ELISA & PCR solutions designed to get you answers

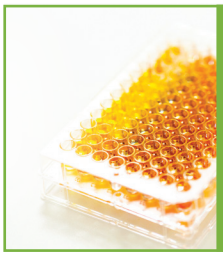
Streptavidin Plates

- **PRICE**
  Less than half the price of competitor plates
- **FLEXIBILITY**
  full plate or single strip breakable well capability
- **CONVENIENCE**
  Room temperature storage, no refrigeration required
- **QUALITY**
  Currently used in many clinical ELISA kits

02

ELISA

- **FATIGUE/WELLNESS**
  Vitamin D, B12, TSH, Ferritin
- **HORMONE/NEONATAL**
  Thyroid, Steriod, Fertility
- **BLOODBORNE**
  HIV Ab, HIV Ag, HCV Ab, HBsAg, Syphilis
- **TROPICAL/PARASITIC**
  Dengue IgG/igM/Ag, Chagas, CHIK
- **HEPATITS**
  HAV, HEV, HCV, HBV,



01

Life science

03

Dual-plate Analyzer

- Instrument available in DUAL (absorbance and/or luminescence) mode for microplates
- Easy to use with full walkaway capability
- Fully automatic instrument measures luminescence or absorbance from enzymatic assay
- Easy to use with full walkaway capability
- Universal open platform
- Accurate temperature control and plate shaking capability
- Automatic aspiration, injection, and well-washing system
- Fast & accurate movement with excellent reproducibility
- One touch software to automatically carry out protocols

04

ELISA Reader

- Flexible programming to meet your needs
- Accommodates different microplate geometries
- Variable speed and duration on plate shaker
- Ability to read plate within seconds
- Storage of calibration curves & plate results
- Dual and tri-wavelength readings

Microplate Washer

- Programmable soak time, wash cycles
- Flexible shaking speed & plate formats
- Continuous aspiration preventing overflow
- Specially designed manifold preventing needle from scratching bottom of wells

Real-Time PCR system

Real-Time PCR Tests

- T. Pallidum Test
- HPV 16/18 Test
- Dengue Virus Test
- Dengue Serotyping Test
- Chikungunya Virus Test
- Zika Virus Test
- Zika/Dengue/Chikungunya Test
- West Nile Virus Test
- Rhinovirus/Enterovirus Test
- Influenza A/B & RSV Test
- HSV1/HSV2/T. Pallidum Test
- Influenza A Typing Test

Nucleic Acid Extractor

Extractor-32

- Automated, walkaway extraction of nucleic acids
- 3.5-inch touchscreen with easy-to-use software
- Magnetic bead-based technology for ultra pure nucleic acids
- Fits low or high throughput workflows with up to 32 samples per run
- Seamless integration into any molecular diagnostics workflow

Thermocycler

RT-96

- 10-inch touchscreen with easy-to-use software
- Fast & uniform heating system for thermal cycling
- Highly sensitive and precise optical system with four channels for detection of multiplexed targets (up to six channels)
- Fits low or high throughput workflows with up to 96 samples per run
- Outstanding data analysis functions built into the software

TEST MENU

S: serum; P: plasma; WB: whole blood; *: CE marked

FATIGUE / WELLNESS

CAT#	Product Name	Specimen	Shelf Life
L5010	Ferritin CLIA Test *	S/P	12M
L8010	Total Vitamin D CLIA Test *	S/P	12M
L8030	Vitamin B12 CLIA Test *	S/P	12M
--	Folate CLIA Test *coming soon*	--	--

HORMONE

CAT#	Product Name	Specimen	Shelf Life
L1000	ß-hCG CLIA Test *	S/P	12M
L1080	PRL CLIA Test *	S/P	12M
L1090	LH CLIA Test *	S/P	12M
L1100	FSH CLIA Test *	S/P	12M
L1240	AMH CLIA Test *	S/P	12M
--	Estradiol CLIA Test *coming soon*	--	--
--	Progesterone CLIA Test *coming soon*	--	--
--	Testosterone CLIA Test *coming soon*	--	--
--	TSH CLIA Test *coming soon*	--	--
--	Total T3 CLIA Test *coming soon*	--	--
--	Free T3 CLIA Test *coming soon*	--	--
--	Total T4 CLIA Test *coming soon*	--	--
--	Free T4 CLIA Test *coming soon*	--	--

CARDIAC

CAT#	Product Name	Specimen	Shelf Life
L3002	cTnI CLIA Test *	S/P/WB	12M
L3010	D-Dimer CLIA Test *	P/WB	12M
L3020	CK-MB CLIA Test *	S/P/WB	12M
L3030	MYO CLIA Test *	S/P	12M
L3050	NT-proBNP CLIA Test *	S/P/WB	12M

INFECTION

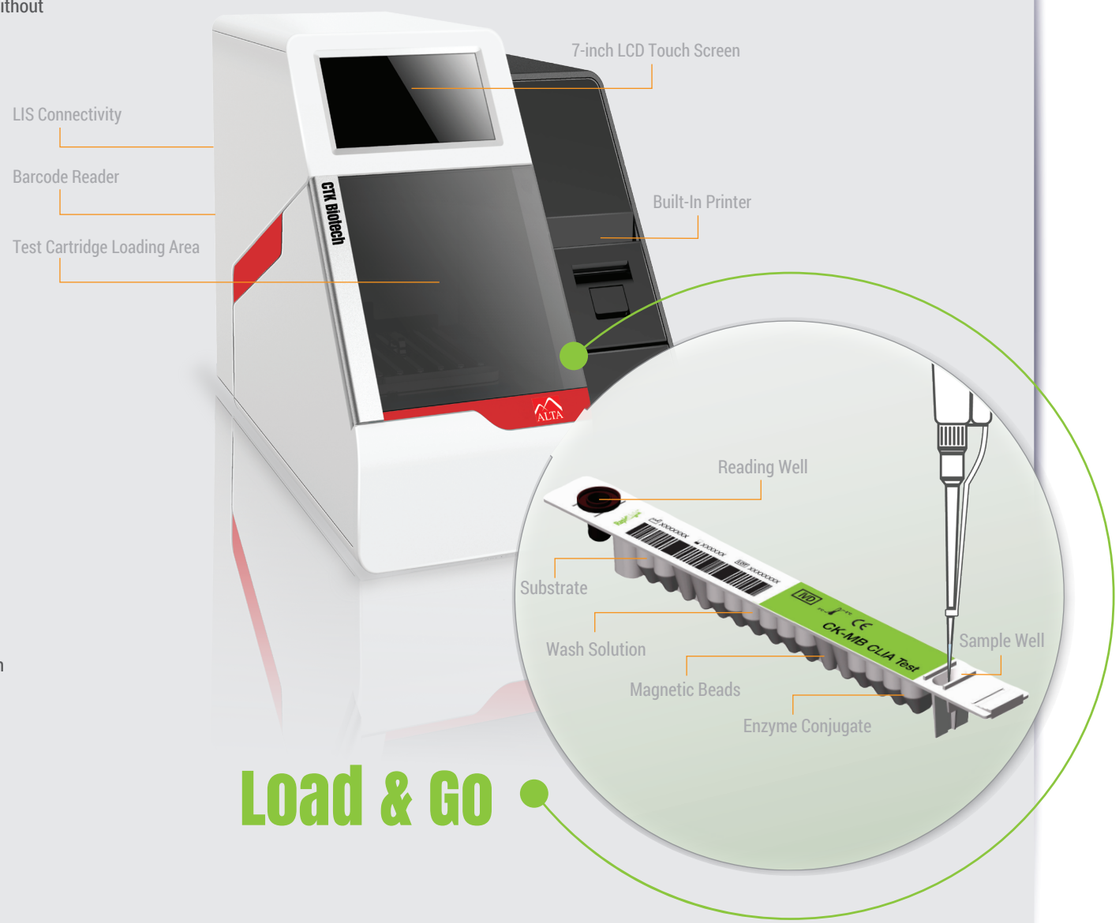
CAT#	Product Name	Specimen	Shelf Life
--	PCT CLIA Test *coming soon*	--	--

CTK'S CHEMILUMINESCENCE SOLUTION

Providing diagnostic accessibility & reliability through automation

CLIA System by CTK - CLIAlyzer + RapidLight CLIA Tests

CTK's Chemiluminescence Diagnostic Solution delivers an accurate, easy-to-use closed system analyzer with an extensive array of tests suiting almost every lab & clinic. Our small bench-top analyzer combined with our unique, ready-to-use test cartridges offer laboratories the efficiency & reliability they've been looking for without compromising space & efficiency.



Reliable Results within Minutes

- Photon Multiplier Tube (PMT) for signal detection provides high sensitivity across all parameters
- Assay time as quick as 15 minutes

User-Friendly Solution

- Requires minimal training
- Easy operation with 7-inch LCD Touch Screen

Accurate Results

- Barcode on test strip verifies assay & stores test kits' information
- External barcode scanner ensures accurate patient identification

Extensive Parameter Range

- Meets the needs of high & low throughput clinical settings
- Allows for on-demand testing

Simple procedure

Load Sample

Load Test Cartridge

Go!

ALTA

CLIAlyzer (CLIA-1) CE

Automatic Chemiluminescence Immunoassay Analyzer

① **Frees up space in the lab**
- Small benchtop analyzer, 30% smaller than other analyzers

② **Reduces the risk of human error**
- Automated walkaway assay procedure

③ **High-efficiency throughput for up to 24 tests per hour**
- Runs up to 6 assays at the same time, Random Mode & Batch Mode

④ **Continuous testing**
- Data storage of 100,000 results

SPECIFICATIONS

System	Fully automated chemiluminescence system
Operation	7-inch LCD Touch Screen
Reaction Mode	Random Mode, Batch Mode
Sample Type	Serum, plasma, whole blood
Methodology	Magnetic particle-based assay with chemiluminescence detection
Volume	420mm x 610mm x 321mm
Weight	35 kg
Connectivity	USB, RS232, LIS Connection
Barcode Scanner	1-D & 2-D barcode
Sample Positions	6

RapidLight®

Chemiluminescence Immunoassay (CLIA) Tests

Test Menu on reverse page

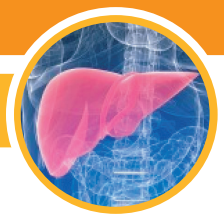
① **All-in-one test kit for ease of use**
- 36 tests per kit, with individual test cartridges and calibrators

② **Excellent performance & stability**
- Calibration stability: 60 days; two-point calibration

③ **Helps ensure consistent, reliable results**
- Two levels of controls available for all tests

OnSite™

HAV + HEV Rapid Tests CE



HAV & HEV - A Life-threatening Need to Differentiate

HEPATITIS INFECTION

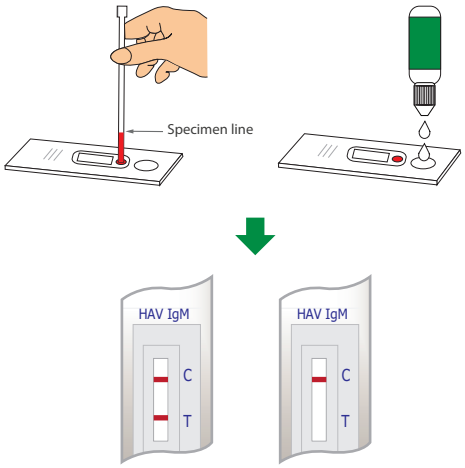
Hepatitis A virus (HAV) is one of the most common forms of hepatitis. This highly contagious disease is spread through contaminated food and water.

Hepatitis E virus (HEV) was identified in 1980 as a new hepatitis pathogen which is found primarily in Asia, Africa, and South America, is contracted in a similar fashion to hepatitis A with an additional possibility of zoonotic transmission.

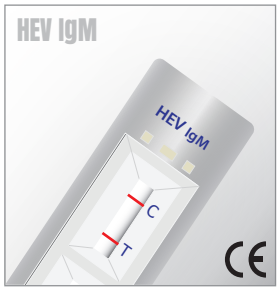
Clinically, both diseases have similar symptoms, but HEV infection is more severe, resulting in a 1-2% death rate in adults, while HAV results in less than 0.4% mortality. In pregnant women HEV is often associated with fulminant hepatic failure often suffering a 20% elevated mortality rate due to the disease in the third trimester.

HAV & HEV RAPID TESTS BY CTK

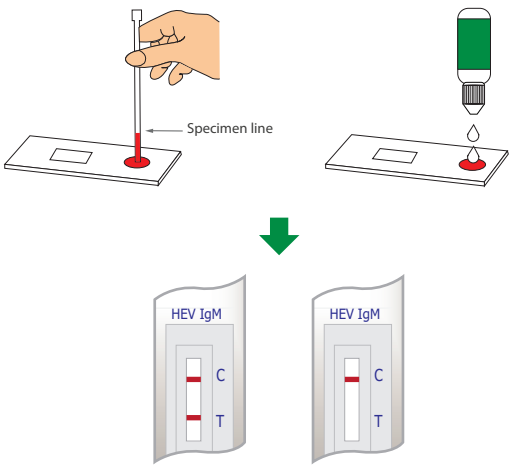
OnSite HAV IgM Rapid Test(R0090C)



- Detection of IgM antibodies in serum, plasma and whole blood specimen
- Comparable performance v.s. EIA: relative sensitivity: 90.6%, relative specificity: 97.6%, overall agreement: 95.4%
- 24 month shelf life at 2-30°C



OnSite HEV IgM Rapid Test(R0095C)

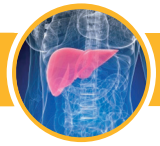


- Detection of IgM antibodies in serum and plasma specimen
- Comparable performance v.s. EIA: relative sensitivity: 98.1%, relative specificity: 99.2%, overall agreement: 98.1%
- 24 month shelf life at 2-30°C

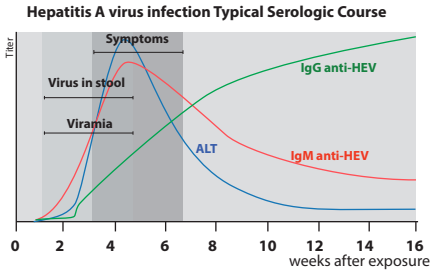
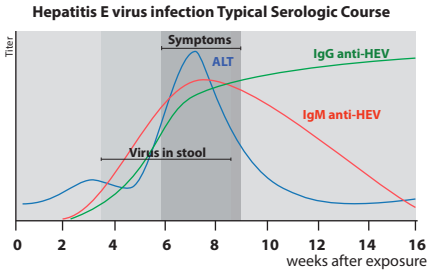
* HAV IgG/IgM Rapid Test now available! see back page for more information

OnSite™ RAPID TEST PRODUCTS CE

OnSite HAV + HEV Rapid Tests



HAV and HEV infection profile

Parameters	HAV infection	HEV Infection
Transmission	Oral-fecal route Contaminated food&water Direct contact with an infectious person Rarely via blood exposure	Oral-fecal route Contaminated food&water Rarely person to person transmission Possibility of zoonotic spread
Incubation Time	2 to 7 weeks, average 4 weeks	2 to 9 weeks, average 6 weeks
Demographics	Affects all age groups	Symptomatic HEV infection is most commont in young adults aged 15-40 yrs A symptomatic or a typical infection seen mostly in children
Disease Course	Self limiting	Self limiting Chronic hepatitis is connected to organ transplant recipients
Mortality Rate	0.4%	1-2% in adults 20% of pregnant women in 3rd trimester
Immunity	Life-long immunity against re-infection	People may become re-infected over the course of their lives
Vaccination	Yes	No
Annual Infection	1.4 million	20 million
Serological Profile		

We also provide

OnSite Rapid Tests

Catalog	Product	Detection	Sample	Shelf Life
R0092C	HAV IgG/IgM Rapid Test CE	Dectect both IgG and IgM in one test	S, P,WB	24 month

RecombiLISA ELISA Tests

Catalog	Product	Detection	Sample	Test Time
E0100	HAV IgM ELISA CE	Qualitatively detects IgM to HAV	S, P	70 mins
E0105	HEV IgM ELISA CE	Qualitatively detects IgM to HEV	S, P	75 mins

Adaptable to fully automated ELISA systems

OnSite™

HAV IgG/IgM Rapid Test CE

The most sensitive HAV test on the point-of-care market

DISEASE DESCRIPTION

Hepatitis A Virus (HAV) is one of the most common causes of viral hepatitis. Every year, about 1.4 million HAV infections worldwide are reported by the WHO. It is usually transmitted by the fecal-oral route, either through person-to-person contact, or consumption of contaminated food or water. Intravenous drug users and homosexual males may also be at high risk of infection.

In most cases HAV is self-limiting, however, in 0.5% of patients it may lead to fulminant hepatitis and death. HAV infection can be prevented by vaccination and by maintaining proper sanitation methods.

INDICATIONS

Serological tests for IgG and IgM anti-HAV are the most common lab tests for diagnosis of HAV infection. The recommended indications include:

- Individuals with signs or symptoms of acute HAV infection
- Individuals planning to travel to HAV endemic areas to determine if vaccination is required
- Individuals prior to working in industries where HAV immunity is needed
- Individuals in close contact with HAV patients

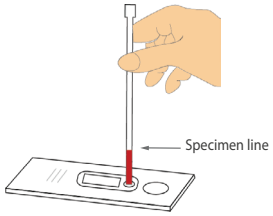
OnSite **HAV IgG/IgM Rapid Test (Cat. # R0092) by CTK Biotech is the most sensitive HAV rapid test on the market for quick and accurate determination of Hepatitis A infection in a single test at every stage:**

- early acute infection (IgM positive)
- late acute infection (IgG and IgM positive)
- protective immunity (IgG positive)

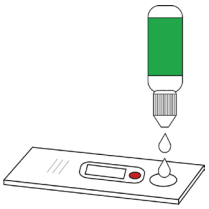
KEY FEATURES

- Single test for identifying acute infection and protective immunity by detecting and differentiating IgG and IgM anti-HAV
- Indicates protective immunity by detecting HAV IgG titers ≥70 mIU/mL
- High confidence as it is traceable to the 2nd WHO International Standard for HAV, and IgM is in agreement with market leading ELISA test: Sensitivity: 94.8%; Specificity: 96.7%
- Flexible specimen types including serum, plasma, or whole blood which allows testing at any time without special specimen preparation
- Small sample volume (5 µL) enables multiple testing on the same specimen without having to re-draw the patient
- Initial patient care action can begin during the patient's visit as test results are available in 15 minutes
- Easily transported, and can be stored for 24 months, 2-30°C

Accurately detects status of HAV infection in single test at the site of doctor visit

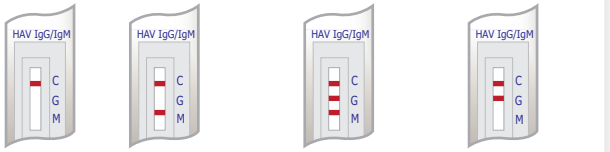


5 µL whole blood/serum/plasma



2 drops of samply diluent

Fast results in 15 minutes

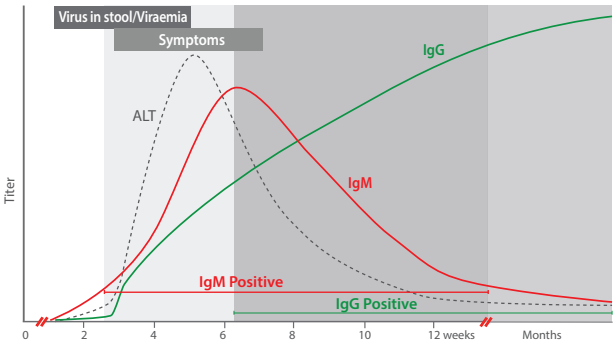


IgM & IgG Neg. **NO INFECTION**

IgM Pos. & IgG Neg. **EARLY ACTUE INFECTION**

IgM & IgG Pos. **LATE ACUTE INFECTION**

IgM Neg. & IgG Pos. **PROTECTIVE IMMUNITY**



OnSite HAV IgG/IgM Rapid Test CE

Analytical Sensitivity of IgG Detection

Defined as the 95% detection level, the limit of detection, or sensitivity for the G test line is 70 mIU/mL, as calibrated against the 2nd WHO International standard for HAV (NIBSC 00/562).

Accuracy of IgG Detection

Relative Sensitivity: 100%; Relative Specificity: 94.7%;
Overall Agreement: 98.0%

	OnSite HAV IgG/IgM Rapid Test		
Reference	Positive	Negative	Total
Positive	125	0	125
Negative	4	71	75
Total	129	71	200

Accuracy of IgM Detection

Relative Sensitivity: 94.8%; Relative Specificity: 96.7%;
Overall Agreement: 96.1%

	OnSite HAV IgG/IgM Rapid Test		
Reference	Positive	Negative	Total
Positive	91	5	96
Negative	7	203	210
Total	98	208	306

Interference

The performance of the ***OnSite*** HAV IgG/IgM Rapid Test is not affected by the following common substances:

- Albumin..... 60 g/L
- Bilirubin..... 20 mg/dL
- Creatinine..... 442 µmol/L
- EDTA..... 3.4 µmol/L
- Glucose..... 55 mmol/L
- Heparin..... 3,000 U/L
- Hemoglobin..... 2 g/L
- Salicylic acid..... 4.24 mmol/L
- Sodium citrate..... 3.4%

Cross-Reactivity

No cross-reactivity was observed on the specimens from the following disease states or special conditions, respectively:

- HBV
- hCG
- TB
- HAMA
- HCV
- Dengue
- Typhoid
- RF (up to 1,000 IU/mL)
- HEV
- *H. pylori*
- *T. pallidum*
- HIV
- Malaria
- ANA

Comparison with Leading ELISA & Competitor Rapid Test

BBI HAV performance panel PHT903 was used in the comparison study. The results show that the sensitivity of ***OnSite*** HAV IgG/IgM Rapid Test is comparable to the leading HAV IgM ELISA on the market, and superior to the competitor rapid test.

Panel Member	*OnSite* HAV IgG/IgM Rapid Test		Abbott IgM ELISA	DiaSorin IgM ELISA	Competitor Rapid Test	
	IgM	IgG			IgM	IgG
01	-	-	-	-	-	-
02	-	-	-	-	-	-
03	+	+	+	+	+	+
04	+	+	+	+	+	+
05	+	+	+	+	+	+
06	+	+	+	+	+	+
07	+	+	+	+	-	+
08	+	+	+	+	-	+
09	+	+	+	+	-	+
10	+	+	+	+	-	+

Positive: +; Negative: -

Positive Rate on Random Clinical Specimens

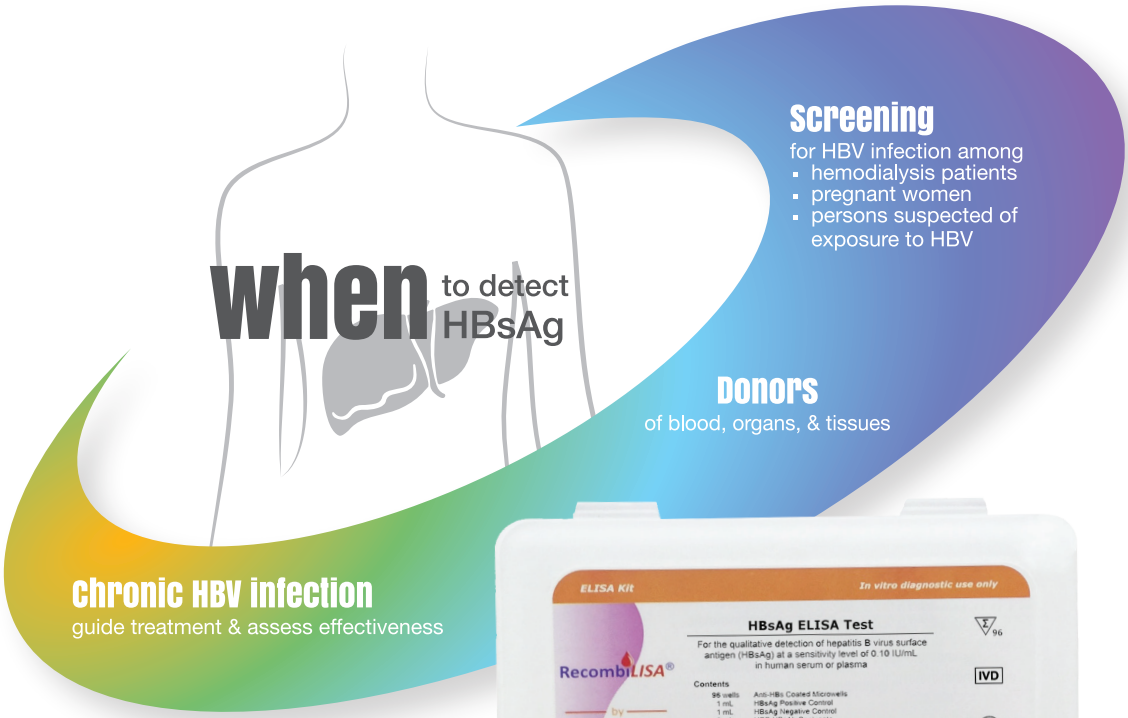
Positive Rate of IgG: 70.4%; Positive Rate of IgM: 4.6%

A total of 990 random, clinical specimens were tested with the ***OnSite*** HAV IgG/IgM Rapid Test.

RecombiLISA®

HBsAg ELISA

Detection of Hepatitis B promotes immediate care and treatment



HBsAg ELISA
E0710 | Serum/Plasma

Meets CE requirement
0.10 IU/mL analytical sensitivity

1-step procedure
Simple one-step reaction incubation

Long shelf life
15-month shelf life at 2-8°C

RecombiLISA®

HBsAg ELISA

PERFORMANCE

Analytical sensitivity	0.10 IU/mL, against WHO 3rd International Standard (12/226)
Sensitivity	100% (95% CI: 97.34% - 100%)
Specificity	100% (95% CI: 98.73% - 100%)
Intra Assay Precision	CV 23% (negative), 9% (weak positive), 7% (medium positive)
Inter Assay Precision	CV 25% (negative), 10% (weak positive), 7% (medium positive)
Cross Reactivity	No false positive results were observed on 3-10 positive specimens of dengue, HAV, HCV, HIV, *H. pylori, syphilis*, ANA, HAMA, RF (up to 8400 IU/mL), respectively.
Interference	No interference was seen with bilirubin (6.7-20 mg/dL), EDTA (1.1-3.4 µM), salicylic acid (1.3-3.8%), creatinine (147-442 µM), heparin (1000-3000 U/L), glucose (18-55 mmol/L)
Shelf life	15 months
Open vial stability	8 weeks at 2-8°C, or until the expiration date

OTHER HBV KITS AVAILABLE

ELISA

HBsAb ELISA	(E0711 |	Serum/plasma)
HBeAg ELISA	(E0720 |	Serum/plasma)
HBeAb ELISA	(E0721 |	Serum/plasma)
HBcAb ELISA	(E0810 |	Serum/plasma)
HBc IgM ELISA	(E0811 |	Serum/plasma)

Rapid Tests

HBsAg Rapid Test	(R0040C |	Serum/plasma)
HBsAg Rapid Test (Strip)	(R0040S |	Serum/plasma)
HBsAg Combo Rapid Test	(R0042C |	Serum/plasma/whole blood)
HBsAg/HCV Rapid Test	(R0028C |	Serum/plasma/whole blood)
HBV-5 Rapid Test	(R0049C |	Serum/plasma)

ALTA INSTRUMENTS

Durability you can count on!

CTK's ALTA instruments are easy to use and features a robust design

ELISA Reader
ADX-110

Microplate Washer
ADX-120

OnSite™

HSV Rapid Tests CE

Simple and Type Specific Detection of HSV-1 and HSV-2 Infection

UTILIZES GLYCOPROTEIN 1 & 2 AS RECOMMENTED BY US CDC

Infection with herpes simplex viruses, HSV-1 or HSV-2, is common though the majority of infected individuals are asymptomatic and go undiagnosed. Both viruses can cause genital herpes, leading to dangerous neonatal infections passed to the newborn during delivery, however they are different in their transmission pathways.

HSV-1 is highly prevalent in the general population, commonly acquired during childhood, and usually limited to the oral area. HSV-2 is usually acquired in adulthood through sexual contact and is an increasing global health problem because it is responsible for most genital herpes infections which increase the risk of transmitting HIV.

Accurate diagnosis and differentiation of HSV-1 and HIV-2 infection facilitates proper action to monitor or control transmission of the disease and prevent neonatal infections.

HSV test is recommended for the following populations

- Pregnant women
- Individuals at risk of HIV infection
- Patients with orolabial or genital ulcers
- Individual seeking STD evaluation

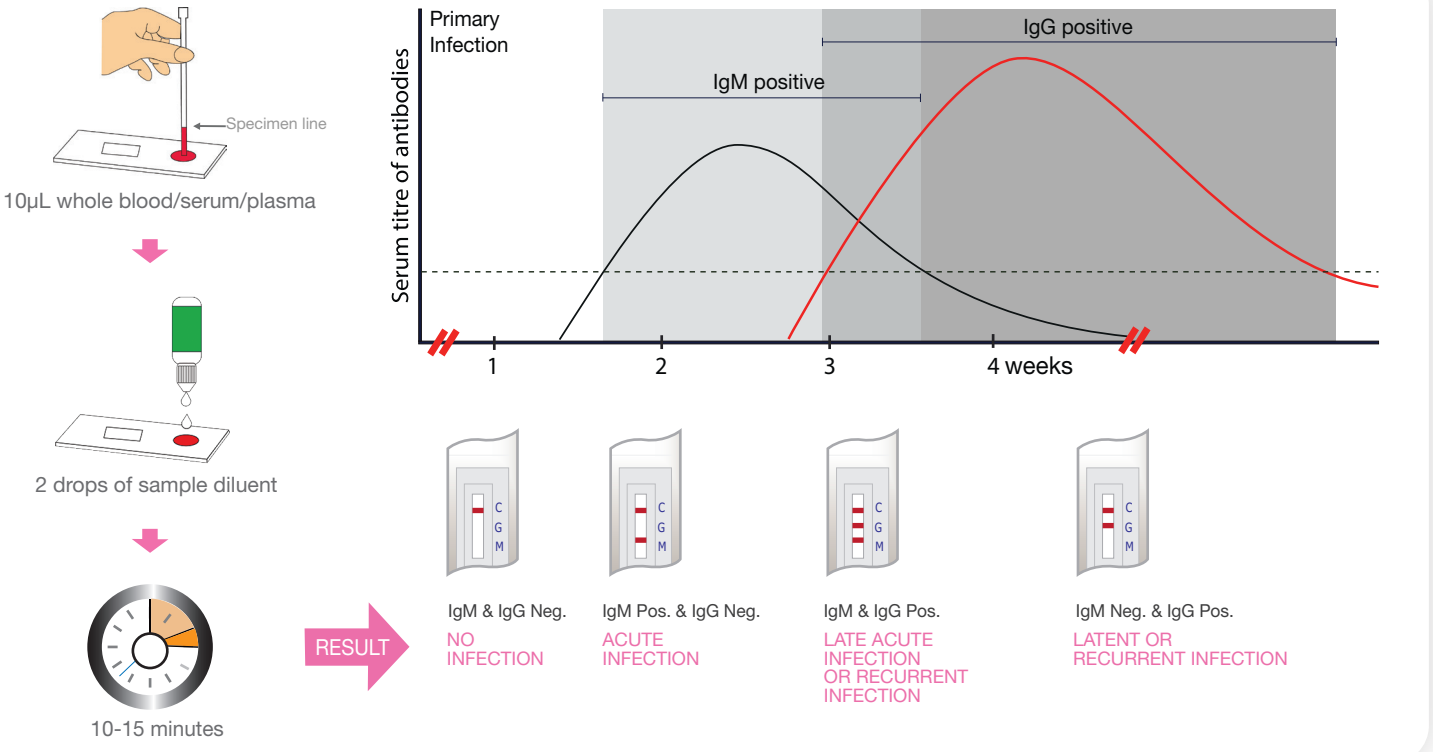
OnSite HSV Rapid Tests are the latest generation of POC test:

Key Features

- Utilizes recombinant HSV-specific glycoprotein G1 and G2 for type specific detection of HSV-1 and HSV-2 infection
- Differentiation of IgG/IgM in one device allows instant determination of infection at any stage
  - early acute
  - late acute
  - latent or recurrent

Additional Features

- Compatible with WHOLE BLOOD, serum or plasma specimens
- Only 10 uL specimen needed
- 10 minutes testing time enables initial diagnosis at the point of care
- 24-month shelf life at room temperature offers convenient storage condition
- Simple procedure increases lab productivity and reduces human error



OnSite™ RAPID TEST PRODUCTS

OnSite HSV-1 IgG/IgM Rapid Test

Expected Values

In non–high-risk populations, HSV-1 prevalence can reach 40% by age 15 and 60-90% in older adults. A clinical study in Saudi Arabia showed that the prevalence of of HSV-1 IgM and IgG in pregnant women is 5.9% and 93.2%, respectively.

Accuracy of IgG Detection

Relative Sensitivity: 90.6%; Relative Specificity: 91.4%;
Overall Agreement: 90.7%

Accuracy of IgM Detection

Overall Agreement: 85.0%

A total of 107 specimens were tested with both the *OnSite* Rapid Test and a commercial IgM ELISA.

Positive Rate on Random Clinical Specimens

Rositive Rate of IgG: 92.8%
Positive Rate of IgM: 4.9%

A total of 10,000 random, clinical specimens were tested with the *OnSite* HSV-1 IgG/IgM Rapid Test.

Cross-Reactivity

No cross-reactivity was observed on specimens from the following disease states or special conditions, respectively:

- CMV
- Dengue
- HAV
- HBV
- HCV
- HEV
- HIV
- H. pylori
- HSV-2
- Pregnancy
- Malaria
- Rubella
- TB
- Toxoplasma
- Syphilis
- Typhoid

- Hemoglobin 2 g/L
- Salicylic acid 4.24 mmol/L
- Sodium citrate 3.8%

We also provide:

Duo HSV-1/2 IgG/IgM Rapid Test

R0218C | serum/plasma/whole blood | 24-month shelf life

OnSite HSV-2 IgG/IgM Rapid Test

Expected Values

HSV-2 infects over 500 million people worldwide. HSV-2 seroprevalence ranges from 3.2% in some Chinese populations to over 80% in some areas of sub-Saharan Africa. Seroprevalence in women can be twice as high as men, and increases with age.

Accuracy of IgG Detection

Relative Sensitivity: 93.8%; Relative Specificity: 96.0%;
Overall Agreement: 95.3%

Performance on BBI Anti-Herpes Panel PTH202

Overall Agreement:
HSV-1: IgG 100%, IgM 100%
no cross reaction to HSV-2 specimen
HSV-2: IgG: 66.7%, IgM 100%
no cross reaction to HSV-1 specimen

Positive Rate on Random Clinical Specimens

Rositive Rate of IgG: 4.6%
Positive Rate of IgM: 1.7%

A total of 1,000 random, clinical specimens were tested with the *OnSite* HSV-2 IgG/IgM Rapid Test.

Cross-Reactivity

No cross-reactivity was observed on specimens from the following disease states or special conditions, respectively:

- CMV
- Dengue
- HAV
- HBV
- HCV
- HEV
- HIV
- H. pylori
- HSV-1
- Pregnancy
- Malaria
- Rubella
- TB
- Toxoplasma
- Syphilis
- Typhoid
- HAMA
- RF (up to 2,500 IU/mL)

e of the *OnSite* HSV-2 IgG/IgM Rapid Test is not following common substances.

- Bilirubin 20 mg/dL
- Creatinine 442 µmol/L
- Glucose 55 mmol/L
- Heparin 3,000 U/L
- Hemoglobin 2 g/L
- Salicylic acid 4.24 mmol/L
- Sodium citrate 3.8%

OnSite™

HSV Rapid Tests CE

Simple and Type Specific Detection of HSV-1 and HSV-2 Infection

UTILIZES GLYCOPROTEIN 1 & 2 AS RECOMMENTED BY US CDC

Infection with herpes simplex viruses, HSV-1 or HSV-2, is common though the majority of infected individuals are asymptomatic and go undiagnosed. Both viruses can cause genital herpes, leading to dangerous neonatal infections passed to the newborn during delivery, however they are different in their transmission pathways.

HSV-1 is highly prevalent in the general population, commonly acquired during childhood, and usually limited to the oral area. HSV-2 is usually acquired in adulthood through sexual contact and is an increasing global health problem because it is responsible for most genital herpes infections which increase the risk of transmitting HIV.

Accurate diagnosis and differentiation of HSV-1 and HIV-2 infection facilitates proper action to monitor or control transmission of the disease and prevent neonatal infections.

HSV test is recommended for the following populations

- Pregnant women
- Individuals at risk of HIV infection
- Patients with orolabial or genital ulcers
- Individual seeking STD evaluation

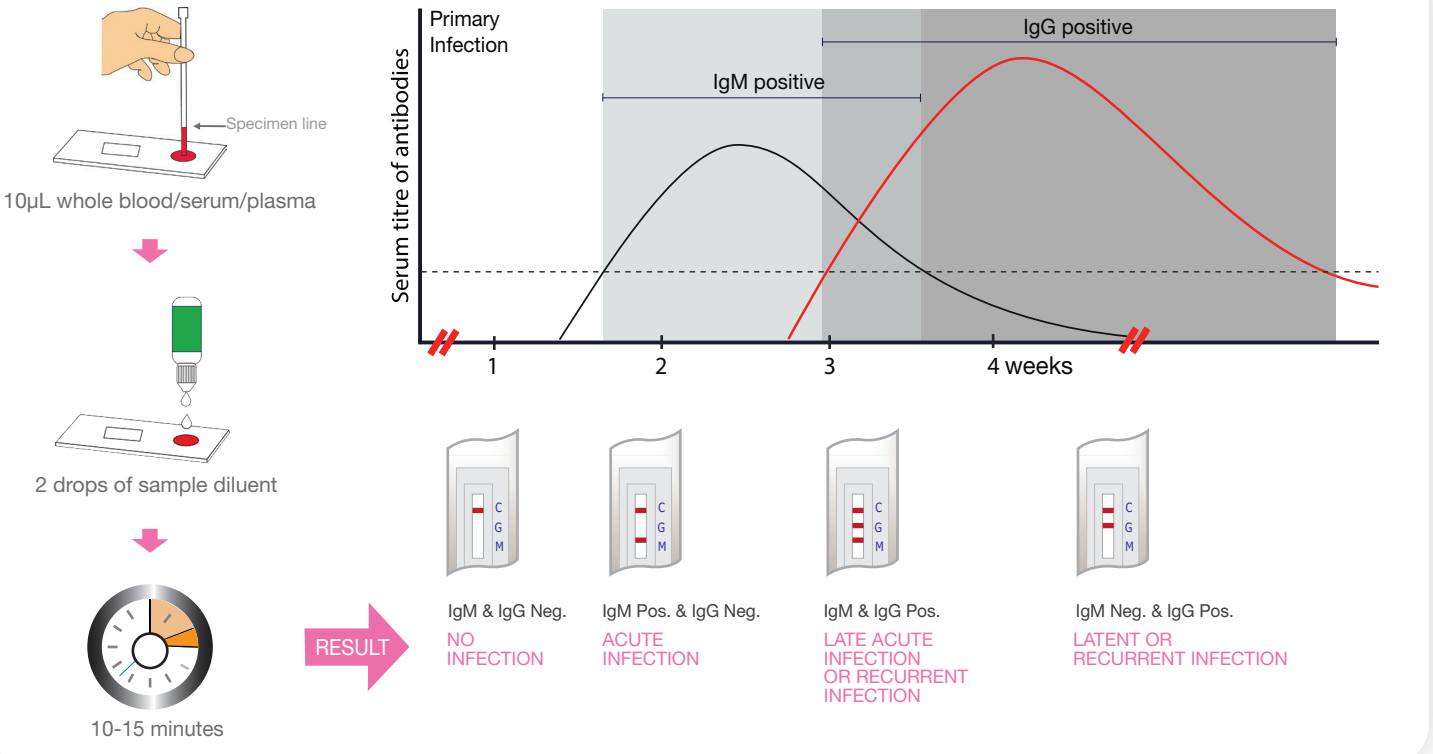
OnSite HSV Rapid Tests are the latest generation of POC test:

Key Features

- Utilizes recombinant HSV-specific glycoprotein G1 and G2 for type specific detection of HSV-1 and HSV-2 infection
- Differentiation of IgG/IgM in one device allows instant determination of infection at any stage
  - early acute
  - late acute
  - latent or recurrent

Additional Features

- Compatible with WHOLE BLOOD, serum or plasma specimens
- Only 10 uL specimen needed
- 10 minutes testing time enables initial diagnosis at the point of care
- 24-month shelf life at room temperature offers convenient storage condition
- Simple procedure increases lab productivity and reduces human error



OnSite™ RAPID TEST PRODUCTS

OnSite HSV-1 IgG/IgM Rapid Test

Expected Values

In non–high-risk populations, HSV-1 prevalence can reach 40% by age 15 and 60-90% in older adults. A clinical study in Saudi Arabia showed that the prevalence of of HSV-1 IgM and IgG in pregnant women is 5.9% and 93.2%, respectively.

Accuracy of IgG Detection

Relative Sensitivity: 90.6%; Relative Specificity: 91.4%;
Overall Agreement: 90.7%

Accuracy of IgM Detection

Overall Agreement: 85.0%

A total of 107 specimens were tested with both the *OnSite* Rapid Test and a commercial IgM ELISA.

Positive Rate on Random Clinical Specimens

Rositive Rate of IgG: 92.8%
Positive Rate of IgM: 4.9%

A total of 10,000 random, clinical specimens were tested with the *OnSite* HSV-1 IgG/IgM Rapid Test.

Cross-Reactivity

No cross-reactivity was observed on specimens from the following disease states or special conditions, respectively:

• CMV	• Dengue	• HAV	• HBV
• HCV	• HEV	• HIV	• H. pylori
• HSV-2	• Pregnancy	• Malaria	• Rubella
• TB	• Toxoplasma	• Syphilis	• Typhoid
• ANA	• HAMA	• RF (up to 1,000 IU/mL)	

Interference

The performance of the *OnSite* HSV-1 IgG/IgM Rapid Test is not affected by the following common substances.

• Albumin 60 g/L	• Bilirubin 20 mg/dL	• Creatinine 442 µmol/L
• EDTA 3.4 µmol/L	• Glucose 55 mmol/L	• Heparin 3,000 U/L
• Hemoglobin 2 g/L	• Salicylic acid 4.24 mmol/L	• Sodium citrate 3.8%

We also provide:

Duo HSV-1/2 IgG/IgM Rapid Test

R0218C | serum/plasma/whole blood | 24-month shelf life

OnSite HSV-2 IgG/IgM Rapid Test

Expected Values

HSV-2 infects over 500 million people worldwide. HSV-2 seroprevalence ranges from 3.2% in some Chinese populations to over 80% in some areas of sub-Saharan Africa. Seroprevalence in women can be twice as high as men, and increases with age.

Accuracy of IgG Detection

Relative Sensitivity: 93.8%; Relative Specificity: 96.0%;
Overall Agreement: 95.3%

Performance on BBI Anti-Herpes Panel PTH202

Overall Agreement:
HSV-1: IgG 100%, IgM 100%
no cross reaction to HSV-2 specimen
HSV-2: IgG: 66.7%, IgM 100%
no cross reaction to HSV-1 specimen

Positive Rate on Random Clinical Specimens

Rositive Rate of IgG: 4.6%
Positive Rate of IgM: 1.7%

A total of 1,000 random, clinical specimens were tested with the *OnSite* HSV-2 IgG/IgM Rapid Test.

Cross-Reactivity

No cross-reactivity was observed on specimens from the following disease states or special conditions, respectively:

• CMV	• Dengue	• HAV	• HBV
• HCV	• HEV	• HIV	• H. pylori
• HSV-1	• Pregnancy	• Malaria	• Rubella
• TB	• Toxoplasma	• Syphilis	• Typhoid
• ANA	• HAMA	• RF (up to 2,500 IU/mL)	

Interference

The performance of the *OnSite* HSV-2 IgG/IgM Rapid Test is not affected by the following common substances.

• Albumin 60 g/L	• Bilirubin 20 mg/dL	• Creatinine 442 µmol/L
• EDTA 3.4 µmol/L	• Glucose 55 mmol/L	• Heparin 3,000 U/L
• Hemoglobin 2 g/L	• Salicylic acid 4.24 mmol/L	• Sodium citrate 3.8%

OnSite™

S. Typhi/Paratyphi Ag Rapid Test

The most sensitive Typhoid Ag test on the market

Cat #	R0162C
Shelf life	24 M
Specimen	Blood culture/Fecal Whole blood/Serum/Plasma

Designed to surpass market demands with unparalleled benefits

Provide Immediate & targeted action

Reduce misuse of antibiotics

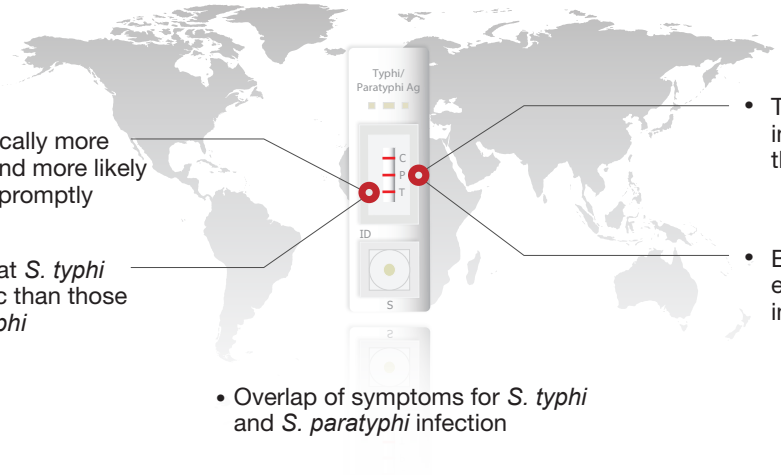
Track treatment efficacy

OnSite™ RAPID TEST PRODUCTS

S. Typhi/Paratyphi Ag Rapid Test

Detects and Differentiates *S. typhi* and *S. paratyphi*

- *S. typhi* infection is typically more severe, longer lasting and more likely to result in death if not promptly treated
- Medication used to treat *S. typhi* infection are more toxic than those used to treat *S. paratyphi*



- The incidence of *S. paratyphi* infections is rising more rapidly than *S. typhi* infections worldwide
- Broader detection capability especially with the growing incidence of *S. paratyphi A*
- Overlap of symptoms for *S. typhi* and *S. paratyphi* infection

OnSite is the clear choice for *S. typhi* and *S. paratyphi* detection

	OnSite allows detection of Typhoid Fever throughout the full spectrum of infection			
Specification	S. Typhi/Paratyphi Ag RDT	IgG/IgM RDT	Blood Culture	Widal Test
Rapid results	•	•		
Easy result interpretation	•	•	•	
Detects *S. typhi* and *S. paratyphi*	•	•*	•	•
Differentiates *S. typhi* and *S. paratyphi*	•			
Differentiates IgG and IgM		•		
Multiple specimen options meet all resource settings	•	•		
Minimal training required	•	•		
Designed for resource limited clinic & labs	•	•		

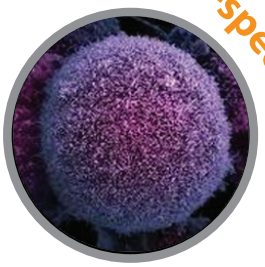
* *Detects antibodies to S. typhi & S. paratyphi*

Positivia™

S.Typhi/Paratyphi Ag Rapid Test External Control Kit

- Enables laboratory quality compliance
- Improves and standardizes QC process

OnSite™



PSA Screening Allows Early Detection of Prostate Cancer

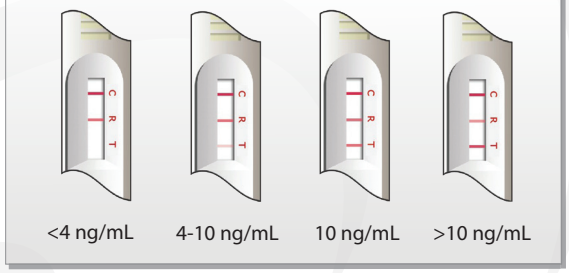
OnSite **Prostate-specific Antigen (PSA) Semi-quantitative Rapid Test provides semi-quantitative, easy to interpret results to screen for prostate cancer or monitor patients in remission.**

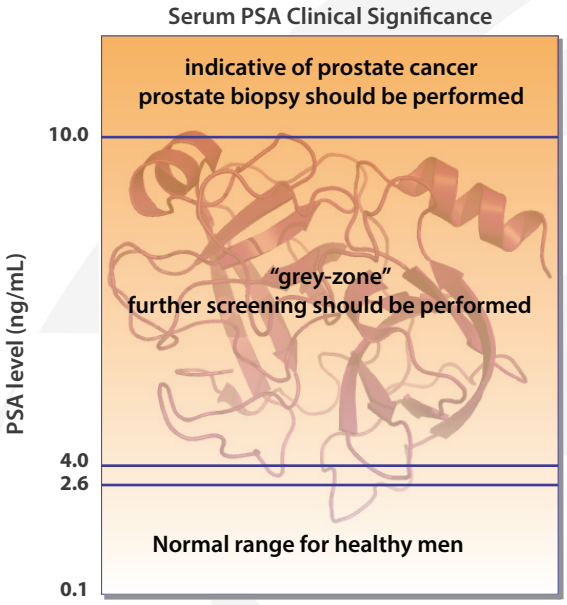
Prostate cancer is the most common type of non-skin cancer in men. Studies have suggested that serum prostate-specific antigen (PSA), a protein produced only by prostate tissue and often elevated in patients with prostate cancer, is one of the most useful tumor markers in oncology.

In addition to cancer screening, PSA tests are also used to monitor recurrence in patients who have a history of prostate cancer. A trend of increasing PSA levels is often the first sign of recurrence, detectable months or years before other clinical symptoms are present.

The ***OnSite*** PSA Rapid Test is a three-line, chromatographic immunoassay for the semi-quantitative detection of PSA. It has a cut-off value of 4 ng/mL and a reference value of 10 ng/mL for easy determination of the PSA range for that patient.

T-line Intensity	PSA level
No color development	<4 ng/mL
Lighter than reference line	4-10 ng/mL
Equal to reference line	10 ng/mL
Darker than reference line	>10 ng/mL





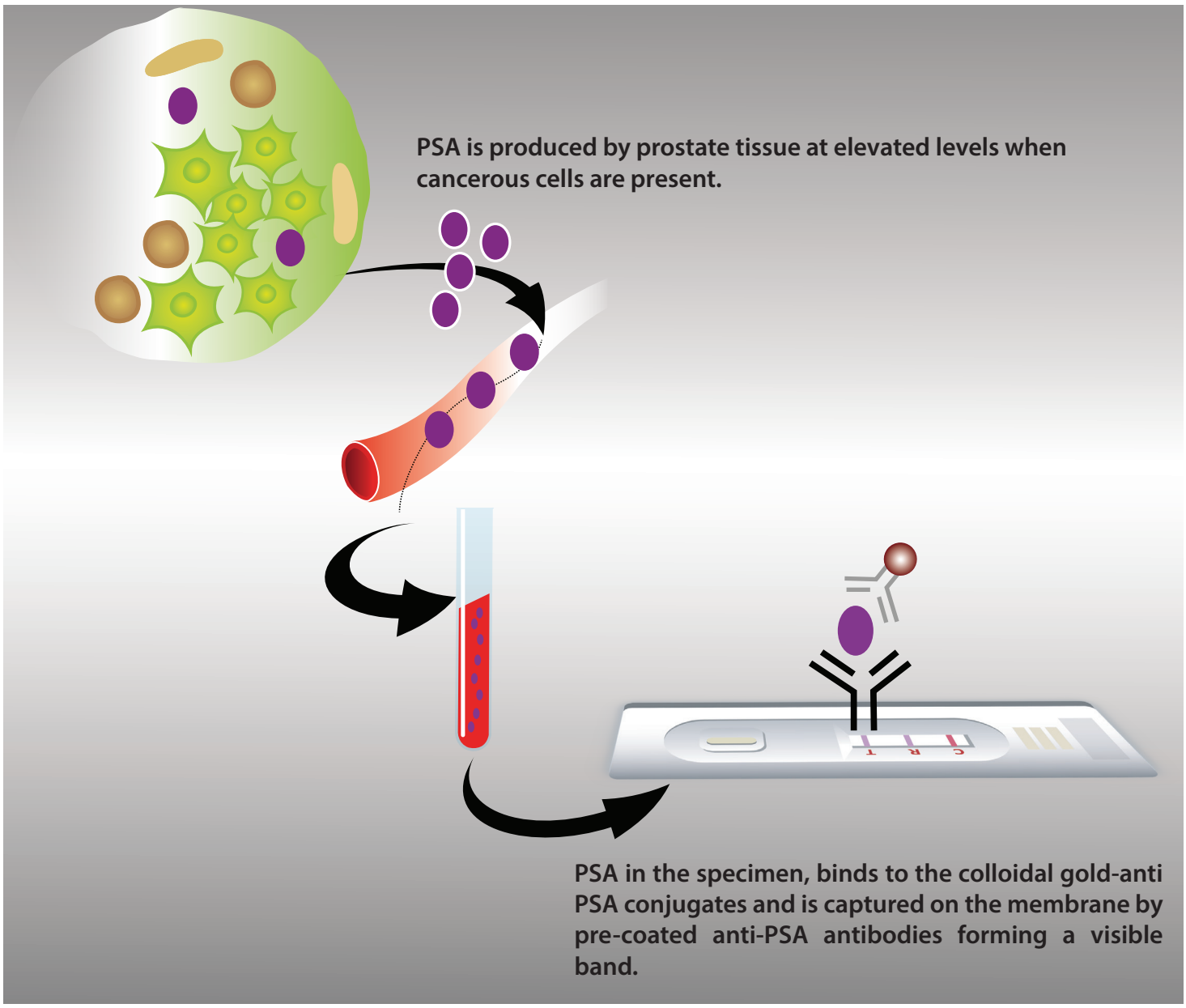
OnSite PSA Rapid Tests are an ideal choice for PSA screening in the physician's office.

- cost-effective
- efficient, rapid result
- no equipment required

OnSite Rapid Test

Catalog	Product	Detection	Sample	Time
R2002C	PSA Semi-quantitative Rapid Test	PSA ≥ 4 ng/mL, semi-quantitative	S, P, WB	15 min

OnSite PSA Rapid Test Principle



Additional *OnSite* Rapid Tests available for cancer screening

Catalog	Product	Detection	Sample	Time
R2010C	FOB Rapid Test CE	hHb ≥ 50 ng/mL	Feces	10 min
R2011C	FOB Hi Rapid Test CE	hHb ≥ 25 ng/mL	Feces	10 min

Rapid Fluorescence Immunoassay System

Laboratory Results at the Point of Care

Portable, Convenient Design

Lightweight analyzer designed for resource-limited settings

Easy to Use

Simple procedure; minimally trained staff can perform testing

Fast Results

Clinicians can take immediate action due to test time turnaround

Quick Test Mode

6-channel incubator with no waiting period; allows for higher throughput

Connectivity & Large Data Storage

Useful in every setting with built-in printer, USB & PC port, scanner connector, & stores up to 10,000 records

Accurate & Consistent

Inter Lot CV ≤ 15%
Intra Lot CV ≤ 20%

Test Menu

HORMONE

Product Name	Cat #	Specimen	Test Time	Working Range
β-hCG FIA Test *	F1000	S/P	10 min	5.0-200000.0 μIU/mL
TSH FIA Test *	F1030	S/P	20 min	0.4-100.0 μIU/mL
PRL FIA Test *	F1080	S	20 min	5.0-4000.0 μIU/mL
LH FIA Test *	F1090	S	20 min	1.0-200.0 μIU/mL
FSH FIA Test *	F1100	S	20 min	0.3-200.0 μIU/mL
TES FIA Test *	F1210	S	10 min	0.2-20.0 ng/mL
PROG FIA Test *	F1220	S	10 min	0.3-80.0 ng/L
AMH FIA Test *	F1240	S/P	10 min	0.1-25.0 ng/mL

CANCER / OTHERS

Product Name	Cat #	Specimen	Test Time	Working Range
tPSA FIA Test	F2003	S	15 min	1.0-1000.0 ng/mL
fPSA FIA Test	F2004	S	15 min	0.1-30.0 ng/mL
CEA FIA Test *	F2015	S/P	10 min	0.5-500.0 ng/mL
AFP FIA Test *	F2030	S/P	10 min	3.0-2000.0 ng/mL
Ferritin FIA Test *	F5010	S	15 min	1.0-1000.0 ng/mL
Total IgE FIA Test	F5020	S/P/WB	12 min	1.0-1000.0 IU/mL
Vitamin D (Total) FIA Test	F8010	WB	10 min	5.0-120.0 ng/mL

INFECTION

Product Name	Cat #	Specimen	Test Time	Working Range
PCT FIA Test *	F0400	S/P/WB	15 min	0.1-100.0 ng/mL
CRP FIA Test *	F0410	S/P/WB	3 min	2.5-200 mg/L

* CE marked product
S Serum
P Plasma
WB Whole Blood

CARDIAC

Product Name	Cat #	Specimen	Test Time	Working Range
cTnI FIA Test *	F3002	P/WB	15 min	0.1-50.0 ng/mL
D-Dimer FIA Test *	F3010	P/WB	3 min	0.1-10.0 mg/L
CK-MB FIA Test *	F3020	S/P	15 min	1.0-80.0 ng/mL
MYO FIA Test *	F3030	S/P	15 min	2.5-400.0 ng/mL
NT-proBNP FIA Test *	F3050	S/P/WB	15 min	100-35000 pg/mL

DIABETES / RENAL INJURY

Product Name	Cat #	Specimen	Test Time	Working Range
MAU FIA Test *	F2020	Urine	10 min	2.0-300.0 mg/L
Cys-C FIA Test *	F2121	P/WB	5 min	0.2-8.0 mg/L
HbA1c FIA Test *	F6100	WB	5 min	4%-15%

A diverse range of fluorescence immunoassays (FIA) for improving global health

For use with the RaFIA System only
25 tests per kit

- Maintains healthy blood cholesterol levels
- Regulates emotional balance
- Essential for healthy bone metabolism

- Hair loss, muscle mass loss
- Sleep disturbances, brain fog
- Abnormal menstrual periods or vaginal bleeding/dryness

Estradiol

- A growth hormone for reproductive well-being
- Triggers ovulation, maintains eggs in ovaries
- Prepares the womb lining for implantation
- Promotes sperm maturation

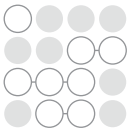
Progesterone

- Regulates blood sugar, brain activity & bone mass
- Regulates thyroid hormone production
- Normalizes blood clotting
- Contributes to initiating sleep
- Maintains the menstrual cycle

Testosterone ELISA CE
E1210 | Serum/Plasma

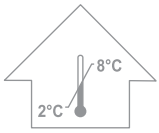
Progesterone ELISA CE
E1220 | Serum/Plasma

Estradiol (E2) ELISA CE
E1230 | Serum/Plasma



Optimized Design

Simple procedure & high Accuracy



High Stability

15-month shelf life, 60 days open vial stability

Open system

Including ALTA instruments by CTK

PERFORMANCE

Testosterone ELISA

Analytical Sensitivity	0.0576 ng/mL at 2SD
Clinical Performance	Correlation coefficient 0.985 with a reference method
Intra Assay Precision	CV ≤ 9.80%
Inter Assay Precision	CV ≤ 9.70%
Shelf Life	15 months

Progesterone ELISA

Analytical Sensitivity	0.078 ng/mL at 2SD
Clinical Performance	Correlation coefficient 0.989 with a reference method
Intra Assay Precision	CV < 10.70%
Inter Assay Precision	CV < 8.90%
Shelf Life	15 months

Estradiol (E2) ELISA

Analytical Sensitivity	8.22 pg/mL at 2SD
Clinical Performance	Correlation coefficient 0.989 with a reference method
Intra Assay Precision	CV < 9.90%
Inter Assay Precision	CV < 4.80%
Shelf Life	15 months

OTHER NEW ELISA

✓ Available now
🕓 Coming soon

Fatigue Panel ELISA	Fertility ELISA	Thyroid ELISA
✓ Vitamin D ELISA	✓ hCG ELISA	✓ fT3 ELISA & fT4 ELISA
✓ Vitamin B12 ELISA	✓ LH ELISA	✓ TT3 ELISA & TT4 ELISA
✓ TSH ELISA	✓ PRL ELISA	✓ TSH ELISA
🕓 Ferritin ELISA	✓ FSH ELISA	

ALTA INSTRUMENTS

Durability you can count on!

CTK's ALTA instruments are easy to use and features a robust design

ELISA Reader
ADX-110

Microplate Washer
ADX-120

Quantitative determination of Testosterone, Progesterone, Estradiol

Testosterone

- Vital for both men & women
- Maintains a healthy body composition & lean body mass
- Maintains healthy blood cholesterol levels
- Regulates emotional balance
- Essential for healthy bone metabolism

Shared Symptoms

- Fatigue/weakness
- Anxiety/mood instability
- Weight gain
- Infertility, low libido
- Hair loss, muscle mass loss
- Sleep disturbances, brain fog
- Abnormal menstrual periods or vaginal bleeding/dryness

Estradiol

- A growth hormone for reproductive well-being
- Triggers ovulation, maintains eggs in ovaries
- Prepares the womb lining for implantation
- Promotes sperm maturation

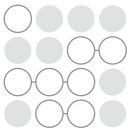
Progesterone

- Regulates blood sugar, brain activity & bone mass
- Regulates thyroid hormone production
- Normalizes blood clotting
- Contributes to initiating sleep
- Maintains the menstrual cycle

Testosterone ELISA CE
E1210 | Serum/Plasma

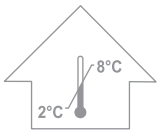
Progesterone ELISA CE
E1220 | Serum/Plasma

Estradiol (E2) ELISA CE
E1230 | Serum/Plasma



Optimized Design

Simple procedure & high Accuracy



High Stability

15-month shelf life, 60 days open vial stability

Open system

Including ALTA instruments by CTK

PERFORMANCE

Testosterone ELISA

Analytical Sensitivity	0.0576 ng/mL at 2SD
Clinical Performance	Correlation coefficient 0.985 with a reference method
Intra Assay Precision	CV ≤ 9.80%
Inter Assay Precision	CV ≤ 9.70%
Shelf Life	15 months

Progesterone ELISA

Analytical Sensitivity	0.078 ng/mL at 2SD
Clinical Performance	Correlation coefficient 0.989 with a reference method
Intra Assay Precision	CV < 10.70%
Inter Assay Precision	CV < 8.90%
Shelf Life	15 months

Estradiol (E2) ELISA

Analytical Sensitivity	8.22 pg/mL at 2SD
Clinical Performance	Correlation coefficient 0.989 with a reference method
Intra Assay Precision	CV < 9.90%
Inter Assay Precision	CV < 4.80%
Shelf Life	15 months

OTHER NEW ELISA

✓ Available now
🕓 Coming soon

Fatigue Panel ELISA	Fertility ELISA	Thyroid ELISA
✓ Vitamin D ELISA	✓ hCG ELISA	✓ fT3 ELISA & fT4 ELISA
✓ Vitamin B12 ELISA	✓ LH ELISA	✓ TT3 ELISA & TT4 ELISA
✓ TSH ELISA	✓ PRL ELISA	✓ TSH ELISA
🕓 Ferritin ELISA	✓ FSH ELISA	

ALTA INSTRUMENTS

Durability you can count on!

CTK's ALTA instruments are easy to use and features a robust design

ELISA Reader
ADX-110

Microplate Washer
ADX-120

OnSite®

TB IgG/IgM Combo Rapid Test CE

Screen for TB on any patient, anywhere

Cat # R0053C
Shelf life 24 M
Specimen Whole blood/Serum/Plasma

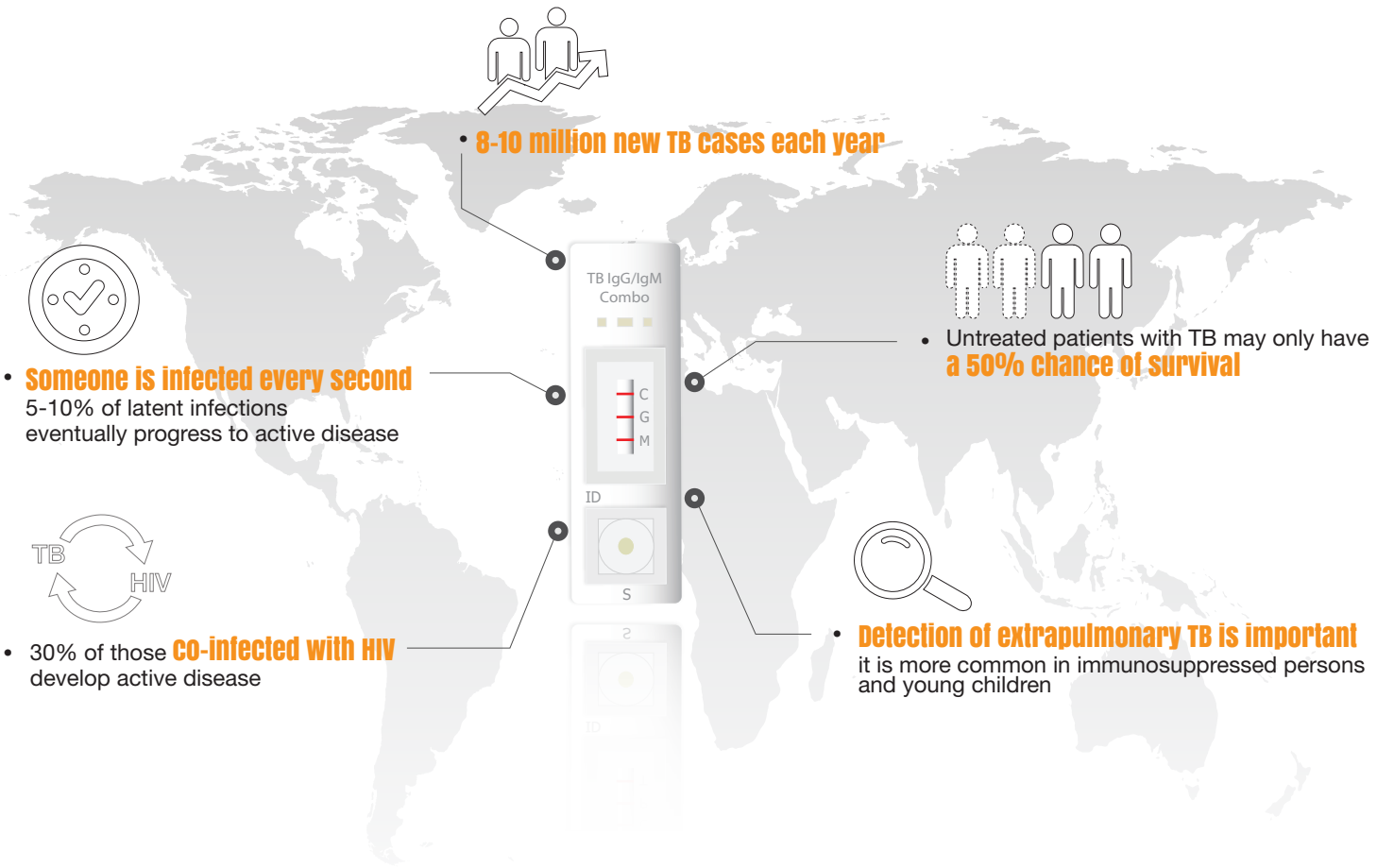
PRODUCT FEATURES

- Simple procedure, results in 10-15 minutes
- Simultaneously detects and differentiates anti-TB IgG & IgM
- Uses blood specimen, instead of sputum for easier specimen collection
- Minimal training needed and no equipment required
- Aids in diagnosis of pulmonary & extrapulmonary TB

OnSite® RAPID TEST PRODUCTS

TB IgG/IgM Combo Rapid Test CE

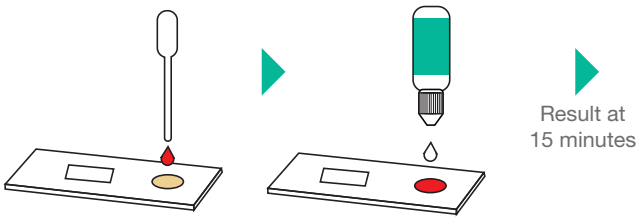
GLOBAL DISEASE PREVALANCE



Simple procedure

1 drop of specimen

1 drop of sample diluent



Interpretation of Assay Result