Humasis

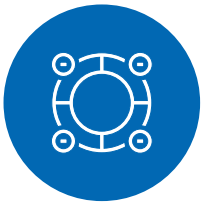
Innovative diagnostic kits for people's better lives.

About Humasis

Since its founding in 2000 as a rapid test kit company, Humasis Co., Ltd. has developed rapid test kits in various test fields such as infectious diseases, hormone tests, cardiac markers and tumor markers through constant research and development and has entered the domestic and overseas markets.

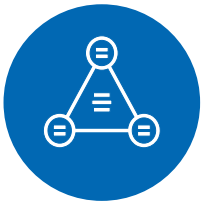
Humasis dedicated to support the healthcare provider. Through experience, innovation, creativity and efficiency, Humasis aims to provide world-class product and service to the customers.

Core Competencies



Technical Support

- Customer-oriented technical support system
- Complaint analysis ability accumulated over 20 years
- Real-time complaint response system by on-line monitoring program



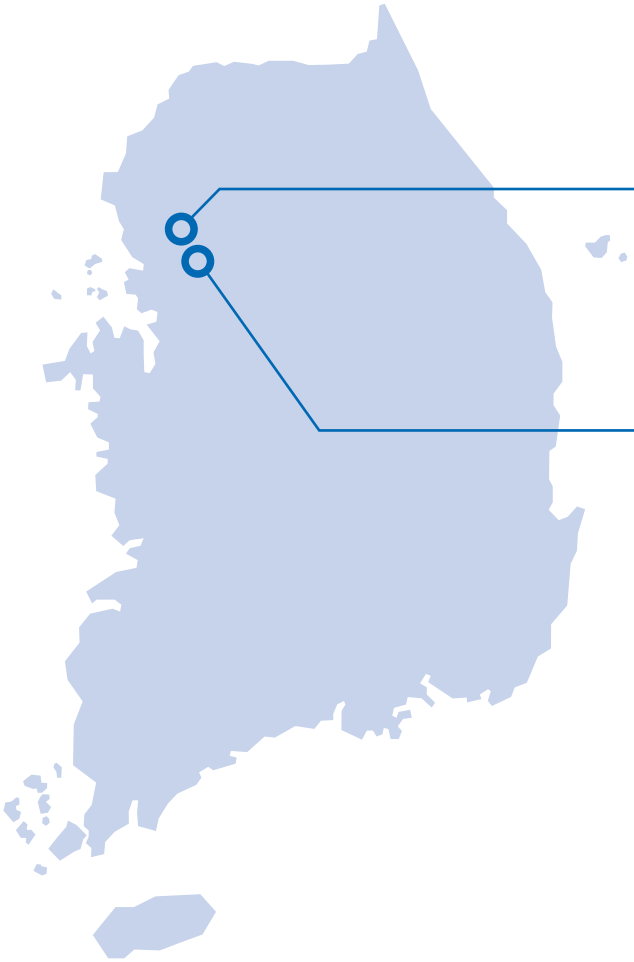
Quality Management

- Compliance with different international standards and regulations
- ISO13485, CE, ANVISA, CFDA, FDA

Human Resource

- Possession of Key technology about POCT
- Know-how and experience over 20 years
- Continuous R&D investment

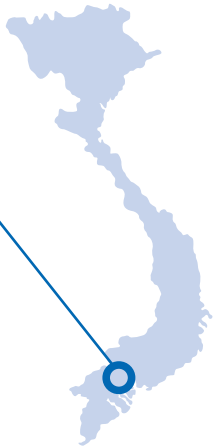
Korea



Humasis Co.,Ltd. (Headquater)
Anyang Factory

Gunpo Factory

Vietnam



Humasis VINA Co., Ltd
Ho Chi Minh City

History

2000 - 2005

00 - Established the company
- Acquired pharmaceutical manufacturing business (kFDA)

03 - Established Central R&D Center
- launched acute myocardial infarction test kit

04 - ISO Certificate

05 - SME technology innovation competition technology innovation award

2011 - 2015

11 - Acquired pharmaceutical manufacturing business (kFDA)Registered as UNPD vendor (UN)
- Registered as UNICEF vendor (UN)
- Registered as KOICA Vendor
- U.S. patent registration
(diagnostic device using similar structure protein ratio measurement)

12 - Acquired drug import business license from Japan Food and Drug Administration

13 - Signed WHO LTA (long term agreement; Malaria pf/pv test) contract
- Proclaimed WHO Malaria RDT4 (No. 1 performance among all Malaria pf/pv products)

14 - Product registration in China NMPA(CFDA)
- Proclaimed WHO Malaria RDT5
- (excellent performance among all Malaria pf/pan items)

2006 - 2010

06
- PCT international application
- China patent registration of abnormal pregnancy test kit
- Obtained IS013485

07
- Certified as INNOBIZ

08
- US patent registration of abnormal pregnancy test kit (Inex screen)

09
- Released POCT immunoquantitative analysis equipment (HUBI-QUAN pro)
- Acquired medical device manufacturing license (kFDA)

2016 - NOW

17
- Listed on KOSDAQ

20
- New headquarter building construction completion
- Signed a strategic partnership agreement for COVID-19 Test kit with Celltrion
- Established Humasis VINA Co. Ltd.

21
- COVID-19 Ag Test approved as Self-testing by MFDS(Korea)

CONTENTS

1. RAPID DIAGNOSTIC TESTS

US FDA EUA · CE · GMP · TÜV · MFDS · ANVISA · BFArM · PEI

Humasis COVID-19 Ag Test

- Dual antibodies – NP*1 & RBD*2
- Detects Variants – progressive studying on mutant detection.
- Nasal or Nasopharyngeal swab available
- Fast results within 10~20 min.
- Reliable with high sensitivity and specificity
- Easy and convenient to use

Specimen	Nasal swab, Nasopharyngeal swab
Testing Time	15 – 20 min
Storage	2 – 30 ℃
Shelf life	18 months

Humasis COVID-19 Ag Home Test Self-test

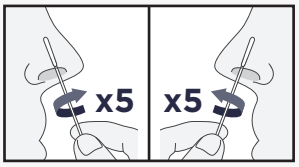
- Test can be done anywhere, anytime
- Fast & Reliable
  - High sensitivity and specificity
  - Test result within 10~20 min.
- No appointment nor doctor's order needed
  Self-testing kit doesn't require medical assistance

Specimen	Nasal swab
Testing Time	15 – 20 min
Storage	2 – 30 ℃
Shelf life	18 months

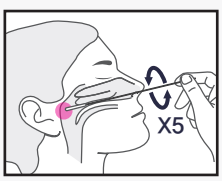
Product	Cat No.	Package	Sensitivity	Specificity
COVID-19 Ag Test	ACOVA-7025	25Test/Case	93.4%	99.3%
COVID-19 Ag Home Test	ACOVGS-7005	5Test/Case	92.9%	98.9%

Test Procedure

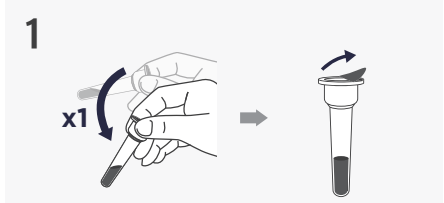
Specimen Collection



Nasal swab



Nasopharyngeal swab



*1 NP: Nucleocapsid Protein / *2 RBD: Receptor Binding Domain of Sars-CoV-2

Humasis is continually observing spike protein occurring mutations

Variant	Mutation Antigen								Live virus		
	Spike							NP			
	S477N	N501Y	L452R	E484K	K417N, E484K, N501Y	D614G	E484Q, T478K	D377Y, P67S	Alpha (B.1.1.7)	Beta (B.1.351)	Delta (B.1.617.2)
Area	All	Europe, US(California)	Europe (20A.EU2)	Europe (20A.EU2)	South Africa, Brazil, U.K, US(New York)	Europe (20A.EU2)	U.K, South Africa, Brazil	U.K, South Africa, Brazil	Europe, US(California)	South Africa, Brazil, U.K, US(New York)	Europe
Humasis COVID-19 Ag Test detects various mutations (*On-going)											

Prospective Study in various countries

1. USA (Nasopharyngeal)

COVID-19 (Nasopharyngeal)		US FDA Emergency Use Authorized RT-PCR		Total
		Positive	Negative	
Humasis COVID-19 Ag test	Positive	28	1	29
	Negative	2	111	113
	Total	30	112	142

Clinical Sensitivity : 93.3% / Clinical Specificity: 99.1%

[Site] Hometown URGENT CARE & RESEARCH in USA, Hospital AGEL, Ruiba Hospital, Trutest laboratories. Lab VIDA

2. USA (Nasal)

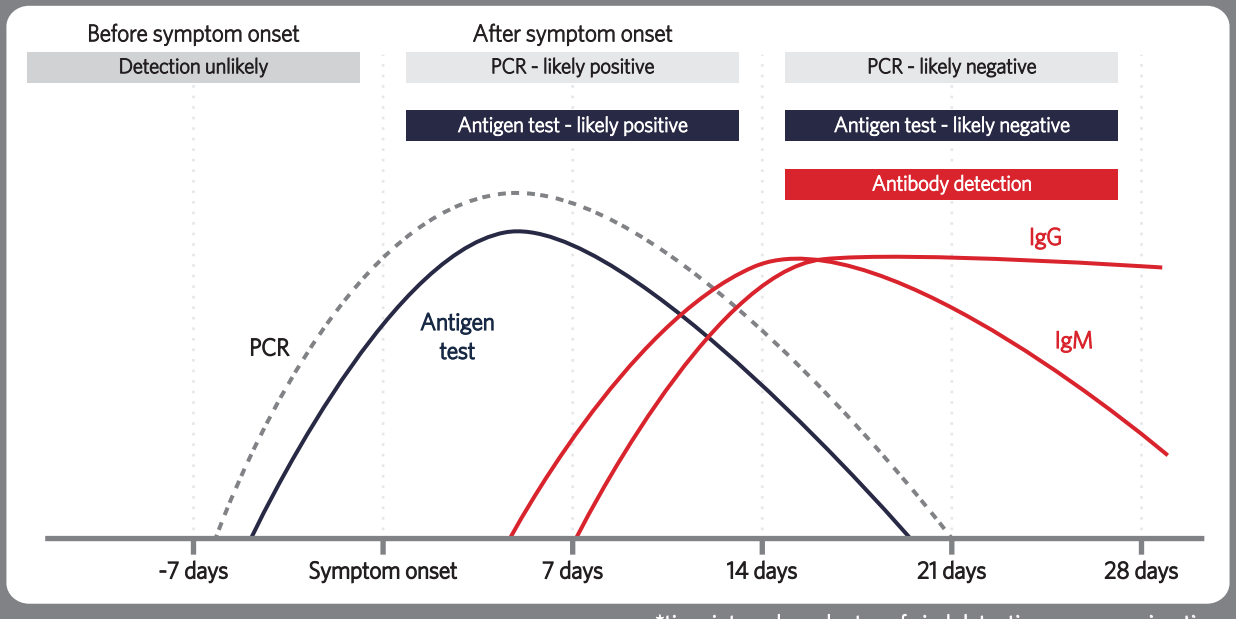
Test Result		RT-PCR		Total
		Positive	Negative	
Humasis COVID-19 Ag Home Test	Positive	102	2	104
	Negative	9	551	560
	Total	111	553	664

Clinical sensitivity: 91.9% (102-111, CI 85.3-95.7%)
Clinical specificity: 99.6% (551/553, CI 98.7-99.9%)

3. Positive agreement by Ct value

Clinical Evaluation		
Positive Agreement % by Ct value	CtM24 (95% CI)	Nasopharyngeal 100%
	CtM27 (95% CI)	(63/63, 95% CI 92.3~100.0%) 98.8%
	CtM30 (95% CI)	(82/83, 95% CI 93.5~99.8%) 97.0%
	Ct>30 (95% CI)	(96/99, 95% CI 91.5~99.0%) 79.2%
Positive agreement % by days from symptom onset	0~4 days (95% CI)	(19/24, 95% CI 59.5~90.8%) 96.3%
	5~7 days (95% CI)	(78/81, 95% CI 89.87~98.7%) 88.1%
		(37/42, 95% CI 75.0~94.8%)

Test method vs. progression of infection*



*time intervals and rates of viral detection are approximations

Humasis

COVID-19/Flu Ag Combo Test

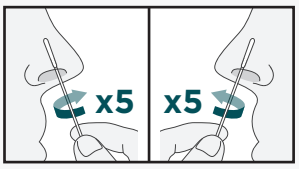
- 1 test 3 results
  - Detects SARS-CoV-2 Ag, Influenza A and B virus
- Dual window
- Easy & Convenient
- Fast & Reliable

Specimen	Nasal swab, Nasopharyngeal swab
Testing Time	15 min
Storage	2 - 30 ℃
Shelf life	18 months

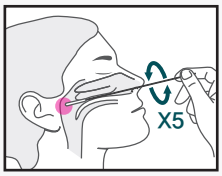
Product	Cat No.	Package	Virus	Sensitivity	Specificity
COVID-19/Flu Ag Combo Test	ACOFG-7025	25Test/Case	SARS-CoV-2	93.4%	99.3%
			Influenza A	91%	99%
			Influenza B	94%	

Test Procedure

Specimen Collection

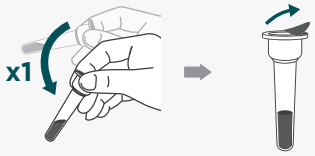


Nasal swab

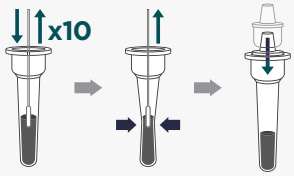


Nasopharyngeal swab

1

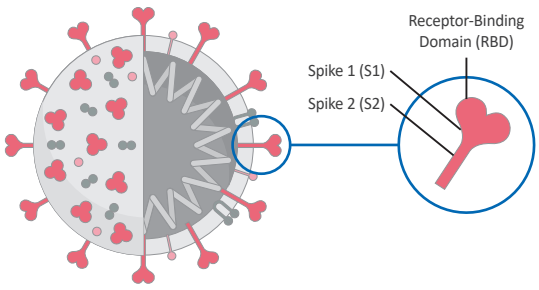


2



3

4



What is a RBD (receptor-binding domain)?

A receptor-binding domain (RBD) is a short immunogenic fragment from a virus that binds to a specific endogenous receptor sequence to gain entry into host cells. Specifically, these refer to a part of the 'spike' glycoprotein (S-domain) which is needed to interact with endogenous receptors to facilitate membrane fusion and delivery to the cytoplasm. Typically, the S-domain is also the site of neutralizing antibodies.

Humasis

COVID-19 IgG/IgM Test

15min.

10ul

- Detects specific antibodies to SARS-CoV-2 in human blood
- Trace the SARS-CoV-2 virus infection
- Easy & Convenient
- Fast & Reliable
  - Test result within 15min.
  - High sensitivity and specificity

Specimen	Whole blood (Capillary or Venous), Serum, Plasma
Testing Time	15 min
Storage	2 - 30 ℃
Shelf life	18 months

Product	Cat No.	Package	Days from RT-PCR/ Symptom Onset	Clinical Sensitivity		Clinical Specificity
				IgG	IgM	
COVID-19 IgG/IgM Test	ACOV-7025	25Test/Case	7 - 13 days	92.8%	93.5%	98.5%
			14 - 21 days	92.8%	96.2%	98.4%

Humasis

COVID-19 RBD/IgG Antibody Test

15min.

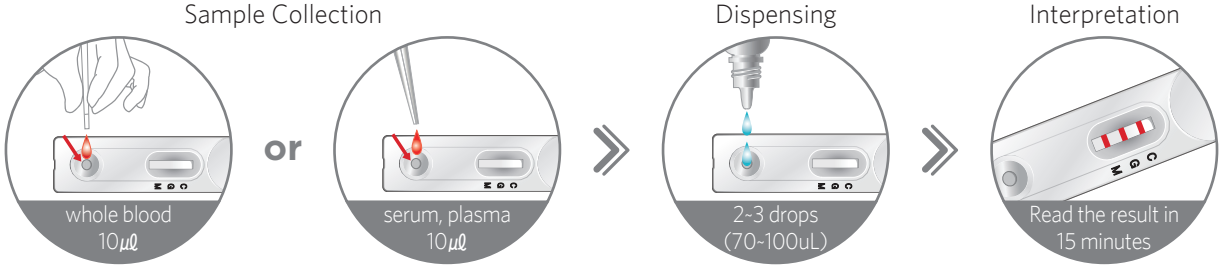
10ul

- Detects specific antibodies to SARS-CoV-2 spike protein(RBD) in human blood
- Human cell origin RBD applied
- Optimized to monitor immune response after vaccination
- Helpful to make decision for boost shots

Specimen	Whole blood (Capillary or Venous), Serum, Plasma
Testing Time	15 min
Storage	2 - 30 ℃
Shelf life	18 months

Product	Cat No.	Package	Sensitivity	Specificity
COVID-19 RBD/IgG Antibody Test	ACOVR-7025	25Test/Case	93%	99%

Test Procedure



- High Sensitivity
  5-6 times more sensitive than Colloidal gold particle
- Superior legibility
  clear test results with 2 color Lines (Red& Blue)
- Fast reading time
  result within 8 minutes

Influenza Antigen Card Plus

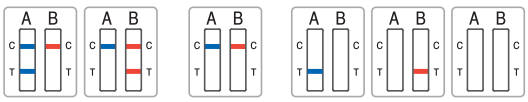
CE

Humasis Influenza Antigen Card Plus is a rapid immunoassay for the qualitative detection of Influenza antigen in Nasopharyngeal sample. This test is intended to be used as an aid in the diagnosis of influenza virus type A and type B infection.

Information

Product name	Package	Feature	Specimen	Shelf life
Influenza Antigen Card Plus Card(AINFC-7030)	30 tests/case	Influenza A (H1N1, H3N2), B	Nasopharyngeal swab	24 months

Interpretation of results



Positive Negative Invalid

Clinical Performance

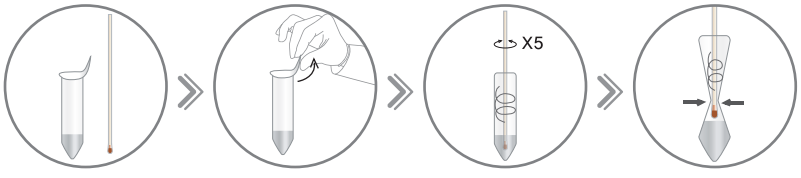
Humasis Influenza Antigen Card Plus-FLU A	Comparator Method (+PCR)		Total
	Positive	Negative	
Positive	47	0	47
Negative	0	125	125
Total	47	125	172

Sensitivity : 47/47 100% (95% CI : 92.45%-100%)
Specificity : 125/125 100% (95% CI : 97.09%-100%)

Humasis Influenza Antigen Card Plus-FLU B	Comparator Method (+PCR)		Total
	Positive	Negative	
Positive	43	0	43
Negative	1	147	148
Total	44	147	191

Sensitivity : 43/44 97.73% (95% CI : 87.98%-99.94%)
Specificity : 147/147 100% (95% CI : 97.52%-100%)

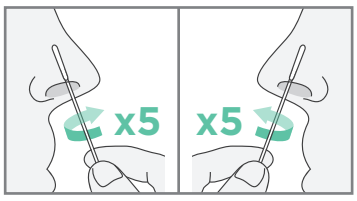
Test Procedure



Prepare and insert swab specimen. Swirl the test tube and squeeze out the swab.

Equip the filter cap on the test tube. Drop sample on the kit and read results.

Specimen Collection



Nasal swab

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)	25 tests/case	Antigen Test	Nasal swab/Throat swab	24 months

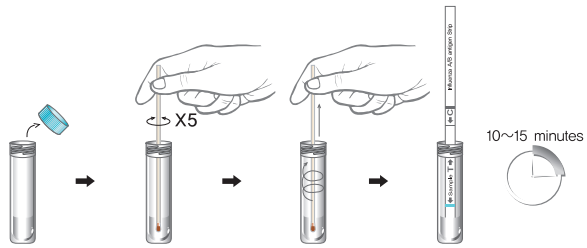
Interpretation of results

Positive Negative Invalid

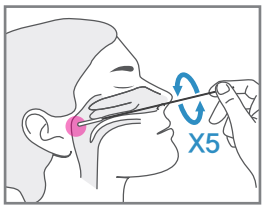
General Information

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

Test Procedure



Specimen Collection



Nasopharyngeal swab

FLU/RSV Combo

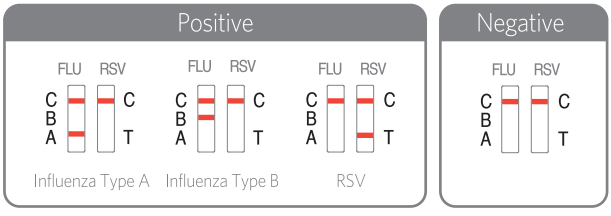
CE

Humasis FLU/RSV Combo is a one step in-vitro diagnostic test based on immunochromatographic assay. It is designed for qualitative determination of influenza type A, type B (not type C) and RSV type A, type 2, type B virus infection using nasopharyngeal swab specimen of symptomatic patients with time to results of 8 minutes.

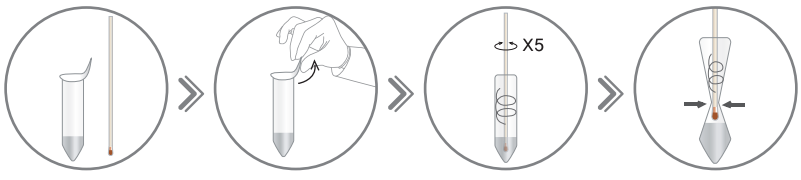
Information

Product name	Package	Feature	Specimen	Shelf life
FLU/RSV Combo Card(AFRC-7030)	30 tests/case	Influenza A (H1N1, H3N2), B & RSV A, A2, B	Nasopharyngeal swab	24 months

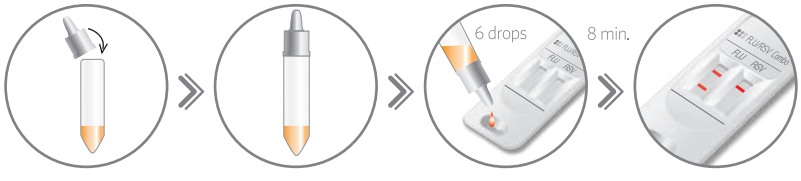
Interpretation of results



Test Procedure

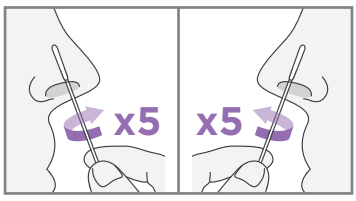


Prepare and insert swab specimen. Swirl the test tube and squeeze out the swab.



Equip the filter cap on the test tube Drop sample on the kit and read results.

Specimen Collection

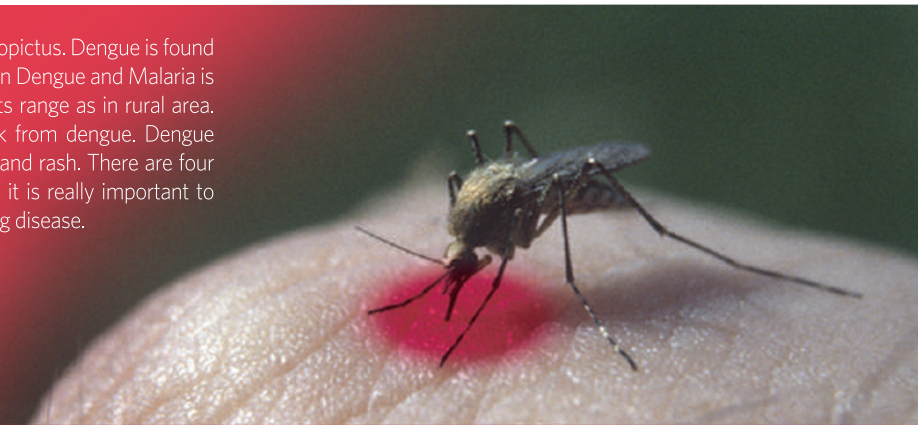


Nasal swab

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

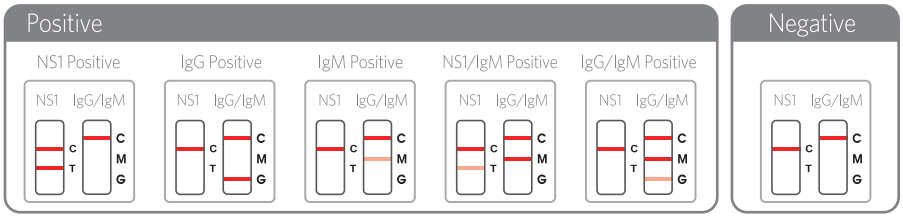
CE

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

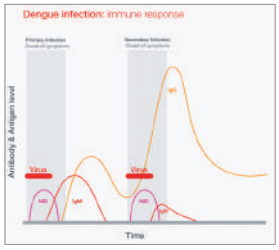
Product name	Package	Feature	Specimen	Shelf life
NS1 & IgG/IgM Combo Test Card(ADEC-5025)	25 tests/case	IgG/IgM, NS1 Antigen	Whole blood/ Serum/Plasma	24 months

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	>97.9%	>98%
Specificity	> 99%	>99%

Dengue NS1 Antigen Test

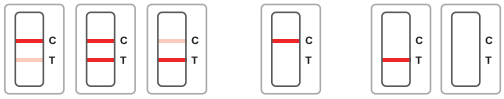
CE

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 Card(ADEG-7025)	25 tests/case	Antigen Test	Whole blood/ Serum/Plasma	24 months

Interpretation of results



Positive Negative Invalid

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

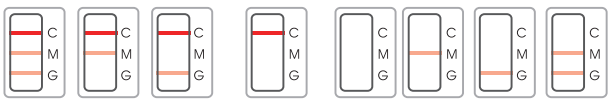
CE

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 Card(ADEN-7025)	25 tests/case	Antibody Test	Whole blood/ Serum/Plasma	24 months

Interpretation of results

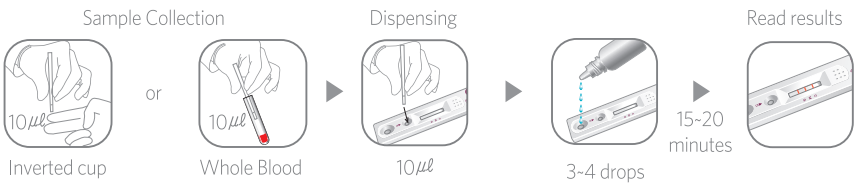


Positive Negative Invalid

Features

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

Test Procedure



INFECTIOUS DISEASE CE

Malaria P.f/Pan Antigen Test
Malaria P.f/P.v Antigen Test
Malaria P.f Antigen Test

Malaria P.f/Pan Antigen Test

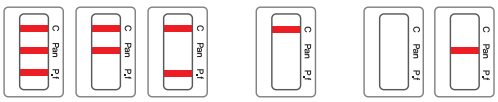
CE

Humasis Malaria P.f./Pan Antigen Test is a one step in-vitro diagnostic test based on immunochromatographic assay. It is designed for detection of P. falciparum(HRP-II) and pLDH(P.falciparum, P.vivax, P.ovale, P.malariae) in human blood.

Information

Product name	Package	Feature	Specimen	Shelf life
Malaria P.f/Pan Antigen Test Card(AMAL-7025)	25 tests/case	HRP-II to P.f pLDH to P.f, P.v, P.o, P.m	whole blood	24 months

Interpretation of results



Positive Negative Invalid

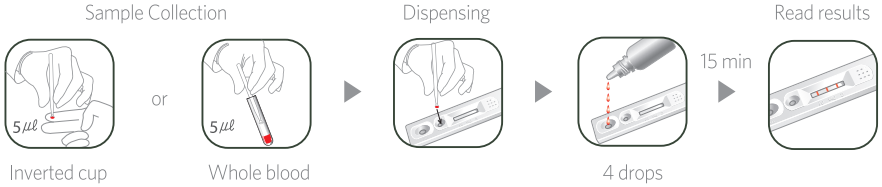
Clinical Performance

Sample			Humasis Malaria P.f/Pan Antigen Test	
			Positive	Negative
Positive	P.falciparum	50	50	0
	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)	

Features

- Detect HRP-II Ag to P.falciparum and pLDH to Plasmodium species
- Distinguish the infection between P.falciparum and other species.

Test Procedure



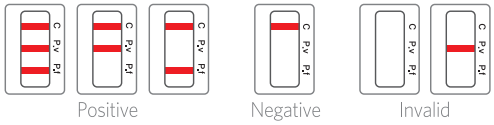
Malaria P.f/P.v Antigen Test

Humasis Malaria P.f./P.v. Antigen Test is a one step in-vitro diagnostic test based on immunochromatographic assay. It is designed for detection of P.falciparum(HRP-II) and P.vivax(pLDH) in human blood.

Information

Product name	Package	Feature	Specimen	Shelf life
Malaria P.f/P.v Antigen Test Card(AMFV-7025)	25 tests/case	HRP-II to P.f pLDH to P.v	whole blood	24 months

Interpretation of results



Positive Negative Invalid

Features

- Detect HRP-II Ag to P.falciparum and pLDH to Plasmodium species
- Distinguish the infection between P.falciparum and P.vivax.

Clinical Performance

Sample			Humasis Malaria P.f/P.v Antigen Test	
			Positive	Negative
Positive	P.falciparum	50	50	0
	P.vivax	150	149	1
	Total	200	199	1
Negative		200	2	198
Relative Sensitivity			99.5%(199/200)	
Relative Specificity			99.0%(198/200)	

Test Procedure

Inverted cup Whole blood 4 drops

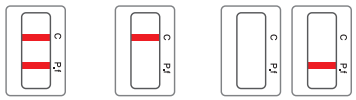
Malaria P.f Antigen Test

Humasis Malaria P.f. Antigen Test is a one step in-vitro diagnostic test based on immunochromatographic assay. It is designed for detection of P.falciparum(HRP-II) in human blood.

Information

Product name	Package	Feature	Specimen	Shelf life
Malaria P.f Antigen Test Card(AMPF-7025)	25 tests/case	HRP-II to P.f	whole blood	24 months

Interpretation of results



Positive Negative Invalid

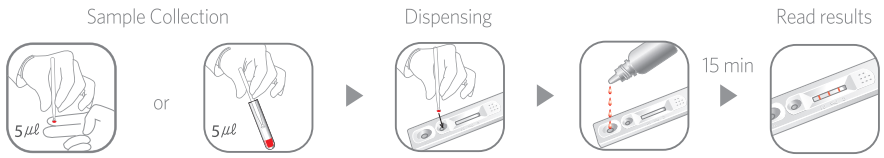
Features

- Detect HRP-II Ag to P.falciparum
- Highly sensitive at low level of parasites.

Clinical Performance

Sample			Humasis Malaria P.f Antigen Test		Sensitivity or Specificity
			Positive	Negative	
Microscopy	P. falciparum Positive	50	50	0	>99.9% (Sensitivity)
	Negative	200	1	199	99.5% (Specificity)

Test Procedure



Inverted cup Whole blood 4 drops

CE

Humasis

G6PD

One Step G6PD Test

G6PD: Glucose-6-phosphate dehydrogenase

Worldwide implementation of G6PD neonatal screening program in force.

Speedy

Results seen in less than 5 minutes
On the spot testing and results

Easy to Use

Simple 1.5-step procedure
Ready-to-use reagent
Clear visual read out of normal or deficient

Temperature Stability

Wide range of test temperature 18~32 ℃

Accurate & Reliable

> 99% sensitivity
95% agreement with whole blood sample

G6PD deficiency is a genetic abnormality that results in an inadequate amount of this necessary enzyme. Qualitative detection test for G6PD deficiency is recommended upon entry in care or before starting therapy with primaquine, an antimalarial drug, and other drugs with high oxidative stress it could cause severe hemolysis or anemia in those with G6PD deficiency.

Test Procedure

Interpretation of Test Result

1. Normal

Red appears in both test(T) and control zone(C).

2. Deficiency

Red appears in control zone(C) and its complementary color (dark green or reddish brown) appears in test zone(T).

3. Invalid

Red does not appear in control zone(C). Do not interpret the result and do a re-test.

Specifications

Product Name	Humasis G6PD Test
Detection	G6PD enzyme
Method	Visual dye colorization method
Test Time	5 minutes
Test Type	Card
Sample Type	Whole Blood (EDTA, Heparin)
Sample Volume	5 ㎕
Storage Condition	2 - 30℃
Shelf-Life	18 months
Kit Components	25 tests/case

humasis

Malaria/G6PD Combo

One Step Malaria/G6PD Combo

G6PD deficiency is of particular concern for people infected with Malaria or HIV

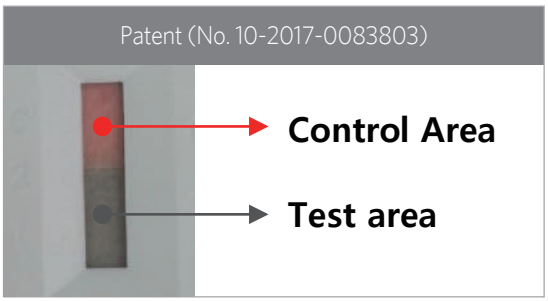
Malaria P.f/Pan + G6PD

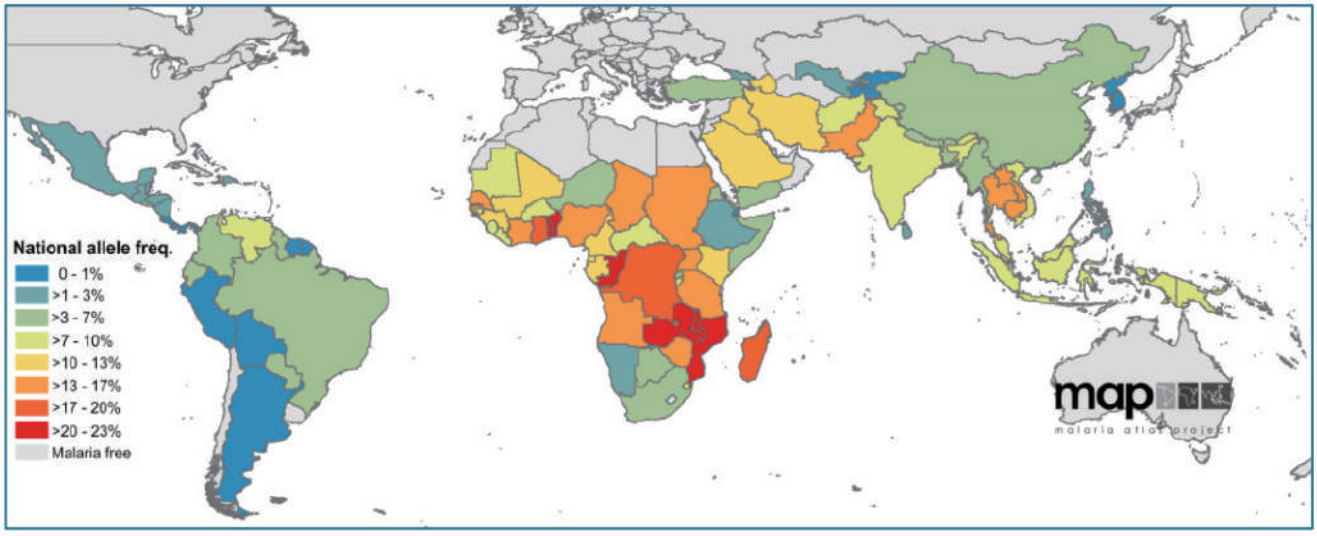
- Fast screening & Safe treatment
- One step solution for screening of Malaria and G6PD Deficiency

Why G6PD Test is essential for Malaria infected patients?

WHO's Recommendations on G6PD Testing and Primaquine anti-relapse therapy (2015)

"All patients with confirmed P. vivax and P. ovale should be tested for G6PD deficiency before administration of 14-day radical treatment with Primaquine or Tafenoquine."





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.

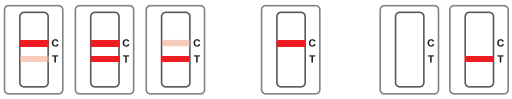
HBsAg Test

Anti-HBs Test

Information

Product name	Package	Feature	Specimen	Shelf life
HBsAg Tests Card(ABSG-7025)	25 tests/case	1 ng/mL	Serum/Plasma	24 months
Multi-Card(ABSG-6100)	100 tests/case	1 ng/mL	Serum/Plasma	24 months
Anti-HBs Tests Card(ABSB-7025)	25 tests/case	30 mIU/mL	Serum/Plasma	24 months
Multi-Card(ABSB-6100)	100 tests/case	30 mIU/mL	Serum/Plasma	24 months

Interpretation of results



Clinical Performance

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

		Commercial HBsAg EIA		Total
		Negative(<1 ng/mL)	Positive(≥1 ng/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(<30 mIU/mL)	Positive(≥30 mIU/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

Card

Multi-device

INFECTIOUS DISEASE

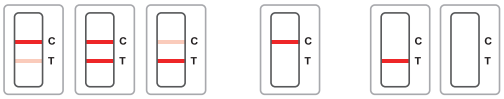
Helicobacter pylori is a helical shaped gram-negative bacterium that infects various area of the stomach and duodenum. Many cases of peptic ulcers, gastritis, duodenitis, and perhaps some cancers are caused by H.pylori infection. However, many who are infected do not show any symptoms of disease. Helicobacter 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 mortility in the mucus gel layer.

H.pylori Test

Information

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

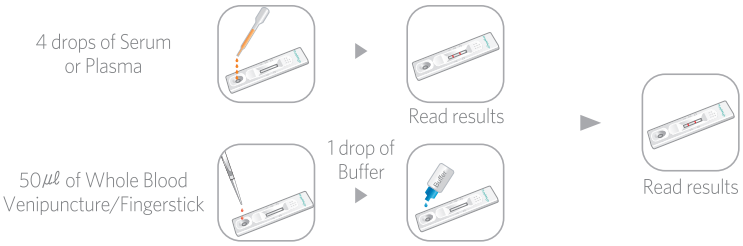
Clinical Performance

		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

Card

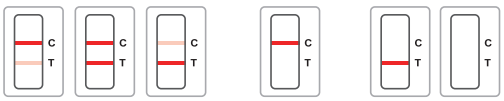


H.pylori Antigen Test

Information

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

Interpretation of results



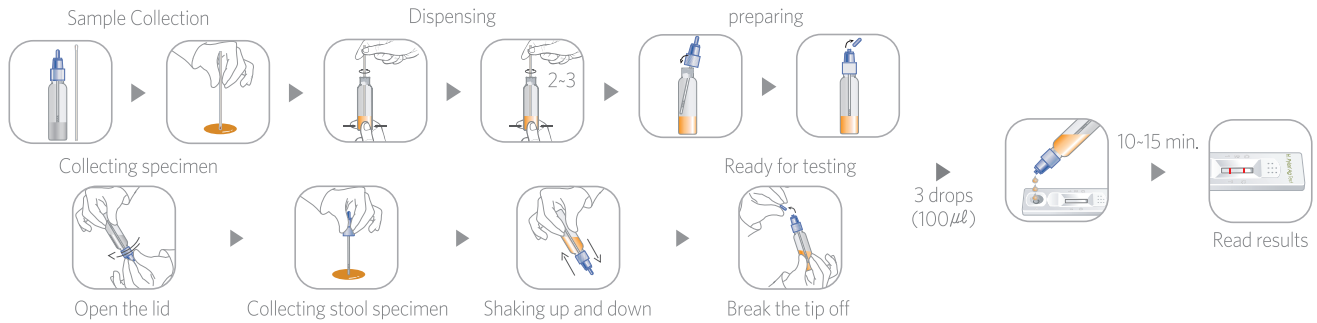
Positive Negative Invalid

General Information

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

Test Procedure

Card



Hepatitis C Virus Test

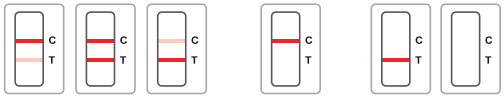
HCV Antibody Test

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

Interpretation of results



Positive Negative Invalid

Clinical Performance

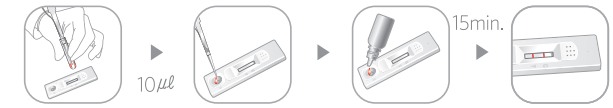
- A study was performed using 302 positive and negative serum specimens.
  Each specimen was assayed with the Humasis HCV Card and a commercially available HCV EIA.

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

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

Test Procedure

Card



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

Multi-Card

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

HIV Test

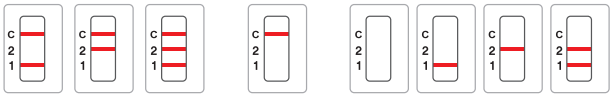
HIV 1/2 Antibody Test

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	Package	Feature	Specimen	Shelf life
HIV 1/2 Card Card(AIB-7030)	30 tests/case	3rd Generation Antibody Test	Whole blood/ Serum/Plasma	18 months
Multi-Card(AIB-6100)	100 tests/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 available HIV EIA.

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

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

Test Procedure

Card

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

Multi-Card

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

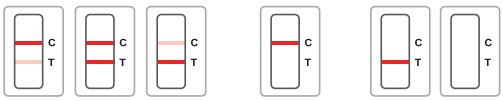
Syphilis is curable sexually transmitted disease caused by the Treponema pallidum spirochete. The route of syphilis is almost always by sexual contact. However, there are examples of congenital syphilis via transmission from mother to fetus.

Syphilis Test

Information

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

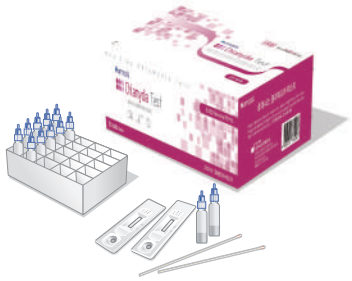
Card

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

Multi-Card

Sample Collection · Dispensing · Add 1drop of assay diluent · Read results

Chlamydia Test

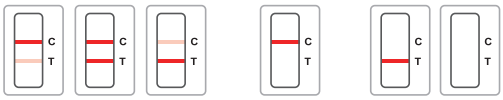


Chlamydia trachomatis is a bacterium which causes a sexually transmitted infection(STI). Chlamydia is very common disease, which should be taken very seriously. The most worried effect of a chlamydia infection in women is potential fertility problem(PID, infertility, etc), due to inflammation of the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

Information

Product name	Package	Feature	Specimen	Shelf life
Chlamydia Test Card(ACHG-7025)	25 tests/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

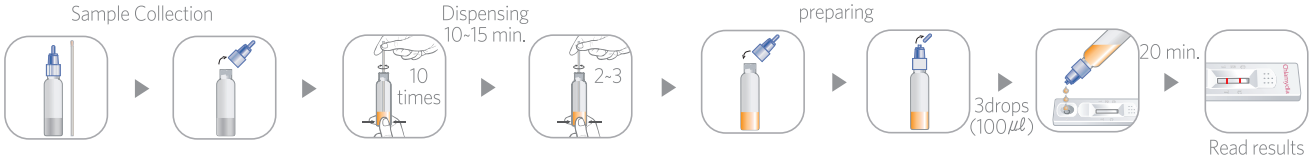
Relative Sensitivity 99%, Relative Specificity 99%, Relative accuracy 99%

		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

Card



Read results

TUMOR

CEA Test

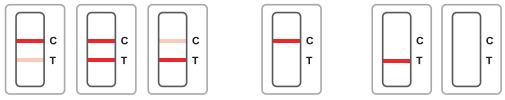
Carcinoembryonic Antigen(CEA) Test

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	Package	Feature	Specimen	Shelf life
CEA Card Card(ACEA-7030)	30 tests/case	5 ng/mL	Whole blood/ Serum/Plasma	14 months
Multi-Card(ACEA-6100)	100 tests/case	5 ng/mL	Whole blood/ Serum/Plasma	14 months

Interpretation of results



Positive Negative Invalid

Test Procedure

Card

1 drop of Serum or Plasma | 2 drops of Venipuncture Whole Blood | 50 μl of Fingerstick Whole Blood | 2 drops of Fingerstick Whole Blood | Read results

FOB Test

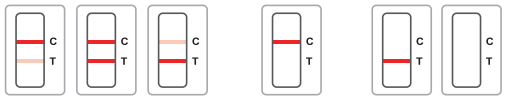
Fecal Occult Blood(FOB) Test

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	Package	Feature	Specimen	Shelf life
FOB Test Card(AFOB-7020)	20 tests/case	50 ng/mL	Stool	18 months
Multi-Card(AFOB-6050)	50 tests/case	50 ng/mL	Stool	18 months

Interpretation of results



Positive Negative Invalid

Test Procedure

Test Preparation

Open the blue lid | Collecting stool specimen | Shaking up and down | Open the yellow lid

Card

Preparing test device | Dispensing | Read results

Multi-Card

Preparing test device | Dispensing | Read results

TUMOR

AFP Test

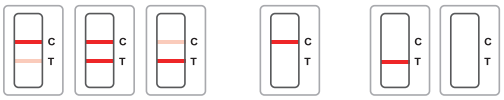
Alpha-Fetoprotein(AFP)Test

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	Package	Feature	Specimen	Shelf life
AFP Card Card(AAFP-7030)	30 tests/case	20 ng/mL	Serum/Plasma	24 months
Multi-Card(AAFP-6100)	100 tests/case	20 ng/mL	Serum/Plasma	24 months

Interpretation of results



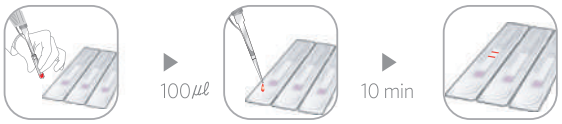
Positive Negative Invalid

Test Procedure

Card

Sample Collection 100μℓ Dispensing 10 min Read results

Multi-Card



Sample Collection 100μℓ Dispensing 10 min Read results

PSA Test

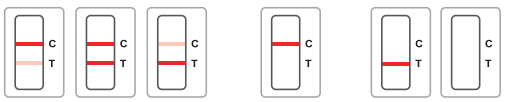
Prostate Specific Antigen(PSA) Test

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 concentration 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	Package	Feature	Specimen	Shelf life
PSA Test Card(APSA-7030)	30tests/case	4.0 ng/mL	Whole blood/ Serum/Plasma	18 months
Multi-Card(APSA-6100)	100tests/case	4.0 ng/mL	Whole blood/ Serum/Plasma	18 months

Interpretation of results



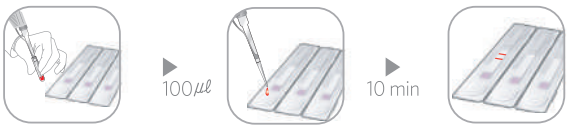
Positive Negative Invalid

Test Procedure

Card

Sample Collection 100μℓ Dispensing 10 min Read results

Multi-Card

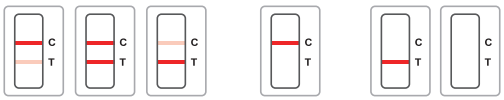


Sample Collection 100μℓ Dispensing 10 min Read results

Single Test

Product name	Package	Analytical sensitivity	Specimen	Shelf life
Troponin I test Card (ACTI-7010)	10 tests/case	Troponin I 0.5 ng/mL	Whole blood/ Serum/Plasma	18 months

Interpretation of results



Positive Negative Invalid

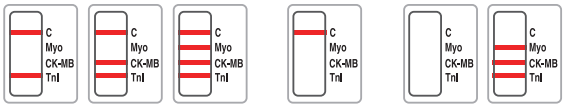
Test Procedure

Sample Collection Dispensing Read results

Triple Test

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

Interpretation of results



Positive Negative Invalid

Test Procedure

Sample Collection Dispensing Read results

Clinical Performance

- Troponin I

		Quantitative Reference Test(Beckman Coulter Access)		Total
		Negative(<0.5 ng/mL)	Positive(> 0.5 ng/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(<5 ng/mL)	Positive(> 5 ng/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(<0.5 ng/mL)	Positive(> 0.5 ng/mL)	
Humasis Myoglobin	Negative	36	0	36
	Positive	4	99	103
Total		40	99	139

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

FERTILITY CE

Pregnancy Test : hCG(Human Chorionic Gonadotropin) Test
Ovulation Test : LH(Luteinizing Hormone) Test
Menopause Test : FSH(Follicle Stimulating Hormone) Test
Abnormal Pregnancy(Abortion or ectopic) Screening Test

Pregnancy Test: hCG detection 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, and accuracy
- Suitable for early pregnancy test

Ovulation Test: LH detection 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 conceive.

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 detection 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 Menopause.

General Information

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

Abnormal Pregnancy (ectopic or abortion) Screening Test.

In the first trimester of pregnancy, there is high risk of miscarriage caused by spontaneous abortion (miscarriage) and ectopic pregnancy. The overall miscarriage rate is reported as 15~20%, which means 15~20% of recognized pregnancies results in miscarriage.

However, this rate can be increased up to 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 Information

Inexscreen can detect two types of hCG isoforms: intact hCG & modified hCG which is β -hCG like isoforms and determine the molar ratio of two isoforms semi-quantitatively.
The analytical sensitivity of intact hGC 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 spontaneous abortion or ectopic pregnancy.
- Monitoring normal pregnancy

CE

Pregnancy Tests
hCG Test

Product name	Package	Detection limit	Specimen	Shelf life	Results
after Midstream(ANP-2001)	1 test/case	25 mIU/mL	Urine	36 months	Positive
hCG Card Card(ANP-7025)	25 tests/case	25 mIU/mL	Urine	24 months	Negative
hCG Combo (ANPC-7025)	25 tests/case	25 mIU/mL	Urine, Serum	24 months	Invalid
High sensitivity hCG Midstream(ANPH-2001)	1 tests/case	15 mIU/mL	Urine	36 months	

Test Procedure
Card

Midstream

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

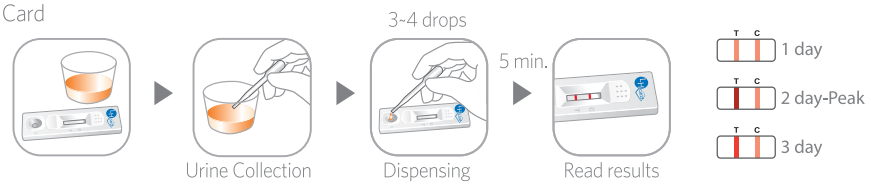
05:00 Wait 5 minutes, and then read the results

CE

Ovulation Tests
LH Test

Product name	Package	Detection limit	Specimen	Shelf life	Results
before Midstream(AOV-2005)	5 tests/case	40 mIU/mL	Urine	24 months	Positive
LH Card Card(AOV-7025)	25 tests/case	40 mIU/mL	Urine	24 months	Negative Invalid

Test Procedure
Card



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	Results
continue Midstream(AME-2001)	1 test/case	25 mIU/mL	Urine	24 months	Positive
continue Card Card(AME-7025)	25 tests/case	25 mIU/mL	Urine	24 months	Negative Invalid

Test Procedure
Card

Midstream

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

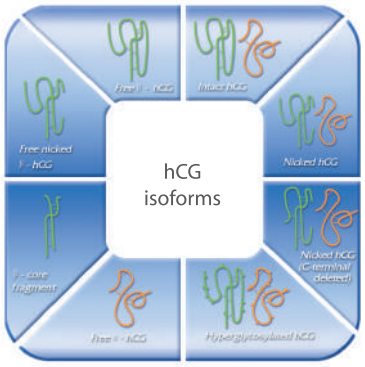
10:00 Wait 10 minutes, and then read the results

CE

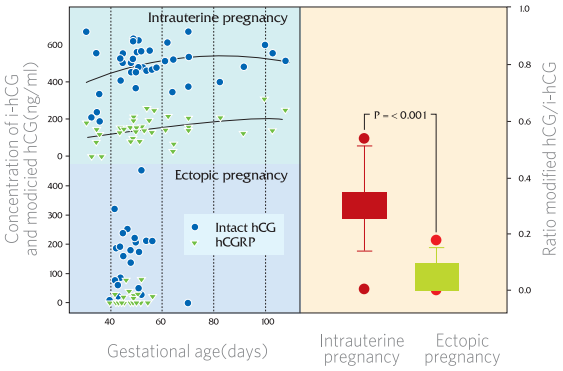
Abnormal Pregnancy Inexscreen

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

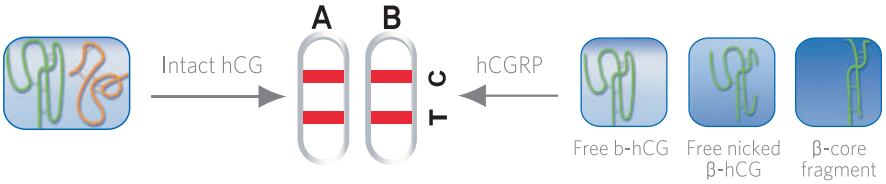
Multiple hCG-related molecules (hCG isoforms) are present in serum and urine samples of pregnant women.



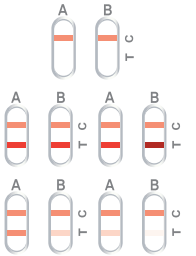
Ectopic & spontaneous abortion are associated with low molar ratio of free β-hCG like isoforms to intact hCG(i-hCG)



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	Results
			A window	B window			
Not pregnant		No hCG			 5 min		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

2. POCT – Point of Care Testing

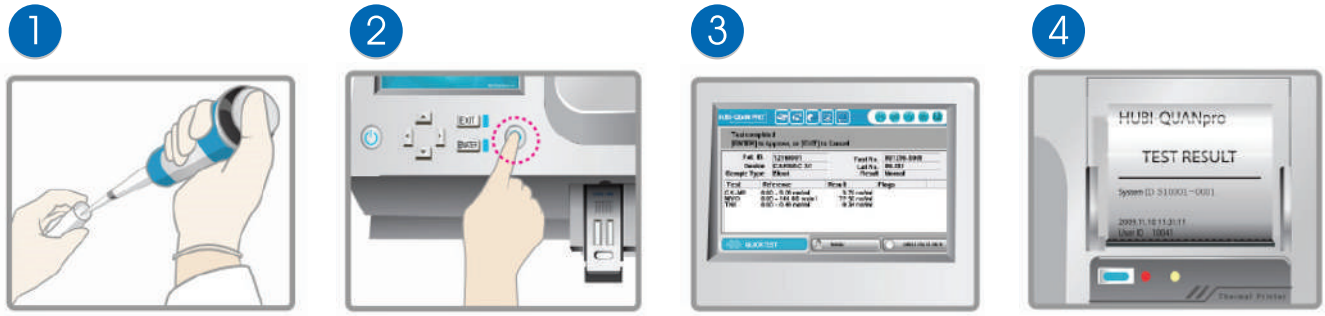
HUBI-QUAN PRO®

One system, for multiple markers
Simple & Fast Point of care system for severity assessment

HUBI-QUAN Pro is a system to carry multiple biomarkers including Cardiac, Hormone, Inflammation, Tumor that provides the reliable test results to make rapid, cost-effective decisions for better patients treatment at the point-of-care (POC).

- Simple test procedure
- Fast result in 5~15 minutes
- Wide Range of test parameter
- Auto-Calibration
- Auto Specimen recognition
- LIS/HIS Connecitivity

Test Procedure



Test information

Product Name	Measuring range	Specimen
HUBI Troponin I	0.05~20 ng/mL	WB, P
HUBI CK-MB	1.5~40 ng/mL	WB, P
HUBI BNP	25~800 pg/mL	WB, P
HUBI D-Dimer	TnI : 0.05~20 ng/mL	WB, P
HUBI DUO(TnI/CK-MB)	100~5,000 ng/mL 0.05~20 ng/mL	WB, P
HUBI Cardiac 3 in 1	TnI : 0.05~20 ng/mL CKMB : 1.5~40 ng/mL Myo : 20~400 ng/mL	WB, P
HUBI 3 in 1 (B)	TnI : 0.05~20 ng/mL CKMB : 1.5~40 ng/mL BNP : 25~800 pg/mL	WB, P

Product Name	Measuring range	Specimen
HUBI hCG	5~500 mIU/mL	WB
HUBI LH	5~200 mIU/mL	WB
HUBI FSH	5~200 mIU/mL	WB
HUBI TSH	0.2~100 mIU/mL	WB, S, P
HUBI BPHScreen	Total PSA : 0.4~20 ng/mL Free PSA : 0.05~10 ng/mL	WB, Capillary WB
HUBI CRP	5~200 mIU/mL	WB, Capillary WB
HUBI PCT	1.5~10 ng/mL	WB, S, P
HUBI IL-6	30~2,000 pg/mL	WB, S, P

* WB=Whole Blood P=Plasma S=Serum

HUBI·TAS

Multiplex platform for Healthcare provider

HUBI-TAS is a multiplex platform optimized for small size on site testing to provide the total solution for improving patients management.

Random accessible Dual Tray

- A combined Immunoassay and Urinalysis analyzer
- Multi parameter testing in 1 test device & specimen
- Touchscreen and user friendly GUI
- Auto-Calibration and Auto Specimen recognition
- Up to 60 tests/hour throughput

Get ready for SARS-CoV-2 Testing! Reliable, timely results

- COVID-19 Ag + Ab Tests are available
- Improving COVID-19 patient management
- Monitoring personal immunity after vaccination

3. URINE ANALYSIS

CE

HUMASIS URINALYSIS

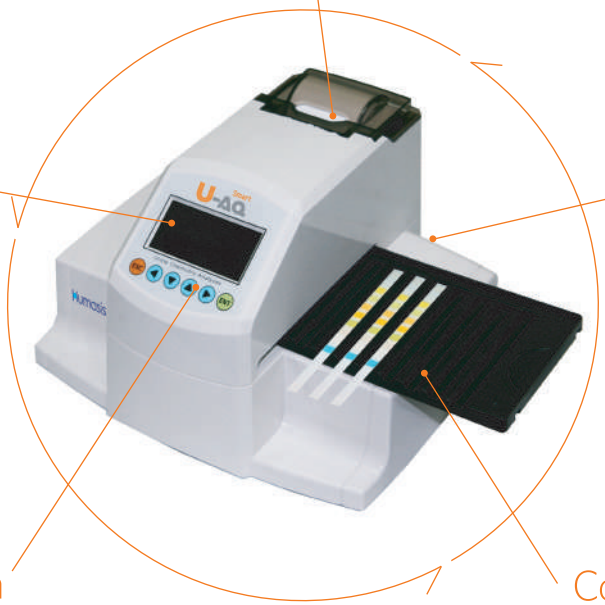
Smart U-AQ

300Tests/h (Max. 800Tests)

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	RS-232 C, PS/2

Urine Chemistry Analyzer more Accurate & Quicker

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

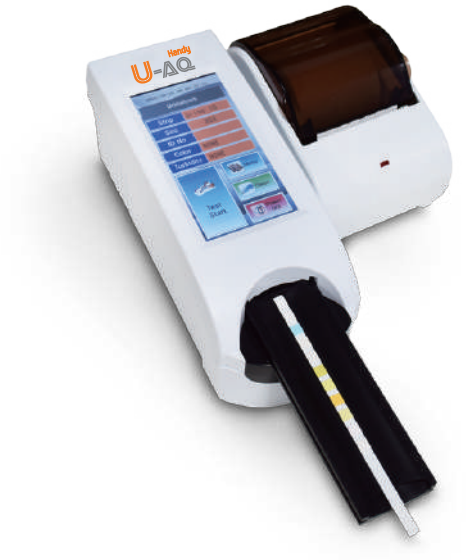


Wide LCD Screen
- Support 7 languages
- Provide various test mode (General, One by One, Quick Mode)

Various Interfaces
- Barcode reader(RS-232 C)
- Keyboard(PS/2)
- LIS Interface(RS-232 C)

Operation Button
- Control of operation with 6 buttons
- Availability of inputting using keyboard

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



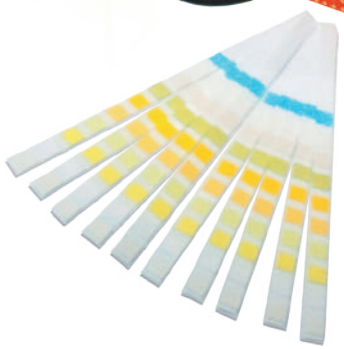
Handy U-AQ

45Tests/h (Max. 120Tests)

Technical Specifications	
Operating mode	Semi-automatic urine analyzer
Dimension	188x74x77mm
Weight	0.40 kg
Power	100-250V, 3.33A or AAA battery 1.5V x 8EA
Oper. Conditions	Temp. : 2℃-30℃ / Humi. : 10%-70%
Method	Reflectance photometer
Test Capacity	45Tests/hour(Max. 120tests)
Memory Capacity	2,000 Samples
Interface	USB

Product	Cat. No.	Power	Keyboard	Bluetooth(option)	Comm.Cable
U-AQ Smart	AAQ-8011	AC Adapter	O	X	RS-232 Cable
U-AQ Handy	AAQ-8012	AC Adapter / Battery(AAAx8)	X	O	USB Cable
U-AQ Core	AAQ-8010	AC Adapter	X	X	RS-232 Cable

U-AQS



Reagent Strips for Urinalysis

- Fast results 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
- MFDS(KFDA) certified & CE marked

	Cat. No.	Urinalysis Strips	Creatinine	Microalbumin	Glucose	Bilirubin	Ketones	Specific Gravity	Blood	pH	Protein	Urobilinogen	Nitrite	Leukocytes
U-AQS 2MAC	AUS2MAC-3050		▬	▬										
U-AQS 12MAC	AUS12MAC-3050		▬	▬	▬	▬	▬	▬	▬	▬	▬	▬	▬	▬
Quality Controls														
Level Ⅰ	MAS UA Controls		10 mg/dL	10 mg/dL	Neg.	Neg.	Neg.	1.015 ~1.030	Neg.	5.0 ~6.0	Neg.	Norm.	Neg.	Neg.
Level Ⅱ	MAS UA Controls		100~300 mg/dL	80~150 mg/L	100~1000 mg/dL	1+~3+	15~100 mg/dL	1.015 ~1.030	10~250 RBC/uL	7.0 ~9.0	30~300 mg/dL	2~8 mg/dL	Pos.	25~500 WBC/uL

	Cat. No.	Urinalysis Strips	Ascorbic Acid	Glucose	Bilirubin	Ketones	Specific Gravity	Blood	pH	Protein	Urobilinogen	Nitrite	Leukocytes
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 ㎎/㎗)	1+~2+	±/~2+ (5~40 ㎎/㎗)	1.010~ 1.015	±/~3+ (10~200 RBC/㎕)	6.5 ~8.0	±/~3+ (15~300 RBC/㎕)	2~8 ㎎/㎗	Pos.	±/~3+ (15~500 WBC/㎗)

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

4. PRODUCT LIST

PRODUCTS LIST

Category		Product Name	Cat.No.	Format	Package	Specimen	Shelf life	
Infectious Disease	Respiratory Disease	COVID-19 Ag Test	ACOVA-7025	Card	25 tests/case	Nasal Swab, Nasopharyngeal Swab	18 months	CE
		COVID-19 Ag Home Test	ACOVGS-7005	Card	5 tests/case	Nasal Swab, Nasopharyngeal Swab	18 months	
		COVID-19/Flu Ag Combo Test	ACOFG-7025	Card	25 tests/case	Nasopharyngeal Swab	18 months	
		COVID-19 IgG/IgM Test	ACOV-7025	Card	25 tests/case	Whole blood, Serum, Plasma	18 months	
		COVID-19 RBD/IgG Antibody Test	ACOVR-7025	Card	25 tests/case	Whole blood, Serum, Plasma	18 months	
		Influenza Antigen Card Plus	AINFC-7030	Card	30 tests/case	Nasopharyngeal Swab	24 months	
		Influenza A/B Antigen Test	AINF-3025	Strip	25 tests/case	Nasal Swab	24 months	
		FLU/RSV Combo	AFRC-7030	Card	30 tests/case	Nasopharyngeal Swab	24 months	
		RSV Antigen Test	ARSV-3025	Strip	25 tests/case	Nasal Swab, Throat Swab	24 months	
	Malaria Antigen Test	Malaria P.f/Pan Antigen Test	AMAL-7025	Card	25 tests/case	Whole blood(Inverted cup)	24 months	CE
		Malaria P.f/P.v Antigen Test	AMFV-7025	Card	25 tests/case	Whole blood(Inverted cup)	24 months	
		Malaria P.f Antigen Test	AMPF-7025	Card	25 tests/case	Whole blood(Inverted cup)	24 months	
	Dengue Test	Dengue Combo Test	ADEC-7025	Card	25 tests/case	Whole blood, Serum, Plasma	24 months	CE
		Dengue NS1 Antigen Test	ADEG-7025	Card	25 tests/case	Whole blood, Serum, Plasma	24 months	
		Dengue IgG/IgM Test	ADEN-7025	Card	25 tests/case	Whole blood, Serum, Plasma	24 months	
	Hepatitis B Virus Test	HBsAg Card	ABSG-7025	Card	25 tests/case	Serum, Plasma	24 months	
		Anti-HBs Card	ABSB-7025	Card	25 tests/case	Serum, Plasma	24 months	
	Hepatitis C Virus Test HCV Antibody	HCV Card	ACB-7030	Card	30 tests/case	Whole blood, Serum, Plasma	18 months	
	Human Immunodeficiency Virus 1/2 Antibody Test	HIV 1/2 Card	AIB-7030	Card	30 tests/case	Whole blood, Serum, Plasma	18 months	
	H-pylori Test	H.pylori Card	AHPY-7030	Card	30 tests/case	Whole blood, Serum, Plasma	24 months	CE
		H.pylori Antigen Test	AHPG-7020	Card	20 tests/case	Stool	24 months	
	Syphilis Test	Syphilis Card	ASB-7030	Card	30 tests/case	Whole blood, Serum, Plasma	24 months	CE
	Chlamydia Test	Chlamydia Test	ACHG-7025	Card	25 tests/case	Vaginal Swab	18 months	
Tumor Marker	Carcinoembryonic Antigen Test	CEA Card	ACEA-7030	Card	30 tests/case	Whole blood, Serum, Plasma	14 months	CE
	Fecal Occult Blood Test	FOB Test	AFOB-7020	Card	20 tests/case	Stool	18 months	
	Alpha-Fetoprotein Test	AFP Card	AAFP-7030	Card	30 tests/case	Serum, Plasma	24 months	
	Prostate Specific Antigen Test	PSA Card	APSA-7030	Card	30 tests/case	Whole blood, Serum, Plasma	18 months	
Cardiac Marker	Acute Myocadial Infarction	Cardiac Triple Test (Troponin I / Myoglobin / CK-MB)	ACTM-7010	Card	10 tests/case	Whole blood, Serum, Plasma	18 months	CE
		Troponin I	ACTI-7010	Card	10 tests/case	Whole blood, Serum, Plasma	18 months	
Fertility	hCG Test (Human Chorionic Gonadotropin)	After	ANP-2001	Midstream	1 test/case	Urine	36 months	CE
		hCG Combo	ANPC-7025	Card	25 tests/case	Urine or Serum	24 months	
	LH Test (Luteinizing Hormone)	Before	AOV-2005	Midstream	5 tests/case	Urine	24 months	
		LH Card	AOV-7025	Card	25 tests/case	Urine	24 months	
	FSH Test (Follicle Stimulation Hormone)	Continue Midstream	AME-2001	Midstream	1 test/case	Urine	24 months	
		Continue Card (FSH)	AME-7025	Card	25 tests/case	Urine	24 months	
	Abnormal Pregnancy (Ectopic or Abortion) Screen	Inexscreen	AEP-5010	Combo	10 tests/case	Urine	22 months	
Others	Glucose-6-phosphate dehydrogenase deficiency Test	G6PD	AG6PD-7025	Card	25 tests/case	Whole blood	18 months	CE
Urinalysis chemistry	Analyzer	U-AQ Smart / Handy		Unit	1 Unit	Semi-Quantitative urinalysis analyzer		CE
	Strip	U-AQS 2GP / 3 / 3GK / 4 / 4SG / 5 / 10 / 11		Strip	100 tests/bottle	Urine	24 months	
	Strip	2MAC / 12MAC		Strip	50 tests/bottle	Urine	24 months	

*Storage : 2 - 30°C

PRODUCTS LIST

Category	Product Name	Cat.No.	Dimension	Power	Test time	
POCT Analyzer	HUBI-QUAN Pro	AHQ-8001	255*178*92.7mm	100 - 240V, 50 - 60 Hz	within 5-15min	CE
	HUBI-TAS	AHT-8001	255*205*115mm	100 - 240V, 50 - 60 Hz	within 5-15min	

Parameters							
Category	Product Name	Cat.No.	Format	Package	Specimen	Shelf life	
Myocardial Cardiac Marker	HUBI Troponin I	ACTI-8025	Card	25 tests/case	Whole blood or Plasma	18 months	CE
	HUBI CK-MB	ACCK-8025	Card	25 tests/case	Whole blood or Plasma	12 months	
	HUBI BNP	ABNP-8025	Card	25 tests/case	Whole blood or Plasma	18 months	
	HUBI D-Dimer	ADIM-8025	Card	25 tests/case	Whole blood or Plasma	18 months	
	HUBI FABP	AFABP-8025	Card	25 tests/case	Whole blood or Plasma	18 months	
	HUBI DUO (TnI/CK-MB)	ACDC-8025	Card	25 tests/case	Whole blood or Plasma	18 months	
	HUBI Cardiac 3 in 1	ACTM-8025	Card	25 tests/case	Whole blood or Plasma	18 months	
	HUBI 3 in 1 (B)	ACTCB-8025	Card	25 tests/case	Whole blood or Plasma	18 months	
Inflammation	HUBI CRP	ACRP-8025	Card	25 tests/case	Capillary or Venous blood	18 months	
	HUBI PCT	APCT-8025	Card	25 tests/case	Whole blood, Serum, Plasma	14 months	
	HUBI IL-6	AIL-6-8025	Card	25 tests/case	Whole blood, Serum, Plasma	18 months	
Hormone	HUBI hCG	ANP-8025	Card	25 tests/case	Whole blood	12 months	
	HUBI LH	AOV-8025	Card	25 tests/case	Venous blood	12 months	
	HUBI FSH	AME-8025	Card	25 tests/case	Venous blood	12 months	
	HUBI TSH	ATSH-8025	Card	25 tests/case	Whole blood, Serum, Plasma	12 months	
Tumor Marker	HUBI BPHScreen	ABPH-8025	Card	25 tests/case	Whole blood (Capillary or Venous)	24 months	

*Storage : 2 - 8°C (except CRP/hCG : 2 - 30°C)

Ordering

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

Humasis

Contact information is as follow:

Humasis Co., Ltd
Head office : 37, Gunpocheomdansaneop 2-ro, Gunpo-si, Gyeonggi-do, 15880, Republic of Korea
Tel: +82-31-8085-6200 **Fax:** +82-31-8085-6249
E-mail: question@humasis.com
www.humasis.com

CAT2021-09-14_R11