



# lumasis

Innovative diagnostic kits for people's better lives.



# GLOBAL

Beyond Korea and around the world, Humasis strives to become the global leading company.

## PRODUCTS LIST

Product Name	Cat.No.	Format	Package	Measuring range	Specimen	Shelf life
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### CE Quantitative POCT Analyzer

Product Name	Cat.No.	Format	Package	Measuring range	Specimen	Shelf life
HUBI QUAN PRO	AHQ-8001	Quantitative assay platform				
HUBI Troponin I	ACTI-8025	Card	25 tests/case	0.05-20 ng/mL	Whole blood or Plasma	18 months
HUBI CK-MB	ACCK-8025	Card	25 tests/case	1.5-40 ng/mL	Whole blood or Plasma	12 months
HUBI Myoglobin	ACMG-8025	Card	25 tests/case	20-400 ng/mL	Whole blood or Plasma	9 months
HUBI BNP	ABNP-8025	Card	25 tests/case	25-800 pg/mL	Whole blood or Plasma	18 months
HUBI D-Dimer	ADIM-8025	Card	25 tests/case	100-5,000 ng/mL	Whole blood or Plasma	18 months
HUBI FABP	AFABP-8025	Card	25 tests/case	1-50 ng/mL	Whole blood or Plasma	18 months
HUBI FABP-Troponin I	AFACT-8025	Card	25 tests/case	FABP: 1-50 ng/mL TnI: 0.05-20 ng/mL	Whole blood or Plasma	18 months
HUBI DUO(TnI/CKMB)	ACDC-8025	Card	25 tests/case	TnI: 0.05-20 ng/mL CKMB: 1.5-30 ng/mL	Whole blood or Plasma	18 months
HUBI Cardiac 3 in 1	ACTM-8025	Card	25 tests/case	TnI: 0.05-20 ng/mL CKMB: 1.5-40 ng/mL Myo: 20-400 ng/mL	Whole blood or Plasma	18 months
HUBI 3 in 1(B)	ACTCB-8025	Card	25 tests/case	TnI: 0.05-20 ng/mL CKMB: 1.5-40 ng/mL BNP: 25-800 pg/mL	Whole blood or Plasma	18 months



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29-30	Urine Chemistry Analysis

Product Name	Cat.No.	Format	Package	Measuring range	Specimen	Shelf life
HUBI hCG	ANP-8025	Card	25 tests/case	5-500 mIU/mL	Whole blood	12 months
HUBI LH	AOV-8025	Card	25 tests/case	5-200 mIU/mL	Venous blood	12 months
HUBI FSH	AME-8025	Card	25 tests/case	5-200 mIU/mL	Venous blood	12 months
HUBI TESTO	ATST-8025	Card	25 tests/case	1.5-10 ng/mL	Whole blood, Serum, Plasma	18 months
HUBI TSH	ATSH-8025	Card	25 tests/case	0.2-100 mIU/L	Whole blood, Serum, Plasma	12 months
HUBI Free T4	AFRT-8025	Card	25 tests/case	0.4-6.0 mIU/L	Whole blood, Serum, Plasma	18 months
HUBI BPHScreen	ABPH-8025	Card	25 tests/case	Total-PSA: 0.4-20 ng/mL Free-PSA: 0.05-10 ng/mL	Capillary or Venous blood	24 months
HUBI Total PSA	APSA-8025	Card	25 tests/case	0.4-20 ng/mL	Capillary or Venous blood	12 months
HUBI Free PSA	AFSA-8025	Card	25 tests/case	0.05-10 ng/mL	Capillary or Venous blood	12 months
HUBI CRP	ACRP-8025	Card	25 tests/case	2-300 mg/L	Capillary or Venous blood	18 months
HUBI PCT	APCT-8025	Card	25 tests/case	0.1-75 ng/mL	Whole blood, Serum, Plasma	12 months
HUBI IL-6	AIL-6-8025	Card	25 tests/case	30-2,000 pg/mL	Whole blood, Serum, Plasma	18 months
HUBI FluSens	AINF-8010	Card	10 tests/case	Influenza A, B	Nasopharyngeal Swab	24 months

# PRODUCTS LIST

Product Name	Cat.No.	Format	Package	Detection limit	Specimen	Shelf life
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## CE FERTILITY

### Pregnancy Tests - hCG(Human Chorionic Gonadotropin)

after	ANP-2001	Midstream	1 test/case	25 mIU/mL	Urine	36 months
hCG Card	ANP-7025	Card	25 tests/case	25 mIU/mL	Urine	24 months
hCG Strip	ANP-3001	Strip	1 test/case	25 mIU/mL	Urine	24 months
	ANP-3100	Strip	100 tests/case	25 mIU/mL	Urine	24 months
hCG Combo	ANPC-7025	Card	25 tests/case	25 mIU/mL	Urine or Serum	24 months

### Ovulation Tests - LH(Luteinizing Hormone)

before	AOV-2005	Midstream	5 tests/case	40 mIU/mL	Urine	24 months
LH Card	AOV-7025	Card	25 tests/case	40 mIU/mL	Urine	24 months
LH Strip	AOV-3001	Strip	1 test/case	40 mIU/mL	Urine	24 months
	AOV-3100	Strip	100 tests/case	40 mIU/mL	Urine	24 months

### Menopause Tests - FSH(Follicle Stimulating Hormone)

continue Midstream	AME-2001	Midstream	1 test/case	25 mIU/mL	Urine	24 months
continue Card	AME-7025	Card	25 tests/case	25 mIU/mL	Urine	24 months

### Abnormal Pregnancy (Ectopic or abortion)Screen

Inexscreen	AEP-5010	Combo	10 tests/case	25 mIU/mL	Urine	22 months
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## CE AMI

### Acute Myocardial Infarction Tests

#### Triple Marker Test (Troponin I / Myoglobin / CK-MB)

Cardiac Triple Test Plus	ACTM-7010	Card	10 tests/case	0.5,50,5ng/mL	Whole blood, Serum, Plasma	18 months
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#### Double Marker Test

Troponin I/Myoglobin	ACDM-7010	Card	10 tests/case	0.5,50 ng/mL	Whole blood, Serum, Plasma	18 months
Troponin I/CK-MB	ACDC-7010	Card	10 tests/case	0.5,5 ng/mL	Whole blood, Serum, Plasma	18 months
FABP/Troponin I	AFACT-5020	Card	20 tests/case	6, 0.5 ng/mL	Whole blood, Serum, Plasma	18 months

#### Single Marker Test

Troponin I	ACTI-7010	Card	10 tests/case	0.5 ng/mL	Whole blood, Serum, Plasma	18 months
Myoglobin Test	ACMG-7025	Card	25 tests/case	50 ng/mL	Whole blood, Serum, Plasma	18 months
CK-MB Test	ACCK-7025	Card	25 tests/case	5 ng/mL	Whole blood, Serum, Plasma	18 months
FABP Test	AFABP-7010	Card	10 tests/case	6 ng/mL	Whole blood, Serum, Plasma	18 months

## INFECTIOUS DISEASE

### Malaria Antigen Test CE

Malaria P.f/Pan Antigen Test	AMAL-7025	Card	25 tests/case	HRP-II(P.f) pLDH(P.f,P.v,P.o or P.m)	Whole blood(Inverted cup)	24 months
Malaria P.f/P.v Antigen Test	AMFV-7025	Card	25 tests/case	HRP-II(P.f) pLDH(P.v)	Whole blood(Inverted cup)	24 months
Malaria P.f Antigen Test	AMPF-7025	Card	25 tests/case	HRP-II(P.f)	Whole blood(Inverted cup)	24 months

### Dengue Test CE

Dengue IgG/IgM Test	ADEN-7025	Card	25 tests/case	IgG/IgM	Whole blood, Serum, Plasma	24 months
Dengue NS1 Antigen Test	ADEG-7025	Card	25 tests/case	NS1 Antigen	Whole blood, Serum, Plasma	24 months
Dengue Combo Test	ADEC-5025	Card	25 tests/case	IgG/IgM, NS1 Antigen	Whole blood, Serum, Plasma	24 months

### Influenza A/B Test CE

Influenza A/B Antigen Test	AINF-3025	Strip	25 tests/case	Influenza A, B	Nasal swab	24 months
Influenza Antigen Card Plus	AINFC-7030	Card	30 tests/case	Influenza A, B	Nasopharyngeal Swab	24 months
FLU/RSV Combo	AFRC-7030	Card	30 tests/case	Influenza A, B & RSV A, A2, B	Nasopharyngeal Swab	24 months

### Rota / Adeno Virus Rapid Tests CE

Rota Test	AROT-7020	Card	20 tests/case	Rota virus	Stool	24 months
Adeno Test	AADE-7020	Card	20 tests/case	Adenovirus antigen	Stool	24 months
Rota/Adeno Test	AROAD-7020	Card	20 tests/case	Rota virus / Adenovirus antigen	Stool	24 months

# PRODUCTS LIST

Product Name	Cat.No.	Format	Package	Detection limit	Specimen	Shelf life
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## INFECTIOUS DISEASE

### Respiratory Syncytial Virus Test **CE**

RSV Antigen Test	ARSV-3025	Strip	25 tests/case		Nasal Swab, Throat Swab	24 months
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### Hepatitis B Virus Tests

HBsAg Card	ABSG-7025	Card	25 tests/case	1 ng/mL	Serum, Plasma	24 months
HBsAg Card, multi	ABSG-6100	Multi Card	100 tests/case	1 ng/mL	Serum, Plasma	24 months
HBsAg Strip	ABSG-3100	Strip	100 tests/case	1 ng/mL	Serum, Plasma	24 months
Anti-HBs Card	ABSB-7025	Card	25 tests/case	30 mIU/mL	Serum, Plasma	24 months
Anti-HBs Card, multi	ABSB-6100	Multi Card	100 tests/case	30 mIU/mL	Serum, Plasma	24 months
Anti-HBs Strip	ABSB-3100	Strip	100 tests/case	30 mIU/mL	Serum, Plasma	12 months

### Hepatitis C Virus(HCV) Test : HCV Antibody

HCV Card	ACB-7030	Card	30 tests/case		Whole blood, Serum, Plasma	18 months
HCV Card, multi	ACB-6100	Multi Card	100 tests/case		Whole blood, Serum, Plasma	18 months

### Human Immunodeficiency Virus(HIV) 1/2 Antibody Tests

HIV 1/2 Card	AIB-7030	Card	30 tests/case		Whole blood, Serum, Plasma	18 months
HIV 1/2 Card, multi	AIB-6100	Multi Card	100 tests/case		Whole blood, Serum, Plasma	18 months

### H-pylori Rapid Tests **CE**

H-pylori Card	AHPY-7030	Card	30 tests/case		Whole blood, Serum, Plasma	24 months
H-pylori Card, multi	AHPY-6100	Multi Card	100 tests/case		Whole blood, Serum, Plasma	24 months
H.pylori Antigen Test	AHPG-7020	Card	20 tests/case		Stool	24 months

### Syphilis Rapid Tests **CE**

Syphilis Card	ASB-7030	Card	30 tests/case		Serum, Plasma	24 months
Syphilis Card, multi	ASB-6100	Multi Card	100 tests/case		Serum, Plasma	24 months

### Chlamydia Rapid Tests

Chlamydia Test	ACHG-7025	Card	25 tests/case	2X10 <sup>3</sup> IFU/mL	Vaginal Swab	18 months
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## **CE** TUMOR

### Tumor Marker Tests

#### Carcinoembryonic Antigen(CEA) Test

CEA Card	ACEA-7030	Card	30 tests/case	5 ng/mL	Whole blood, Serum, Plasma	14 months
CEA Card, multi	ACEA-6100	Multi Card	100 tests/case	5 ng/mL	Whole blood, Serum, Plasma	14 months

#### Fecal Occult Blood(FOB) Test

FOB Test	AFOB-7020	Card	20 tests/case	50 ng/mL	Stool	18 months
FOB Test, multi	AFOB-6050	Multi Card	50 tests/case	50 ng/mL	Stool	18 months

#### Alpha-Fetoprotein(AFP) Test

AFP Card	AAFP-7030	Card	30 tests/case	20 ng/mL	Serum, Plasma	24 months
AFP Card, multi	AAFP-6100	Multi Card	100 tests/case	20 ng/mL	Serum, Plasma	24 months

#### Prostate Specific Antigen(PSA) Test

PSA Card	APSA-7030	Card	30 tests/case	4 ng/mL	Whole blood, Serum, Plasma	18 months
PSA Card, multi	APSA-6100	Multi Card	100 tests/case	4 ng/mL	Whole blood, Serum, Plasma	18 months

## ENZYME ACTIVITY

### Glucose-6-phosphate dehydrogenase deficiency Test

G6PD	AG6PD-7025	Card	25 tests/case	150 ± 45 - 1000 ± 300 U/L	Whole blood	18 months
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## COTININE TEST

### Cotinine Test

Nicofind	ANC-7025	Card	25 tests/case	200 ng/mL	Urine	24 months
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## **CE** Urinalysis Chemistry

U-AQ Smart / Core / Handy	Semi-Quantitative urinalysis analyzer				
U-AQ 2GP / 3 / 3GK / 4 / 4SG / 5 / 10 / 11	Strip	100 tests/bottle	Urine	24 months	
2MAC / 12MAC	Strip	50 tests/bottle	Urine	24 months	

# HUBI-QUAN PRO

Point-of-Care Testing Blood Analysis System  
The Right Result at the Right Time

## Specification

- Dimension : 255(W) x 178(D) X 92.7(H)mm
- Weight : 1.35kg
- Window XP Embedded

## Interface

- Built-in thermal printer
- RS232 / PS2 / USB Port / Ethernet
- LIS / HIS compatible
- Data Back-up System

## Data Capacity

- Patient log : 4M PCS
- Patient result : 1M tests
- Data secured by Supervisor card

## Quality Control

- Internal QC : Auto calibration, IQC device
- Optional 2 levels of QC solution (Low/High)

## Key Feature

- RFID System  
(Automatic Calibration and Test Identification)
- Auto sample type recognition
- Efficient use on consumables
- Test Modes (Run Test / Quick Test)
- Test Time : 5-15 minutes

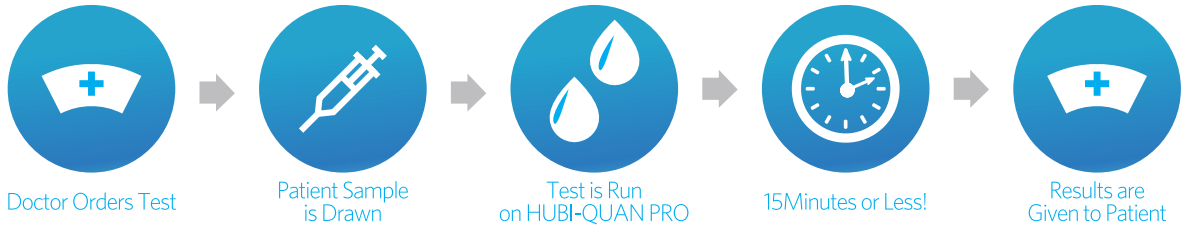


**HUBI-QUAN PRO** is a portable, self-contained and easy system. It is designed to provide quantitative result from HUBI Cartridges. HUBI-QUAN PRO can be used anywhere near to the patient.

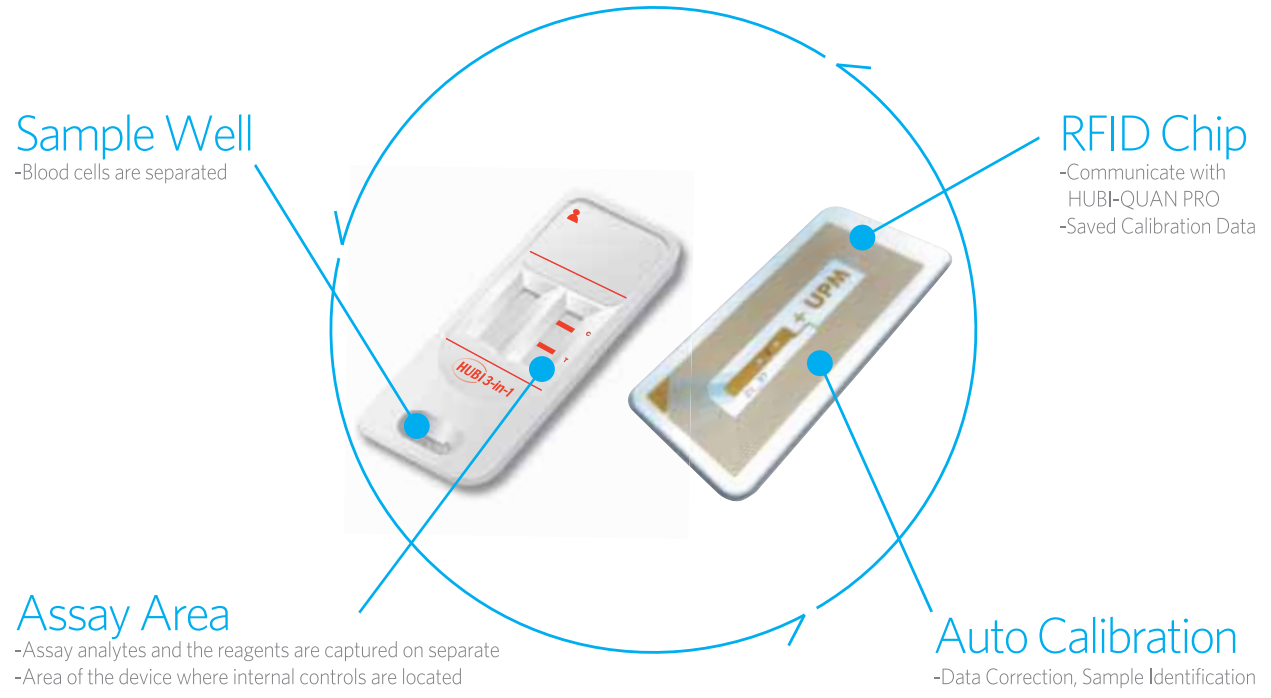
## Test Procedure



# Measure up to 20 parameters with Full lab quality in 15 Minutes or Less!



- Reduce labor cost & Lab send-out costs
- Minimize need for patient call-backs / Enhance practice efficiency
- No capital required for start-up / Rapid return to investment



## Products List

### Quantitative POCT Analyzer

HUBI QUAN PRO | Quantitative assay platform

Product Name	Measuring range	Specimen	Shelf life
HUBI Troponin I	0.05-20 ng/mL	Whole blood or Plasma	18 months
HUBI CK-MB	1.5-40 ng/mL	Whole blood or Plasma	12 months
HUBI Myoglobin	20-400 pg/mL	Whole blood or Plasma	9 months
HUBI BNP	25-800 pg/mL	Whole blood or Plasma	18 months
HUBI D-Dimer	100-5,000 ng/mL	Whole blood or Plasma	18 months
HUBI FABP	1-50 ng/mL	Whole blood or Plasma	18 months
HUBI FABP-Troponin I	FABP : 1-50 ng/mL TnI : 0.05-20 ng/mL	Whole blood or Plasma	18 months
HUBI DUO(TnI/CK-MB)	TnI : 0.05-20 ng/mL CKMB : 1.5-30 ng/mL	Whole blood or Plasma	18 months
HUBI Cardiac 3 in 1	TnI : 0.05-20 ng/mL CKMB : 1.5-40 ng/mL Myo : 20-400 ng/mL	Whole blood or Plasma	18 months
HUBI 3 in 1 (B)	TnI : 0.05-20 ng/mL CKMB : 1.5-40 ng/mL BNP : 25-800 pg/mL	Whole blood or Plasma	18 months

Product Name	Measuring range	Specimen	Shelf life
HUBI hCG	5-500 mIU/mL	Whole blood	12 months
HUBI LH	5-200 mIU/mL	Venous blood	12 months
HUBI FSH	5-200 mIU/mL	Venous blood	12 months
HUBI TESTO	1.5-10 ng/mL	Whole blood, Serum, Plasma	18 months
HUBI TSH	0.2-100 mIU/mL	Whole blood, Serum, Plasma	12 months
HUBI Free T4	0.4-6.0 mIU/mL	Whole blood, Serum, Plasma	18 months
HUBI BPHScreen	Total PSA : 0.4-20 ng/mL Free PSA : 0.05-10 ng/mL	Capillary or Venous blood	24 months
HUBI Total PSA	0.4-20 ng/mL	Capillary or Venous blood	12 months
HUBI Free PSA	0.5-10 ng/mL	Capillary or Venous blood	12 months
HUBI CRP	2-300 mg/L	Capillary or Venous blood	12 months
HUBI PCT	0.1-75 ng/mL	Whole blood, Serum, Plasma	12 months
HUBI IL-6	30-2,000 pg/mL	Whole blood, Serum, Plasma	18 months
HUBI FluSens	Influenza A, B	Nasopharyngeal Swab	24 months



## 'HUBI FluSens' testing can be performed near the site of patient care.

The advancement in performance and objectivity in reading test results with HUBI QUAN PRO allows for timely decision making at the point of care, accelerating diagnosis and helping to ensure appropriate patient decisions and timely treatment.

## Specifications

Product Name	HUBI FluSens
Detection	Influenza A and B
Method	Immunoassay
Test Time	8 minutes
Test Type	Card
Sample Type	Nasopharyngeal Swab
Storage Condition	2 - 8 °C
Shelf-Life	24 months
Kit components	Test Device, Extraction buffer, Swab, Instruction manual

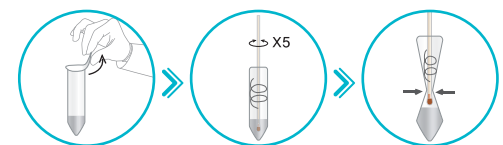
# HUBI FluSens

Influenza A/B Antigen Test

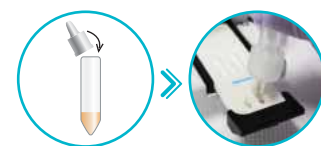
For rapid detection of Influenza on HUBI-QUAN PRO

- High sensitive detection
- Differentiates Influenza A and B by colors red and blue

## Test Procedure



Preparation of sample



Dropping sample



Analysis of test device

Reading test result

Interpretation of result



## NEW PRODUCT



### 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 °C

### Accurate & Reliable

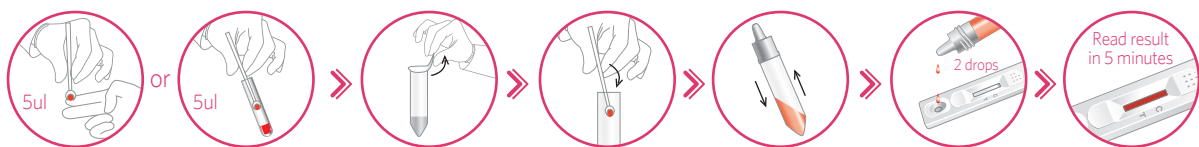
> 99% sensitivity  
95% agreement with whole blood sample

## Humasis G6PD One Step G6PD Test



**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 (olive or blue green) 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 µl
Storage Condition	1 - 30 °C
Shelf-Life	18 months
Kit Components	25 tests/box



## FERTILITY

Pregnancy Test : hCG(Human Chorionic Gonadotropin) Test

Ovulation Test : LH(Luteinizing Hormone) Test

Menopause Test : FSH(Follicle Stimulating Hormone) 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. Luteinizing 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



## 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	
hCG Strip	Strip(ANP-3001) 1 test/case	25 mIU/mL	Urine	24 months	 Negative
	Strip(ANP-3100) 100 tests/case	25 mIU/mL	Urine	24 months	
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



## 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	
Strip	Strip(AOV-3001) 1 test/case	40 mIU/mL	Urine	24 months	 Negative
	Strip(AOV-3100) 100 tests/case	40 mIU/mL	Urine	24 months	
	Strip(AOV-3200) 200 tests/case	40 mIU/mL	Urine	24 months	

### Test Procedure Card



### Midstream



## 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	
Strip	Strip(AME-3001) 1 test/case	25 mIU/mL	Urine	24 months	 Negative
	Strip(AME-3100) 100 tests/case	25 mIU/mL	Urine	24 months	
	Strip(AME-3200) 200 tests/case	25 mIU/mL	Urine	24 months	

### Test Procedure Card



### Midstream





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## Abnormal Pregnancy (Abortion or ectopic) Screening Test

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### 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  $\beta$ -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 spontaneous abortion or ectopic pregnancy.
- Monitoring normal pregnancy

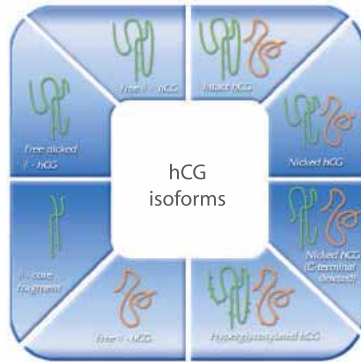


# Abnormal Pregnancy Inexscreen

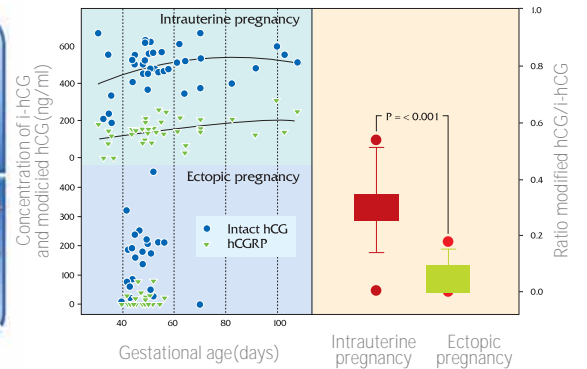


Product name	Package	Detection limit	Specimen	Shelf life
Inexscreen Combo(AEP-5010)	10 tests/case	25 mIU/mL	Urine	22 months

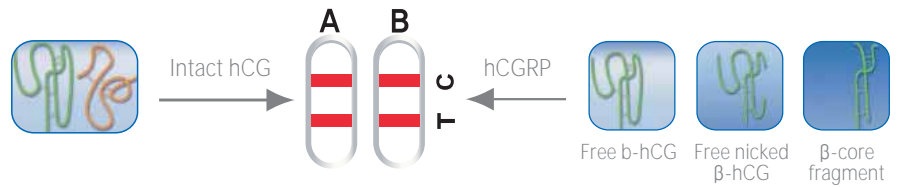
Multiple hCG-related molecules (hCG isoforms) are present in serum and urine samples of pregnant women.



Ectopic & spontaneous abortion are associated with low molar ratio of free  $\beta$ -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.



**Positive 2:** High risk of abnormal pregnancy (ectopic or abortion). It is necessary to increase intensity of observation and recommended to retest within one week

## 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					Negative
Normal pregnancy (IUP) (A<B)		Intact hCG free $\beta$ hCG					Positive 1
Abnormal pregnancy (EP or Abortion) (A>B)		Intact hCG					Positive 2

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



AMI

Cardiac Single Test : Troponin I /Myoglobin /CK-MB /FABP

Cardiac Duo Test : Troponin I/CK-MB

FABP/Troponin I

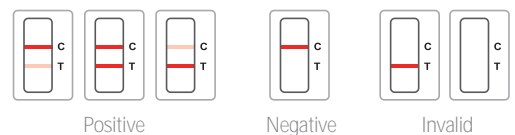
Cardiac Triple Test : Troponin I /CK-MB / Myoglobin

### Single Test

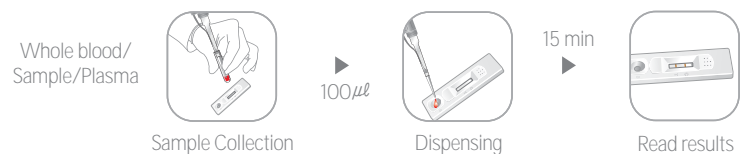


Product name	Package	Analytical sensitivity	Specimen	Shelf life
Troponin I test Card (ACTI-7010)	10 tests/case	Troponin I 0.5 ng/mL	Whole blood/ Serum/Plasma	18 months
Myoglobin test Card (ACMG-7025)	25 tests/case	Myoglobin 50 ng/mL	Whole blood/ Serum/Plasma	18 months
CK-MB test Card (ACCK-7025)	25 tests/case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

### Interpretation of results



### Test Procedure

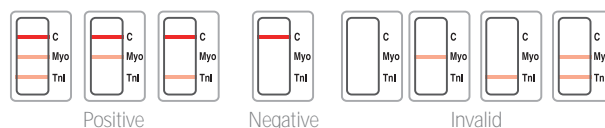


## Duo Test



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

### Interpretation of results



### Test Procedure

Whole blood/  
Sample/Plasma



Sample Collection

100  $\mu$ l



Dispensing

15 min



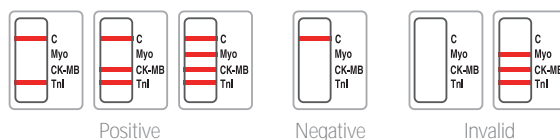
Read results

## 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



### Test Procedure

Whole blood/  
Sample/Plasma



Sample Collection

100  $\mu$ l



Dispensing

15 min



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%

### • FABP

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

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

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.



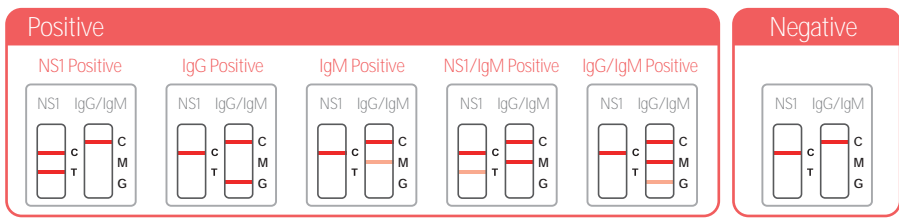
Dengue COMBO Test 

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

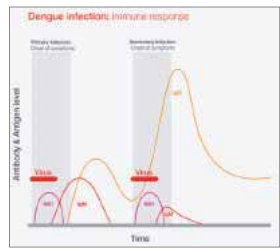
Product name	Package	Feature	Specimen	Shelf life
NS1 & IgG/IgM Combo Test Card(ADEC-5025)	25 tests/case	IgG/IgM, NS1 Antigen	Whole blood/ Serum/Plasma	24 months

Interpretation of results



General information

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



	Dengue NS1 Rapid Test	Dengue IgG/IgM Rapid Test
Position	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%



# INFECTIOUS DISEASE

## Dengue NS1 Antigen Test

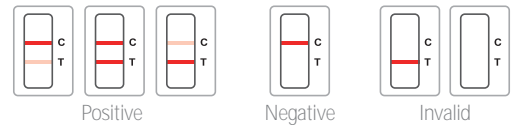


Humasis Dengue NS1 Antigen Test is an immunochromatographic test for qualitative detection of Dengue virus NS1 antigen in human serum, plasma or whole blood.

### 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



### Features

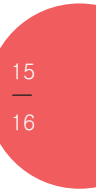
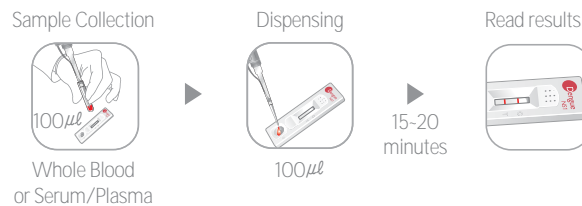
- Early detection right after the onset of the symptoms
- Highly sensitive and easy to use
- Detection of infection prior to seroconversion

### 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

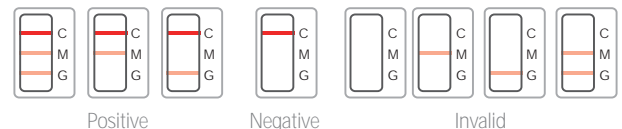


Humasis Dengue IgG/IgM Antibody Test is an immunochromatographic for qualitative detection of dengue virus serotype DEN-1,2,3 and 4.

### 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

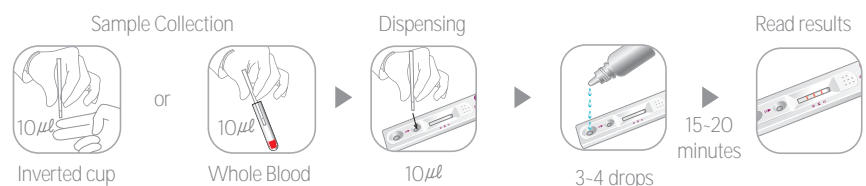
### Interpretation of results



### Features

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

### Test Procedure



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

## Malaria P.f./Pan Antigen Test

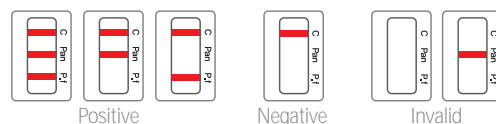


Humasis Malaria P.f./Pan Antigen Test is a one step in-vitro diagnostic test based on immunochromatographic assay. It is designed for detection of P. falciparum(HRP-II) and pLDH(P.falciparum, P.vivax, P.ovale, P.malariae) in human blood.

### 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



### 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

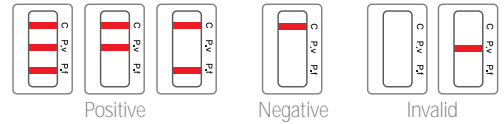


Humasis Malaria P.f./P.v. Antigen Test is a one step in-vitro diagnostic test based on immunochromatographic assay. It is designed for detection of P.falciparum (HRP-II) and P.vivax (pLDH) in human blood.

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



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



17  
18

Malaria P.f Antigen Test

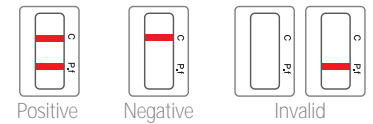


Humasis Malaria P.f. Antigen Test is a one step in-vitro diagnostic test based on immunochromatographic assay. It is designed for detection of P.falciparum (HRP-II) in human blood.

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



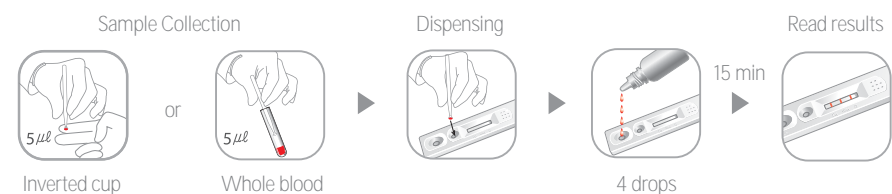
Features

- 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



# INFECTIOUS DISEASE

## Rota Virus Test

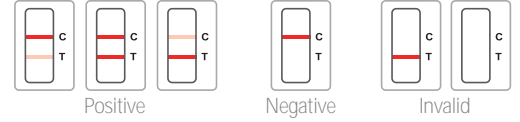


Humasis Rota Test is a rapid immunoassay for the qualitative presumptive detection of rotavirus in human fecal specimens. This test is intended to be used as an aid in the diagnosis of rotavirus infection.

### Information

Product name	Package	Feature	Specimen	Shelf life
Rota Test Card (AROT-7020)	20 tests/case	Rota virus	Stool	24 months

### Interpretation of results



### Clinical Performance

		Humasis Rota Test		Total
		Positive	Negative	
Rota ELISA Test	Positive	79	3	82
	Negative	0	160	160
Total		79	163	242

Relative Sensitivity >99.9%, Relative Specificity 98.2%, Relative Accuracy 98.8%

## Adeno Virus Test

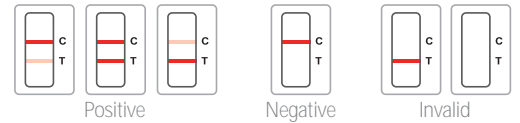


Humasis Adeno Test is a rapid immunoassay for the qualitative presumptive detection of adenovirus in human fecal specimens. This test is intended to be used as an aid in the diagnosis of adenovirus infection.

### Information

Product name	Package	Feature	Specimen	Shelf life
Adeno Test Card (AADE-7020)	20 tests/case	Adeno virus	Stool	24 months

### Interpretation of results



### Clinical Performance

		Humasis Adeno Test		Total
		Positive	Negative	
Adeno ELISA Test	Positive	82	1	83
	Negative	0	127	127
Total		82	128	210

Relative Sensitivity >99.9%, Relative Specificity 99.2%, Relative Accuracy 99.5%

## Rota/Adeno Test



Humasis Rota/Adeno Test is a rapid immunoassay for the qualitative presumptive detection of rotavirus and adenovirus in human fecal specimens. This test is intended to be used as an aid in the diagnosis of rotavirus and adenovirus infection.

### Information

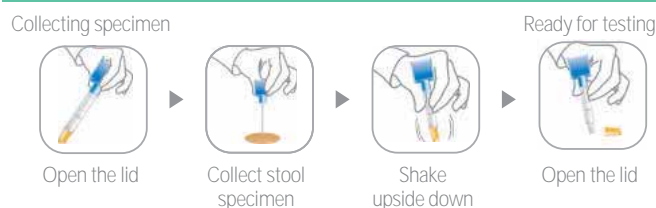
Product name	Package	Feature	Specimen	Shelf life
Rota/Adeno Combo Test Card (AROA-7020)	20 tests/case	Rota/Adeno virus	Stool	24 months

### Interpretation of results



### Test Procedure

#### Test Preparation



#### Card



# INFECTIOUS DISEASE

## Influenza Antigen Card Plus

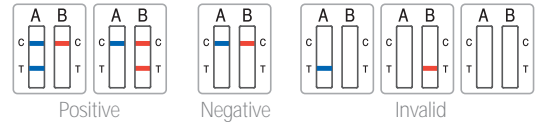


Humasis Influenza Antigen Card Plus is a rapid immunoassay for the qualitative detection of Influenza antigen in Nasopharyngeal sample. This test is intended to be used as an aid in the diagnosis of influenza virus type A and type B infection.

### Information

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

### Interpretation of results



### Clinical Performance

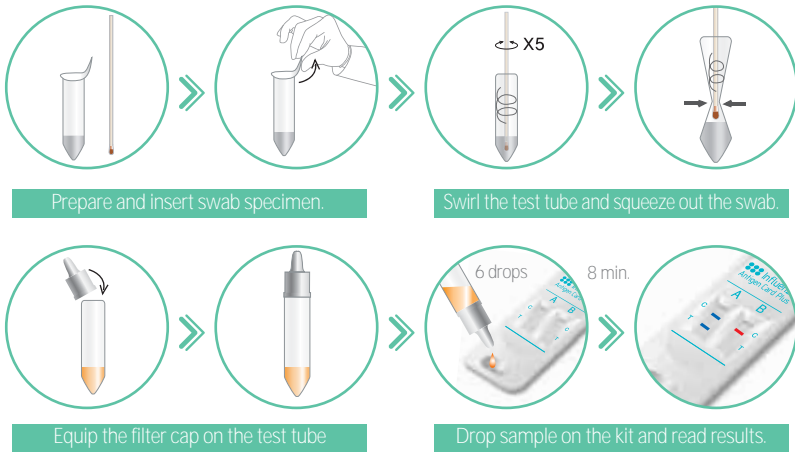
Humasis Influenza Antigen Card Plus-FLU A	Comparator Method (+PCR)		Total
	Positive	Negative	
Positive	47	0	47
Negative	0	125	125
Total	47	125	172

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

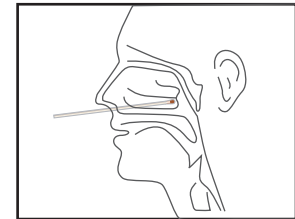
Humasis Influenza Antigen Card Plus-FLU B	Comparator Method (+PCR)		Total
	Positive	Negative	
Positive	43	0	43
Negative	1	147	148
Total	44	147	191

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

### Test Procedure



### Method of sample collection



Nasopharyngeal swab

## Influenza A/B Antigen Test

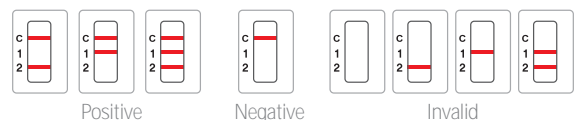


Humasis Influenza A/B Antigen Test uses monoclonal antibodies specific to influenza type A and type B antigen for accurate determination of Influenza infection. When the nasal or throat patient sample is infected with Influenza type A or B, as visible line appears in the test region on the membrane,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

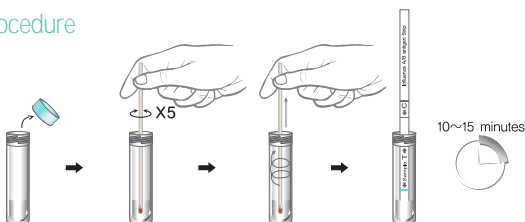
### Interpretation of results



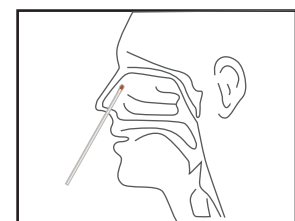
### General Information

- 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



### Method of sample collection



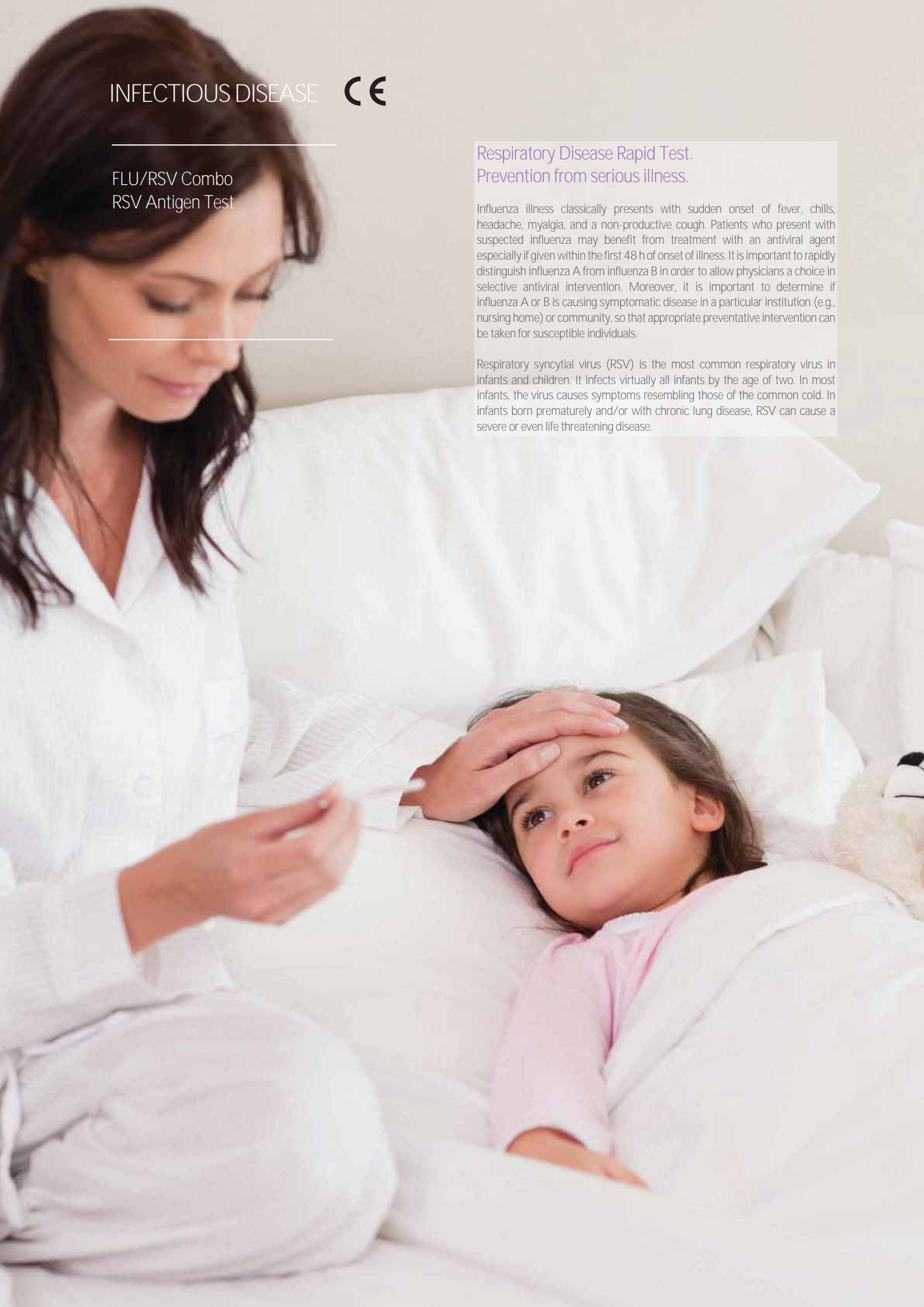
Nasal swab

FLU/RSV Combo  
RSV Antigen Test

Respiratory Disease Rapid Test.  
Prevention from serious illness.

Influenza illness classically presents with sudden onset of fever, chills, headache, myalgia, and a non-productive cough. Patients who present with suspected influenza may benefit from treatment with an antiviral agent especially if given within the first 48 h of onset of illness. It is important to rapidly distinguish influenza A from influenza B in order to allow physicians a choice in selective antiviral intervention. Moreover, it is important to determine if influenza A or B is causing symptomatic disease in a particular institution (e.g., nursing home) or community, so that appropriate preventative intervention can be taken for susceptible individuals.

Respiratory syncytial virus (RSV) is the most common respiratory virus in infants and children. It infects virtually all infants by the age of two. In most infants, the virus causes symptoms resembling those of the common cold. In infants born prematurely and/or with chronic lung disease, RSV can cause a severe or even life threatening disease.



# INFECTIOUS DISEASE

## FLU/RSV Combo

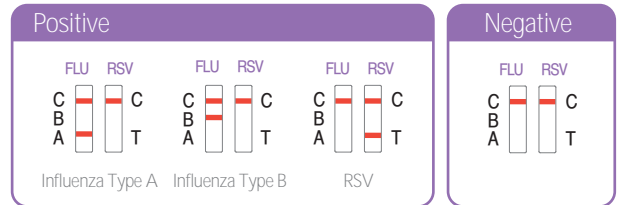


Humasis FLU/RSV Combo is a one step in-vitro diagnostic test based on immunochromatographic assay. It is designed for qualitative determination of influenza type A, type B (not type C) and RSV type A, type 2, type B virus infection using nasopharyngeal swab specimen of symptomatic patients with time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

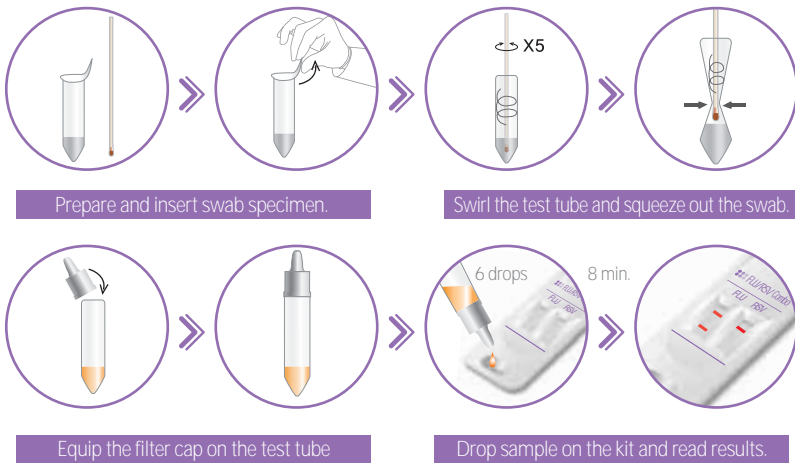
### Information

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

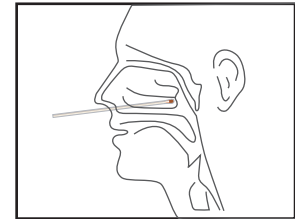
### Interpretation of results



### Test Procedure



### Method of sample collection



Nasopharyngeal swab

## Respiratory Syncytial Virus (RSV) Antigen Test

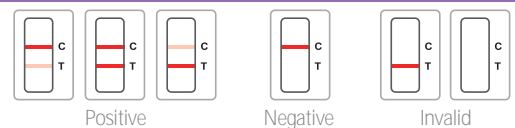


RSV Antigen Test is one step to screen the respiratory syncytial virus infection in human nasal or throat swab specimen. Respiratory syncytial virus is the most common respiratory virus in infants and children. It infects virtually all infants by the age of two, causing symptoms similar as one of the 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)	25 tests/case	Antigen Test	Nasal Swab/Throat Swab	24 months

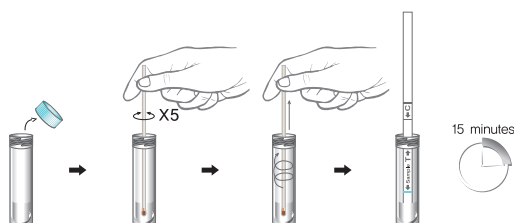
### Interpretation of results



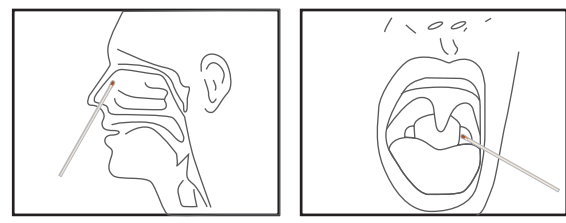
### General Information

- 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



Nasal swab

Throat Swab

# INFECTIOUS DISEASE

## 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



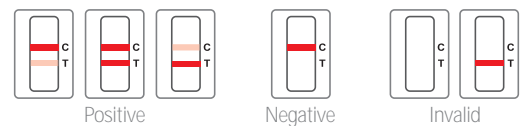
## Anti-HBs Test



### Information

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

## H.pylori Test

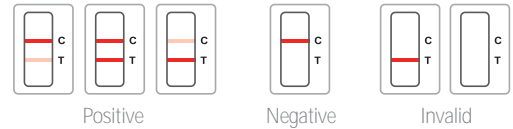


Helicobacter pylori is a helical shaped gram-negative bacterium that infects various area of the stomach and duodenum. Many cases of peptic ulcers, gastritis, duodenitis, and perhaps some cancers are caused by H.pylori infection. However, many who are infected do not show any symptoms of disease. Helicobacter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

### 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



### 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

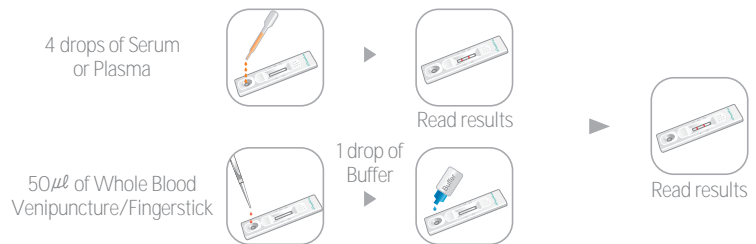
### Clinical Performance

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

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

### Test Procedure

#### Card



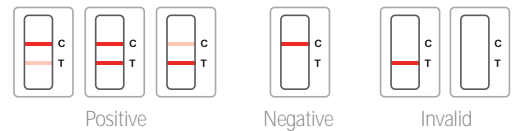
## H.pylori Antigen Test



### 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

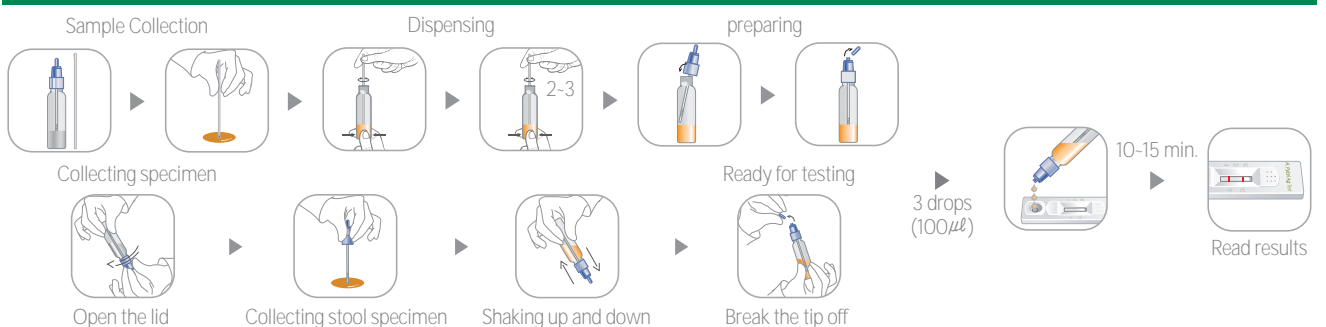


### General Information

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

### Test Procedure

#### Card



# INFECTIOUS DISEASE

## Hepatitis C Virus Test



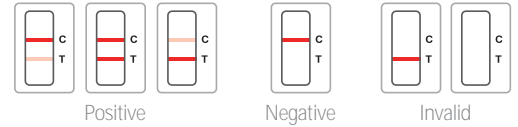
### HCV Antibody Test

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	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



#### Clinical Performance

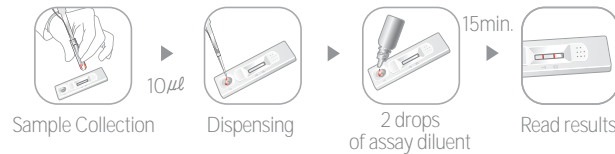
- A study was performed using 302 positive and negative serum specimens. Each specimen was assayed with the Humasis HCV Card and a commercially available HCV EIA.

		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



##### Multi-Card



## HIV Test



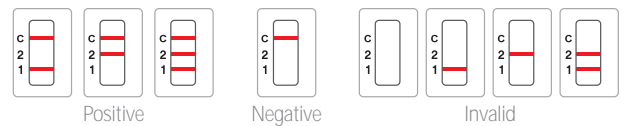
### HIV 1/2 Antibody Test

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



#### Clinical Performance

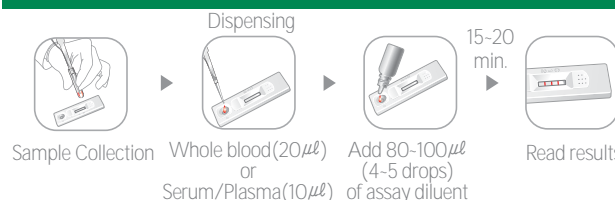
- A study was performed using 265 positive and negative serum specimens. Each specimen was assayed with the Humasis HIV 1/2 Card and a commercially available HIV EIA.

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

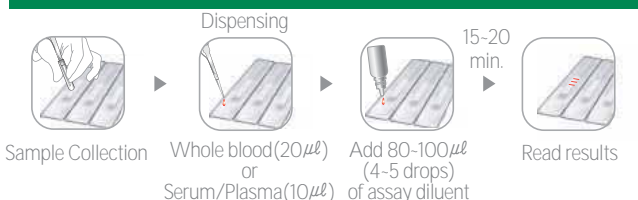
Relative Sensitivity >99%, Relative Specificity 99%, Relative accuracy 99%

#### Test Procedure

##### Card



##### Multi-Card



# 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.

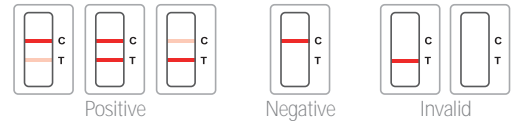
## Syphilis Test



### Information

Product name	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



### 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

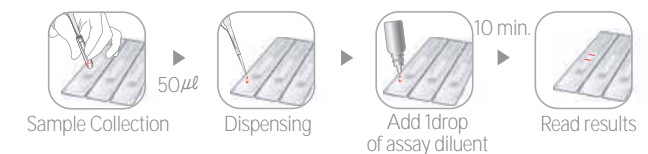
Relative Sensitivity >99%, Relative Specificity 99.3%, Relative accuracy 99.5%

### Test Procedure

#### Card



#### Multi-Card



## Chlamydia Test

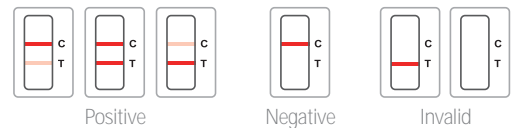
Chlamydia trachomatis is a bacterium which causes a sexually transmitted infection (STI). Chlamydia is very common disease, which should be taken very seriously. The most worried effect of a chlamydia infection in women is potential fertility problem (PID, infertility, etc), due to inflammation of the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



### Information

Product name	Package	Feature	Specimen	Shelf life
Chlamydia Test Card(ACHG-7025)	25 tests/case	$2 \times 10^3$ IFU/mL	Vaginal Swab	18 months

### Interpretation of results



### 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

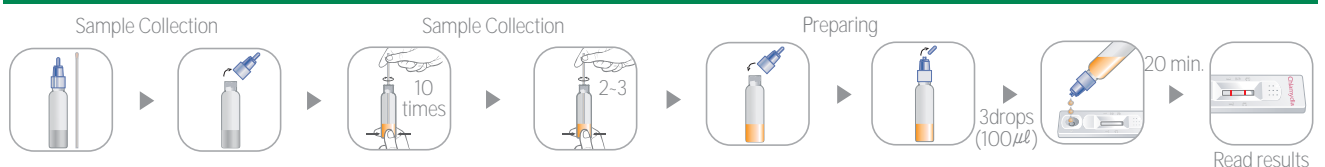
Relative Sensitivity 99%, Relative Specificity 99%, Relative accuracy 99%

		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



# TUMOR

## CEA Test



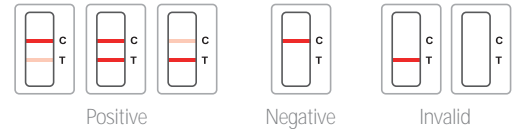
### Carcinoembryonic Antigen(CEA) Test

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

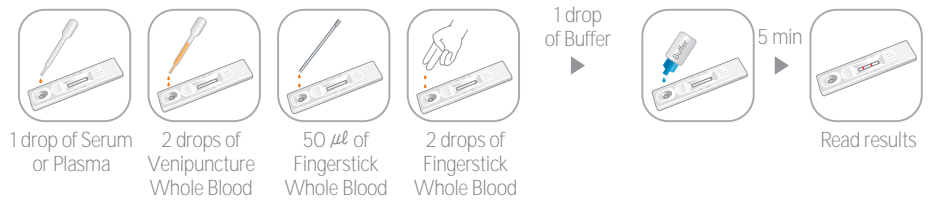
Product name	Package	Feature	Specimen	Shelf life
CEA Card Card(ACEA-7030)	30 tests/case	5 ng/mL	Whole blood/ Serum/Plasma	14 months
Multi-Card(ACEA-6100)	100 tests/case	5 ng/mL	Whole blood/ Serum/Plasma	14 months

#### Interpretation of results



#### Test Procedure

##### Card



## FOB Test



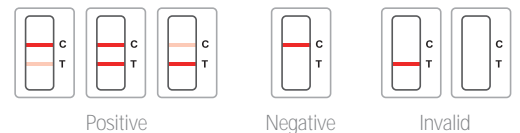
### Fecal Occult Blood(FOB) Test

The presence of hemoglobin 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



#### Test Procedure

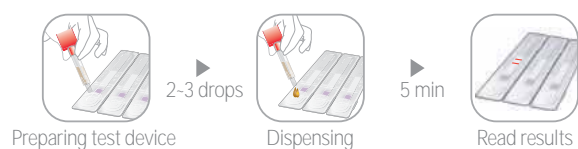
##### Test Preparation



##### Card



##### Multi-Card



# TUMOR

## AFP Test



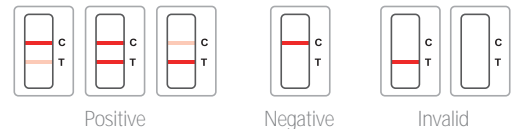
### Alpha-Fetoprotein(AFP)Test

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



#### Test Procedure

##### Card



##### Multi-Card



## PSA Test



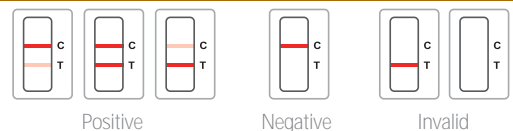
### Prostate Specific Antigen(PSA) Test

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



#### Test Procedure

##### Card



##### Multi-Card





# HUMASIS URINALYSIS

## Smart U=AQ

300Tests/h (Max. 800Tests)

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°C-30°C / Humi. : 10%-70%
Method	Reflectance photometer
Test Capacity	300Tests/hour(Max. 800Tests)
Memory Capacity	2,000 Samples
Interface	RS-232 C, 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 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°C-30°C / 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

# HUMASIS Urinalysis



## 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

		Creatinine	Microalbumin	Glucose	Bilirubin	Ketones	Specific Gravity	Blood	pH	Protein	Urobilinogen	Nitrite	Leukocytes
		<b>Urinalysis Strips</b>											
U-AQS 2MAC	Cat. No. AUS2MAC-3050	—	—	—	—	—	—	—	—	—	—	—	—
U-AQS 12MAC	Cat. No. AUS12MAC-3050	—	—	—	—	—	—	—	—	—	—	—	—
<b>Quality Controls</b>													
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

		Ascorbic Acid	Glucose	Bilirubin	Ketones	Specific Gravity	Blood	pH	Protein	Urobilinogen	Nitrite	Leukocytes	
		<b>Urinalysis Strips</b>											
U-AQS 2GP	Cat. No. AUS2GP-3100	—	—	—	—	—	—	—	—	—	—	—	
U-AQS 3	Cat. No. AUS3-3100	—	—	—	—	—	—	—	—	—	—	—	
U-AQS 3GK	Cat. No. AUS3GK-3100	—	—	—	—	—	—	—	—	—	—	—	
U-AQS 4	Cat. No. AUS4-3100	—	—	—	—	—	—	—	—	—	—	—	
U-AQS 4SG	Cat. No. AUS4SG-3100	—	—	—	—	—	—	—	—	—	—	—	
U-AQS 5	Cat. No. AUS5-3100	—	—	—	—	—	—	—	—	—	—	—	
U-AQS 10	Cat. No. AUS10-3100	—	—	—	—	—	—	—	—	—	—	—	
U-AQS 11	Cat. No. AUS11-3100	—	—	—	—	—	—	—	—	—	—	—	
<b>Quality Controls</b>													
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/μL)	6.5-8.0	±/-3+ (15-300 RBC/μL)	2-8 mg/dL	Pos.	±/-3+ (15-500 WBC/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, 14042, Korea
- Tel: +82-31-478-8591 Fax: +82-31-478-8586
- E-mail: [question@humasis.com](mailto:question@humasis.com)
- [www.humasis.com](http://www.humasis.com)