Humasis

Innovative diagnostic kits for people's better lives.

GLOBAL

Beyond Korea and around the world,
Humasis is rapidly growing
to become the global company

Contents

Company Introduction

Humasis was founded as a bio-venture company that develops, manufactures and promotes innovative in-vitro diagnostic products in 2000. Thanks to our dedication and effort specializing in R&D, we keep developing and launching the new products every year and have fulfilled the customers' need for high quality of products. As a result, Humasis has been certified ISO13485 as well as GMP, which proves that all of Humasis products are manufactured under the strict quality control.

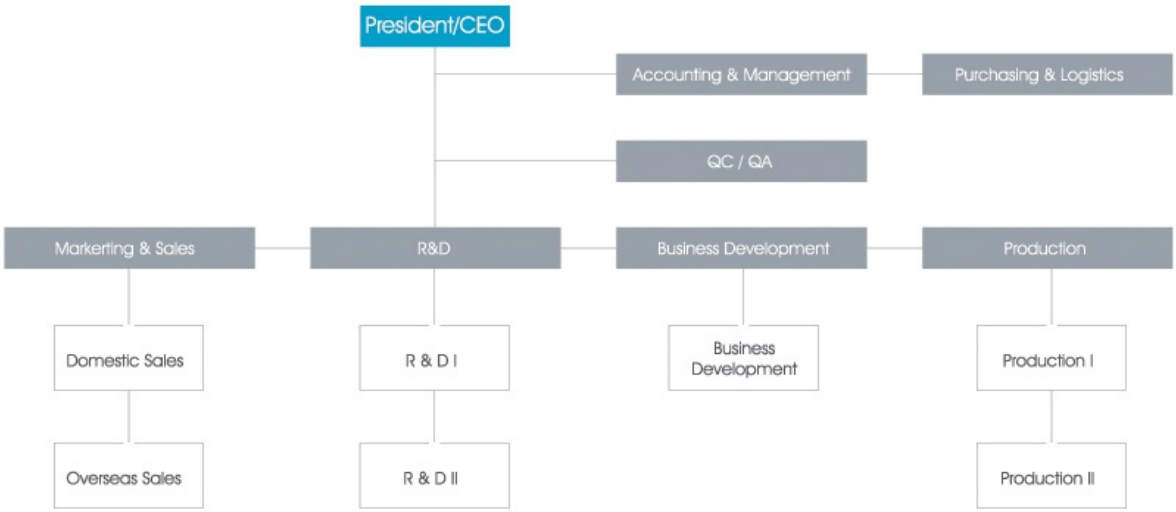
In addition to our technology and the know-how, Humasis has been communicating and working with several social networking such as pharmaceutical companies, hospitals and universities to share the knowledge and contribute more.

We believe our passion to our vision, "innovative products for people's better life", will lead to provide the excellent medical and health care system.

Company History

2000
06 - Founded Company (kowon Institute of Technology Innovation B/D, Suwon University).
09 - Moved Head Office (345-1, Dangjeong-dong, Gunpo-si, Gyeonggi-do).
12 - Executed Government (MOCIE) Project of "Development of Biomarkers and Detection System for Evaluation of Chemical Exposure".
12 - Launched Pregnancy Test.
12 - Approved Manufacturing Certificate of In-vitro Diagnostics(KFDA).
2001
05 - Launched Ovulation Tests.
08 - Applied Inexscreen, "Diagnostic Device for Pregnancy and Ectopic Pregnancy Screening" to World Patent (PCT/KR01/01365).
2002
03 - Registered Trade Mark, "HUMASIS" (No. 40-2001-0043375).
03 - Allied with Han-All Pharmaceutical Co Ltd.
07 - Acquired Certificate of CLEAN WORKPLACE (KOSHA).
11 - Launched Hepatitis B Virus Test.
2003
03 - Established Humasis Research Center.
03 - Launched Acute Myocardial Infarction Tests (Troponin I, Myoglobin, CK-MB).
04 - Launched Inexscreen.
08 - Launched Menopause Test.
10 - Registered Patent of Inexscreen in Korea (No. KP0403871).
2004
03 - Launched HCV Test and HIV 1/2 Test.
04 - ISO 9001 Certified.
04 - Launched Botulinum A/B/E Triple Test and Anthrax PA/LF Test
07 - Launched PSA Test.
2005
03 - Entered into Partnership with Yuhan Corporation for Development of New Diagnostic Platform Technology.
04 - Launched AFP Test.
2006
04 - Launched Acute Myocardial Infarction Tests(Single, Double, Triple Plus).
05 - ISO 13485 Certified.
06 - Launched FOB Test.
07 - Executed Government Project of "The Development of web-based POCT system", supported by Korea Ministry of Commerce, Industry and Energy.
Registered Patent of Inexscreen in China (No. ZL01814071.8)
09 - CE Mark certified (5 Products with Cardiac Troponin I)
2007
04 - Transfer of the Head Office/Factory (Shinwon Vision Tower, Anyang-si, Hogye-dong, Korea).
06 - INNO BIZ Certified.
08 - CE Mark certified (FSH & LH self tests)
2008
01 - CE Mark Certified (CK-MB & Myoglobin)
02 - Patented Inexscreen (for screening Ectopic Pregnancy) in US (Patent No.:7332350)
06 - Chosen by SMBA (Small & Medium Business Administration) for Government Project
10 - CE Mark Certified (PSA Card-ListB)
2009
01 - CE Mark Certified (CEA, H.pylori, Syphilis)
12 - Certified KGMP
2010
01 - Launched Influenza A/B antigen Test
02 – CE Mark certified (HUBI-QUAN pro®, HUBI TNI, HUBI 3-in-1)
04 - Launched quantitative strip reader, HUBI-QUAN pro®
05 - Chosen by SMBA (Small & Medium Business Administration) for eco-friendly technology at facilities.
07 – Launched Malaria P.f/Pan Antigen Test
2011
04 – Launched Rapid Flu™ - Influenza antibody Test
05 – Launched Malaria P.f/P.v. Test & Malaria P.f Antigen Test
07 – Launched Dengue IgG/IgM test
09 – Registered patent of 'Diagnostic device for measuring the ratio of Proteins with similar structure' in Korea (No. KP1068612)
2012
01 – Registered Patent of 'Diagnostic device for measuring the ratio of Proteins with similar structure' in US (No.8101369)
03 – Launched Urine analyzer, U-AQ core and U-AQ smart and strip
05 – Launched Dengue NS1 antigen Test
12 – Executed government R&D project for Malaria P.f/(pLDH) and G6PD diagnosis.
2013
03 – Launched *Helicobacter pylori Antigen test* and RSV antigen Test
09 – Select as the company to develop the device and the monitoring system based on quantitative system by Ministry of trade, industry & energy
09 – Launched Dengue Combo (NS1 and IgG/IgM) Test

Organization chart



GLOBAL

Dream of becoming the best and global Healthcare company.
Humasis is realizing its dream.

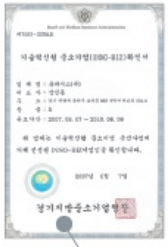
Certification

US Patent

China Patent

CE

ISO 13485



INNO-BIZ

GMP

PRODUCTS LIST

Product Name	Cat.No.	Format	Package	Measuring range	Specimen	Shelf life
Quantitative POCT Analyzer						
HUBI QUAN PRO	AHQ-8001	Quantitative assay platform				
HUBI Troponin I	ACTI-8025	Cassette	25tests/case	0.05~20ng/mL	Whole blood or Plasma	12Months
HUBI CKMB	ACCK-8025	Cassette	25tests/case	1.5~30ng/mL	Whole blood or Plasma	12Months
HUBI Myoglobin	ACMG-8025	Cassette	25tests/case	20~350ng/mL	Whole blood or Plasma	9Months
HUBI BNP	ABNP-8025	Cassette	25tests/case	25~800ng/mL	Whole blood or Plasma	12Months
HUBI DUO(TnI/CKMB)	ACDC-8025	Cassette	25tests/case	0.05~20ng/mL 1.5~30ng/mL	Whole blood or Plasma	12Months
HUBI Cardiac 3 in 1	ACTM-8025	Cassette	25tests/case	TnI-0.05~20ng/mL CKMB-1.5~30ng/mL Myo-20~350ng/mL	Whole blood or Plasma	12Months
HUBI 3 in 1(B)	ACTCB-8025	Cassette	25tests/case	TnI-0.05~20ng/mL CKMB-1.5~30ng/mL BNP- 25~800ng/mL	Whole blood or Plasma	12Months
HUBI hCG	ANP-8025	Cassette	25tests/case	5~500mIU/mL	Whole blood	12Months
HUBI LH	AOV-8025	Cassette	25tests/case	1.0~200ng/mL	Finger Puncture or Whole blood	12Months
HUBI FSH	AME-8025	Cassette	25tests/case	1.0~200ng/mL	Finger Puncture or Whole blood	12Months
HUBI BPHScreen	ABPH-8025	Cassette	25tests/case	T-PSA-0.4~20ng/mL T-PSA-0.05~10ng/mL	Finger Puncture or Whole blood	12Months
HUBI Total PSA	APSA-8025	Cassette	25tests/case	0.4~20ng/mL	Finger Puncture or Whole blood	12Months
HUBI Free PSA	AFSA-8025	Cassette	25tests/case	0.05~10ng/mL	Finger Puncture or Whole blood	12Months
HUBI hsCRP	AHCRP-8025	Cassette	25tests/case	0.2~50ng/mL	Finger Puncture or Whole blood	12Months
HUBI CRP	ACRP-8025	Cassette	25tests/case	2.5~300mg/L	Finger Puncture or Whole blood	12Months
HUBI FABP	AFABP-8025	Cassette	25tests/case	3~50ng/mL	Whole blood or Plasma	18Months
HUBI FABP-Troponin I	AFACT-8025	Cassette	25tests/case	FABP: 3~50ng/mL TnI: 0.05~20ng/mL	Whole blood or Plasma	12Months

Product Name	Cat.No.	Format	Package	Detection limit	Specimen	Shelf life
CE **FERTILITY**						
Pregnancy Tests - hCG(Human Chorionic Gonadotropin)						
after	ANP-2001	Midstream	1test/case	25mIU/mL	Urine	24Months
hCG Card	ANP-7025	Cassette	25tests/case	25mIU/mL	Urine	24Months
hCG Strip	ANP-3001	Strip	1test/case	25mIU/mL	Urine	24Months
	ANP-3100	Strip	100tests/case	25mIU/mL	Urine	24Months
hCG Combo	ANPC-7025	Cassette	25tests/case	25mIU/mL	Urine, Serum	24Months
Ovulation Tests - LH(Luteinizing Hormone)						
before	AOV-2005	Midstream	5tests/case	40mIU/mL	Urine	24Months
LH Card	AOV-7025	Cassette	25tests/case	40mIU/mL	Urine	24Months
LH Strip	AOV-3001	Strip	1test/case	40mIU/mL	Urine	24Months
	AOV-3100	Strip	100tests/case	40mIU/mL	Urine	24Months
Menopause Tests - FSH(Follicle Stimulating Hormone)						
continue Midstream	AME-2001	Midstream	1test/case	25mIU/mL	Urine	24Months
continue Card	AME-7025	Cassette	25tests/case	25mIU/mL	Urine	24Months
Abnormal Pregnancy (Ectopic or abortion)Screen						
Inexscreen	AEP-5010	Combo	10tests/case	25mIU/mL	Urine	22Months
CE **AMI**						
Acute Myocadial Infarction Tests						
Triple Marker Test (Troponin I / Myoglobin / CK-MB)						
Cardiac Triple Test Plus	ACTM-7010	Cassette	10tests/case	0.5,50,5ng/mL	Whole blood, Serum, Plasma	18Months
Double Marker Test						
Troponin I/Myoglobin	ACDM-7010	Cassette	10tests/case	0.5,50ng/mL	Whole blood, Serum, Plasma	18Months
Troponin I/CK-MB	ACDC-7010	Cassette	10tests/case	0.5,5ng/mL	Whole blood, Serum, Plasma	18Months
FABP/Troponin I	AFACT-7020	Cassette	20tests/case	6, 0.5ng/mL	Whole blood, Serum, Plasma	18Months
Single Marker Test						
Troponin I	ACTI-7010	Cassette	10tests/case	0.5ng/mL	Whole blood, Serum, Plasma	18Months
Myoglobin Test	ACMG-7025	Cassette	25tests/case	50ng/mL	Whole blood, Serum, Plasma	18Months
CK-MB Test	ACCK-7025	Cassette	25tests/case	5ng/mL	Whole blood, Serum, Plasma	18Months
FABP Test	AFABP-7010	Cassette	10tests/case	6ng/mL	Whole blood, Serum, Plasma	18Months

PRODUCTS LIST

Product Name	Cat.No.	Format	Package	Detection limit	Specimen	Shelf life
INFECTIOUS DISEASE						
Malaria Antigen Test CE						
Malaria P.f/Pan Antigen Test	AMAL-7025	Cassette	25tests/case	HRP-II(P.f) pLDH(P.f,P.v,P.o or P.m)	Whole blood(Finger Puncture)	24Months
Malaria P.f/P.v Antigen Test	AMFV-7025	Cassette	25tests/case	HRP-II(P.f) pLDH(P.v)	Whole blood(Finger Puncture)	24Months
Malaria P.f Antigen Test	AMPF-7025	Cassette	25tests/case	HRP-II(P.f)	Whole blood(Finger Puncture)	24Months
Dengue Test CE						
Dengue IgG/IgM Test	ADEN-7025	Cassette	25tests/case	IgG/IgM	Whole blood/serum/plasma	24Months
Dengue NS1 Antigen Test	ADEG-7025	Cassette	25tests/case	NS1 Antigen	Whole blood/serum/plasma	24Months
Dengue Combo Test	ADEC-5025	Cassette	25tests/case	IgG/IgM, NS1 Antigen	Whole blood/serum/plasma	24Months
Influenza A/B Test CE						
Influenza A/B Antigen Test	AINF-3025	Strip	25tests/case	Nasopharyngeal, Throat, Nasal swab		24Months
Respiratory Syncytial Virus Test CE						
RSV Antigen Test	ARSV-3025	Strip	25tests/case	NPS, Nasal Swab		24Months
Hepatitis B Virus Tests						
HBsAg Card	ABSG-7025	Cassette	25tests/case	1ng/mL	Serum, Plasma	24Months
HBsAg Card, multi	ABSG-6100	Multi device	100tests/case	1ng/mL	Serum, Plasma	24Months
HBsAg Strip	ABSG-3100	Dip strip	100tests/case	1ng/mL	Serum, Plasma	24Months
Anti-HBs Card	ABSB-7025	Cassette	25tests/case	30mIU/mL	Serum, Plasma	24Months
Anti-HBs Card, multi	ABSB-6100	Multi device	100tests/case	30mIU/mL	Serum, Plasma	24Months
Anti-HBs Strip	ABSB-3100	Dip strip	100tests/case	30mIU/mL	Serum, Plasma	12Months
Hepatitis C Virus(HCV) Test : HCV Antibody						
HCV Card	ACB-7030	Cassette	30tests/case	Whole blood, Serum, Plasma		18Months
HCV Card, multi	ACB-6100	Multi device	100tests/case	Whole blood, Serum, Plasma		18Months
Human Immunodeficiency Virus(HIV) 1/2 Antibody Tests						
HIV Card	AIB-7030	Cassette	30tests/case	Whole blood, Serum, Plasma		18Months
HIV Card, multi	AIB-6100	Multi device	100tests/case	Whole blood, Serum, Plasma		18Months
H-pylori Rapid Tests						
H-pylori Card	AHPY-7030	Cassette	30tests/case	Whole blood, Serum, Plasma		24Months
H-pylori Card, multi	AHPY-6100	Multi device	100tests/case	Whole blood, Serum, Plasma		24Months
H.pylori Antigen Test	AHPG-7020	Cassette	20Tests/case	Stool		24Months
Syphilis Rapid Tests						
Syphilis Card	ASB-7030	Cassette	30tests/case	Serum, Plasma		24Months
Syphilis Card, multi	ASB-6100	Multi device	100tests/case	Serum, Plasma		24Months
Chlamydia Rapid Tests						
Chlamydia Test	ACHG-7025	Cassette	25tests/case	$2X10^3$IFU/mL	Vaginal Swab	18Months
CE **TUMOR**						
Tumor Marker Tests						
Carcinoembryonic Antigen(CEA)Test						
CEA Card	ACEA-7030	Cassette	30tests/case	5ng/mL	Whole blood, Serum, Plasma	14Months
CEA Card, multi	ACEA-6100	Multi device	100tests/case	5ng/mL	Whole blood, Serum, Plasma	14Months
Fecal Occult Blood(FOB) Test						
FOB Test	AFOB-7020	Cassette	20tests/case	50ng/mL	Stool	18Months
FOB Test, multi	AFOB-6050	Multi device	50tests/case	50ng/mL	Stool	18Months
Alpha-Fetoprotein(AFP) Test						
AFP Card	AAFP-7030	Cassette	30tests/case	20ng/mL	Serum, Plasma	24Months
AFP Card, multi	AAFP-6100	Multi device	100tests/case	20ng/mL	Serum, Plasma	24Months
Prostate Specific Antigen(PSA) Test						
PSA Card	APSA-7030	Cassette	30tests/case	4ng/mL	Whole blood, Serum, Plasma	18Months
PSA Card, multi	APSA-6100	Multi device	100tests/case	4ng/mL	Whole blood, Serum, Plasma	18Months
COTININE TEST						
Cotinine Test						
Nicofind	ANC-7025	Cassette	25tests/case	200ng/mL	Urine	24Months
Urinalysis Chemistry						
U-AQ core / smart			Semi-Quantitative urinalysis analyzer			
U-AQ 2GP / 3 / 3GK / 4 / 4SG / 5 / 10 / 11		Strip	100tests/bottle		Urine	24Months

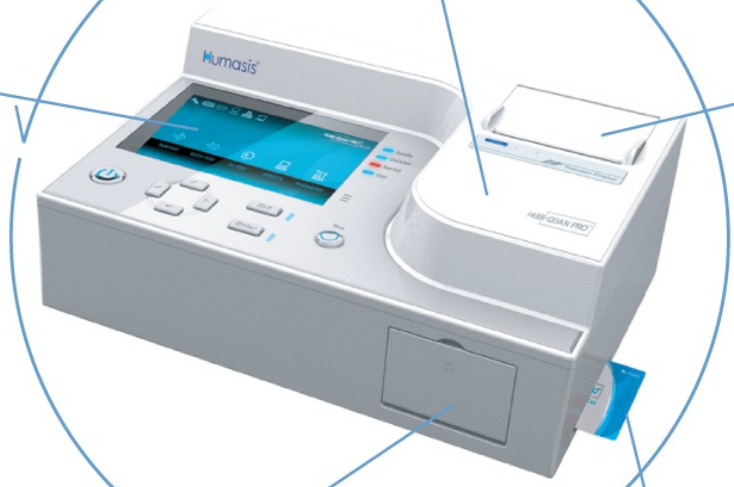
CE

Point-Of-Care Testing Analyzer
Reduce Turnaround Time(TAT) & Length of Stay(LOS)

CMOS Image Sensor
- Better Image Quality (More Accurate Test Results)
- No Interference caused by temperature
- Less contamination

Color LCD -4.5' TFT LCD

Thermal Printer



RFID Reader
- Auto Sample Identification
- Auto Calibration
- Auto Test type recognition

Security Card
- Provide the access to HUBI-QUAN Pro®

Connectivity

PS2, RS 232, LAN, 2xUSB
Provide various ways to link to other systems

Point-Of-Care Testing Analyzer

Test Procedure

1. Insert device and drop the sample

2. Press Test button

3. Read result

General information

- Dimension : 255 (W) x 178(D) X 92.7(H) mm
- Weight : 1.35kg
- Built-in Printer and HIS/LIS Interface for reporting Result

ACCURATE and EASY

- A quantitative results
- RFID System : Auto Calibration, Cartridge information
- Operational System : Windows XP

FAST

- Be able to check the test result within 10-15 minutes
- Panel Test : Maximum 6 different parameters by 1 device
- Reduce the Turnaround Time for hospital
- Immediate and proper treatment is available with the test result.

ENHANCED QC

- Liquid QC : Verification of proper reagent handling and storage.
- IQC : Reusable test device with multiple levels of color.
  Monitors for Alignment and color performance

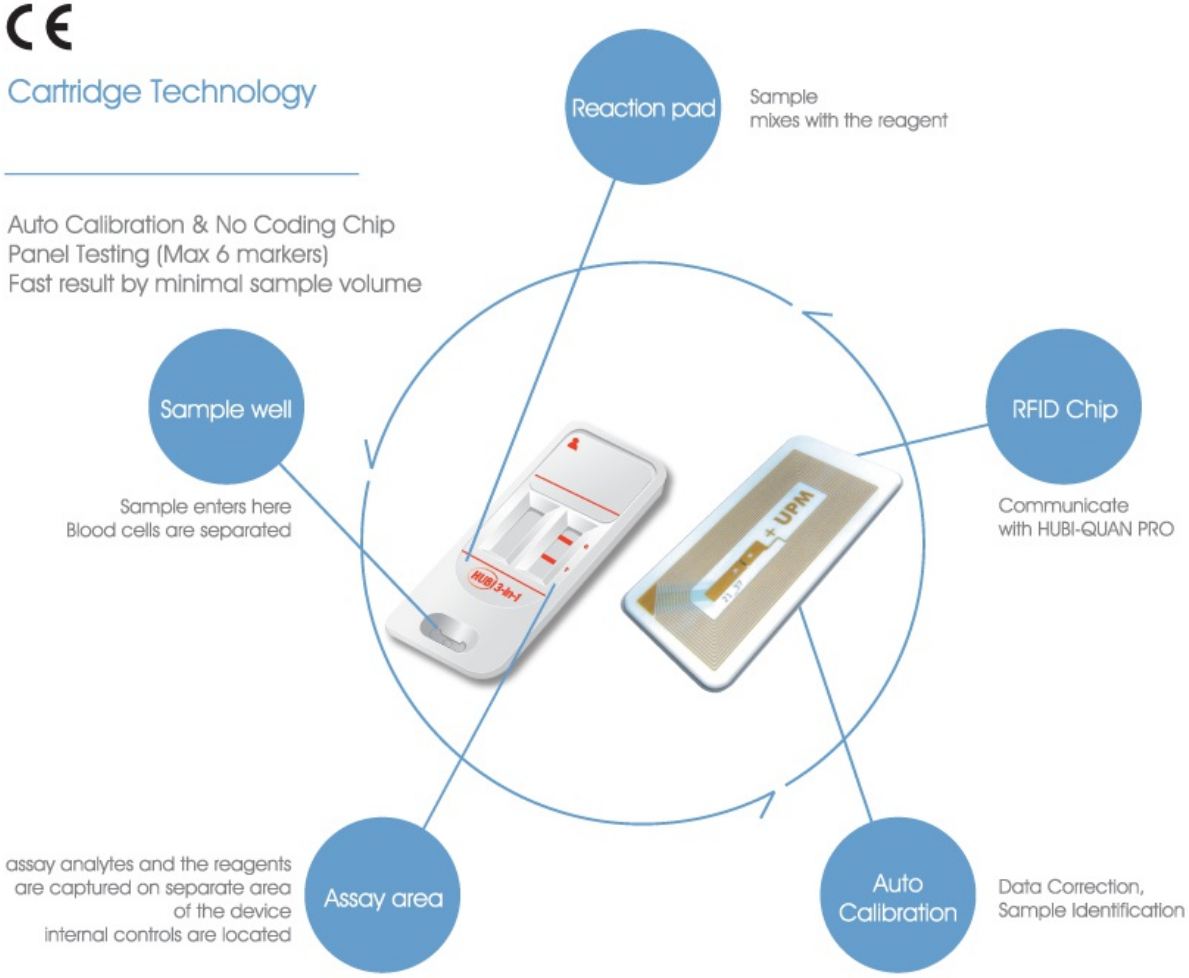
Ordering information

Product name	Catalogue No.	Type
HUBI-QUAN Pro®	AHQ-8001	Unit

CE

Cartridge Technology

Auto Calibration & No Coding Chip
Panel Testing (Max 6 markers)
Fast result by minimal sample volume



Emergency Testing

Rapid - Result in 15 minutes
Simple - Only 3 easy steps
Practical - Allow fast patient disposition

HUBI hCG
- Reduce Turnaround Time(TAT) and length of stay(LOS)
- Maximize the efficiency by using Whole Blood

HUBI Troponin I
- A standard for the diagnosis of Myocardial Infaction(MI)

HUBI DUO(TnI/CK-MB)
- Significantly improve the positive predicted value with two specific markers

HUBI Cardiac 3 in 1(TnI/CK-MB/Myo)
- Provide better risk stratification for diagnosis of Acute Myocardial Infaction (AMI)

General information

Product name	Format	Package	Specimen	Sample volume	Measuning range
HUBI-hCG	Cassette(ANP-8025)	25Tests/case	Whole blood or plasma	100ul	5~500mIU/mL
HUBI-Troponin I	Cassette(ACTI-8025)	25Tests/case	Whole blood or plasma	100ul	0.05~20ng/mL
HUBI-CK-MB	Cassette(ACCK-8025)	25Tests/case	Whole blood or plasma	100ul	1.5~30ng/mL
HUBI-Myoglobin	Cassette(ACMG-8025)	25Tests/case	Whole blood or plasma	100ul	20~350ng/mL
HUBI-FABP	Cassette(AFABP-8025)	25Tests/case	Whole blood or plasma	100ul	3~50ng/mL
HUBI FABP-Troponin I	Cassette(AFACT-8025)	25Tests/case	Whole blood or plasma	200ul	TnI : 0.05~20ng/mL FABP : 3~50ng/mL
HUBI-DUO(TnI/CK-MB)	Cassette(ACDC-8025)	25Tests/case	Whole blood or plasma	200ul	TnI : 0.05~20ng/mL CKMB : 1.5~30ng/mL
HUBI-Cardiac 3 in 1	Cassette(ACTM-8025)	25Tests/case	Whole blood or plasma	200ul	TnI : 0.05~20ng/mL CKMB : 1.5~30ng/mL Myo : 20~350ng/mL
HUBI-3 in 1(B)	Cassette(ACTCB-8025)	25Tests/case	Whole blood or plasma	200ul	TnI : 0.05~20ng/mL CKMB : 1.5~30ng/mL BNP : 25~~800ng/mL

Point-Of-Care Testing

Early detection, leading to early treatment, can have a profound impact on your patients health.
One step, One device and Quantitative

Urology(Tumor)
BPH(Benign Prostatic Hyperplasia, f-PSA/t-PSA Ratio)
Total PSA, Free PSA(Prostate Specific Antigen)

Gynecology(Fertility)
PCOS(Polycystic Ovary Syndrome, LH/FSH Ratio)*
Ovulation, Menopause
Prognancy, Abnormal Pregnancy(Abortion/Ectopic)*

General information

Product name	Format	Package	Specimen	Sample volume	Measuning range
HUBI-BPHScreen	Cassette(ABPH-8025)	25Tests/case	Finger puncture or Whole blood	30ul	T-PSA : 0.4~20ng/mL F-PSA : 0.05~10ng/mL
HUBI-Total PSA	Cassette(APSA-8025)				0.4~20ng/mL
HUBI-Free PSA	Cassette(AFSA-8025)				0.05~10ng/mL
HUBI-LH	Cassette(A0V-8025)				1.0~200mIU/mL
HUBI-FSH	Cassette(AME-8025)				1.0~200mIU/mL
HUBI-hCG	Cassette(ANP-8025)		Whole blood	100ul	5~500mIU/mL

* Developing item : HUBI PCOScreen/HUBI-TSH/HUBI-Free T4/HUBI-Malaria

Cardiovascular Testing

Accelerate diagnosis and treatment initiation
Reduce re-admission rate for cardiovascular patients and related costs

HUBI-BNP
Empowering immediate Heart Failure treatment
HUBI-D-Dimer*
Exclusion of deep vein thrombosis and pulmonary embolism
HUBI-hsCRP
Useful in predicting a patient's risk for cardiovascular disease, heart attacks and strokes
HUBI-FABP
More sensitive and reliable for early detection of MI and unstable angina

General information

Product name	Format	Package	Specimen	Sample volume	Measuning range
HUBI-BNP	Cassette(ABNP-8025)	25Tests/case	Whole blood	100ul	25~800pg/mL
HUBI-D-Dimer*	Cassette(ADIM-8025)			5ul	200~5,000ng/mL
HUBI-hsCRP	Cassette(AHCRP-8025)				0.2~50ng/mL
HUBI-CRP	Cassette(ACRP-8025)			30ul	2.5~300mg/L
HUBI-FABP	Cassette(AFBP-8025)			100ul	3~50ng/mL

* Developing item

CE

FERTILITY

Pregnancy Test : hCG(Human Chorionic Gonadotropin) Test
Ovulation Test : LH(Luteinizing Hormone) Test
Menopause Test : FSH(Follicle Stimulating Hormone) Test

Pregnancy Test:hCG(Human Chorionic Gonadotropin) Test

hCG is glycoprotein hormone secreted by the placenta shortly after implantation. In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after fertilization. The appearance of hCG and its subsequent rapid rise in urine and serum after conception during early gestational growth makes it an excellent marker.

General Information
- Simple & Easy : Result in 5 minutes & one step procedure
- Excellent performance : 25mIU/mL of detection limit
  : >99% clinical sensitivity;specificity;accuracy
- Suitable for early pregnancy test

Ovulation Test:LH(Luteinizing Hormone) Test

Ovulation is the release of an egg from ovary. Luteinzing hormone(LH) which stimulates ovulation is suddenly increased(LH surge) a day before ovulation. Because the few days around ovulation are the most likely time to be pregnant, it is very important to find the time when the women ovulate. Urine LH detection is very helpful way to be pregnant.

General Information
-Fast & Easy : Result in 5 minutes & one step procedure
-Excellent performance : 40mIU/ml of detection limit
-Standardization with WHO international reference standards : NIBSC, 2 IS 80/552

Menopause Test:FSH(Follicle Stimulating Hormone) Test

In women, elevated level of FSH is associated with the symptoms and stages of menopause. FSH levels are dependent upon the menstrual cycle, but usually remain below 15mIU/mL. If FSH levels remain elevated at 25mIU/mL or greater during the entire cycle, this is the evidence of menopaus.

General Information
-Quick & Simple : Result in 10 minutes & one step procedure
-Excellent performance : 25mIU/ml analytical sensitivity
  : >96% clinical sensitivity;specificity;accuracy

CE

Pregnancy Tests
hCG Test

Product name	Package	Detection limit	Specimen	Shelf life	Interpretation of results
after Midstream(ANP-2001)	1test/case	25mIU/mL	Urine	24 Months	
hCG Card Cassette(ANP-7025)	25tests/case	25mIU/mL	Urine	24 Months	Positive
hCG Strip	Strip(ANP-3001) 1test/case	25mIU/mL	Urine	24 Months	
	Strip(ANP-3100) 100tests/case	25mIU/mL	Urine	24 Months	Negative
	Strip(ANP-3200) 200tests/case	25mIU/mL	Urine	24 Months	
hCG Combo (ANPC-7025)	25tests/case	25mIU/mL	Urine, Serum	24 Months	Invalid

Test Procedure

Cassette

Midstream

00:10 Place the absorbent tip in the urine stream for at least 10 seconds

05:00 Wait 5 minutes, and then read the results

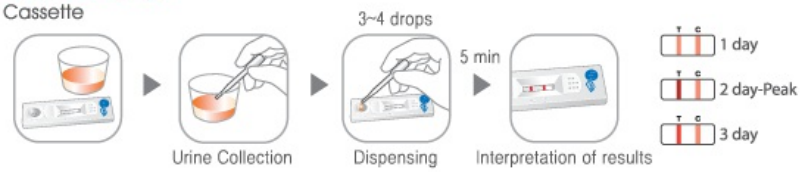
CE

Ovulation Tests
LH Test

Product name	Package	Detection limit	Specimen	Shelf life	Interpretation of results
before Midstream(AOV-2005)	5tests/case	40mIU/mL	Urine	24 Months	
LH Card Cassette(AOV-7025)	25tests/case	40mIU/mL	Urine	24 Months	Positive
LH Strip	Strip(AOV-3001) 1test/case	40mIU/mL	Urine	24 Months	
	Strip(AOV-3100) 100tests/case	40mIU/mL	Urine	24 Months	Negative
	Strip(AOV-3200) 200tests/case	40mIU/mL	Urine	24 Months	
					Invalid

Test Procedure

Cassette



Midstream

00:10 Place the absorbent tip in the urine stream for at least 10 seconds

05:00 Wait 5 minutes, and then read the results

CE

Menopause Tests
FSH Test

Product name	Package	Detection limit	Specimen	Shelf life	Interpretation of results
continue Midstream(AME-2001)	1test/case	25mIU/mL	Urine	24 Months	Positive
continue Card Cassette(AME-7025)	25tests/case	25mIU/mL	Urine	24 Months	Negative
					Invalid

Test Procedure

Cassette

Midstream

00:10 Place the absorbent tip in the urine stream for at least 10 seconds

10:00 Wait 10 minutes, and then read the results

CE FERTILITY

Abnormal Pregnancy(Ectopic or abortion) Screening Test

Abnormal Pregnancy(Ectopic or abortion) Screening Test

In the first trimester of pregnancy women, there is high risk of failed pregnancy caused by spontaneous abortion(miscarrige) and ectopic pregnancy. The overall miscarriage rate is reported as 15~20%, which means 15~20% of recognized pregnancies result in miscarriage. But this rate can be increased upto about 60~70% when highly sensitive hCG assays are used in early pregnancy. Ectopic pregnancy is a condition in which a fertilized egg settles and grows in any location other than the inner lining of the uterus. Ectopic pregnancy occurs in about one in 50 pregnancies and remains the leading cause of pregnancy-related death in the first trimester of pregnancy. Inexscreen is a new hCG test device for screening abnormal pregnancy, ectopic and spontaneous, as well as routine pregnancy test.

General Informaion
- Inexcreen can detect two types of hCG isoform, intact hCG and modified hCG which is free β-hCG like isoforms and determine the molar ratio of two isoforms semi-quantitatively.
- The analytical sensitivity of intact hCG which is detected with "A" window is 25mIU/ml.

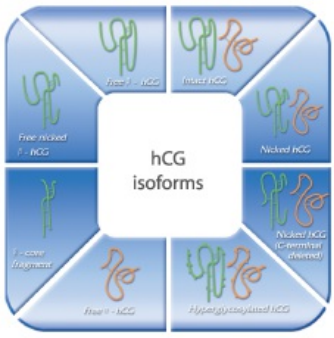
Application
- Simple pregnancy test determining whether it is pregnant or not.
- Early detection or screening of ectopic pregnancy or spontaneous abortion.
- Monitoring normal pregnancy

CE

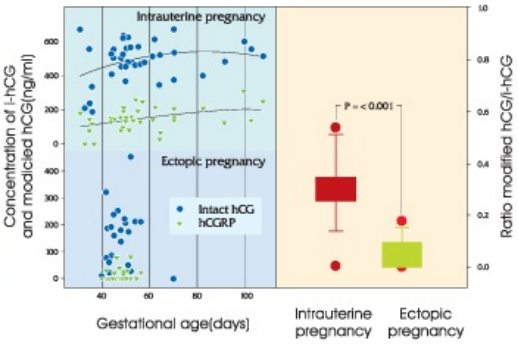
Abnormal Pregnancy
Inexscreen

Product name	Package	Detection limit	Specimen	Shelf life
Inexscreen Combo(AEP-5010)	10tests/case	25mIU/mL	Urine	22 Months

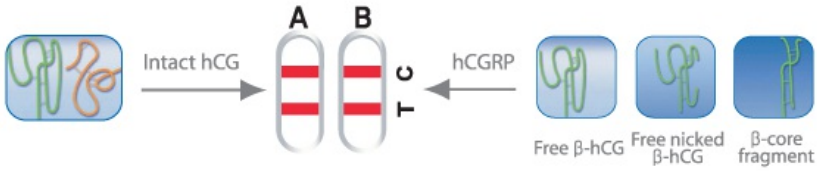
Multiple hCG-related molecules (hCG isoforms) are present in serum and urine samples of pregnant women.

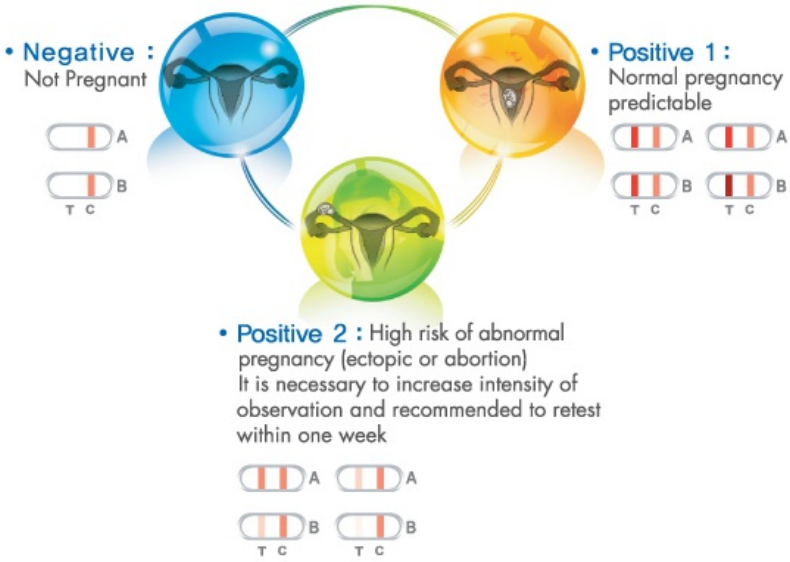


Ectopic & spontaneous abortion are associated with low molar ratio of free β-hCG like isoforms to intact hCG(i-hCG)



HUMASIS developed specific monoclonal antibodies to detect hCGRP & intact hCG in urine of pregnant women. The test line of window A and B detect intact hCG and hCGRP respectively.





How to test

	Test Procedure	Urine hCG	Immune Reaction In T-Zone		Time to result	Kit	Interpretation of results
			A window	B window			
Not pregnant	Urine 4~5 drops	No hCG			5		Negative
Normal pregnancy (IUP) (A≤B)		Intact hCG free β hCG					Positive 1
Abnormal pregnancy (EP or Abortion) (A>B)		Intact hCG					Positive 2

■ Symbols : , Capture antibodies(Ab) / Detection Ab gold conjugates

CE

AMI

Cardiac Triple Test : Cardiac Triple Test Plus
Cardiac Double Test : Troponin I/Myoglobin Double Test
Troponin I/CK-MB Double Test
Cardiac Single Test : Troponin I Test/Myoglobin Test/CK-MB Test

Acute Myocardial Infarction Tests

Acute myocardial infarction (AMI) is a medical condition that occurs when the blood supply to a part of the heart is interrupted. The resulting ischemia or oxygen shortage causes damage and potential death of heart tissue.

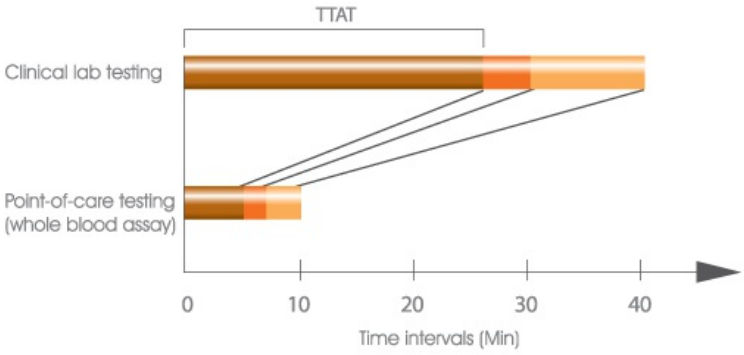
Cardiac Troponin I (cTnI) is specific and sensitive cardiac marker which is released into the bloodstream 4-6 hours after onset of symptoms and peaked levels are reached after 12-24 hours. Levels of Troponin I remain elevated for 5-7 days. Unlikely cTnI, cTnT may be falsely increased when specimen is collected from renal failure patient. Therefore the use of cTnI has become the standard for the detection of myocardial cell damage and for risk stratification of chest pain patients.

While less cardiac specific than cTnI, CK-MB can complement a positive cTnI result to help clarify the time of an AMI. Reinfarction is clinically important because it is associated with incremental risk; however, it presents special diagnostic difficulties. Because increases of cTnI can be lasting for long time, the use of CK-MB may help clarify the time of the reinfarction. Myoglobin, a low molecular weight heme protein found in cardiac and skeletal muscle, is valuable in the early evaluation of chest pain patients. It may appear in the blood in abnormal levels as early as 1 to 3 hours after onset of myocardial ischemia. While Myoglobin is not specific to cardiac muscle, it is useful in the detection of AMI in the absence of skeletal muscle trauma or other factors that may be associated with a noncardiac-related increase.

AMI

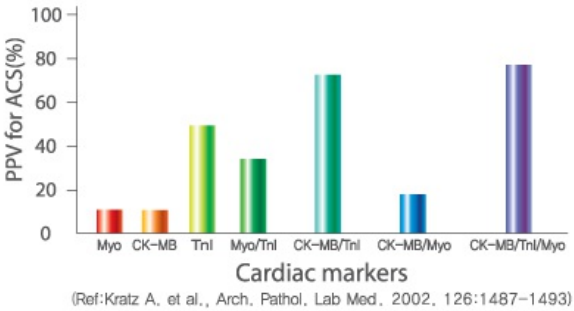
General Information

Point-of-care testing achieves a short turnaround time with all-in-one device and elimination of multiple steps involved in the clinical laboratory.



Figure; Ability of point-of-care testing for cardiac injury markers to reduce turnaround time for availablity of results to ordering physicians. TTAT(therapeutic turnaround time).

Any of the individual cardiac markers has a low positive predictive values(PPV) for the acute coronary syndrome(ACS) but it increases if all 3 markers(myoglobin, CK-MB and Troponin I) are used.



(Ref:Kratz A. et al., Arch. Pathol. Lab Med. 2002. 126:1487-1493)

CE

AMI

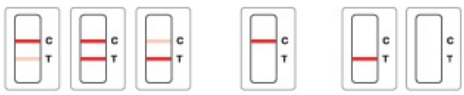
Cardiac Single Test : Troponin I Test/Myoglobin Test/CK-MB Test/FABP Test
Cardiac Double Test : Troponin I/Myoglobin Double Test
Troponin I/CK-MB Double Test
FABP/Troponin I double test
Cardiac Triple Test : Cardiac Triple Test Plus

Single Test




Product name	Package	Analytical sensitivity	Specimen	Shelf life
Troponin I test Cassette (ACTI-7010)	10tests/case	Troponin I 0.5ng/mL	Whole blood/ Serum/ Plasma	18 Months
Myoglobin test Cassette (ACMG-7025)	25tests/case	Myoglobin 50ng/mL	Whole blood/ Serum/ Plasma	18 Months
CK-MB test Cassette (ACCK-7025)	25tests/case	CK-MB 5ng/mL	Whole blood/ Serum/ Plasma	18 Months
FABP test Cassette (AFABP-7010)	10tests/case	FABP 6ng/mL	Whole blood/ Serum/ Plasma	18 Months

Interpretation of results

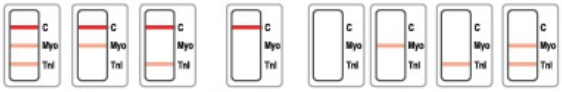


Test Procedure

Double Test

Product name	Package	Analytical sensitivity	Specimen	Shelf life
Troponin I/Myoglobin double test Cassette (ACDM-7010)	10tests/case	Troponin I 0.5ng/mL Myoglobin 50ng/mL	Whole blood/ Serum/ Plasma	18 Months
Troponin I/CK-MB double test Cassette (ACDC-7010)	10tests/case	Troponin I 0.5ng/mL CK-MB 5.0ng/mL	Whole blood/ Serum/ Plasma	18 Months
FABP/Troponin I double test Cassette (AFACT-7020)	20tests/case	FABP 6ng/mL TnI 0.5ng/mL	Whole blood/ Serum/ Plasma	18 Months

Interpretation of results



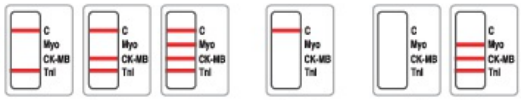
Test Procedure

Whole blood/ Sample/Plasma

Triple Test

Product name	Package	Analytical sensitivity	Specimen	Shelf life
Cardiac Triple Test Plus Cassette (ACTM-7010)	10tests/case	Troponin I 0.5ng/mL Myoglobin 50ng/mL CK-MB 5.0ng/mL	Whole blood/ Serum/ Plasma	18 Months

Interpretation of results



Test Procedure

Whole blood/ Sample/Plasma

Clinical Performance

- Troponin I

		Quantitative Reference Test(Beckman Coulter Access)		Total
		Negative(<0.5ng/mL)	Positive(≥0.5ng/mL)	
Humasis Troponin I	Negative	82	0	82
	Positive	4	83	87
Total		86	83	169

Relative Sensitivity>99%, Relative Specificity 95%, Relative accuracy 97%

- CK-MB

		Quantitative Reference Test(Beckman Coulter Access)		Total
		Negative(<5ng/mL)	Positive(≥5ng/mL)	
Humasis CK-MB	Negative	38	1	39
	Positive	1	49	50
Total		39	50	89

Relative Sensitivity 98%, Relative Specificity 97%, Relative accuracy 97%

- Myoglobin

		Quantitative Reference Test(Beckman Coulter Access)		Total
		Negative(<0.5ng/mL)	Positive(≥0.5ng/mL)	
Humasis Myoglobin	Negative	36	0	36
	Positive	4	99	103
Total		40	99	139

Relative Sensitivity >99%, Relative Specificity 90%, Relative accuracy 97%

- FABP

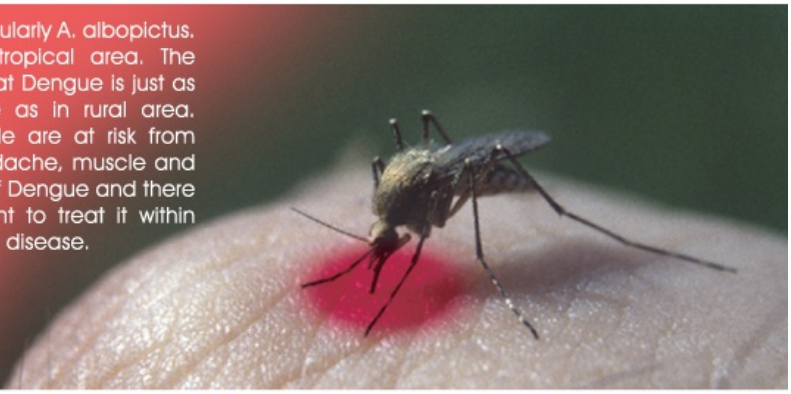
		Quantitative Test (Hycult ELISA)		Total
		Negative(<6ng/mL)	Positive(≥6ng/mL)	
Humasis FABP	Negative	228	4	232
	Positive	7	82	89
Total		235	86	321

Relative Sensitivity 95%, Relative Specificity 97%, Relative Accuracy 96%

INFECTIOUS DISEASE CE

Dengue COMBO Test
Dengue NS1 Antigen Test
Dengue IgG/IgM Antibody Test

Dengue is caused by Aedes mosquitoes, particularly A. albopictus. Dengue is found well in tropical and subtropical area. The difference between Dengue and Malaria is that Dengue is just as prevalent in the urban districts of its range as in rural area. According to WHO, around 2.5 billion people are at risk from dengue. Dengue manifests as fever with headache, muscle and joint pains and rash. There are four serotypes of Dengue and there is no cross-protection. So it is really important to treat it within proper time since it can be the life-threatening disease.



Dengue COMBO Test

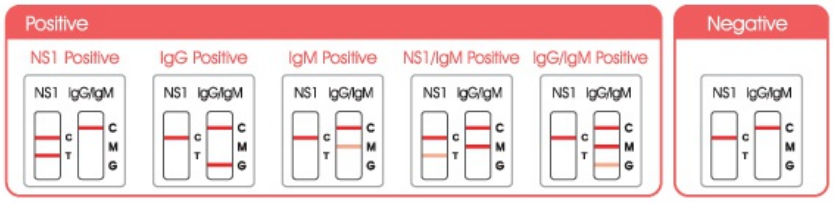
CE

Humasis Dengue COMBO test is one step assay designed to detect both dengue virus NS1 antigen and different IgG/IgM antibodies to dengue virus in human serum, plasma or whole blood. It contains two devices (left side: Dengue NS1 Ag test, right side: Dengue IgG/IgM test).

Information

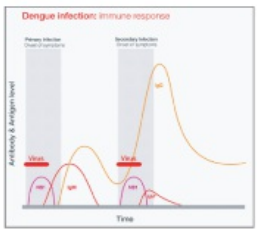
Product name	Package	Feature	Specimen	Shelf life
NS1 & IgG/IgM Combo Test Cassette(ADEC-5025)	25tests/case	IgG/IgM, NS1 Antigen	Whole blood/ Serum/Plasma	24 Months

Interpretation of results



General information

- Qualitative detection of NS1 Antigen and IgG/IgM Antibody to Dengue
- Specimen : Serum, Plasma, Whole Blood
- Differentiation between primay and secondary dengue
- Test Result : 15 minutes



	Dengue NS1 Rapid Test	Dengue IgG/IgM Rapid Test
Positon	Left Window	Right Window
Use	Qualitative determination of dengue virus NS1 Antigen	Detection of IgG and IgM antibodies to dengue virus
Sensitivity	>97.7%	>99%
Specificity	> 99%	>94%

Dengue NS1 Antigen Test

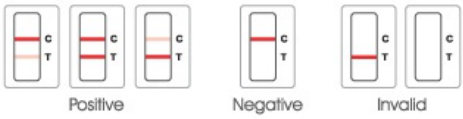
CE

Humasis Dengue NS1 Antigen Test is an immunochromatographic test for qualitative detection of Dengue virus NS1 antigen in human serum, plasma or whole blood.

Information

Product name	Package	Feature	Specimen	Shelf life
Dengue NS1 Antigen Test Cassette(ADEG-7025)	25tests/case	Antigen Test	Whole blood/ Serum/Plasma	24 Months

Interpretation of results



Features

- Early detection right after the onset of the symptoms
- Highly sensitive and easy to use
- Detection of infection prior to seroconversion

Clinical Performance

		Virus Culture/RT-PCR		Total
		Positive	Negative	
Humasis Dengue NS1 Antigen Test	Positive	93	2	95
	Negative	2	198	200
Total		95	200	295

Relative Sensitivity 97.9%, Relative Specificity 99.0%, Relative accuracy 98.6%

Test Procedure

Dengue IgG/IgM Antibody Test

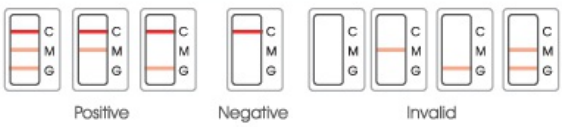
CE

Humasis Dengue IgG/IgM Antibody Test is an immunochromatographic for qualitative detection of dengue virus serotype DEN-1,2,3 and 4.

Information

Product name	Package	Feature	Specimen	Shelf life
Dengue IgG/IgM Antibody Test Cassette(ADEN-7025)	25tests/case	Antibody Test	Whole blood/ Serum/Plasma	24 Months

Interpretation of results



Features

- To show high sensitivity and specificity
- To detect dengue IgG/IgM at early stage
- To Reauire no other reagent

Test Procedure

INFECTIOUS DISEASE

Malaria Antigen Test

General Information

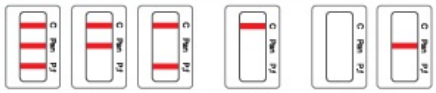
- Excellent whole blood separation(5㎕)
- Advanced item for Malaria diagnosis
- No blood lysis and preprocessing
- Maximized sensitivity and specificity
- Result in 15~30 minutes

Information

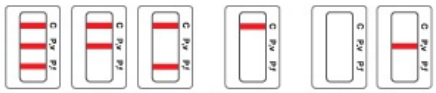
Product name	Package	Feature	Specimen	Shelf life
Malaria P.f/Pan Antigen Test Cassette(AMAL-7025)	25tests/case	HRP-II to P.f pLDH to P.f, P.v, P.o, P.m	Whole blood or Fingure puncture	24 Months
Malaria P.f/P.v Antigen Test Cassette(AMFV-7025)	25tests/case	HRP-II to P.f pLDH to P.v	Whole blood or Fingure puncture	24 Months
Malaria P.f Antigen Test Cassette(AMPF-7025)	25tests/case	HRP-II to P.f	Whole blood or Fingure puncture	24 Months

Interpretation of results

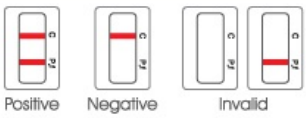
Malaria P.f/Pan Antigen Test



Malaria P.f/P.v Antigen Test



Malaria P.f Antigen Test



Clinical Performance

Sample			Humasis Malaria P.f/Pan Antigen Test	
			Positive	Negative
Positive	P.falciparum	50	50	10
	P.vivax	150	149	1
	Total	200	199	1
Negative		200	1	199
	Relative Sensitivity		99.5%(199/200)	
	Relative Specificity		99.5%(199/200)	

Test Procedure

INFECTIOUS DISEASE

Influenza A/B Antigen Test

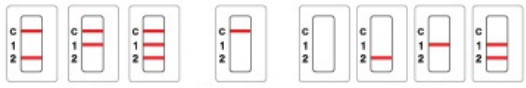
CE

Humasis Influenza A/B Antigen Test uses monoclonal antibodies specific to influenza type A and type B antigen for accurate determination of Influenza infection. When the nasal or throat patient sample is infected with Influenza type A or B, as visible line appears in the test region on the membrane, Humasis Influenza A/B Test can also discriminate between Influenza type A and type B antigen.

Information

Product name	Package	Feature	Specimen	Shelf life
Influenza A/B Antigen Test Strip(AINF-3025)	25tests/case	Antigen Test	Nasopharyngeal swab/ Throat swab	24 Months

Interpretation of results



General Information

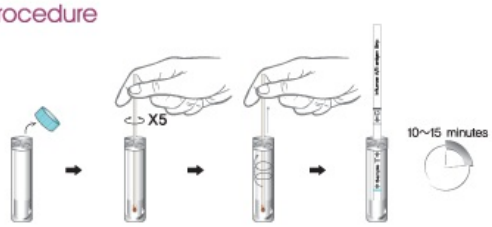
- Detect Influenza Group A(including H1N1) & Group B virus Antigen.
- Accurate sample collection by Copan swab
- One step procedure to use the extracted diluents

Clinical Performance

	Result			Humasis Influenza A/B Antigen Test		Commercial Rapid Test	
				POS	NEG	POS	NEG
Virus culture/ RT-PCR	POS	Type A	150	137	13	135	15
		Type B	50	47	3	47	3
		Sub Total	200	184	16	182	18
	NEG		200	2	198	2	198
Total			400	186	214	184	216

Relative Sensitivity 92%, Relative Specificity 99%, Relative accuracy 95.5%

Test Procedure



Method of sample collection

Respiratory Syncytial Virus (RSV) Antigen Test

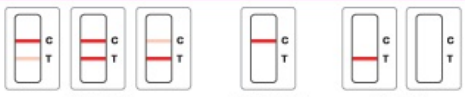
CE

RSV Antigen Test is one step to screen the respiratory syncytial virus infection in human nasal or throat swab specimen. Respiratory syncytial virus is the most common respiratory virus in infants and children. It infects virtually all infants by the age of two, causing symptoms similar as one of the common cold. In infants born prematurely and/or with chronic lung disease, RSV can cause a severe or even life threatening disease.

Information

Product name	Package	Feature	Specimen	Shelf life
RSV Antigen Test Strip(ARSV-3025)	25tests/case	Antigen Test	NPS, Nasal Swab	24 Months

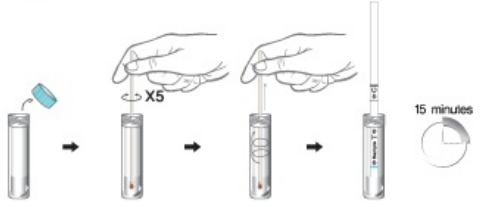
Interpretation of results



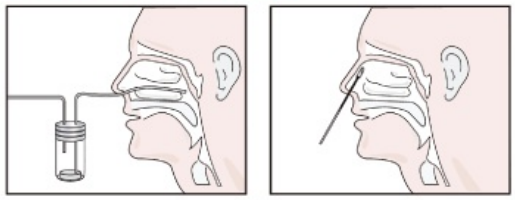
General Information

- Rapid test to detect RSV from various respiratory samples
- All necessary materials included for analyzing all sample types
- Hands-on time approximately 30 seconds

Test Procedure

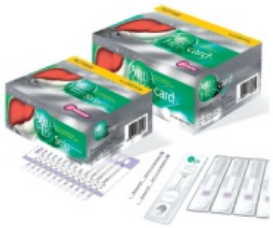


Method of sample collection



HBsAg Test

Anti-HBs Test



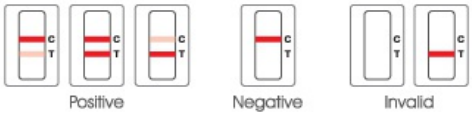
Hepatitis B Virus Test

Hepatitis B is a widespread serious liver disease. Hundreds of millions of people, mostly from regions with poor medical care, are chronically infected with the virus and face an elevated risk of acquiring liver cancer.
The hepatitis B virus (HBV) is made up of an inner core surrounded by an outer capsule. HBsAg is also found within the core. The detection of anti-HBs has become important in the follow-up of patients with the Hepatitis B virus(HBV). It is also important when monitoring the recipients of vaccination.

Information

Product name	Format	Package	Analytical sensitivity	Specimen	Shelf life
HBsAg Tests	Cassette (ABSG-7025)	25tests/case	1ng/mL	Serum/Plasma	24 Months
	Multi-device (ABSG-6100)	100tests/case	1ng/mL	Serum/Plasma	24 Months
	Dip Strip (ABSG-3100)	100tests/case	1ng/mL	Serum/Plasma	24 Months
Anti-HBs Tests	Cassette (ABSB-7025)	25tests/case	30mIU/mL	Serum/Plasma	24 Months
	Multi-device (ABSB-6100)	100tests/case	30mIU/mL	Serum/Plasma	24 Months
	Dip Strip (ABSB-3100)	100tests/case	30mIU/mL	Serum/Plasma	12 Months

Interpretation of results



Clinical Performance

● Humasis HBsAg had been compared with a leading commercial HBsAg EIA.

		Commercial HBsAg EIA		Total
		Negative(<1ng/mL)	Positive(≥1ng/mL)	
Humasis HBsAg	Negative	98	1	99
	Positive	0	97	97
Total		98	98	196

Relative Sensitivity 98%, Relative Specificity >99%, Relative accuracy 99%

● Humasis Anti-HBs had been compared with a leading commercial anti-HBs antibody EIA.

		Commercial anti-HBs EIA		Total
		Negative(<30mIU/mL)	Positive(≥30mIU/mL)	
Humasis Anti-HBs	Negative	100	1	101
	Positive	0	99	99
Total		100	100	200

Relative Sensitivity 99%, Relative Specificity >99%, Relative accuracy 99%

Test Procedure

Cassette

Multi-device

INFECTIOUS DISEASE

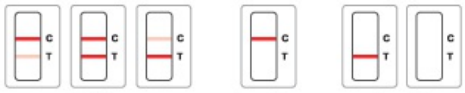
Helicobacter pylori is a helical shaped gram-negative bacterium that infects various area of the stomach and duodenum. Many cases of peptic ulcers, gastritis, duodenitis, and perhaps some cancers are caused by H.pylori infection. However, many who are infected do not show any symptoms of disease. *Helicobacter spp.* are the only known microorganisms that can thrive in the highly acidic environment of the stomach. Its helical shape (from which the genus name is derived) is thought to have to penetrate and favor its motility in the mucus gel layer.

H.pylori Test CE

Information

Product name	Format	Package	Feature	Specimen	Shelf life
H-pylori Card	Cassette (AHPY-7030)	30tests/case	Antibody Test	Whole blood/ Serum/Plasma	24 Months
	Multi-device (AHPY-6100)	100tests/case	Antibody Test	Whole blood/ Serum/Plasma	24 Months

Interpretation of results



Positive Negative Invalid

General Information

- Qualitative detection of antibodies to H.pylori
- Whole blood or serum/plasma can be used as specimen
- Result in 10 minutes or less

Clinical Performance

		Reference Test(Biopsy/Histology/Rapid Urease Test)		Total
		Negative	Positive	
Humasis H.pylori Card	Negative	165	9	175
	Positive	20	119	139
Total		185	128	313

Relative Sensitivity 93.4%, Relative Specificity 91.2%, Relative accuracy 94.4%

Test Procedure

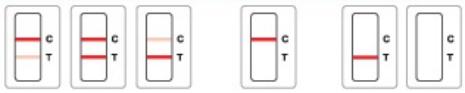
Cassette

H.pylori Antigen Test CE

Information

Product name	Format	Package	Feature	Specimen	Shelf life
H-pylori Antigen Test	Cassette (AHPG-7020)	20tests/case	Antigen Test	Stool	24 Months

Interpretation of results



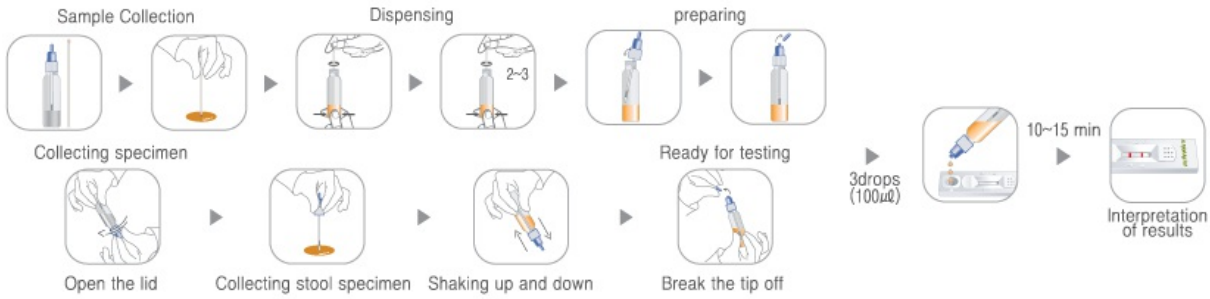
Positive Negative Invalid

General Information

- Less affected by concomitant PPI
- Stool specimens
- Various sampling tool provided
- High Sensitivity and specificity

Test Procedure

Cassette



INFECTIOUS DISEASE

Hepatitis C Virus Test

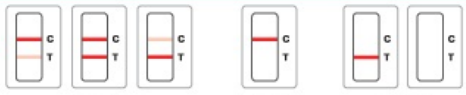
HCV Antibody Test

HCV is a positive, single-stranded RNA virus in the Flaviviridae family. Approximately 170 million people worldwide are infected with HCV. The virus is transmitted primarily by blood and blood products. It is generally believed that the majority of HCV infections give rise to an acute illness up to 80% which may develop into chronic hepatitis.

Information

Product name	Format	Package	Feature	Specimen	Shelf life
HCV Card	Cassette (ACB-7030)	30tests/case	3rd Generation Antibody Test	Whole blood/ Serum/Plasma	18 Months
	Multi-device (ACB-6100)	100tests/case	3rd Generation Antibody Test	Whole blood/ Serum/Plasma	18 Months

Interpretation of results



Positive Negative Invalid

Clinical Performance

- A study was performed using 302 positive and negative serum specimens.
  Each specimen was assayed with the Humasis HCV Card and a commercially available HCV EIA.

		Commercial HCV EIA		Total
		Negative	Positive	
Humasis	Negative	148	0	148
HCV Card	Positive	2	152	154
Total		150	152	302

Relative Sensitivity >99%, Relative Specificity 98%, Relative accuracy 99%

Test Procedure

Cassette

Sample Collection → Dispensing → 2 drops of assay diluent → 15 min → Interpretation of results

Multi-device

Sample Collection → Dispensing → 2 drops of assay diluent → 15 min → Interpretation of results

HIV Test

HIV 1/2 Antibody Test

Human immunodeficiency virus(HIV) is a retrovirus that can lead to acquired immunodeficiency syndrome(AIDS), a condition in humans in which the immune system begins to fail, leading to life-threatening opportunistic infections. Infection with HIV occurs by the transfer of blood, semen vaginal fluid, pre-ejaculate. or breast milk. AIDS has killed more than 25 million people since it was first recognized on December 1, 1981, making it one of the most destructive pandemics in recorded history.

Information

Product name	Format	Package	Feature	Specimen	Shelf life
HIV 1/2 Card	Cassette (AIB-7030)	30tests/case	3rd Generation Antibody Test	Whole blood/ Serum/Plasma	18 Months
	Multi-device (AIB-6100)	100tests/case	3rd Generation Antibody Test	Whole blood/ Serum/Plasma	18 Months

Interpretation of results

Positive Negative Invalid

Clinical Performance

- A study was performed using 265 positive and negative serum specimens.
  Each specimen was assayed with the Humasis HIV 1/2 Card and a commercially avalable HIV EIA.

		Commercial HIV EIA		Total
		Negative	Positive	
Humasis	Negative	129	0	129
HIV 1/2 Card	Positive	1	135	136
Total		130	135	265

Relative Sensitivity >99%, Relative Specificity 99%, Relative accuracy 99%

Test Procedure

Cassette

Sample Collection → Whole blood(20㎕) or Serum/Plasma(10㎕) → Add 80~100㎕ (4~5 drops) of assay diluent → 15~20 min → Interpretation of results

Multi-device

Sample Collection → Whole blood(20㎕) or Serum/Plasma(10㎕) → Add 80~100㎕ (4~5 drops) of assay diluent → 15~20 min → Interpretation of results

INFECTIOUS DISEASE

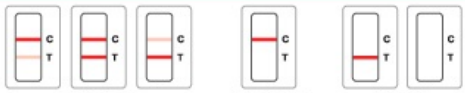
Syphilis is curable sexually transmitted disease caused by the Treponema pallidum spirochete. The route of syphilis is almost always by sexual contact. However, there are examples of congenital syphilis via transmission from mother to fetus.

Syphilis Test

Information

Product name	Format	Package	Feature	Specimen	Shelf life
Syphilis Card	Cassette (ASB-7030)	30tests/case	Treponemal pallidum Antibody Test	Serum/Plasma	18 Months
	Multi-device (ASB-6100)	100tests/case	Treponemal pallidum Antibody Test	Serum/Plasma	18 Months

Interpretation of results



Positive Negative Invalid

General Information

- One Step qualitative immunochromatographic assay
- Specimen : Serum, Plasma
- The optimal choice for mass screening program
- Room temperature storage

Clinical Performance

		Syphilis EIA		Total
		Negative	Positive	
Humasis Syphilis Card	Negative	148	0	148
	Positive	1	60	61
Total		149	60	209

Relative Sensitivity >99%, Relative Specificity 99.3%, Relative accuracy 99.5%

Test Procedure

Cassette

Sample Collection → Dispensing → Add 1drop of assay diluent → Interpretation of results

Multi-device

Sample Collection → Dispensing → Add 1drop of assay diluent → Interpretation of results

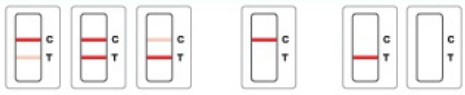
Chlamydia Test

Chlamydia trachomatis is a bacterium which causes a sexually transmitted infection(STI). Chlamydia is very common disease, which should be taken very seriously. The most worried effect of a chlamydia infection in women is potential fertility problem(PID, infertility, etc), due to inflammation of the fallopian tubes or cevix. The disease is particulary common among young people.

Information

Product name	Format	Package	Analytical sensitivity	Specimen	Shelf life
Chlamydia Test	Cassette (ACHG-7025)	25tests/case	2X10^{3}IFU/mL	Vaginal Swab	18 Months

Interpretation of results



Positive Negative Invalid

General Information

- Test Device
- Swab
- Pre-dispensed Extraction Solution
- Test Rack

Clinical Performance

		PCR		Total
		Negative	Positive	
Humasis Chlamydia Test	Negative	85	0	85
	Positive	0	51	51
Total		85	51	136

Relative Sensitivity 99%, Relative Specificity 99%, Relative accuracy 99%

		Commercial Rapid Test		Total
		Negative	Positive	
Humasis Chlamydia Test	Negative	85	0	85
	Positive	0	51	51
Total		85	51	136

Relative Sensitivity 99%, Relative Specificity 99%, Relative accuracy 99%

Test Procedure

Cassette

TUMOR

CEA Test

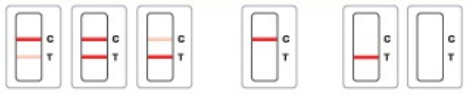
Carcinoembryonic Antigen(CEA) Test

Carcinoembryonic Antigen(CEA) is a glycoprotein involved in cell adhesion. It is normally produced during fetal development, but the production of CEA stops before birth. Therefore, it is not usually present in the blood of healthy adults, but levels are raised in heavy smokers. So, CEA measurement is mainly used as a tumor marker to identify recurrences after surgical resection.

Information

Product name	Format	Package	Analytical sensitivity	Specimen	Shelf life
CEA Card	Cassette (ACEA-7030)	30tests/case	5ng/mL	Whole blood/ Serum/Plasma	14 Months
	Multi-device (ACEA-6100)	100tests/case	5ng/mL	Whole blood/ Serum/Plasma	14 Months

Interpretation of results



Test Procedure

Cassette

FOB Test

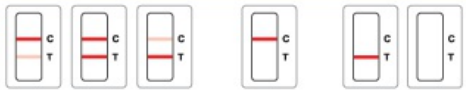
Fecal Occult Blood(FOB) Test

The presence of femoglobin in feces can be indicative of gastrointestinal tract conditions associated with bleeding such as colorectal carcinoma, diverticulitis, colon polyps, Crohn's disease, and ulcerative colitis.

Information

Product name	Format	Package	Analytical sensitivity	Specimen	Shelf life
FOB Test	Cassette (AFOB-7020)	20tests/case	50ng/mL	Stool	18 Months
	Multi-device (AFOB-6050)	50tests/case	50ng/mL	Stool	18 Months

Interpretation of results



Test Procedure

Test Preparation

Cassette

Multi-device

TUMOR

AFP Test

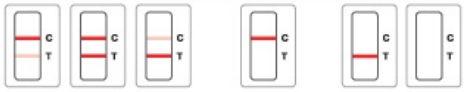
Alpha-Fetoprotein(AFP)Test

Alpha-Fetoprotein(AFP)Test is synthesized primarily in the liver and yolk sac of the fetus. It is secreted into fetal serum, reaching a peak at about 13 weeks gestation and gradually declining thereafter. Elevated serum AFP levels reappear during pregnancy and in conjunction with several malignant diseases such as testicular cancer, hepatocellular carcinoma, viral hepatitis and cirrhosis. Normal AFP value in healthy men and nonpregnant women is less than 20ng/mL but in pregnant women, it varies according to the age of fetus and women's weight and race.

Information

Product name	Format	Package	Analytical sensitivity	Specimen	Shelf life
AFP Card	Cassette (AAFP-7030)	30tests/case	20ng/mL	Serum/Plasma	24 Months
	Multi-device (AAFP-6100)	100tests/case	20ng/mL	Serum/Plasma	24 Months

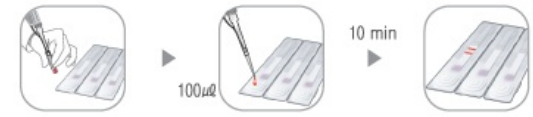
Interpretation of results



Test Procedure

Cassette

Multi-device



PSA Test

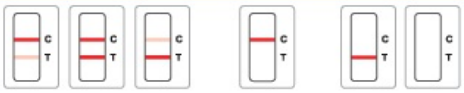
Prostate Specific Antigen(PSA) Test

Prostate Specific Antigen(PSA) is synthesized only by the prostate gland. The amount of PSA in the blood normally increases as a men's prostate enlarges with age. However, normal total PSA concentratin of men, age 40 to 50, is less 2.5ng/ml. The concentration of PSA is elevated in blood of prostate cancer patients. The PSA test is effective in screening prostate cancer and monitoring its development and the response to treatment.

Information

Product name	Format	Package	Analytical sensitivity	Specimen	Shelf life
PSA Test	Cassette (APSA-7030)	30tests/case	4.0ng/mL	Whole blood/ Serum/Plasma	18 Months
	Multi-device (APSA-6100)	100tests/case	4.0ng/mL	Whole blood/ Serum/Plasma	18 Months

Interpretation of results



Test Procedure

Cassette

Multi-device

CE

HUMASIS Urinalysis

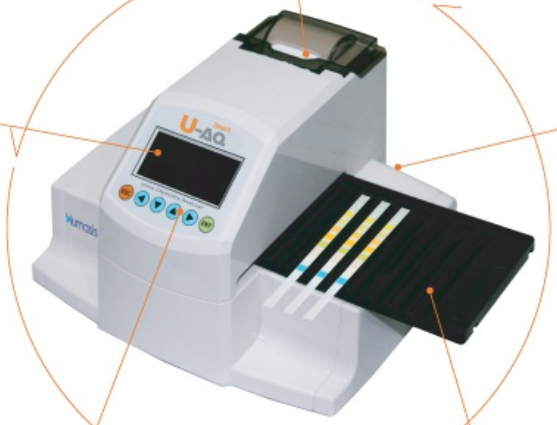
Smart U-AQ

300Tests/h

Urine Chemistry Analyzer
more Accurate & Quicker

Technical Specifications	
Operating mode	Semi-automatic urine analyzer
Dimension	275x250x170mm
Weight	1.3 kg
Power	100-250V, 3A
Oper. Conditions	Temp. : 2℃-30℃ / Humi. : 10%-70%
Method	Reflectance photometer
Test Capacity	300Tests/hour(Max. 800tests)
Memory Capacity	2,000 Samples
Interface	RS232C, PS/2

Printer
- High Speed thermal-printer
- Easy access to review test results and patients ID

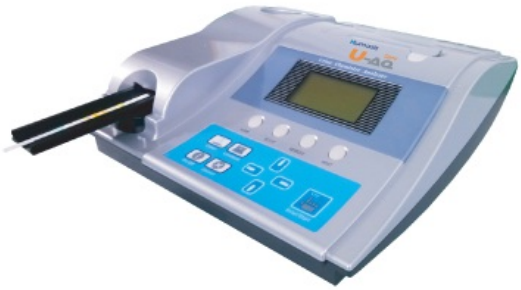


Wide LCD Screen
- Support 7 languages
- Provide various test mode (General, One by One, Quick Mode)

Various Interface
- Bar Code reader(RS232C)
- Key board(PS/2)
- LIS Interface(RS232C)

Operation button
- Control of operation with 6 buttons
- Availability of inputting using key board

Convenient Strip plate
- User-friendly and user-Oriented environment with multi-strip plate



Core U-AQ 50Tests/h

Technical Specifications	
Operating mode	Semi-automatic urine analyzer
Dimension	300x250x90mm
Weight	1.2 kg
Power	100-250V, 2A
Oper. Conditions	Temp. : 2℃-30℃ / Humi. : 10%-70%
Method	Reflectance photometer
Test Capacity	50Tests/hour(Max. 120tests)
Memory Capacity	2,000 Samples
Interface	RS232C, PS/2

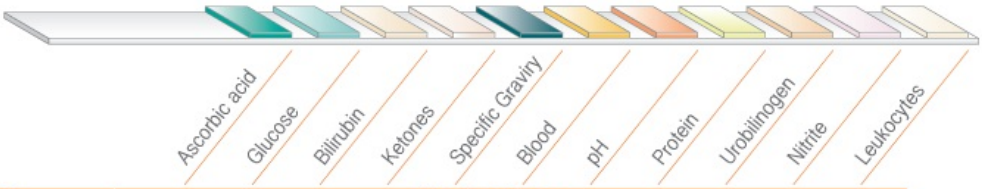
Product	Cat. No.	Quantity/Set			
U-AQ smart	AAQ-8011	1Set	* option : Keyboard / Barcode Reader		
AC Adapter	**Power cable**	**Thermal Printer paper**	**User Manual**	**Plate**	**RS 232C Cable**
1EA (100-240V / 12VDC 3A)	1EA	2 Roll	1EA	2EA	1EA

Product	Cat. No.	Quantity/Set			
U-AQ core	AAQ-8010	1Set	* option : Keyboard		
AC Adapter	**Power cable**	**Thermal Printer paper**	**User Manual**	**User's program CD**	**RS 232C Cable**
1EA (100-240V / 12VDC 3A)	1EA	2 Roll	1EA	1EA	1EA

U-AQS

Reagent Strips for Urinalysis

- Fast result visually or instrumentally
- High accuracy and reproducibility
- No interference in various conditions
- Quick Results(all reagent pads are read at one time, between one and two minutes after dipping).
- Good resistance to humidity
- Long shelf life : 24 months
- Unusual color of urine can be reported and compensated
- kFDA & CE marked



	Cat. No.	Urinalysis Strips										
U-AQS 2GP	AUS2GP-3100		—					—				
U-AQS 3	AUS3-3100		—				—	—				
U-AQS 3GK	AUS3GK-3100		—		—			—				
U-AQS 4	AUS4-3100		—			—	—	—				
U-AQS 4SG	AUS4SG-3100		—			—		—				
U-AQS 5	AUS5-3100		—		—		—	—				
U-AQS 10	AUS10-3100		—	—	—	—	—	—	—	—	—	—
U-AQS 11	AUS11-3100	—	—	—	—	—	—	—	—	—	—	—
Quality Controls												
Level I	Liquicheck Controls	N/A	Neg.	Neg.	Neg.	1.010~1.020	Neg.	5.0~6.0	Neg.	Norm.	Neg.	Neg.
Level II	Liquicheck Controls	N/A	±/-~4+ (100~2000 mg/dℓ))	1+~2+	±/-~2+ (5~40 mg/dℓ)	1.010~1.015	±/-~3+ (10~200 RBC/㎕)	6.5~8.0	±/-~3+ (15~300 RBC/㎕)	2~8 mg/dℓ	Pos.	±/-~3+ (15~500 ㎕/dℓ)

Abb.: Neg., negative; Pos., positive; Norm., normal

Ordering

When you place an order, please inform us full description, product catalogue number, package, quantity required including any special instructions with the correct billing and shipping address.

Contact information is as follow:

- Humasis Co.,Ltd
- Rm. 504, Shinwon Vision Tower, 88 Jeonpa-ro, Dongan-Gu, Anyang-si, Gyeonggi-do, 431-836, Korea
- Tel: +82-31-478-8591 Fax: +82-31-478-8586
- E-mail: question@humasis.com

Humasis

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