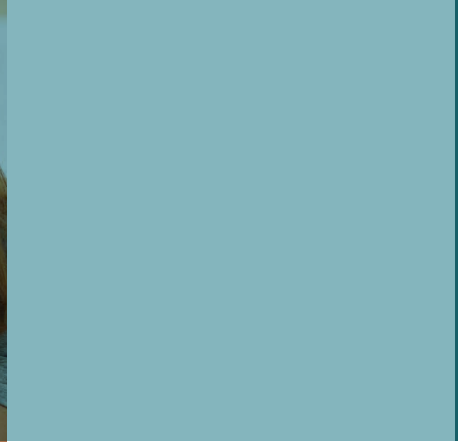




SD BIOLINE Rapid Hepatitis Tests

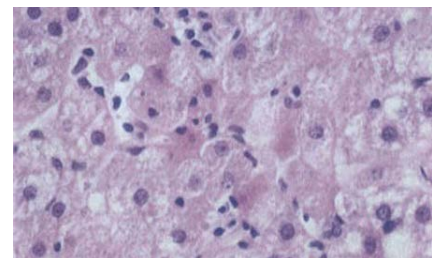
SD BIOLINE HAV IgG/IgM
SD BIOLINE HBV Tests (Anti-HBs, HBsAg, HBeAg)
SD BIOLINE HCV



HCV Hepatitis C Virus

What causes the disease?

Hepatitis C is caused by infection with the hepatitis C virus (HCV). The virus infects liver cells and can cause severe inflammation of the liver with long-term complications (anorexia, vague abdominal discomfort, nausea and vomiting, fever and fatigue) progressing to jaundice in about 25% of patients (less frequently than hepatitis B), of those exposed to HCV, about 40% recover fully, of these, 20% develop cirrhosis, of those with cirrhosis, up to 20% develop liver cancer.



Liver cells infected with the hepatitis C virus

How is HCV spread?

- Sharing infected needles with a carrier.
- From accidental exposure to infected blood.
- Sexual transmission in persons with high risk behavior, although transmission of HCV is less common than that of HBV and HIV

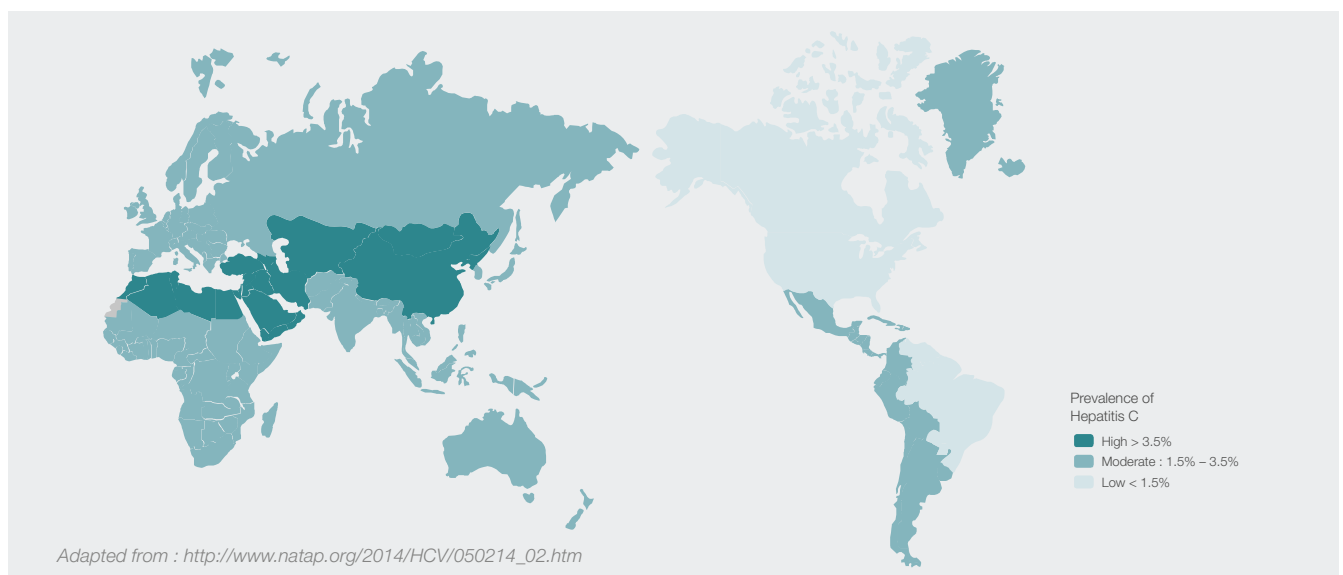
When is HCV contagious?

All HCV positive persons are considered potentially infectious.

HCV positive persons are those who :

- Have anti-HCV antibodies in their blood.
- Have HCV RNA or HCV core antigen detected in their blood.

Prevalence of hepatitis C virus ²





SD BIOLINE HCV Hepatitis C Virus

Clinical Performance : SD BIOLINE HCV

Reference assay		SD BIOLINE HCV		Total Results
		Positive	Negative	
Anti-HCV ELISA	Positive	141	1	142
	Negative	3	154	157
Sensitivity (95% CI)		99.3% (96.1-99.9%)		
Specificity (95% CI)		98.1% (94.5-99.4%)		



Easy to Use

1 Add Specimen
Dispense **10 µl** of specimen into the specimen well.

Capillary pipette Micropipette Multi Device

2 Add Assay Diluent
Dispense **4 drops** of the assay diluent.

Device Multi Device

3 Read Results

Negative:

Positive:

Invalid:

Wait 5-20 mins.

5-20
mins.

1 Add Assay Diluent and Specimen
Dispense **4 drops of assay diluent** to the empty test tube, and then dispense **10 µl of serum or plasma** to the test tube.

Strip

2 Insert Strip
Insert strip into the test tube.

Strip

Cat. No.	Description	Specimen	Type	Pack Size
02FK10	HCV	Serum/Plasma/Whole blood	Device	30T/Kit
02FK11	HCV	Serum/Plasma/Whole blood	Multi-Device	10Tx10/Kit
02FK16 *	HCV	Serum/Plasma/Whole blood	Device	25T/Kit
02FK17 **	HCV	Serum/Plasma/Whole blood	Device	25T/Kit
02FK10CE	HCV (CE Marked)	Serum/Plasma/Whole blood	Device	30T/Kit
02FK16CE *	HCV (CE Marked)	Serum/Plasma/Whole blood	Device	25T/Kit
02FK17CE **	HCV (CE Marked)	Serum/Plasma/Whole blood	Device	25T/Kit
02FK12	HCV Fast	Serum/Plasma	Strip	25T/Kit

(*) Lancet, Capillary pipette, Alcohol swab included. (**) Safety lancet, Capillary pipette, Alcohol swab included.



HBV Hepatitis B Virus

Hepatitis B is a contagious liver disease that results from infection with the Hepatitis B virus. It can range in severity from a mild illness lasting few weeks to a serious, lifelong illness.

Hepatitis B can be either acute or chronic. Acute Hepatitis B virus infection

is a short-term illness that occurs within the first 6 months after someone is exposed to the Hepatitis B virus. Acute infection can but does not always lead to chronic infection. Chronic Hepatitis B virus infection is a long-term illness that occurs when the Hepatitis B virus

remains in a person's body. Chronic Hepatitis B is a serious disease that can result in long-term health problems, and even death. The best way to prevent Hepatitis B is by getting vaccinated.

Hepatitis B serologic markers

HBsAg

Hepatitis B surface antigen

A protein on the surface of HBV; it can be detected in high levels in serum during acute or chronic HBV infection. The presence of HBsAg indicates that the person is infectious. The body normally produces antibodies to HBsAg as part of the normal immune response to infection.

anti-HBs

Hepatitis B surface antibody

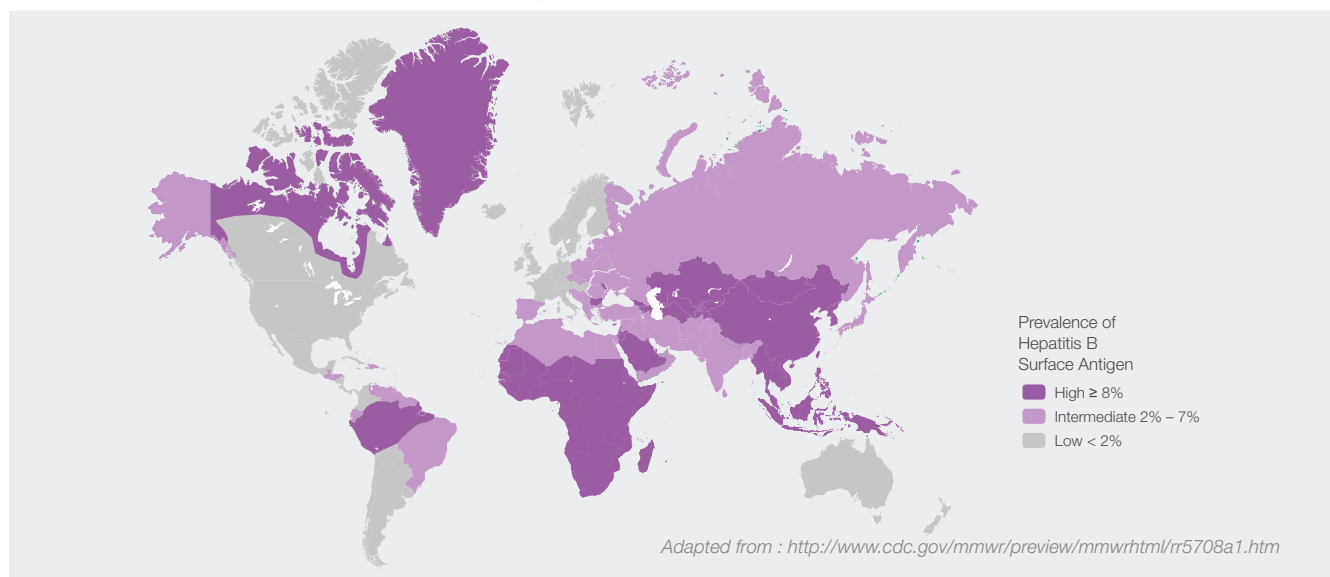
The presence of anti-HBs is generally interpreted as indicating recovery and immunity from HBV infection. Anti-HBs also develops in a person who has been successfully vaccinated against Hepatitis B.

HBeAg

Hepatitis B e antigen

A secreted product of the nucleocapsid gene of HBV that is found in serum during acute and chronic Hepatitis B. Its presence indicates that the virus is replicating and the infected person has high levels of HBV.

Prevalence of chronic infection with hepatitis B virus³





SD BIOLINE HBV Hepatitis B Virus

Clinical Performance : SD BIOLINE HBsAg WB

Specimen type	Number of specimens	SD BIOLINE HBsAg WB	
		Reactive	Non-reactive
HBsAg Positive	Serum	203	0
	Whole blood	20	0
	Total	223	0
HBsAg Negative serum	792	0	792
Sensitivity (95% CI)		100% (98.3 - 100%)	
Specificity (95% CI)		100% (99.5 - 100%)	



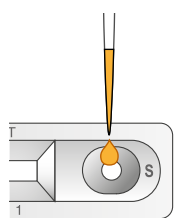
Easy to Use

1

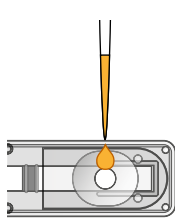
Add Specimen

Dispense **100 µl** of specimen into the specimen well.

Device



Multi Device



Strip

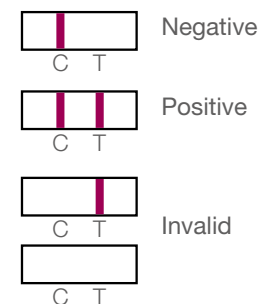


Wait 20 mins.
(HBeAg : 5~20 mins.)



2

Read Results



Please refer to Instructions for use for complete instructions, limitations and warnings.

Cat. No.	Description	Type	Pack size
01FK10	HBsAg	Device	1Tx30/Kit
01FK11	HBsAg	Multi-Device	10Tx10/Kit
01FK12	HBsAg Fast	Strip	25Tx4/Kit
01FK10W	HBsAg W/B	Device	1Tx30/Kit
01FK11W	HBsAg W/B	Multi-Device	10Tx10/Kit

Cat. No.	Description	Type	Pack size
01FK20	Anti-HBs	Device	1Tx30/Kit
01FK21	Anti-HBs	Multi-Device	10Tx10/Kit
01FK22	Anti-HBs Fast	Strip	25Tx4/Kit
01FK30	HBeAg	Device	1Tx30/Kit



HAV Hepatitis A Virus

What is HAV?

Hepatitis A, one of the oldest diseases known to humankind, is a self-limited disease which results in fulminant hepatitis and death in only a small proportion of patients. But, it is a significant cause of morbidity and socio-economic losses in many parts of the world.

Transmission

Transmission of HAV is typically by the faecal-oral route. Occur in life in areas where sanitation is poor and living conditions are crowded. Direct person to person spread is common under poor hygienic conditions. Transmission by sexual contact (anal-oral) and blood transfusions is rare.

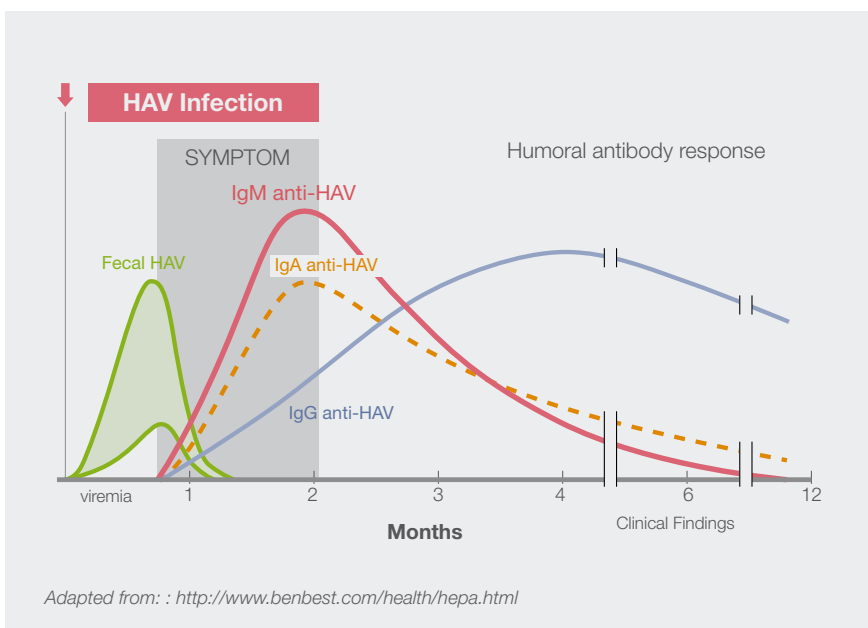
Symptoms

Loss of appetite, fatigue, abdominal pain, nausea and vomiting, fever, diarrhoea, dark urine and pale stools

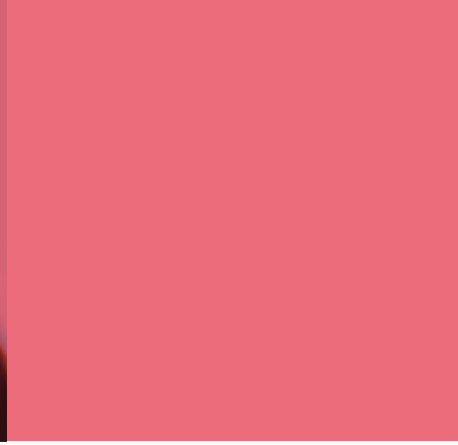
Prevention

Improved sanitation and hygiene, vaccine for HAV

Virologic Events in HAV Infection⁴



- In acute phase, anti-HAV IgM is detectable about 3 weeks after exposure,
- Increases over 4 to 6 weeks, then declines to nondetectable levels within 6 months of infection.
- Anti-HAV IgA and IgG are detectable within a few days of the onset of symptoms.
- IgG antibodies persist for years after infection and provide lifelong immunity.



SD BIOLINE HAV Hepatitis A Virus

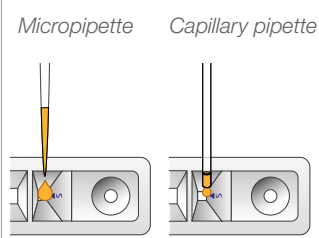
Clinical Performance : SD BIOLINE HAV IgG/IgM

Reference assay		SD BIOLINE HAV IgG/IgM		Total
		Positive.	Negative.	
Confirmed by ELISA	Positive	122	3	125
	Negative	3	147	150
Sensitivity (95% CI)		97.6% (93.2 - 99.2%)		
Specificity (95% CI)		98.0% (94.3 - 99.3%)		

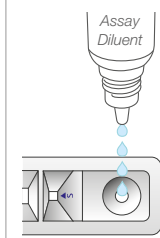


Easy to Use

1 Add Specimen
Dispense **5 µl** of specimen into the specimen well.



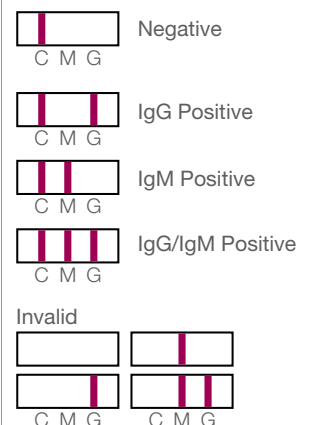
2 Add Assay Diluent
Dispense **4 drops** of the assay diluent.



Wait 20 mins.



3 Read Results



Cat. No.	Description	Specimen	Type	Pack size
13FK10	HAV IgG/IgM	Serum / Plasma	Device	25T/Kit

Reference

1. Sensitivity and Specificity are extracted from the Instruction for use of each product.
2. Impact of New Hepatitis C Treatments in Different Regions of the World
[Online] http://www.natap.org/2014/HCV/050214_02.htm
3. Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection.
[Online] <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5708a1.htm>
4. Do Hepatitis A Antibodies Indicate Infectivity? [Online] <http://www.benbest.com/health/hepa.html>

alere.com

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