PRODUCT CATALOGUE

Inverness Medical Innovations Hong Kong Limited

inverness medical

Inverness Medical Innovations Hong Kong Limited
#17th Floor, Building B, Modern International Plaza,
159 Tianmu Shan Road, Hangzhou 310007, P.R.China
Please visit our website for details: www.imihongkong.com
E-mail: IMIHK.info@invmed.com

DN：IMIHK-Product Brochure-004

Authorized Distributor

inverness medical

CATALOGUE

ABOUT US

ABON is a leading global brand of lateral flow rapid tests, which are marketed throughout Asia, Africa, the Middle-East, Latin America and the former CIS countries. We believe that each individual has a right to the best health care. ABON stands for high quality products at affordable prices plus an unmatched customer service.

Our manufacturing and research facility complies to the latest quality systems, employs state of the art manufacturing processes and cutting edge technology which is recognized by our accreditation with the major global regulatory authorities such as the US FDA, the Japanese GMP and the Brazilian ANVISA.

Maintaining our legacy and unenviable trusted reputation is paramount thus we are committed to provide our business partners with unparalleled opportunities for growth and to earn significant market share. At our heart is the constant endeavor to deliver cost-effective IVD solutions and the highest quality products.

ABON™

ID/ INFECTIOUS DISEASES

BLOOD BORNE PATHOGEN:

- HIV
- HBV
- HCV
- SYPHILIS
- MALARIA
- TB

OTHER ID:

- H.PYLORI
- STREP A
- INFLUENZA A&B
- ROTA&ADENO
- MONONUCLEOSIS

HIV Rapid Tests

HIV (Human immunodeficiency virus) is a lentivirus that causes acquired immunodeficiency syndorme (AIDS). Infection with HIV occurs by the transfer of blood, semen, vaginal fluid, or pre-ejaculate. It may also be transmitted from mother to fetus during pregnancy or delivery breast milk.

Materials Provided

- ABON™ HIV Rapid Test Strip/Device
- Droppers
- Buffer (for whole blood only)
- Lancet and alcohol swab (for single use only)

General Information

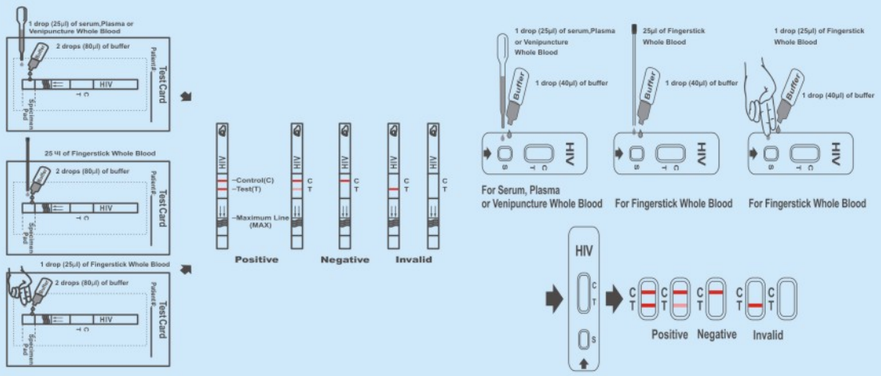
ABON™ HIV 1/2/O Tri Line Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies specific to HIV-1 including subtype O and HIV-2 simultaneously, in human serum, plasma or whole blood.

ABON™ HIV 1/2 Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies specific to HIV-1 and HIV-2 simultaneously, in human serum, plasma or whole blood.

- No need additional equipment
- Room temperature storage
- HIV 1/2/O Tri-Line Rapid Test – CE marked
- Specimen:Whole Blood/Serum/Plasma

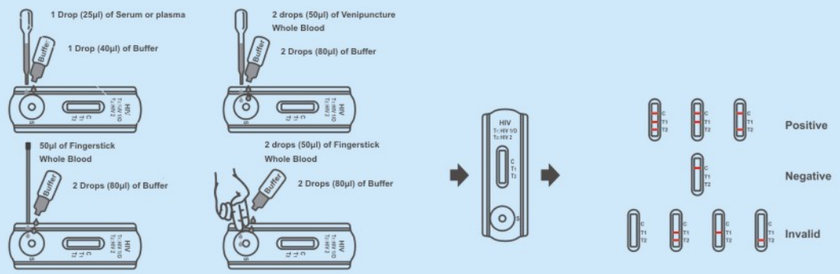
Test Procedure and Interpretation

IHI-401



IHI-402

IHI-T402



Ordering information

√ CE Marked CE

Description	Specimen	Format	Catalog No.	Tests Per Kit
HIV Tri Line Rapid Test	WB/S/P	Device	IHI-T402H	10 (Single use)
HIV Tri Line Rapid Test	WB/S/P	Device	IHI-T402√	40
HIV 1/2 Rapid Test	WB/S/P	Strip	IHI-401	50
HIV 1/2 Rapid Test	WB/S/P	Device	IHI-402	40

CE

Hepatitis B Virus Antibody Tests

Chronic hepatitis B is a serious, debilitating illness that can cause cirrhosis of the liver, liver cancer and death. Chronic hepatitis B is the main cause of liver cancer and the tenth leading cause of death worldwide, with 400,000,000 people infected with the virus. Every year, one million people worldwide are expected to die from this infection.

	HBsAg	HBsAb	HBeAg	HBeAb	HBcAb
Specimen	Serum, Plasma or whole blood	Serum, Plasma	Serum, Plasma	Serum, Plasma	Serum, Plasma
Sensitivity	>99.0%	>99.0%	98.2%	94.5%	96.3%
Specificity	>99.0%	98.7%	98.2%	97.3%	96.8%

General Information

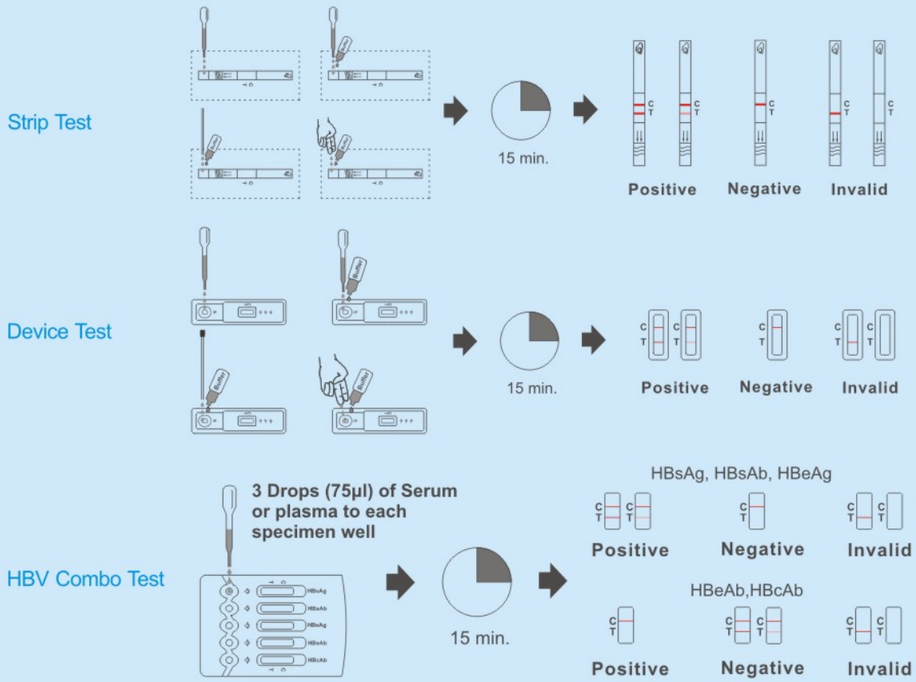
ABON™ Hepatitis B Virus Rapid Tests are intended for professional use as an aid in the diagnosis of hepatitis B.

- High sensitive and specific rapid tests for HBsAg, HBsAb, HBcAb, HBeAb, HBeAg
- No need additional equipment
- Room temperature storage
- Specimen: Serum/Plasma/Whole Blood

Materials Provided

- ABON™ Hepatitis B Virus Rapid Test Device/ Strip/Combo Device
- Droppers
- Buffer
- Test Card (for strip only)

Test Procedure and Interpretation



Ordering Information

√ CE Marked CE

Description	Specimen	Format	Catalog No.	Sensitivity	Tests Per Kit
Hepatitis B Surface Antigen	S/P	Strip	IHBsg-301	1 ng/mL	50
Hepatitis B Surface Antigen	S/P	Device	IHBsg-302	1 ng/mL	40
Hepatitis B Surface Antigen	S/P	Strip	IHBsg-U301	0.5 ng/mL	50
Hepatitis B Surface Antigen	S/P	Device	IHBsg-U302	0.5 ng/mL	40
Hepatitis B Surface Antigen	S/P	Strip	IHBsg-U311	0.5 ng/mL	25
Hepatitis B Surface Antigen	WB/S/P	Strip	IHBsg-401	1 ng/mL	50
Hepatitis B Surface Antigen	WB/S/P	Device	IHBsg-402√	1 ng/mL	40
Hepatitis B Surface Antibody	S/P	Strip	IHBsb-301	10 mIU/mL	50
Hepatitis B Surface Antibody	S/P	Device	IHBsb-302	10 mIU/mL	40
Hepatitis B Envelope Antigen	S/P	Device	IHBeg-302	See Insert	40
Hepatitis B Envelope Antibody	S/P	Device	IHBeb-302	See Insert	40
Hepatitis B Core Antibody	S/P	Device	IHBcb-302	See Insert	40
Hepatitis B Virus Combo Test	S/P	Device	IHB-355	See Insert	25

Hepatitis C Virus Antibody Tests

The Hepatitis C Virus (HCV) is now known to be the major cause of parenterally transmitted non-A, non-B hepatitis. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis.

CE

General Information

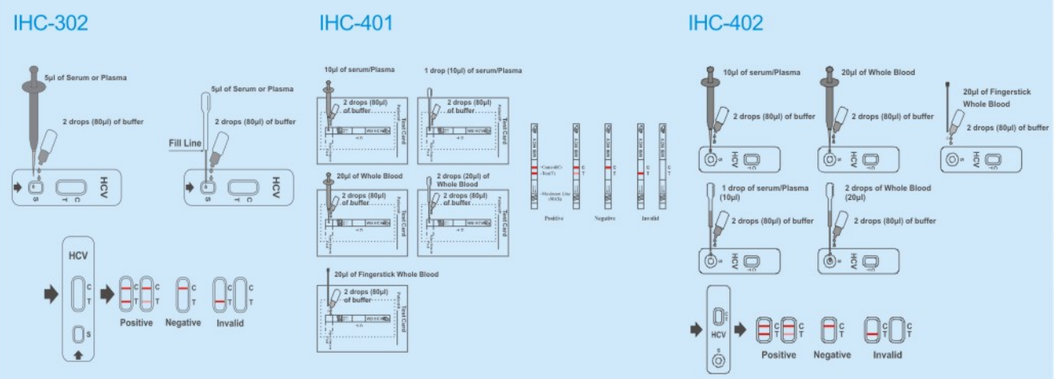
ABON™ Hepatitis C Virus Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of antibody to Hepatitis C Virus.

- Recombinant HCV core, NS3, NS4, NS5 Ag used as capture materials
- No need additional equipment
- Room temperature storage
- Specimen: Serum/Plasma/Whole Blood

Materials Provided

- ABON™ Hepatitis C Virus Rapid Test Device/Strip
- Droppers
- Buffer
- Test Card (for strip only)

Test Procedure and Interpretation



Ordering information

√ CE Marked CE

Description	Specimen	Format	Catalog No.	Tests Per Kit
Hepatitis C Virus Test Strip	Strip	S/P	IHC-301	50
Hepatitis C Virus Test Device	Device	S/P	IHC-302√	40
Hepatitis C Virus Rapid Test Strip	Strip	WB/S/P	IHC-401	50
Hepatitis C Virus Rapid Test Device	Device	WB/S/P	IHC-402	40

Syphilis Antibody Ultra Tests

Syphilis is a sexually transmitted infection caused by *Treponema pallidum* (TP). The primary route of transmission is through sexual contact however it may also be transmitted from mother to fetus during pregnancy or at birth resulting in congenital syphilis.

General Information

ABON™ Ultra Syphilis Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies to *Treponema Pallidum* (TP) to aid in the diagnosis of Syphilis.

- One Step qualitative immunoassay
- No need additional equipment
- Room temperature storage

Materials Provided

- ABON™ Syphilis Ultra Rapid Test Device/ Strip
- Droppers
- Buffer (for whole blood only)
- Test Card (for strip only)

Performance Characteristics

ISY-U302

Sensitivity: 99.9%(vs TPHA)
Specificity: 99.7%(vs TPHA)

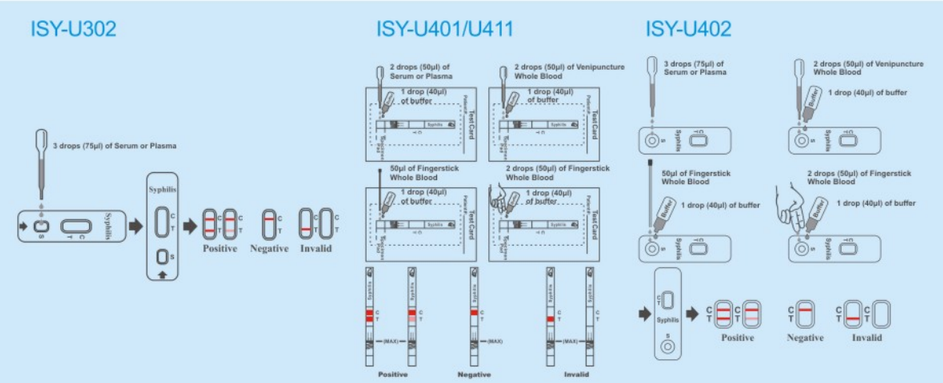
Method		TPHA		Total Results
ABON™ Syphilis Ultra Test Device	Result	Positive	Negative	
	Positive	200	1	201
	Negative	0	330	330
Total Results		200	331	531

ISY-U401/U402/U411

Sensitivity: 99.7% (vs TPHA)
Specificity: 99.6% (vs TPHA)

Method		TPHA		Total Results
ABON™ Syphilis Ultra Test	Result	Positive	Negative	
	Positive	384	2	386
	Negative	1	493	494
Total Results		385	495	880

Test Procedure and Interpretation



Order information

√ CE Marked

Description	Specimen	Format	Catalog No.	Tests Per Kit
Syphilis Ultra Rapid Test	WB/S/P	Strip	ISY-U401√	50
Syphilis Ultra Rapid Test	WB/S/P	Strip	ISY-U411	25 (Canister)
Syphilis Ultra Rapid Test	WB/S/P	Device	ISY-U402√	40
Syphilis Ultra Rapid Test	S/P	Device	ISY-U302√	40

Malaria Ag Tests

Malaria is an infective disease caused by protozoan parasites that are transmitted through the bite of an infected Anopheles mosquito; marked by paroxysms of chills and fever. It is widespread in tropical and subtropical regions, including much of Sub-Saharan Africa, Asia and the Americas. Compared to P.vivax, P. falciparum is less widespread, but more likely to result in severe complications and be fatal.

General Information

ABON™ Malaria P.f. Rapid Test (Whole Blood) is a rapid chromatographic immunoassay for the qualitative detection of circulating plasmodium falciparum (HRP-II, Histidine-rich protein II) in whole blood.

- Suitable test for prevalence of P.falciparum
- Sensitivity: >99.0% Specificity: >99.0%

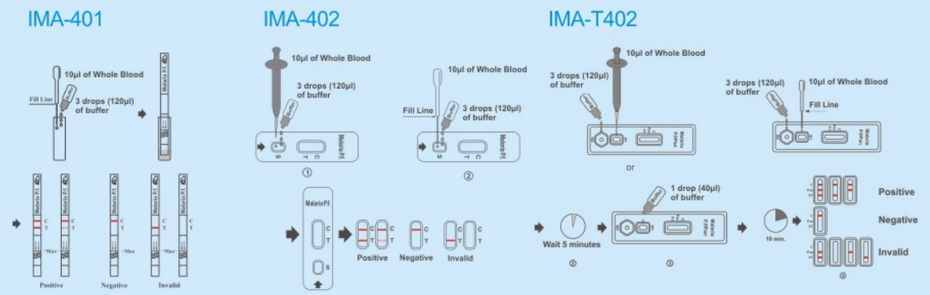
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood) is a rapid chromatographic immunoassay for the qualitative detection of circulating antigens of P. falciparum (P.f.), P. vivax (P.v.), P. ovale (P.o.), and P. malariae (P.m.) in whole blood in vitro.

- Differential diagnosis between Plasmodium falciparum and the other plasmodium species (P.vivax, P.ovale, P.malariae)
- Sensitivity: >99.9% Specificity: >99.0%

Materials Provided

- ABON™ Malaria Rapid Test
- Droppers
- Buffer

Test Procedure and Interpretation



Ordering information

√ CE Marked

Description	Specimen	Format	Catalog No.	Tests Per Kit
ABON™ Malaria P.f. Rapid Test	Whole Blood	Strip	IMA-401	50
ABON™ Malaria P.f. Rapid Test	Whole Blood	Device	IMA-402√	40
ABON™ Plus Malaria P.f/Pan Rapid Test	Whole Blood	Device	IMA-T402	25
ABON™ Plus Malaria pf/pan Single Use Rapid Test	Whole Blood	Device	IMA-T402H	10

TB Antibody Rapid Tests

CE

Tuberculosis (TB) is spread primarily via airborne transmission of aerosolized droplets developed by coughing, sneezing and talking. Areas of poor ventilation pose the greatest risk of exposure to infection. TB is a major cause of morbidity and mortality worldwide, resulting in the greatest number of deaths due to a single infectious agent. The World Health Organization reports that more than 8 million new cases of active tuberculosis are diagnosed annually. Almost 3 million deaths are attributed to TB as well. Timely diagnosis is crucial to TB control, as it provides early initiation of therapy and limits further spread of infection.

General Information

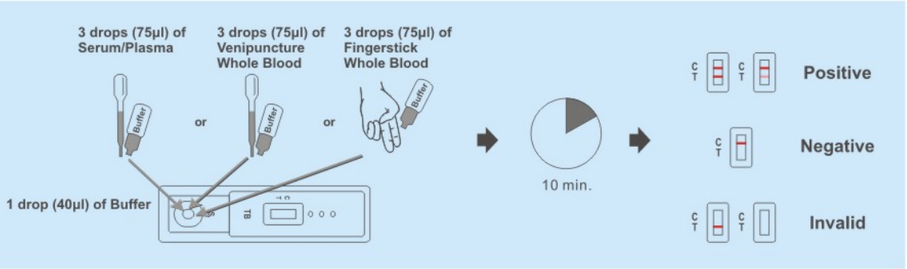
ABON™ TB Tuberculosis Rapid Test (Whole Blood/ Serum/ Plasma) is a rapid chromatographic immunoassay for the qualitative detection of anti-TB antibodies (Isotypes IgG, IgM and IgA) in whole blood, serum or plasma specimens.

- No need additional equipment
- Specimen: Whole Blood/Serum/Plasma

Materials Provided

- ABON™ TB Rapid Test Device
- Buffer
- Droppers

Test Procedure and Interpretation



Order information

√ CE Marked CE

Description	Specimen	Format	Catalog No.	Tests Per Kit
TB Tuberculosis Rapid Test Device	WB/S/P	Device	ITB-402√	40
TB Tuberculosis Rapid Test Device	WB/S/P	Device	ITB-402	25

H.pylori Rapid Tests

CE FDA

H. pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis.

General Information

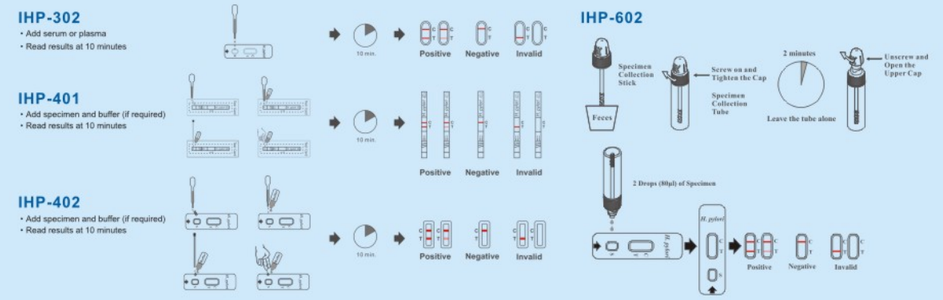
ABON™ *H.pylori* Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of *H. pylori* antibodies in serum, plasma or whole blood or *H.pylori* antigens in human feces specimens to aid in the diagnosis of H. pylori infection.

- Non-invasive for *H.pylori* antigen test : No puncturing, no insertion of tubes inside the body
- Test time: 10 minutes

Materials Provided

- ABON™ H. pylori Rapid Test
- Specimen collection tubes (for antigen test only)
- Droppers
- Buffer (for whole blood only)
- Test Card (for strip only)

Test Procedure and Interpretation



Ordering information

†US FDA Cleared √ CE Marked CE

Description	Specimen	Format	Catalog No.	Tests Per Kit
H. pylori Antigen Test	Feces	Device	IHP-602 √	25
H. pylori Antibody Test	S/P	Device	IHP-302 √	40
H. pylori Antibody Test	WB/S/P	Strip	IHP-401 √ †	50
H. pylori Antibody Test	WB/S/P	Device	IHP-402 √ †	40

ID Strep A

Strep A Rapid Tests

CE FDA

Streptococcus pyogenes is non-motile gram-positive cocci, which contains the Lancefield Group A antigen that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis. Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess. Traditional identification procedures for Group A Streptococci infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.

General Information

ABON™ Strep A Rapid Test (Throat Swab) is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection.

- No need additional equipment
- Optional packaging formats available
- Specimen: Throat swab
- High sensitivity and specificity

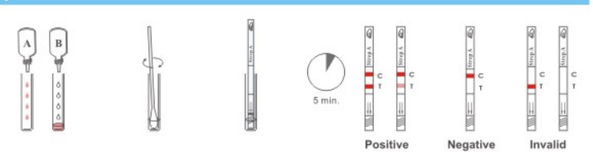
Materials Provided

- ABON™ Strep A Rapid Test Strip/Device/Twist
- Tubes
- Negative/Positive control
- Strep A Reagent A/B

Test Procedure and Interpretation

Strip Test

- Add 4 drops (240µl) Reagent A, then 4 drops (160µl) Reagent B
- Rotate swab 10 times, wait 1 minutes, then remove swab while squeezing tube to remove liquid
- Immerse strip in specimen
- Read results at 5 minutes

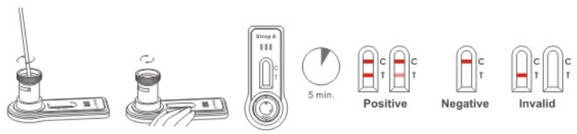


Device Test

- Add 4 drops (240µl) Reagent A, then 4 drops (160µl) Reagent B
- Rotate swab 10 times, wait 1 minutes, then remove swab while squeezing tube to remove liquid
- Add dropper tip to top of tube
- Add 3 drops (100µl) of specimen
- Read results at 5 minutes

Twist Device Test

- Add 5 drops (300µl) Reagent A, then 5 drops (200µl) Reagent B to the extraction chamber
- Add swab to chamber, agitate vigorously 10 times, then wait 1 minute
- Remove swab by pressing against ribs inside chamber and rotating
- Open valve by twisting clockwise until it stops
- Read results at 5 minutes



Ordering information

†US FDA Cleared ★- Components included in package √ CE Marked

Description	Catalog No.	Format	Specimen	Read Time	Sensitivity	Tests Per Kit	Components									
							Test Strip	Test Device	Reagent A & B	Positive & Negative Controls	Swab	Workstation	Test Tube	Dropper Tip	Tongue Depressor	Package Insert
Strep A	IST-501√ †	Strip	Throat Swab	5min	See insert	25	★		★	★	★	★	★			★
	IST-502√ †	Device	Throat Swab	5min	See insert	20		★	★	★	★	★	★	★		★
	IST-502S√					25										
	IST-502T√†	Twist Device	Throat Swab	5min	See insert	25		★	★	★	★					★

ID Influenza A&B

Influenza A&B Tests

CE

Influenza (commonly known as 'flu') is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus. Influenza outbreaks occur each year during the fall and winter months. Type A viruses are typically more prevalent than type B viruses and are associated with most serious influenza epidemics, while type B infections are usually milder.

General Information

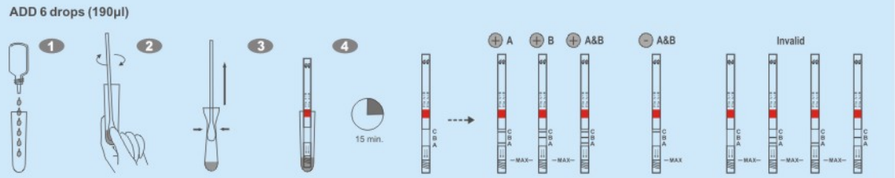
ABON™ Influenza A&B Rapid Test Strip (Swab) is a rapid chromatographic immunoassay for the qualitative detection of influenza A and B antigens in nasal swab specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.

- Differential detection of Influenza virus type A & B
- Specimen: Swab
- Accuracy
  Influenza A – Sensitivity: >99% Specificity: >99%
  Influenza B – Sensitivity: >99% Specificity: 98.6%

Materials Provided

- ABON™ Influenza A&B Rapid Test Strip
- Swabs
- Extraction Reagent
- Tubes
- Workstation

Test Procedure and Interpretation



Ordering information

√ CE Marked CE

Description	Specimen	Format	Catalog No.	Tests Per Kit
Influenza A&B Rapid Test Strip	Swab	Strip	IFL-501√	20

Rotavirus and Adenovirus Rapid Tests

CE

Rotavirus is the most common agent responsible for acute gastroenteritis, mainly in young children. Untreated rotavirus infection may result in severe illness with dehydration and disturbances of the body's normal electrolyte balance, especially in babies and preschool children.

Adenovirus has been implicated in a wide range of clinical diseases affecting mainly the respiratory, ocular and the gastrointestinal systems of the human. Research has shown that enteric adenoviruses are a leading cause of diarrhea in many of these children.

General Information

ABON™ Adenovirus Test Device (Feces) is a rapid chromatographic immunoassay for the qualitative detection of Adenovirus in human feces specimens to aid in the diagnosis of adenovirus infection.

ABON™ One Step Rotavirus Test Device (Feces) is a rapid chromatographic immunoassay for the qualitative detection of rotavirus in human feces specimens to aid in the diagnosis of rotavirus infection.

ABON™ One Step Rotavirus and Adenovirus Combo Test Device (Feces) is a rapid chromatographic immunoassay for the qualitative detection of rotavirus and adenovirus in human feces specimens to aid in the diagnosis of rotavirus or adenovirus infection.

- No need additional equipment
- Specimen: Feces
- Test time: 10 minutes

Materials Provided

- ABON™ Adenovirus /Rotavirus / Rota&Adeno Rapid Test Device
- Specimen collection tubes
- Droppers

Test Procedure and Interpretation

Ordering information

√ CE Marked CE

Description	Specimen	Format	Catalog No.	Tests Per Kit
Adenovirus Rapid Test	Feces	Device	IAD-602√	25
Rotavirus Rapid Test	Feces	Device	IRO-602√	25
Rotavirus and Adenovirus Combo Test	Feces	Device	IRA-625√	25

Mononucleosis Rapid Test

CE FDA

Infectious Mononucleosis (IM) is caused by the Epstein-Barr virus, which is a member of the herpesvirus family. Symptoms of IM are fever, sore throat and swollen lymph glands. In very rare cases, heart or central nervous system problems may occur.

General Information

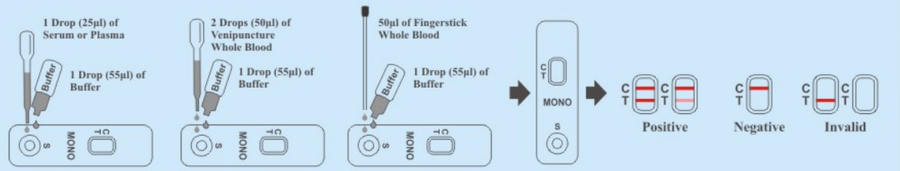
ABON™ Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Infectious Mononucleosis heterophile antibodies in whole blood, serum or plasma as an aid in the diagnosis of Infectious Mononucleosis.

- No need additional equipment
- Specimen: Whole Blood/Serum/Plasma
- Test time: 5 minutes (up to 10 minutes)

Materials Provided

- ABON™ Mononucleosis Rapid Test Device
- Buffer
- Droppers
- Negative/Positive control

Test Procedure and Interpretation



Ordering information

†US FDA Cleared √ CE Marked CE

Description	Specimen	Format	Catalog No.	Tests Per Kit
Mononucleosis Rapid Test Device	WB/S/P	Device	IMO-402√†	20

DOA/ DRUGS OF ABUSE

SINGLE-DRUG (STRIP OR DEVICE) ◂
MULTI-DRUG (PANEL/HOME TEST/DEVICE/CUP) ◂
ORAL FLUID ◂

DOA Single-drug (Strip or Device) Tests

CE FDA

Drug of abuse is also known as substance abuse, involves the repeated and excessive use of chemical substances to achieve a certain effect. These substances may be “street” or “illicit” drugs, illegal due to their high potential for addiction and abuse.

General Information

The One Step Drug Screen Test Strip & Device are lateral flow chromatographic immunoassays for the qualitative detection of drugs and drug metabolites in human urine at a cut-off concentration.

- Accurate Results
- Fast Turnaround Time
- Convenient Usage
- Wide Range

Materials Provided

Test strips or Test devices
Droppers (only for devices)
Package insert
Specimen collection container (Materials Required But Not Provided)
Timer (Materials Required But Not Provided)

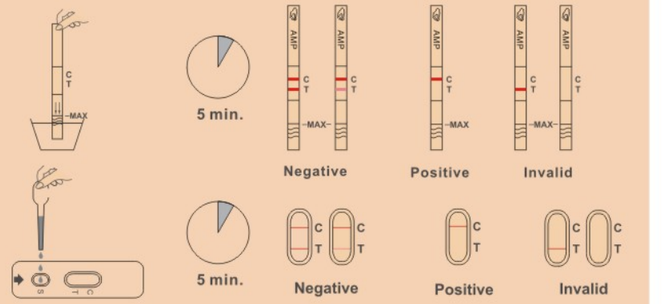
Test Procedure and Interpretation

Strip Test

- Immerse the strip into urine
- Read results at 5 minutes

Device Test

- Add 3 full drops (100μl) of urine
- Read results at 5 minutes



DOA Single-drug (Strip or Device)

Ordering Information

√ CE Marked † US FDA Cleared

Description	Specimen	Format	Catalog No.	Sensitivity	Tests Per kit
AMP Amphetamine	Urine	Strip	DAM-101√†	1000 ng/mL	50
			DAM-A101√†	300 ng/mL	
		Device	DAM-102√†	1000 ng/mL	40
			DAM-A102√†	300 ng/mL	
BAR Barbiturates	Urine	Strip	DBA-101√†	300 ng/mL	50
		Device	DBA-102√†		40
BUP Buprenorphine	Urine	Strip	DBU-101√†	10 ng/mL	50
		Device	DBU-102√†		40
BZO Benzodiazepines	Urine	Strip	DBZ-101√†	300 ng/mL	50
		Device	DBZ-102√†		40
COC Cocaine	Urine	Strip	DCO-101√†	300 ng/mL	50
			DCO-U101√†	150 ng/mL	
		Device	DCO-102√†	300 ng/mL	40
			DCO-U102√†	150 ng/mL	
COT Cotinine	Urine	Device	DCT-A102√	100 ng/mL	40
EDDP 2-Ethylidene-1,5-dimethyl-3, 3-diphenylpyrrolidine (EDDP)	Urine	Strip	DED-A101√	100 ng/ml	50
		Device	DED-A102√		40
FTY Fentanyl	Urine	Strip	DFT-101√	20 ng/ml	50
		Device	DFT-102√		40
KET Ketamine	Urine	Strip	DKE-101√	1000 ng/mL	50
			DKE-A101√	100 ng/mL	
		Device	DKE-102√	1000 ng/mL	40
			DKE-A102√	100 ng/mL	
MDMA Ecstasy	Urine	Strip	DMD-101√†	500 ng/mL	50
		Device	DMD-102√†		40
MET Methamphetamine	Urine	Strip	DME-101√†	1000 ng/mL	50
			DME-A101√	300 ng/mL	
		Device	DME-102√†	1000 ng/mL	40
			DME-U102√†	500 ng/mL	
MOP Morphine 300	Urine	Strip	DMO-101√†	300 ng/mL	50
		Device	DMO-102√†		40
MOP Morphine 100	Urine	Strip	DMO-A101√	100 ng/mL	50
		Device	DMO-A102√		40
MQL Methaqualone	Urine	Strip	DMQ-101√	300 ng/mL	50
		Device	DMQ-102√		40
MTD Methadone	Urine	Strip	DMT-101√†	300 ng/mL	50
		Device	DMT-102√†		40
OPI Opiate 2000	Urine	Strip	DOP-101√†	2000 ng/mL	50
		Device	DOP-102√†		40
OXY Oxycodone	Urine	Strip	DOX-101√†	100 ng/mL	50
		Device	DOX-102√†		40
PCP Phencyclidine	Urine	Strip	DPC-101√†	25 ng/mL	50
		Device	DPC-102√†		40
PPX Propoxyphene	Urine	Strip	DPP-101√†	300 ng/mL	50
		Device	DPP-102√†		40
TCA Tricyclic Antidepressants	Urine	Strip	DTC-101√†	1000 ng/mL	50
		Device	DTC-102√†		40
THC Marijuana	Urine	Strip	DTH-101√†	50 ng/mL	50
		Device	DTH-102√†		40
TRA Tramadol	Urine	Strip	DTR-101√	100 ng/mL	50
		Device	DTR-102√		40
Urine Adulteration Strips (Creatinine/Nitrite/Glutaraldehyde/ pH/Specific Gravity/Oxidant)	Urine	6 parameter strip	DUC-111	See Insert	25

DOA Multi-drug (Panel/Home Test/Device/Cup)

CE FDA

DOA Multi-Drug Panel/Home Test/Device/Cup

- Multi-Drug One Step Drug Screen Test Panel
- Multi-Drug One Step Multi-Line Drug Screen Test Device
- Multi-Drug One Step Multi-Line Screen Test Panel with Integrated E-Z Split Key™ Cup (Urine)

Urine based screen tests for multiple drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method to screen urine for multiple drugs of abuse.

Materials Provided

Test panels or Test devices or Cups with multi-drug panels
Droppers (only for devices)
Security seal labels (only for cups)
Keys (only for cups)
SVT/Adulterant color chart (if applicable)
Package insert
Specimen collection container (materials required but not provided)
Timer (materials required but not provided)

General Information

The Multi-Drug Screen Tests are lateral flow chromatographic immunoassays for the qualitative detection of multiple drugs and drug metabolites in human urine at their respective cut-off concentration.

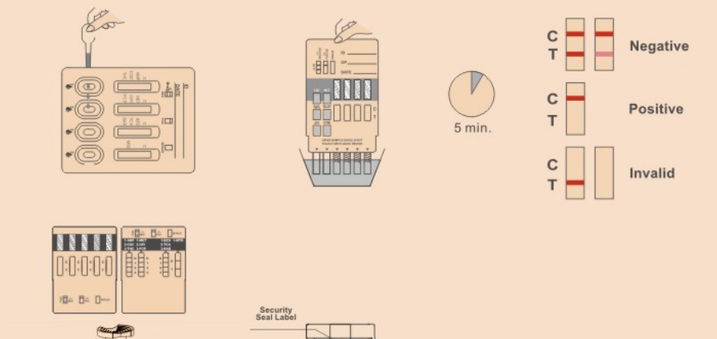
Configurations of the Multi-Drug One Step Screen Test Panel (Urine) come with any combination of the available drug analytes with or without S.V.T.

Including Specimen Validity Tests (S.V.T.) for Oxidants/Pyridinium Chlorochromate (OX/PCC), Specific Gravity (S.G.), pH, Nitrite (NIT), Glutaraldehyde (GLUT) and Creatinine (CRE).

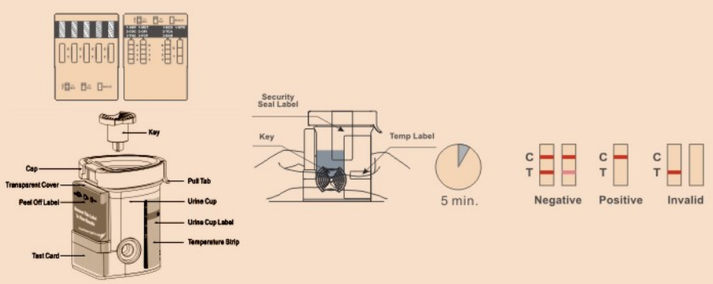
- Accurate Results
- Quick Results
- Wide Choice of Test Combinations
- Easy to Use

Test Procedure and Interpretation

Multi-Drug Device/
Panel Test



Multi-Drug Panel
with Integrated/Non-
Integrated Cup Ⅱ



Ordering Information

†US FDA Cleared √ CE Marked CE

Description	Specimen	Format	Catalog No.	Sensitivity	Tests Per kit
Multi-Drug One Step Drug Screen Test Panel	Urine	2-12 Drugs	DOA-124 to DOA-1124√ †	See Insert	25
		2-10 Drugs with S.V.T.	DUD-124 to DUD-1104 √ †		
Multi-Drug One Step Multi-Line Drug Screen Test Device	Urine	2-12 Drugs	DOA-125 to DOA-1125√†	See Insert	25
Multi-Drug Panel with Integrated E-Z Split Key™ Cup II	Urine	2-12 Drugs	DBO-127 to DBO-1127√†	See Insert	25
		2-10 Drugs with S.V.T.	DBD*-127 to DBD*-1107√†		
Home Drug Test	Urine	6 drugs	DOA-164H (COC/AMP300/THC /MDMA/MOP/BZO)	See Insert	1

* *"D" means with adulteration strip A+B, strip A means with OX/PCC, S.G. pH tests, strip B means with NIT, GLUT CRE tests, multi-drug panel/ cup with strip A or strip B are also available.

CE

DOA Oral Fluid Tests

- Multi-Drug One Step Multi-Line Screen Test Device (Oral Fluid)
- Multi-Drug Multi-Line Twist Screen Test Device (Oral Fluid)

The rapid, screening tests for the simultaneous, qualitative detection of multiple drugs and metabolites in human oral fluid.

Materials Provided

Test devices
Collectors
Security seals (only for DSD-7x5)
Collection tubes (only for DSD-7x5)
Caps (only for DSF-7x5)
Tamper evident tape (only for DSF-7x5)
Package insert
Timer (Materials Required But Not Provided)

General Information

The Multi-Drug Screen Tests (Oral Fluid) are immunoassays based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugates for binding sites on their specific antibody.

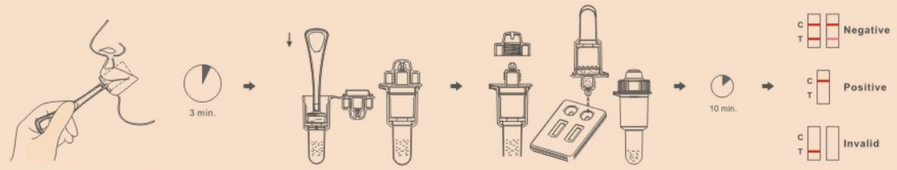
- Ideal for on-the-spot testing
- Eliminates fear of specimen adulteration
- User-friendly
- Multi-drug detection available

DOA Oral Fluid

Test Procedure and Interpretation

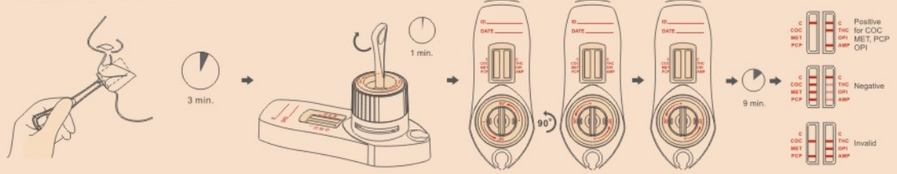
Device Test

- Collect oral fluid with sponge and extract into collection tube
- Add 3 drops (100µl) of oral fluid specimen and read results at 10 minutes



Twist Device Test

- Collect oral fluid with sponge
- Insert collector into device, rotate collector clockwise and wait 1 minute
- Rotate collection chamber counterclockwise
- Read test result at 9 minutes



Ordering Information

√ CE Marked CE

Description	Specimen	Format	Catalog No.	Drugs	Sensitivity	Tests Per Kit	Components
One Step Multi-Line Screen Test Device	Oral Fluid	2-6 drugs	DSD-7x5√	AMP Amphetamine	50 ng/mL	25	Test Device Collectors Collection Tubes Security Seals Package insert
				COC Cocaine	20 ng/mL		
				MET Methamphetamine	50 ng/mL		
				MTD Methadone	30 ng/mL		
				OPI Opiates	40 ng/mL		
				OXY Oxycodone	20 ng/mL		
				PCP Phencyclidine	10 ng/mL		
				COT Cotinine	30 ng/mL		
				THC Marijuana	12 ng/mL		
Multi-Line Twist Screen Test Device			DSF-7x5√	AMP Amphetamine	50 ng/mL		Test Devices Collectors Security Seals Package insert
				BZO Benzodiazepines	20 ng/mL		
				COC Cocaine	20 ng/mL		
				MET Methamphetamine	50 ng/mL		
				MTD Methadone	30 ng/mL		
				OPI Opiates	40 ng/mL		
				OXY Oxycodone	20 ng/mL		
				PCP Phencyclidine	10 ng/mL		
				THC Marijuana	100 ng/mL (Parent compound)		

CM/CARDIOVASCULAR

- TROPONIN I
- MYOGLOBIN/CK-MB
- MYOGLOBIN/CK-MB/TROPONIN I COMBO
- CRP

CM Troponin I

Troponin I Test Device

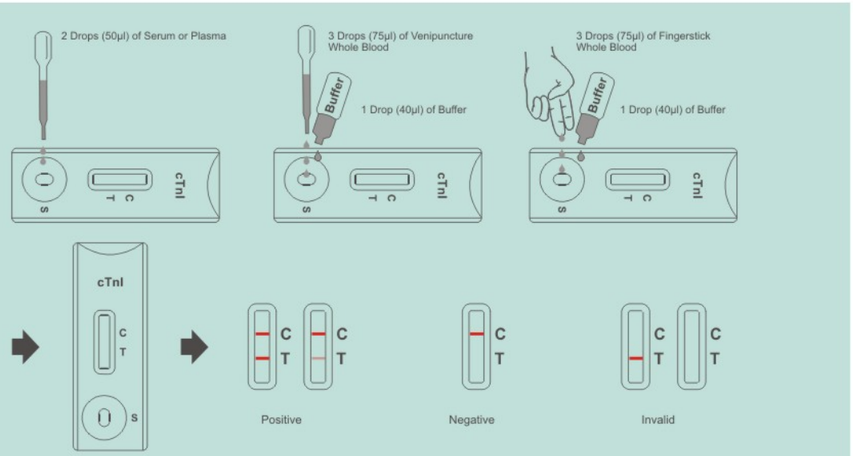
Troponin I is released into the blood 4-6 hours after the Myocardial infarction. It remains elevated for 6-10 days after cardiac injury occurs. It is the most preferred biomarker for myocardial infarction.

General Information

ABON™ One Step Troponin I Test Device is a rapid chromatographic immunoassay for the qualitative detection of human cardiac Troponin I in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI).

- Specimen: Serum, plasma or whole blood
- Test Result: In 10 minutes
- Cutoff: 0.5 ng/mL

Test Procedure and Interpretation



Ordering Information

√ CE Marked CE

Description	Specimen	Format	Catalog No.	Tests Per Kit
cTnI Troponin I	Whole Blood/Serum/Plasma	Device	CTI-402√	20

CM Myoglobin/CK-MB

Myoglobin/CK-MB Test Device

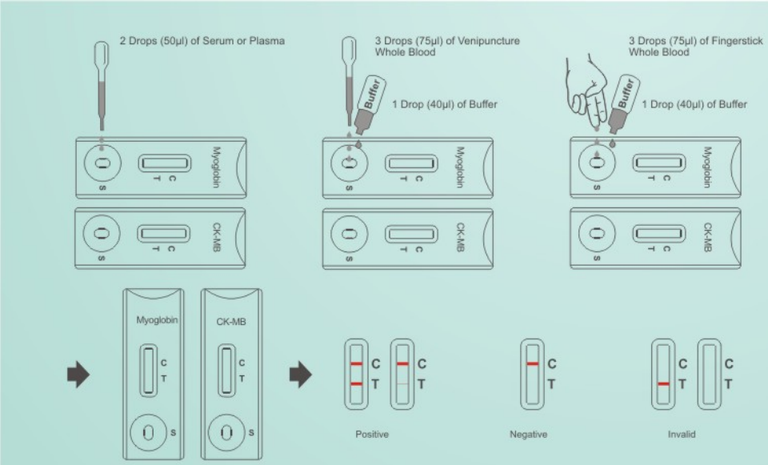
Myoglobin and CK-MB are cardiac markers released from heart muscle as a result of myocardial infarction.

General Information

ABON™ Myoglobin/CK-MB Test Device is a rapid chromatographic immunoassay for the qualitative detection of human Myoglobin and CK-MB in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI).

- Specimen: Serum, plasma or whole blood
- Test Result: In 10 minutes
- Cutoff: Myoglobin 50ng/mL , CK-MB 5ng/mL

Test Procedure and Interpretation



Ordering Information

√ CE Marked CE

Description	Specimen	Format	Catalog No.	Tests Per Kit
CK-MB	Whole Blood/Serum/Plasma	Device	CCK-402√	20
Myoglobin	Whole Blood/Serum/Plasma	Device	CMY-402√	20

CM CK-MB/Myoglobin/Troponin I Combo Test

Myoglobin/CK-MB/Troponin I Combo Test Device

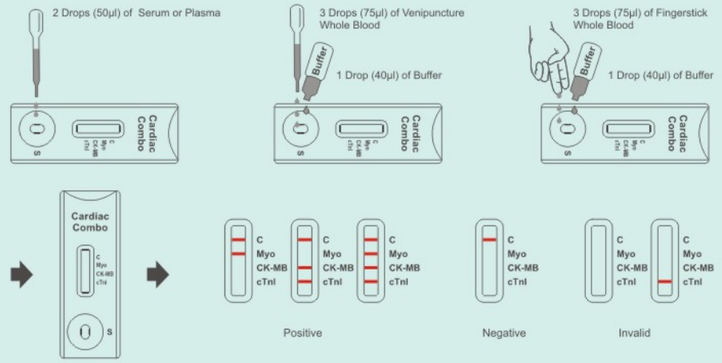
Myoglobin, CK-MB and Troponin I are cardiac markers released from heart muscle as a result of myocardial infarction.

General Information

ABON™ One Step Myoglobin/CK-MB/Troponin I Test Device is a rapid chromatographic immunoassay for the qualitative detection of human myoglobin, CK-MB and cardiac Troponin I in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI).

- Specimen: Serum, plasma or whole blood
- Test Result: In 10 minutes
- Cutoff: Myoglobin 50ng/mL , CK-MB 5ng/mL, Troponin I 0.5 ng/mL

Test Procedure and Interpretation



Ordering Information

√ CE Marked CE

Description	Specimen	Format	Catalog No.	Sensitivity	Tests Per Kit
Myoglobin/CK-MB/ cTnI Troponin I Combo	Whole Blood/ Serum/Plasma	Device	CMA-435√	See Insert	20

CM CRP C-Reactive Protein

C-Reactive Protein Semi-Quantitative Rapid Test Device

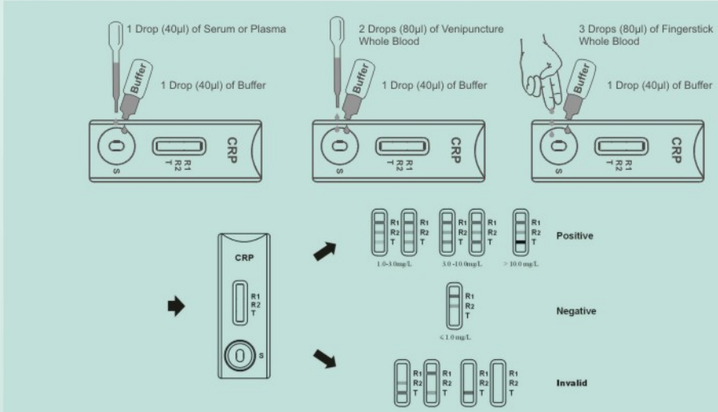
C-Reactive Protein (CRP) is a marker of acute phase response to inflammatory disorder. CRP is a predictor of future coronary events in apparently healthy subjects and of prognostic value in patients with acute coronary syndromes. CRP concentrations below 1 mg/L signify low risk, concentrations of 1-3 mg/L signify moderate risk and concentrations greater than 3 mg/L signify high risk for CVD. CRP level above 10mg/L does not signify cardiac risk, it can be indicative of inflammation.

General Information

ABON™ CRP C-Reactive Protein Semi-Quantitative Rapid Test Device is a rapid chromatographic immunoassay for semi-quantitative detection of C-Reactive Protein in whole blood, serum or plasma as an aid in evaluating risks of cardiovascular disease.

- Specimen: Serum, plasma or whole blood
- Test Result: In 10 minutes
- Minimum detection level: 1mg/L

Test Procedure and Interpretation



Ordering Information

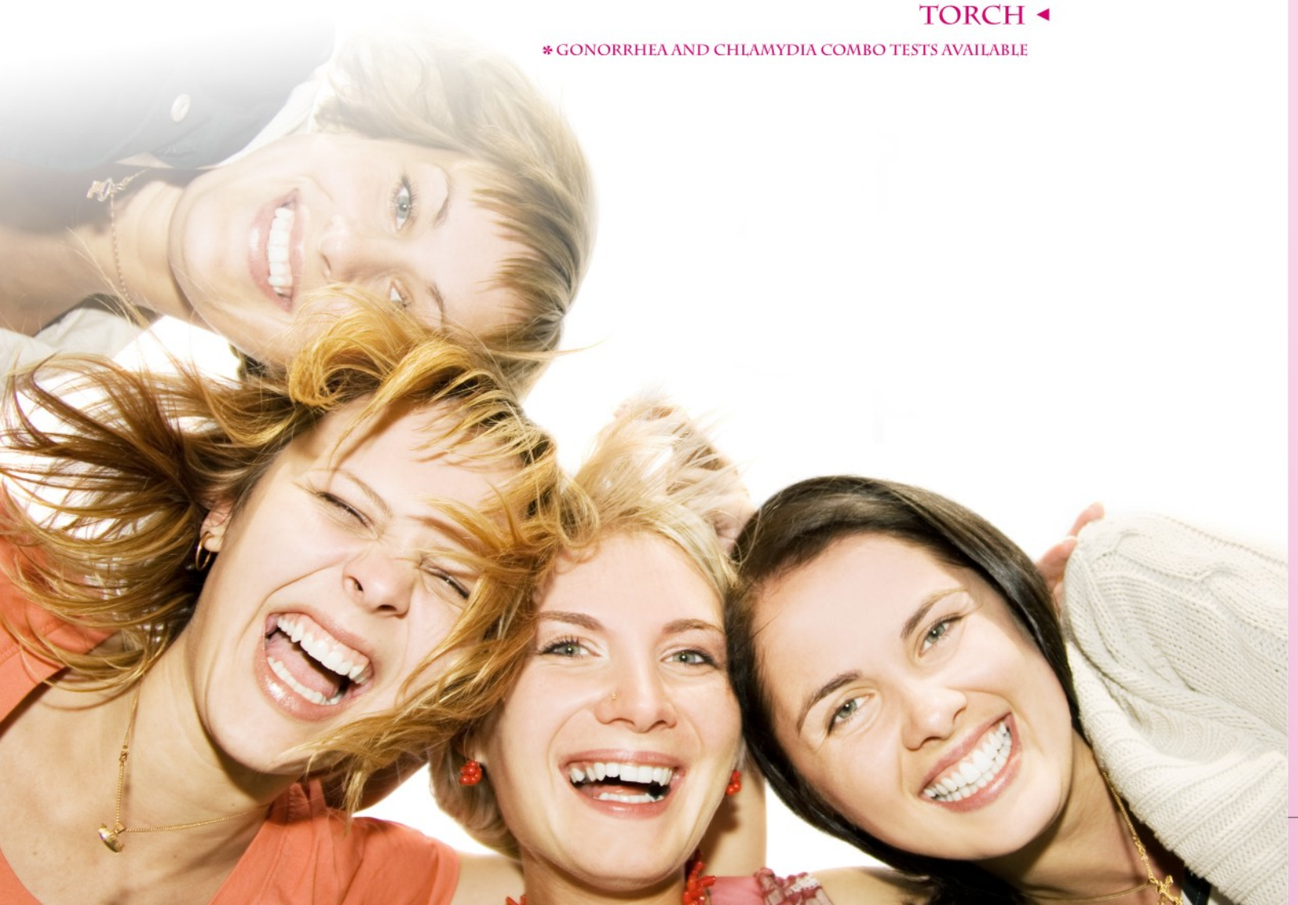
√ CE Marked CE

Description	Specimen	Format	Catalog No.	Tests Per Kit
CRP	Whole Blood/Serum/Plasma	Device	CCR-402√	20

WH/ WOMEN'S HEALTH

- HCG
- LH
- FSH
- * CHLAMYDIA
- *GONORRHEA
- TORCH

* GONORRHEA AND CHLAMYDIA COMBO TESTS AVAILABLE



WH HCG

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization, In normal prednancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conception.

General Information

The hCG One Step Pregnancy Test Strip (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

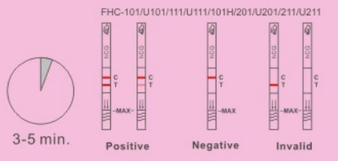
- Detection level: 25 mIU/ml and 10 mIU/ml
- Specimen: Urine, Urine/Serum
- Test time: Urine 3 minutes / Serum 5 minutes

WH HCG

Test Procedure and Interpretation

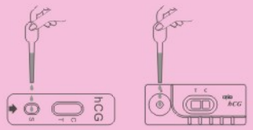
Strip Test

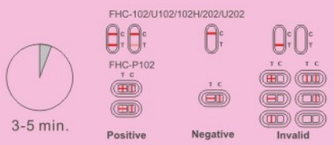
- Immerse the strip into urine or serum
- Read results at 3-5 minutes



Device Test

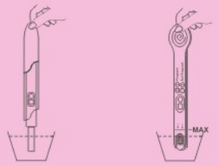
- Add 3-5 drops (100µl) of urine or serum
  Read results at 3 minutes for urine or 5 minutes for serum

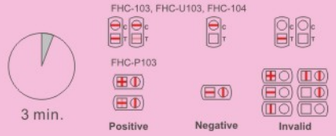




Midstream Test

- Pass the urine on the Absorbent Tip or dip it into urine
- Read results at 3 minutes





Ordering Information

†US FDA Cleared √ CE Marked CE

Description	Specimen	Format	Catalog No.	Sensitivity	Tests Per kit
hCG	Urine	Strip	FHC-101 √†	25mIU/mL	50 Tests/25 Tests
			FHC-U101 √	10mIU/mL	50 Tests
			FHC-111 √†	25mIU/mL	25 Tests/Canister**
			FHC-U111 √	10mIU/mL	
			FHC-101H √†	25mIU/mL	1 Test
		Device	FHC-102 √†	25mIU/mL	40 Tests/25 Tests
			FHC-U102 √	10mIU/mL	
			FHC-102H √†	25mIU/mL	1 Test
			FHC-P102	25mIU/mL	25 Tests
		Midstream	FHC-103 √†	25mIU/mL	1 or 2 Tests
			FHC-U103 √	10mIU/mL	
			FHC-P103 √†	25mIU/mL	1 Test
			FHC-104	25mIU/mL	20 Tests
		Cup	FHC-107H √	25mIU/mL	1 Test
	Urine/Serum	Strip	FHC-201 √†	25mIU/mL	50 Tests
			FHC-U201 √	10mIU/mL	
			FHC-211 √†	25mIU/mL	25 Tests/Canister**
			FHC-U211 √	10mIU/mL	
		Device	FHC-202 √†	25mIU/mL	40 Tests
			FHC-U202 √	10mIU/mL	

**Also available in canisters of 20 or 30

WH LH

Ovulation is the release of an egg from the ovary. The egg then passes into the fallopian tube where it is ready to be fertilized. Immediately prior to ovulation, the body produces a large amount of luteinizing hormone (LH) which triggers the release of a ripened egg from the ovary.

CE FDA

General Information

The LH One Step Ovulation Test Strip (Urine) is a rapid chromatographic immunoassay for the qualitative detection of luteinizing hormone (LH) in urine to aid in the detection of ovulation.

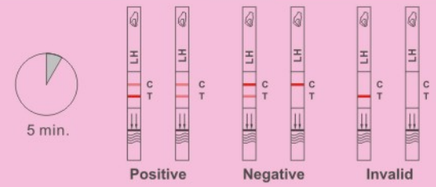
- Detection level: 40 mIU/ml and 30 mIU/ml
- Specimen: Urine

Test time:

Test Procedure and Interpretation

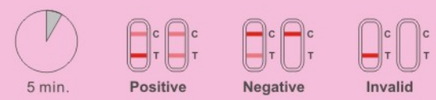
Strip Test

- Immerse the strip into urine
- Read results at 5 minutes



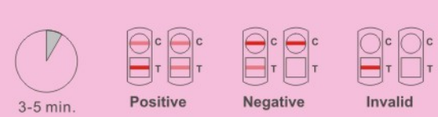
Device Test

- Add 3 drops (100µl) of urine
- Read results at 5 minutes



Midstream Test

- Pass the urine on the absorbent tip or dip it into urine
- Read results at 3-5 minutes



Ordering information

†US FDA Cleared √ CE Marked CE

Description	Specimen	Format	Catalog No.	Sensitivity	Tests Per kit
LH Ovulation	Urine	Strip	FLH-101 √†	40 mIU/mL	50
LH Ovulation	Urine	Device	FLH-102 √†	40 mIU/mL	40
			FLH-102H √	40 mIU/mL	5
LH Ovulation	Urine	Midstream	FLH-103 √†	40 mIU/mL	5

WH FSH

The onset of perimenopause is caused by changes in the levels of hormones in the female body that regulate the menstrual cycle. As the body produces less and less estrogen, it increases its production of FSH, which normally regulates the development of a female's eggs. Therefore, testing for FSH can help determine whether a woman is in the perimenopause stage.

CE FDA

General Information

The FSH One Step Menopause Test Device (Urine) is a rapid lateral flow chromatographic immunoassay for the qualitative detection of Follicle-Stimulating Hormone (FSH) level in urine to evaluate the onset of menopause in women.

Detection level: 25 mIU/ml

Specimen: Urine

3-5 minutes

Test time:

Test Procedure and Interpretation

Device Test

- Add 3 drops (100μl) of urine
- Read results at 5 minutes

Midstream Test

- Pass the urine on the absorbent tip or dip it into urine
- Read results at 3-5 minutes

Ordering Information

†US FDA Cleared √ CE Marked CE

Description	Specimen	Format	Catalog No.	Sensitivity	Tests Per kit
FSH Menopause	Urine	Device	FFS-102√	25 mIU/mL	40
			FFS-102H√		2
FSH Menopause	Urine	Midstream	FFS-103√†	25 mIU/mL	2

WH Chlamydia

Chlamydia trachomatis is the most common cause of sexually transmitted venereal infection in the world. Chlamydia trachomatis has both a high prevalence and asymptomatic carriage rate, with frequent serious complications in both women and neonates. Complications of Chlamydia infection in women include cervicitis, urethritis, endometritis, pelvic inflammatory disease (PID) and increased incidence of ectopic pregnancy and infertility.

CE

General Information

The ABON™ Chlamydia Rapid Test Device (Swab/Urine) is a rapid chromatographic immunoassay for the qualitative detection of Chlamydia trachomatis in female cervical swab, male urethral swab and male urine specimens to aid in the diagnosis of Chlamydia infection.

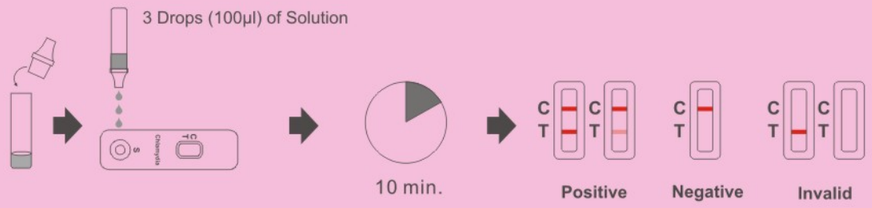
Specimen: Female Cervical Swab, Male Urine and Male Urethral Swab

10 minutes

Test time:

Specimen Type	Sensitivity	Specificity
Female Cervical Swab	88.5%	96.7%
Male Urine	90.9%	>99.0%
Male Urethral Swab	78.4%	92.9%

Test Procedure and Interpretation



Ordering information

* - Components included in package √ CE Marked CE

Description	Specimen	Format	Catalog No.	Read Time	Tests Per kit	Components								
						Test	Reagent A & B	Controls	Female Cervical Swab	Workstation	Test Tube	Dropper Tip	Quantitative Pipette	Package Insert
Chlamydia	Swab/ Urine	Device	ICH-502√	10 min.	20	*	*		*	*	*	*	*	*
			ICH-502S√		25	*	*			*	*	*	*	*
			ICH-502C		20	*	*	*	*	*	*	*		*

WH Gonorrhea

Gonorrhea is a sexually transmitted disease caused by the bacterium *Neisseria gonorrhoeae.* Gonorrhea is one of the most common infectious bacterial diseases and is most frequently transmitted during sexual intercourse, including vaginal, oral and anal sex. In women, Gonorrhea is a common cause of pelvic inflammatory disease (PID). PID can lead to internal abscesses and long-lasting, chronic pelvic pain. PID can damage the fallopian tubes enough to cause infertility or increase the risk of ectopic pregnancy.

General Information

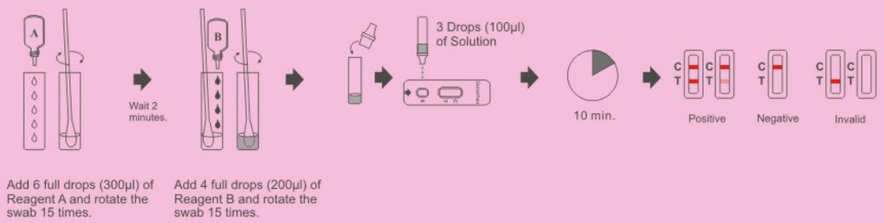
The ABON™ Gonorrhea Rapid Test Device (Swab) is a rapid chromatographic immunoassay for the qualitative detection of *Neisseria gonorrhoeae* in female cervical swab and male urethral swab specimens to aid in the diagnosis of Gonorrhea infection.

Specimen: Female Cervical Swab and Male Urethral Swab

Test time:

Specimen Type	Sensitivity	Specificity
Female Cervical Swab	91.5%	96.1%
Male Urethral Swab	89.2%	96.5%

Test Procedure and Interpretation



Ordering information

√ CE Marked CE

Description	Specimen	Format	Catalog No.	Read Time	Tests Per kit	Components								
						Test	Reagent A & B	Contr-ols	Female Cervical Swab	Worksta-tion	Test Tube	Dropper Tip	Quantitative Pipette	Package Insert
Gonorrhea	Swab	Device	IGO-502√	10 min.	20	*	*		*	*	*	*		*

WH Toxo/Rubella/CMV/HSV 1/2 IgM Ab

ToRCH is an acronym for a group of infectious diseases that, while infecting the pregnant women, may cause birth defects in their newborns. ToRCH stands for 4 different infections that can adversely affect the pregnant women and the fetus, newborn children including birth defects and often leading to abortion. The four infections are *Toxomplasma gondii* (A spirochete), Rubella (Virus), CMV - Cytomegalovirus (Virus), HSV 1/2 - Herpes Simplex Virus 1 and/or 2 (Virus). The infections usually cause few, if any, symptoms in the pregnant woman, but pose greater risks of serious birth defects for neonates.

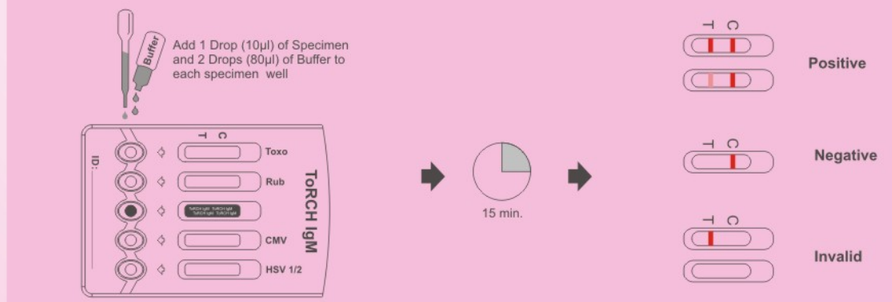
General Informa tion

The ABON™ ToRCH IgM Antibodies Combo Rapid Test Device (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgM antibodies to Toxoplasma gondii (Toxo), Rubella virus (Rubella), Cytomegalovirus (CMV), and Herpes simplex virus 1/2 (HSV 1/2) in serum or plasma to aid in the diagnosis of ToRCH.

Specimen: Serum or Plasma

	Toxo	Rubella	CMV	HSV1/2
Sensitivity	94.7%	95.0%	94.7%	85.7%
Specificity	98.6%	99.3%	98.9%	99.7%

Test Procedure and Interpretation



Ordering Information

√ CE Marked CE

Description	Specimen	Format	Catalog Number	Tests Per kit
ABON™ToRCH IgM Antibodies Combo Rapid Test Device	Serum/Plasma	Device	ITOM-345 √	25 Tests/Kit
ABON™ Toxo IgM Antibodies Rapid Test Device	Serum/Plasma	Device	ITM-302 √	40 Tests/Kit
ABON™ Rubella IgM Antibodies Rapid Test Device	Serum/Plasma	Device	IRM-302 √	40 Tests/Kit
ABON™ CMV IgM Antibodies Rapid Test Device	Serum/Plasma	Device	ICM-302 √	40 Tests/Kit
ABON™ HSV 1/2 IgM Antibodies Rapid Test Device	Serum/Plasma	Device	ISM-302 √	40 Tests/Kit

TM/ ONCOLOGY

AFP/CEA ◂
FOB ◂
PSA ◂

TM AFP/CEA

AFP: In general, an elevated level of Alpha-Fetoprotein in serum which is higher than 10 ng/mL occurs in several malignant diseases including hepatocellular carcinoma, testicular nonseminomatous origin, and occasionally of other entodermal origin.
CEA: Carcinoembryonic Antigen is a tumor-associated antigen which is expressed in a variety of malignancies, particularly pulmonary or gastrointestinal tumors. Therefore, elevated levels of CEA can be of significant value in the diagnosis of primary carcinomas.

CE

General Information

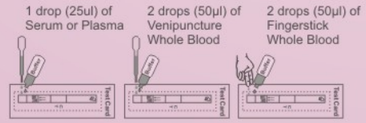
The AFP, CEA Rapid Tests are using rapid chromatographic immunoassay for the qualitative detection of AFP and CEA in whole blood, serum or plasma.

Description	Specimen	Detection	Cut-off	Sensitivity	Specificity
AFP	Whole Blood/Serum/Plasma	Alpha-Fetoprotein	10 ng/mL	99.0%	98.7%
CEA	Whole Blood/Serum/Plasma	Carcinoembryonic antigen	5 ng/mL	98.7%	99.2%

Test Procedure and Interpretation

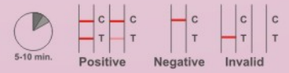
CEA Whole Blood Strip Test

- Add specimen and buffer
- Read results in minutes



AFP CEA Whole Blood Device Test

- Add specimen and buffer
- Read results in minutes



Ordering Information

√ CE Marked CE

Description	Specimen	Format	Catalog No.	Read Time	Sensitivity	Tests Per kit
AFP Alpha-Fetoprotein	Whole Blood/Serum/Plasma	Device	TAF-402√	10 min.	10 ng/mL	40
CEA Carcinoembryonic Antigen	Whole Blood/Serum/Plasma	Device	TCE-402 √	5 min.	5ng/mL	40

TM FOB

Fecal Occult Blood (FOB) is the hidden blood in the feces which can be found in many gastrointestinal diseases. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood.

General Information

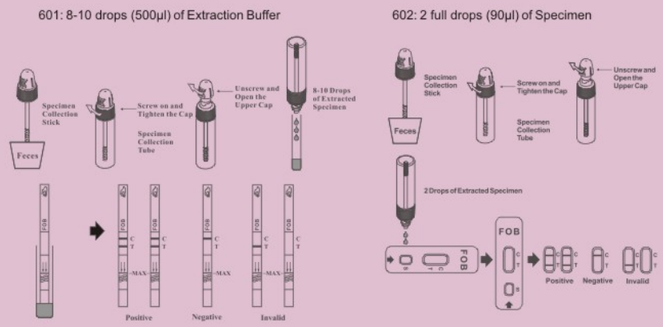
The FOB One Step Fecal Occult Blood Test Strip (Feces) is a rapid chromatographic immunoassay for the qualitative detection of Human Occult Blood in feces.

- Detection level: 50 ng/mL, 6 μg/g
- Specimen: Feces
- Test time: 5 minutes

Test Procedure and Interpretation

FOB Strip/Device Test

- Collect specimen with collection stick
- Agitate vigorously to mix specimen and buffer
- Immerse or add extracted specimen to the device and read results at 5 minutes



Ordering Information

√ CE Marked CE

Description	Specimen	Format	Catalog No.	Sensitivity	Tests Per kit
FOB Fecal Occult Blood	Feces	Strip	TFO-601 √	50 ng/mL 6 μg/g	25
FOB Fecal Occult Blood	Feces	Strip	TFO-601S√	50 ng/mL 6 μg/g	40
FOB Fecal Occult Blood	Feces	Device	TFO-602 √	50 ng/mL 6 μg/g	25

TM PSA

Prostate specific antigen (PSA) is produced by prostate glandular and endothelial cells. It can be elevated in malignant conditions such as prostate cancer, and in benign condition such as benign prostatic hyperplasia and prostatitis.

General Information

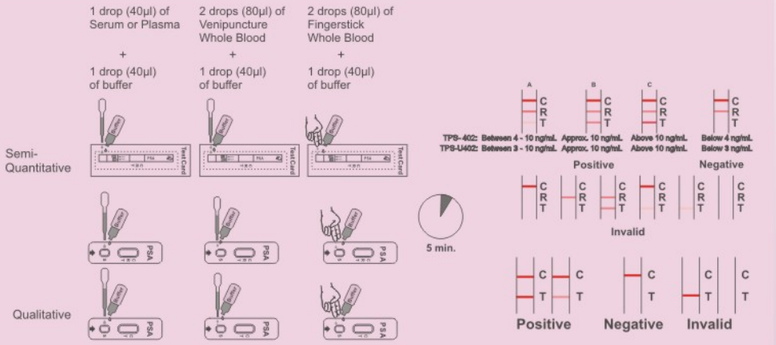
The PSA Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for semi-quantitative and qualitative detection of Prostate Specific Antigen in whole blood, serum or plasma.

Description	Specimen	Detection	Cut-off	Reference Level	Sensitivity	Sensitivity
PSA semi-quantitative	Whole Blood/Serum/Plasma	Prostate Specific Antigen	4 ng/mL 3 ng/mL	10 ng/mL	98.7%	98.5%
PSA qualitative	Whole Blood/Serum/Plasma	Prostate Specific Antigen	10 ng/mL	N/A	98.7%	98.5%

Test Procedure and Interpretation

PSA Whole Blood Strip/Device Test

- Add specimen and buffer
- Read results at 5 minutes



Ordering Information

√ CE Marked CE

Description	Specimen	Format	Catalog No.	Sensitivity	Tests Per kit
PSA Prostate Specific Antigen Semi-Quantitative	Whole Blood/Serum/Plasma	Device	TPS-402 √	4 ng/mL(R=10 ng/mL)	40/25
			TPS-U402 √	3 ng/mL(R=10 ng/mL)	
PSA Prostate Specific Antigen Qualitative	Whole Blood/Serum/Plasma	Device	TPS-UB402	3 ng/mL	40

ABON™