<10 IU/mL
	Anti-IA2 REF:130#05508M	100 µL	1:40	2-1000 IU/mL	28 days	<10 IU/mL
Bone metabolism	ICA REF:130#05506M	50 µL	1:10	2-280 U/mL	7 days	≤28 U/mL
	IAA (Anti Insulin) REF:130#55003M	10 µL	1:10	0.5-175 AU/mL	28 days	≤20.0 AU/mL
	Proinsulin REF:130#55004M	100 µL	1:5	2-5000 pg/mL	28 days	30-180 pg/mL
	Calcitonin REF:130#61002M	100 µL	1:10	0.3-2000 pg/mL	7 days	Males: ≤9.72 pg/mL Females: ≤6.70 pg/mL
	Osteocalcin REF:130#61003M	80 µL	1:5	0.50-300 ng/mL	28 days	Women Pre-menopausal: 11-46 ng/mL; Women Post-menopausal: 14-50 ng/mL; Men 18-30: 22-76 ng/mL; Men 30-50: 12-45 ng/mL; Men 50-70: 11-50 ng/mL;
	25-OH Vitamin D REF:130#61004M	10 µL	1:2	0.05-150 ng/mL	28 days	Deficiency <10 ng/mL; Insufficiency 10-29 ng/mL; Sufficiency 30-100 ng/mL; Toxicity >100 ng/mL;
	Intact PTH REF:130#61001M	100 µL	1:10	1-5000 pg/mL	28 days	15-65 pg/mL
	β-CTX REF:130#11006M	100 µL	/	0.005-6 ng/mL	28 days	Comprehensive reference range, please refer to IFU
	total P1NP REF:130#11005M	10 µL	1:2	2-1200 ng/mL	28 days	Pre-menopausal women: 15.0-59 ng/mL Post-menopausal women: 20.0-76.5 ng/mL
	Autoimmune	Anti-Jo-1 IgG REF: 130#17509M	10 µL	1:20	0.500-400 AU/mL	7 days
Anti-Scl-70 IgG REF: 130#17505M		10 µL	1:20	0.500-400 AU/mL	7 days	Negative: <20.0 AU/mL Positive: ≥ 20.0 AU/mL
Anti-nRNP/Sm IgG REF: 130#17511M		10 µL	1:20	0.500-400 AU/mL	7 days	Negative: <20.0 AU/mL Positive: ≥ 20.0 AU/mL
Anti-Sm IgG REF: 130#17512M		10 µL	1:20	0.500-400 AU/mL	7 days	Negative: <20.0 AU/mL Positive: ≥ 20.0 AU/mL
Anti-SS-A IgG REF: 130#17513M		10 µL	1:20	0.500-400 AU/mL	7 days	Negative: <20.0 AU/mL Positive: ≥ 20.0 AU/mL
Anti-SS-B IgG REF: 130#17514M		10 µL	1:20	0.500-400 AU/mL	7 days	Negative: <20.0 AU/mL Positive: ≥ 20.0 AU/mL
GAD 65 REF: 130#55005M		50 µL	1:100	0.200-2000 IU/mL	28 days	Negative: <10 AU/mL Positive: ≥ 10 AU/mL
ANA Screen REF: 130#17503M		20 µL	1:20	0.500-400 AU/mL	7 days	Negative: <40AU/mL Positive: ≥40.0 AU/mL
Anti-Rib-P IgG REF: 130#17510M		10 µL	1:20	0.500-400 AU/mL	7 days	Negative: <20 AU/mL Positive: ≥ 20 AU/mL
Anti-CCP REF: 130#17501M		10 µL	1:20	0.500-500 U/mL	7 days	Negative: <17.0 U/mL Positive: ≥17.0 U/mL
Anti-TPO REF: 130#53011M		10 µL	1:10	0.050-1000 IU/mL	28 days	≤10 IU/mL
TGA (Anti-Tg) REF: 130#53007M		10 µL	1:10	0.500-2800 IU/mL	28 days	≤95 IU/mL
TMA (Anti-TM) REF: 130#53008M		10 µL	1:10	0.150-500 IU/mL	28 days	<10 IU/mL
ENA Screen REF: 130#17504M		20 µL	1:20	0.500-200 AU/mL	7 days	Negative: <20 AU/mL Positive: ≥20.0 AU/mL
Anti-IA2 REF: 130#05508M		100 µL	1:40	2.00-1000 IU/mL	28 days	Negative: <10 IU/mL Positive: ≥10 IU/mL
Anti-dsDNA IgG REF: 130#17502M		10 µL	1:20	0.500-800 IU/mL	7 days	Negative: <30 IU/mL Positive: ≥30.0 IU/mL
Anti-MPO IgG REF: 130#17015M		10 µL	1:40	0.500-400 AU/mL	7 days	≤20 AU/mL
Anti-M2-3E IgG (AMA-M2 IgG) REF: 130#17507M		10 µL	1:20	0.500-400 AU/mL	7 days	Negative: < 20 AU/mL Positive: ≥20.0 AU/mL
IAA REF: 130#55003M		10 µL	1:10	0.500-175 AU/mL	28 days	≤ 20 AU/mL
ICA REF: 130#05506M		50 µL	1:10	2.00-280 U/mL	7 days	≤ 28 U/mL
Anti-Centromeres IgG REF: 130#17506M	10 µL	1:20	0.500-400 AU/mL	7 days	Negative: < 20 AU/mL Positive: ≥20.0 AU/mL	
Anti-Histones IgG REF: 130#17508M	10 µL	1:20	0.500-400 AU/mL	7 days	Negative: < 20 AU/mL Positive: ≥20.0 AU/mL	
Anti-Cardiolipin IgG REF: 130#17017M	10 µL	1:20	0.50-400 AU/mL	7 days	Negative: < 20 AU/mL Positive: ≥20.0 AU/mL	

Panel	Assay	Sample Volume	Recommended Dilution Ratio	Measuring Range	Calibration Frequency	Reference Range
Autoimmune	Anti-Cardiolipin IgM REF: 130#17016M	10 µL	1:20	0.50-400 AU/mL	7 days	Negative: < 20 AU/mL Positive: ≥20.0 AU/mL
	Anti-β2-Glycoprotein 1 IgG REF: 130#17018M	10 µL	1:20	0.50-400 AU/mL	7 days	Negative: < 20 AU/mL Positive: ≥20.0 AU/mL
	Anti-β2-Glycoprotein 1 IgM REF: 130#17019M	10 µL	1:20	0.500-400 AU/mL	7 days	Negative: < 20 AU/mL Positive: ≥20.0 AU/mL
	Anti-TG IgA REF: 130#17020M	10 µL	1:20	0.500-400 AU/mL	7 days	Negative: < 20 AU/mL Positive: ≥20.0 AU/mL
	Anti-TG IgG REF: 130#17021M	10 µL	1:20	0.500-400 AU/mL	7 days	Negative: < 20 AU/mL Positive: ≥20.0 AU/mL
	DGP IgA REF: 130#17022M	10 µL	1:20	0.500-400 AU/mL	7 days	Negative: < 20 AU/mL Positive: ≥20.0 AU/mL
Hepatic function	DGP IgG REF: 130#17023M	10 µL	1:20	0.500-400 AU/mL	7 days	Negative: < 20 AU/mL Positive: ≥20.0 AU/mL
	C IV (Col IV) REF: 130#59003M	40 µL	1:10	1.00-2000 ng/mL	28 days	≤30.0 ng/mL
	Laminin REF: 130#59004M	80 µL	1:5	1.00-1000 ng/mL	28 days	≤50.0 ng/mL
	Cholyglycine REF: 130#59005M	20 µL	1:5	0.025-40.0 µg/mL	28 days	≤2.7 µg/mL
	PIIP N-P REF: 130#59002M	40 µL	1:5	0.200-2000 ng/mL	28 days	≤30 ng/mL
	HA REF: 130#59001M	60 µL	1:5	1.00-2000 ng/mL	28 days	≤100 ng/mL
Drug Monitoring	GP73 REF: 130#09006M	10 µL	1:10	1.00-1000 ng/mL	28 days	≤45 ng/mL
	Digoxin REF: 130#57002M	40 µL	/	0.070-50.0 ng/mL	28 days	0.9-2.0 ng/mL
	CSA REF: 130#57001M	80 µL	1:2	10.0-2000 ng/mL	28 days	/
	FK 506 REF: 130#57003M	40 µL	1:2	0.100-50.0 ng/mL	28 days	/
	Vitamin B12 REF: 130#63002M	100 µL	1:2	5.00-2000 pg/mL	28 days	192-827 pg/mL
	Ferritin REF: 130#51001M	20 µL	1:20	0.100-3000ng/mL	28 days	Males: 24-425 ng/ mL Females: 7-227 ng/mL
Anemia	Folate (FA) REF: 130#63001M	80 µL	1:5	0.200-24ng/mL	7 days	Serum and Plasma folate: ≥25.2ng/mL RBC folate: 284-786ng/mL
	EPO REF: 130#13003M	50 µL	1:5	0.300-1500IU/mL	28 days	2.6-19.0 mIU/mL
	IgM REF: 130#58002M	10 µL	/	25.0-20000 µg/mL	28 days	Serum: <1 years old : <25 - 1456 µg/mL 1-3 years old: 187-1490 µg/mL 4-6 years old: 234 - 2139 µg/mL 7-9 years old: 301 - 2097 µg/mL 10-11 years old: 303 - 1795 µg/mL 12-13 years old: 340 - 2433 µg/mL 14-15 years old: 147 - 1916 µg/mL 16-18 years old: 229 - 2621 µg/mL Adults: 385 - 2381 µg/mL
	IgA REF: 130#58004M	10 µL	/	serum and plasma 2.50-20000µg/mL urine: 0.100-40 µg/mL	28 days	Serum: <1 years old : <2.50 - 842 µg/mL 1-3 years old: 197-1024 µg/mL 4-6 years old: 268 - 2007 µg/mL 7-9 years old: 335 - 3055 µg/mL 10-11 years old: 517 - 2053 µg/mL 12-13 years old: 563 - 3631 µg/mL 14-15 years old: 457 - 2547 µg/mL 16-18 years old: 603 - 3561 µg/mL Adults: 745 - 4102 µg/mL Urine: 18-79 years olds 6 µg/mL
	IgE REF: 130#58001M	20 µL	1:3	0.100-3200IU/mL	28 days	<1 years old : 15 IU/mL 1-5 years old: 60 IU/mL 6-9 years old: 90 IU/mL 10-17 years old: 200 IU/mL Adults: 100 IU/m
	IgG REF: 130#58005M	10 µL	/	serum, plasma: 25.0-80000µg/mL urine: 1.00-2000µg/mL	28 days	Serum: <1 years old : 2296 - 14246 µg/mL 1-3 years old: 4483 - 9218 µg/mL 4-6 years old: 4962 - 14813 µg/mL 7-9 years old: 5591 - 14944 µg/mL 10-11 years old: 6940 - 15962 µg/mL 12-13 years old: 7455 - 15820 µg/mL 14-15 years old: 6965 - 17219 µg/mL 16-18 years old: 5472 - 16021 µg/mL Adults: 7454 - 16878 µg/mL Urine: 5-79 years olds 8.5 mg/24-hour
Kidney function	β2-MG REF: 130#54001M	10 µL	1:10	0.005-10 µg/mL	28 days	Serum: ≤2.1 µg/mL urine: ≤0.15 µg/mL
	Albumin REF: 130#54002M	20 µL	1:10	0.200-480 µg/mL	28 days	Excretion rates: ≤19.6 µg/min 24-hour urine: ≤28.4 mg/24-hour
	Pepsinogen I REF: 130#51019M	20 µL	1:5	0.100-500ng/mL	28 days	Less than 70 ng/mL for the PG I level and less than 3.0 for the PG I/II ratio as cut-off values gave the highest detection rate in the diseases with atrophy of fundic gland mucosa
Metabolism	Pepsinogen II REF: 130#51020M	50 µL	1:5	0.050-100ng/mL	28 days	Less than 70 ng/mL for the PG I level and less than 3.0 for the PG I/II ratio as cut-off values gave the highest detection rate in the diseases with atrophy of fundic gland mucosa
	Gastrin-17 REF: 130#01522M	80 µL	1:10	0.200-500pmol/L	14 days	1.7 pmol/L ~7.6 pmol/L
	GH (hGH) REF: 130#70001M	20 µL	1:10	0.010-50ng/mL	28 days	Men: 0-10 years old: 0.085 - 6.61 ng/mL 11-19 years old: 0.071 - 11.2 ng/mL 20-79 years old: <0.010 - 2.54 ng/mL Women: 0-10 years old: 0.113 - 7.95 ng/mL 11-20 years old: 0.119 - 8.30 ng/mL 21-77 years old: 0.116 - 9.17 ng/mL
	IGF-I REF: 130#55007M	10 µL	1:2	2.500-2000 ng/mL	28 days	Comprehensive reference range, please refer to IFU
	IGFBP-3 REF: 130#98505M	10 µL	/	0.050-16 µg/mL	7 days	Comprehensive reference range, please refer to IFU

Opened at 2-8°C, the stability of all reagents is 6 weeks except for the assays below

Assay	Opened Stability	Assay	Opened Stability
free Estriol	4 weeks	Toxo IgG	4 weeks
AFP(Prenatal Screening)	4 weeks	Toxo IgM	4 weeks
free-β-HCG	4 weeks	Rubella IgG	4 weeks
HBeAg	4 weeks	Rubella IgM	4 weeks
Anti-HCV	4 weeks	CMV IgG	4 weeks
Anti-HAV	4 weeks	CMV IgM	4 weeks
HIV Ag/Ab Combi	4 weeks	Direct Renin	4 weeks
Chagas	4 weeks	Angiotensin I	4 weeks
HTLV I+II	4 weeks	Angiotensin II	4 weeks
Rev T3	4 weeks		

Conversion factor of MAGLUMI® immunoassays

Assay	Conversion Factor	Assay	Conversion Factor
TT4	nmol/L x 0.077688 = µg/dL µg/dL x 12.872 = nmol/L	D-dimer	µg FEU/mL×1=mg FEU/L µg FEU/mL×1000=ng FEU/mL
TT3	nmol/L x 0.651 = ng/mL ng/mL x 1.536 = nmol/L	Angiotensin I	nmol/L = 0.771 ng/mL
FT4	pmol/L x 0.077688 = ng/dL ng/dL x 12.872 = pmol/L	Angiotensin II	pmol/L = 0.956 pg/mL
FT3	pmol/L x 0.651 = pg/mL pg/mL x 1.536 = pmol/L	ACTH	pg/mL x 0.2202 = pmol/L
AFP	IU/mLx1.21=ng/mL	C-Peptide	ng/mL×0.3333= nmol/L; nmol/L×3.0=ng/mL
PRL(Prolactin)	ng/mL×21.2=µIU/mL	Calcitonin	pg/mL×0.293=pmol/L
Estradiol	pmol/L×0.272 = pg/mL	Osteocalcin	ng/mL × 0.171 = nmol/L
Testosterone	ng/mL×3.47= nmol/L	25-OH Vitamin D	ng/mL×2.50=nmol/L
DHEA-S	µg/dL×0.02714=µmol/L	Intact PTH	pg/mL×0.106=pmol/L
Progesterone	ng/mL×3.18=nmol/L	C IV (Col IV)	ng/mL×0.002=nmol/L
Free Estriol	ng/mL×3.467=nmol/L	Cholyglycine	2.148×µg/mL=µmol/L nmol/L x 0.78 = ng/mL ng/mL x 1.28 = nmol/L
SHBG	nmol/L×0.095=µg/mL	Digoxin	ng/mL×1=µg/L; ng/mL×0.8315=nmol/L
Androstenedione	ng/mL×3.492=nmol/L	CSA	ng/mL×1=µg/L; ng/mL×0.8315=nmol/L
AFP(Prenatal Screening)	IU/mL×1.21= ng/mL	Vitamin B12	pg/mL×0.738=pmol/L µg/mL×0.001=µg/L µg/mL×0.00103 = µmol/L
hs-cTnI	pg/mL×1=ng/L	IgM	µmol/L×971 =µg/mL
NT-proBNP	pg/mL × 0.118 = pmol/L	IgA	µg/mL×0.001 = g/L µg/mL×0.00625 = µmol/L
BNP	pg/mL×0.289= pmol/L	IgE	IU/mL×2.4=ng/mL
GH (hGH)	ng/mL×3.0 = mIU/L	IgG	µg/mL×0.001=ng/L µg/mL×1=mg/L µg/mL×0.00667= µmol/L

Except for the following assays, all assays can be applied in serum and plasma

Assay	Sample Type	Assay	Sample Type
PAP	serum	Angiotensin I	plasma
NSE	serum	BNP	plasma
S-100	serum	D-dimer	plasma
TPA-snibe	serum	MPO	plasma
PIGF	serum	D-dimer	plasma
sFlt-1	serum	TAT	plasma
AFP(Prenatal Screening)	serum	TM	plasma
free-β-HCG	serum	IPIC	plasma
PAPP-A	serum	IPaIC	plasma
Anti-HAV	serum	Direct Renin	plasma
Toxo IgG	serum	Angiotensin II	plasma
Toxo IgM	serum	ACTH	plasma
Rubella IgG	serum	Aldosterone	serum/plasma/urine
Rubella IgM	serum	C-Peptide	serum/plasma/urine
CMV IgG	serum	IgA	serum/plasma/urine
CMV IgM	serum	IgG	serum/plasma/urine
ICA	serum	β2-MG	serum/plasma/urine
Proinsulin	serum	Folate (FA)	serum/plasma/whole blood
ICA	serum	Albumin	urine
Cholyglycine	serum	CSA	whole blood
Gastrin-17	serum	FK 506	whole blood
IGFBP-3	serum	SARS-CoV-2 Ag	nasopharyngeal swab / oropharyngeal swab