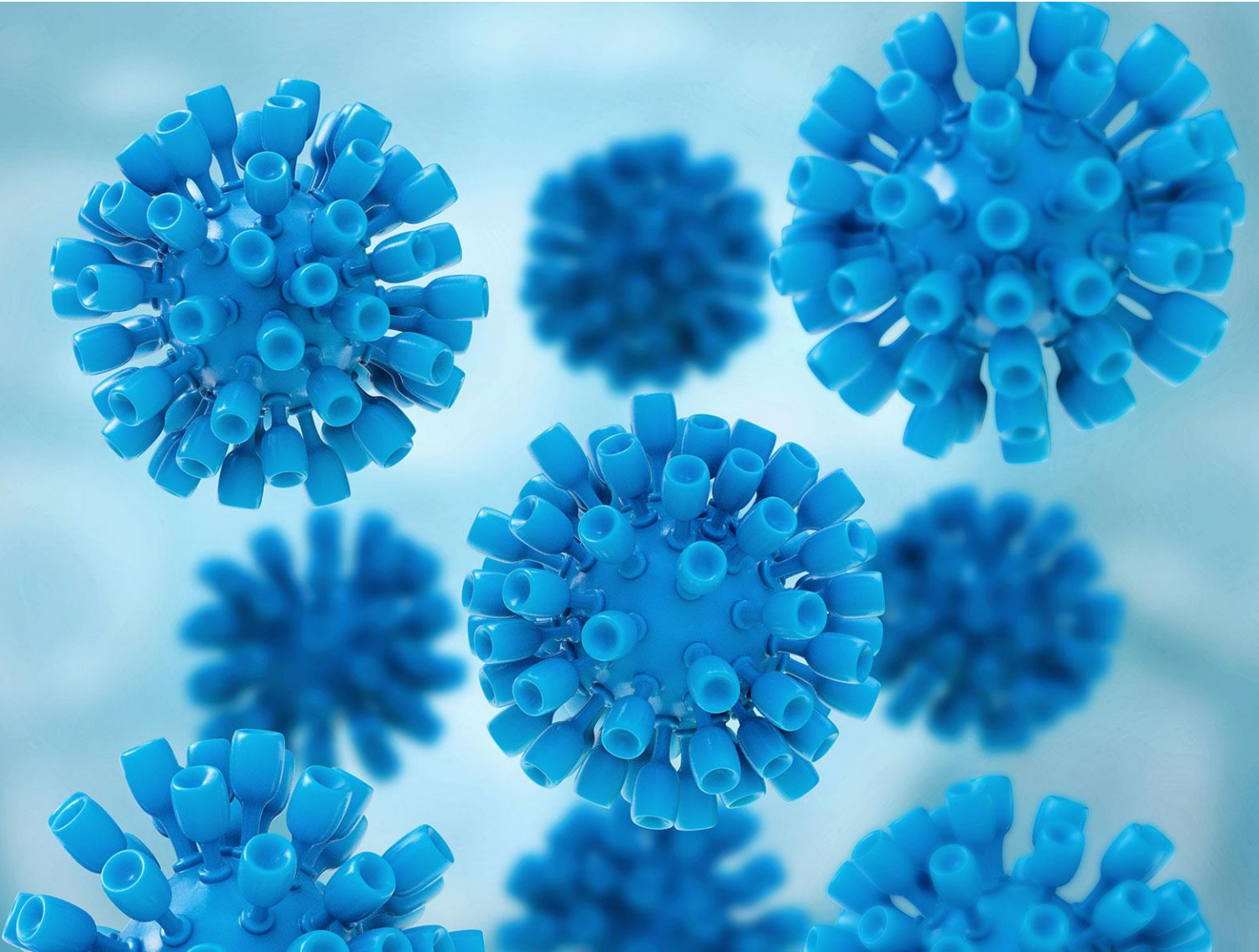


Hepatitis Virus



Viral Hepatitis Reagents for Assay Development

Creative Diagnostics provides high quality and sensitive hepatitis virus antibodies, antigens and ELISA kits

CD Creative Diagnostics[®]

Hepatitis Virus

Viral hepatitis is an infection that causes liver inflammation and damage. Viral hepatitis remains a significant public health problem throughout the world. There are at least five different viruses causing hepatitis. Each of the five major hepatitis viruses, hepatitis A virus (HAV), hepatitis B virus (HBV), hepatitis C virus (HCV), delta hepatitis virus (HDV) and hepatitis E virus (HEV) belong to a separate family. Currently, all these viral hepatitis (A-E) have been classified into different genotypes and subgenotypes. A, B, and C viruses are most commonly seen. The hepatitis A and E viruses typically cause acute infections. The hepatitis B, C, and D viruses can cause acute and chronic infections.

Creative Diagnostics can offer both a range of hepatitis virus antigens and antibodies that can be used for the development of in vitro diagnostic kits and related ELISA kits, all with good specificity and sensitivity.

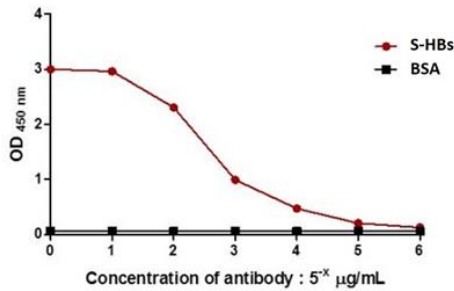


Fig. 1 Anti-HBsAg Ab (DMABT-51328MH) Direct ELISA

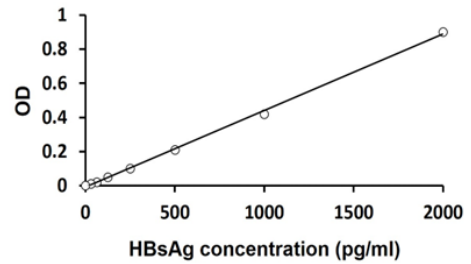


Fig. 2 Anti-HBsAg antibody (Capture-Detection: DMAB3534- DMAB3535) standard curve image

The hepatitis A virus (HAV)

HAV, first identified in 1973, is a nonenveloped, spherical, positive-stranded RNA virus, classified within the genus *Hepatovirus* of the *Picornaviridae* family and is the cause of infectious or epidemic hepatitis transmitted by the fecal-oral route. HAV infection causes acute hepatitis in humans and nonhuman primates. HAV strains recovered from widely separated regions of the world are antigenically similar. There is only one serotype of HAV. In vitro, the wild-type virus is generally difficult to grow and no cytopathic effect is observed. Attenuated HAV strains adapted to cell culture have been used to develop vaccines.

Because of its unique features within the *Picornaviridae* family, HAV has been classified in a separate *Hepatovirus* genus and is the only species. The HAV genome consists of a single-stranded, positive-sense polycistronic RNA genome of approximately 7.5 kilobases (kb) that encodes 11 genes. The HAV genome has been divided into three regions: P1 encodes the capsid proteins, and the P2 and P3 regions encode functional proteins. The viral capsid protein (P1) is further divided into VP4, VP2, VP3 and VP1 regions. The non-structural P2 and P3 polyproteins are divided into 2A, 2B, 2C and 3A, 3B, 3C, 3D respectively.

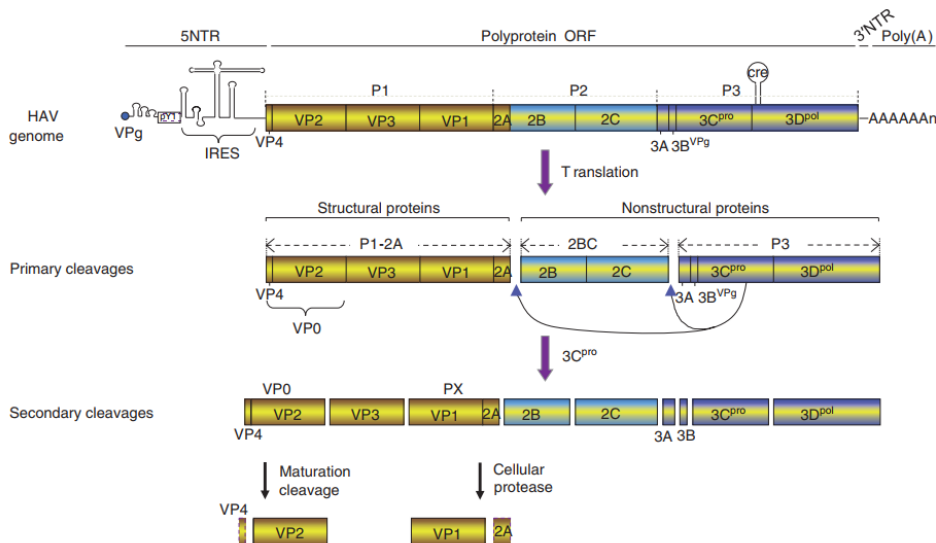


Fig. 3 Genomic organization and cleavage of the HAV polyprotein

Since both clinically and biochemically, acute hepatitis due to HAV cannot be distinguished from that due to other hepatitis viruses, serologic tests are necessary for a virus-specific diagnosis. The specific routine diagnosis of acute hepatitis A is made by finding anti-HAV IgM in the serum of patients. A second option is the detection of virus and/or antigen in the feces. Virus and antibody can be detected by commercially available RIA, EIA or ELISA kits. At the onset of disease, the presence of IgG anti-HAV is always accompanied by the presence of IgM anti-HAV. As IgG anti-HAV persists lifelong after acute infection, detection of IgG anti-HAV alone indicates past infection.

HAV antibodies

Cat.	Product Name	Host	Application
DMAB3490	Anti-HAV Mab, clone A819	Mouse	ELISA, IF, IHC
DMAB3491	Anti-HAV Mab, clone A582	Mouse	ELISA
CABT-CS483	Anti-HAV Mab, clone BC13	Mouse	ELISA, LFIA
DMABT-51306MH	Anti-HAV VP3 Mab, Clone 2992	Mouse	IHC, ELISA, IF, WB
CABT-B8699	Anti-HAV 2C Mab	Mouse	ELISA, WB, IF
DCABY-074	Anti-HAsAg Mab	Mouse	ELISA, IRMA

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HAV antigens

Cat.	Name	Host/Source	Application
DAG178	Native Inactivated HAV Antigen	Strain LV8	ELISA
DAG1444	Recombinant HAV VP1-P2A (a.a. 722-830) [GST]	E. coli	ELISA, WB
DAG1445	Recombinant HAV VP1-P2A (a.a. 669-782)	E. coli	ELISA, WB
DAG1451	Recombinant HAV VP2-VP4 [GST]	E. coli	ELISA, WB
DAG1448	Recombinant HAV P2C-P3A (a.a. 1392-1521)	E. coli	ELISA, WB
DAG671	Recombinant HAV P2C-P3B (a.a. 1492-1606) [GST]	E. coli	ELISA
DAG2417	Recombinant HAV VP3 (a.a. 248-491) [His]	E. coli	ELISA, WB
DAG540	Recombinant HAV VP3 [GST]	E. coli	ELISA, WB
DAG2418	Recombinant HAV VP4 (a.a. 6-245) [His]	E. coli	ELISA, WB

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HAV ELISA Kits

Cat.	Product Name	Species Reactivity	Detection Sample
DEIA007	Anti-HAV IgG ELISA Kit, Qualitative	Human	serum, plasma
DEIA008	Anti-HAV IgM ELISA Kit, Qualitative	Human	serum, plasma
DEIASL276	Anti-HAV IgG ELISA Kit, Quantitative	Human	serum, plasma

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The hepatitis B virus (HBV)

HBV infection is very common worldwide with more than 350 million (5%) of the world's population being chronic carriers. Chronic hepatitis B (CHB) is responsible for 1 million deaths per year globally. It is a major cause of cirrhosis of the liver and hepatocellular carcinoma (HCC) worldwide. A safe and effective vaccine that offers 98% to 100% protection against hepatitis B is available. Preventing hepatitis B infection averts the development of complications including chronic disease and liver cancer.

HBV is a partially double-stranded DNA virus belongs to the family *Hepeviridae*. The viral genome encodes four overlapping open reading frames (ORFs: S, C, P, and X). The S ORF encodes the viral surface envelope proteins, the HBsAg, and can be structurally and functionally divided into the pre-S1, pre-S2, and S regions. HBsAg is heterogeneous antigenically, with a common antigen designated a, and two pairs of mutually exclusive antigens, d and y, and w (including several subdeterminants) and r, resulting in 4 major subtypes: adw, ayw, adr and ayr. The distribution of subtypes varies geographically. The core or C gene has the pre-core and core regions. Multiple in-frame translation initiation codons are a feature of the S and C genes, which give rise to related but functionally distinct proteins. The C ORF encodes either the viral nucleocapsid HBcAg or hepatitis B e antigen (HBeAg) depending on whether the translation is initiated from the core or pre-core regions, respectively. The function of HBeAg remains largely undefined, although it has been implicated as an immune tolerogen, whose function is to promote persistent infection. The polymerase (pol) is a large protein (about 800 amino acids) encoded by the P ORF and is functionally divided into three domains. The HBV X ORF encodes a 16.5-kd protein (HBxAg) with multiple functions, including signal transduction, transcriptional activation, DNA repair, and inhibition of protein degradation. It is well established that HBxAg is necessary for productive HBV infection in vivo and may contribute to the oncogenic potential of HBV.

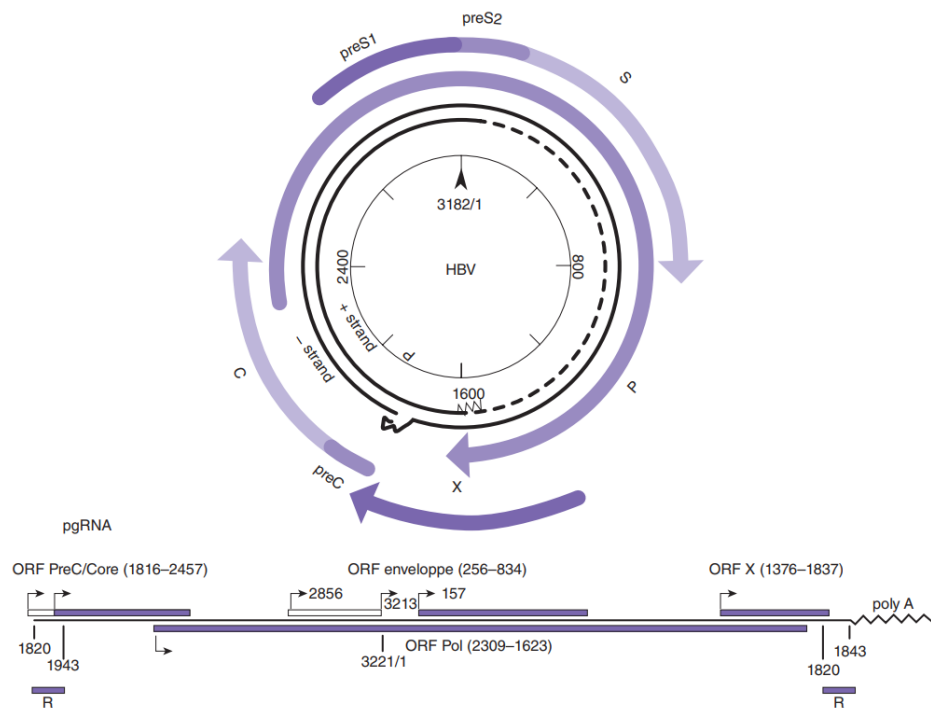


Fig. 4 Genetic organization of HBV

Diagnosis is confirmed by demonstration in sera of specific antigens and/or antibodies. Three clinically useful antigen-antibody systems have been identified for hepatitis B:

HBsAg and antibody to HBsAg (anti-HBs).

Antibody (IgM and IgG) to HBcAg (anti-HBc).

HBeAg and antibody to HBeAg (anti-HBe).

HBsAg can be detected in the serum from several weeks before the onset of symptoms to months after onset. The presence of HBsAg indicates that the person is potentially infectious.

Anti-HBc is the first antibody to appear. IgM anti-HBc is present in high titer during acute infection and usually disappears within 6 months. IgG anti-HBc generally remains detectable for a lifetime.

Anti-HBe appears after anti-HBc and its presence correlates to a decreased infectivity.

The three standard blood tests for hepatitis B can determine if a person is currently infected with HBV, has recovered, is a chronic carrier, or is susceptible to HBV infection.

HBV antibodies

Target	Cat.	Product Name	Host	Application
HBcAg	DMAB7716	Anti-HBcAg Mab, clone 31C22	Mouse	ELISA, CLIA, LFIA
HBsAg	DMAB3529	Anti-HBsAg Mab	Mouse	ELISA (Cap)
	DMAB3528	Anti-HBsAg Mab	Mouse	ELISA (Det)
	DMAB3534	Anti-HBsAg Mab	Mouse	LFIA (Cap)
	DMAB3535	Anti-HBsAg Mab	Mouse	LFIA (Det)
	DCABH-15	Anti-HBsAg Mab, clone SF	Mouse	ELISA (Cap), LFIA, CLIA
	DMAB8896	Anti-HBsAg Mab, clone 15D1	Mouse	ELISA (Cap), LFIA, CLIA
	DMABT-H21603	Anti-HBsAg Mab, clone 42B6	Mouse	ELISA (Cap), LFIA, CLIA
	DMABT-H21604	Anti-HBsAg Mab, clone 6C10	Mouse	ELISA (Cap), LFIA, CLIA
	DMABT-Z60995	Anti-HBsAg Mab, clone 2C1	Mouse	ELISA (Cap), LFIA, CLIA
	DCABY-4450	Anti-HBsAg Mab, clone N2303096	Mouse	ELISA (Cap), LFIA
	DCABY-4451	Anti-HBsAg Mab, clone N2303097	Mouse	ELISA (Det), LFIA
	CABT-NS1797	Anti-HBsAg Mab, clone IN472	Mouse	ELISA (Cap), LF, WB
	CABT-NS1798	Anti-HBsAg Mab, clone IN473	Mouse	ELISA (Det), LF, WB
	DMABT-51328MH	Anti-HBsAg Mab, clone 2945	Mouse	IHC, ELISA, FC, IF, IP, WB
HBeAg	DMAB3511	Anti-HBeAg Mab, clone CDI822	Mouse	ELISA (Cap)
	DMAB3512	Anti-HBeAg Mab, clone CDI832	Mouse	ELISA (Det)
	DMAB3513	Anti-HBeAg Mab, clone CDI815	Mouse	ELISA (Det)
	DCABH-20044	Anti-HBeAg Mab	Mouse	ELISA, CLIA, RIA, IHC, WB
	DCABH-20045	Anti-HBeAg Mab	Mouse	ELISA, CLIA, RIA, IHC, WB
	DMAB3511-A1	Anti-HBeAg Mab, clone IG1	Mouse	ELISA, LFIA
HBV pres1	DMAB3518	Anti-HBV pres1 Mab	Mouse	ELISA (Det), CLIA, LFIA
	DMAB7722	Anti-HBV pres1 Mab	Mouse	ELISA (Cap), CLIA, LFIA
	CABT-B9114	Anti-HBV (C subtype) PreS1 Mab	Mouse	ELISA, CLIA, LFIA
	CABT-B9115	Anti-HBV (B subtype) PreS1 Mab, clone 16D12	Mouse	ELISA, CLIA, LFIA

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HBV antigens

Target	Cat.	Name	Host/Source	Application
HBcAg	DAG593	Recombinant HBcAg	P. pastoris	ELISA
	DAG-P2633	Recombinant HBcAg (a.a. 1 - 183)	E. coli	SDS-PAGE, ELISA, WB

	DAG2293	Recombinant HBcAg (a.a. 1-149) (subtype ayr) [His]	E. coli	ELISA, WB
HBsAg	DAGC278	Native HBsAg (subtype ad)	Human plasma	ELISA
	DAG-WT366	Recombinant HBsAg VLP [His]	HEK293	ELISA
	DAG-WT529	Recombinant HBsAg	E. coli	ELISA, LF, CLIA
	DAG435	Recombinant HBsAg	Yeast	ELISA
	DAG2717	Recombinant HBsAg (subtype adw)	P. pastoris	ELISA
	DAG1470	Recombinant HBsAg (subtype adr)	CHO	ELISA
	DAG-P2844	Recombinant HBsAg (subtype ayw)	S. cerevisiae	SDS-PAGE, ELISA
	DAGA-121	Recombinant HBsAg (subtype ay)	E. coli	ELISA, WB, LFIA
	DAGA-122	Recombinant HBsAg (subtype ad)	E. coli	ELISA, WB, LFIA
	DAG-T2261	Recombinant HBsAg (Subtype ad)	Yeast	ELISA, WB
	DAG3938	Recombinant HBsAg (Subtype adw, Mutation Q-129-H)	P. pastoris	ELISA, WB
	DAG4720	Recombinant HBsAg (Subtype adw, Mutation Q-129-L)	P. pastoris	ELISA, WB
	DAG3934	Recombinant HBsAg (Subtype adw, Mutation K-141-E)	P. pastoris	ELISA, WB
	DAG3937	Recombinant HBsAg (Subtype adw, Mutation P-142-S)	P. pastoris	ELISA, WB
	DAG3941	Recombinant HBsAg (Subtype adw, Mutation T-143-K)	P. pastoris	ELISA, WB
	DAG3940	Recombinant HBsAg (Subtype adw, Mutation T-126-N)	P. pastoris	ELISA, WB
	DAG3936	Recombinant HBsAg (Subtype adw, Mutation M-133-L)	P. pastoris	ELISA, WB
	DAG3935	Recombinant HBsAg (Subtype adw, Mutation M-133-H)	P. pastoris	ELISA, WB
	DAG3933	Recombinant HBsAg (Subtype adw, Mutation G-145-R)	P. pastoris	ELISA, WB
	DAG1468	Recombinant HBsAg (subtype ayw, mutation G-145-R)	P. pastoris	ELISA, WB
DAG-T1038	Recombinant HBsAg (Subtype adw, Mutation Q-129-R)	P. pastoris	ELISA, WB	
DAGC047	Recombinant HBsAg L-protein	Yeast	ELISA	
HBeAg	DAG2294	Recombinant HBeAg (a.a. 1-212) (subtype adw) [His]	E. coli	ELISA, WB
HBV pres1	DAG672	Recombinant HBV Pre S1/S2	E. coli	ELISA

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HBV ELISA Kits

Cat.	Product Name	Species Reactivity	Detection Sample
DEIA002	Human Anti-HBsAb ELISA Kit, Qualitative	Human	Serum, plasma
DEIA005	Human Anti-HBcAb ELISA Kit, Qualitative	Human	Serum, plasma
DEIA004	Human Anti-HBeAb ELISA Kit, Qualitative	Human	Serum, plasma
DEIA006	Human Anti-HBc IgM ELISA Kit, Qualitative	Human	Serum, plasma

DEIA001	HBsAg ELISA Kit, Qualitative	Human	Blood
DEIA003	HBeAg ELISA Kit, Qualitative	Human	Serum, plasma
DEIA061	HBV-NRAG ELISA Kit, Qualitative	Human	Serum, plasma
DEIA060	Human Anti-HBsAb ELISA Kit, Quantitative	Human	Serum, plasma

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The hepatitis C virus (HCV)

HCV is a major cause of liver associated disease all over the world and spread predominantly via blood transfusion and blood products and intravenous drug use. An estimated 3% of the world's population is chronically infected. In some endemic areas, such as the Middle East, North-East Asia and South Africa, the prevalence of HCV infection is as high as 20-30%. Chronic infection often progresses to liver fibrosis, cirrhosis and hepatocellular carcinoma (HCC) in a substantial number of patients. Chronic hepatitis C is often silent, most of the times discovered only by routine serological, biochemical and radiological testing.

HCV is an enveloped positive-strand RNA virus of the genus *Hepacivirus* in the *Flaviviridae* family. This virus is target specific and replicates in the hepatocytes. The virus particle is about 30 to 60nm across. The genome has a single open reading frame coding for a polyprotein of 3010 amino acids. The poly-protein is cleaved after translation into structural and non-structural proteins necessary for viral replication and virion formation. The structural proteins situated towards the N-terminus of the genome and non-structural genes located near C-terminal. The structural genes code for the capsid (core) protein (C) and envelope glycoproteins (E1, E2). The first 27 amino acids of the E2 gene constitute the hyper-variable region 1 (HVR1) of the genome and seems to be involved in virus evasion of the immune system and disease progression. The non-structural genes code for a protease (xlink, NS3) and its cofactor (NS4A), a helicase (NS3), a protein of unknown function (NS4B), a phosphoprotein (NS5A), and an RNA-dependent RNA polymerase (NS5B).

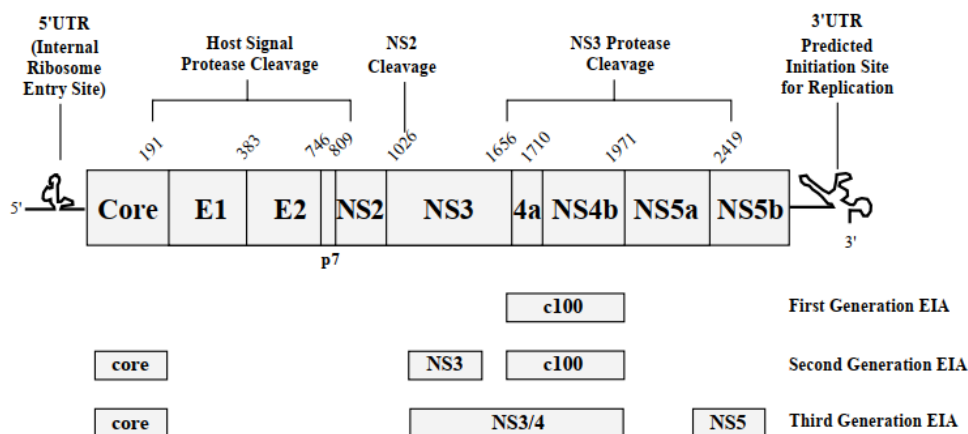


Fig. 5 HCV Genome organization and proteins used in blood screening assays

There are two general strategies for detecting HCV exposure. One relies on the detection of antibodies to HCV, which, when confirmed positive by supplemental antibody tests, indicates past or ongoing HCV infection. Antibody testing is used to prevent HCV transmission by removing seropositive donors from the blood donation pool and to determine if HCV infection is associated with acute or chronic cases of hepatitis. The second strategy relies on the detection of viral-specific molecules (e.g. HCV RNA or HCV core proteins) in serum/plasma and is indicative of active HCV replication. These tests are most useful in detecting HCV infection during the "window period" (time between exposure and seroconversion), and in determining viral presence and titer in chronically infected individuals, especially as a means to monitor the efficacy of antiviral therapy.

HCV antibodies

Cat.	Product Name	Host	Application
DCABY-4470	Anti-HCV Mab, Clone N60996	Mouse	ELISA (Cap), IF, IHC
DCABY-4469	Anti-HCV Mab, Clone N60998	Mouse	ELISA (Det), IF, IHC
DMAB3550	Anti-HCV Core protein Mab, clone C056M	Mouse	ELISA (Cap)
DMAB3551	Anti-HCV Core protein Mab, clone C057M	Mouse	ELISA (Det)
CABT-CS872	Anti-HCV Core protein Mab, Clone 640	Mouse	ELISA (Cap), LFIA, IF
CABT-CS873	Anti-HCV Core protein Mab, Clone 652	Mouse	ELISA (Det), LFIA, IF
CABT-L540MH	Anti-HCV Core protein Mab, clone IN651	Mouse	ELISA (Cap), LFIA, IF, WB
CABT-L541MH	Anti-HCV Core protein Mab, clone IN652	Mouse	ELISA (Det), LFIA, IF, WB
DMAB3552	Anti-HCV Core Protein Mab, Clone C058M	Mouse	ELISA (Cap), WB, IF
DMAB3560	Anti-HCV Core Protein (a.a. 33-38) Mab, Clone C318M	Mouse	ELISA (Det), IF, IHC, WB
DMABT-Z60952	Anti-HCV Mab, Clone J37	Mouse	IHC-P, ELISA
DCABH-1319	Anti-HCV Mab, Clone OT6C-7 [Biotin]	Mouse	ELISA, WB, FC, ICC/IF
DCABH-1322	Anti-HCV Mab, Clone OT6C-7 [FITC]	Mouse	ELISA, WB, ICC/IF
DMAB3557	Anti-HCV Core Protein (a.a. 1-80) Mab, Clone 7B2	Mouse	ELISA
DMAB3561	Anti-HCV Core Protein (a.a. 70-90) Mab, Clone 12-C4	Mouse	ELISA, WB, IHC
DMAB3554	Anti-HCV Core Protein (structural) Mab, Clone A1852	Mouse	ELISA, IF, WB
DMAB3555	Anti-HCV Core Protein Mab, Clone 7B2 [Biotin]	Mouse	ELISA, IHC-Fr
DMAB3556	Anti-HCV Core Protein Mab, Clone 7B2 [FITC]	Mouse	ELISA, IHC-Fr
DMABT-Z60984	Anti-HCV Core Protein Mab, Clone 3G7 [Rhodamine]	Mouse	IP, ELISA
DMABT-51333MH	Anti-HCV E1 Mab, Clone 2980	Mouse	IHC, ELISA, IF, WB
DMABT-51334MH	Anti-HCV E2 Mab, Clone 2987	Mouse	IHC, ELISA, FC, IF, WB
CABT-L222H	Anti-HCV NS3 Mab, clone Hfab-aNS3	Human	ICC, ELISA
DMAB3577	Anti-HCV NS4 Mab, Clone A882	Mouse	ELISA, WB
DMAB3574	Anti-HCV NS4 Mab, Clone 9B2 [FITC]	Mouse	ELISA, WB, IF, IHC
DMAB3579	Anti-HCV NS5 Mab, clone A389	Mouse	ELISA, IF, WB
DCABY-016	Anti-HCV NS5 Mab, Clone CHO/2357/6H8	Mouse	IHC-Fr, ELISA, IHC-P, WB

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HCV antigens

Cat.	Name	Host/Source	Application
DAG-NS008	Recombinant HCV Antigen	E. coli	LF (Det)
DAG-NS009	Recombinant HCV Antigen	E. coli	LF (Cap)
DAG594	Recombinant HCV Core Antigen [His]	P. pastoris	ELISA, WB

DAGC068	Recombinant HCV (subtype 1b) Core Protein (a.a. 1-115)	E. coli	SDS-PAGE
DAG-P2941	Recombinant HCV (subtype 2b) Core Protein (a.a. 2-119)	E. coli	SDS-PAGE, ELISA, WB
DAG1988	Recombinant HCV (subtype 2a) Core Protein (a.a. 2-191) [GST]	E. coli	ELISA, WB, Immunogen
DAG2001	Recombinant HCV E2 Protein (a.a. 383-663) [His]	HEK293	WB
DAGC468	Recombinant HCV Core/NS3/NS4/NS5 Protein	E. coli	ELISA, LFIA
DAG-2800	Recombinant HCV NS3 [His]	E. coli	ELISA
DAGC069	Recombinant HCV (subtype 1b) NS3 (a.a. 1207-1488)	E. coli	ELISA
DAG1420	Recombinant HCV NS4 [HRP]	E. coli	ELISA, WB
DAG536	Recombinant HCV NS4 [GST]	E. coli	ELISA, WB
DAG2722	Recombinant HCV NS4 Mosaic Protein	E. coli	ELISA, WB
DAG572	Recombinant HCV NS4a+b (a.a. 1658-1863) [Beta-galactosidase]	E. coli	ELISA, WB
DAG585	Recombinant HCV NS4a+b (a.a. 1658-1863) [Fluorescein]	E. coli	ELISA, WB
DAGC071	Recombinant HCV (subtype 1b) NS4 (a.a. 1617-1864)	E. coli	SDS-PAGE
DAG1440	Recombinant HCV NS5 [GST, Biotin]	E. coli	ELISA, WB
DAG1441	Recombinant HCV NS5 [HRP]	E. coli	ELISA, WB
DAG506	Recombinant HCV (type 1) NS5 (a.a. 2212-2313) [GST]	E. coli	ELISA, WB
DAG1427	Recombinant HCV (subtype 1a) NS5 (a.a. 2212-2313) [His]	E. coli	ELISA, WB
DAG509	Recombinant HCV (subtype 1a) NS5 (a.a. 2322-2423) [GST]	E. coli	ELISA, WB
DAG1429	Recombinant HCV (type 2) NS5	E. coli	ELISA, WB
DAG2353	Recombinant HCV (subtype 2a) NS5 (a.a. 2212-2313) [GST]	E. coli	ELISA, WB
DAG2358	Recombinant HCV (type 4) NS5 (a.a. 2212-2313) [GST]	E. coli	ELISA, WB

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HCV ELISA Kits

Cat.	Product Name	Species Reactivity	Detection Sample
DEIA1871	Human Anti-HCV Ab ELISA Kit, Qualitative	Human	Serum, plasma
DEIA063	Human Anti-HCV IgM ELISA Kit, Qualitative	Human	Serum, plasma
DEIA1867	Human Anti-HCV IgA ELISA Kit, Quantitative	Human	Serum, plasma

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Hepatitis D virus (HDV)

HDV was first recognized following the detection of a novel protein, delta antigen (HDAg), by immunofluorescent staining in the nuclei of hepatocytes from patients with chronic active hepatitis B in 1977. HDV is now known to depend on HBV to provide hepatitis B surface antigen (HBsAg) for virion assembly and propagation. HDV is present worldwide, but the distribution pattern is not uniform. Different viral strains are classified into eight genotypes found in specific geographical areas and often associated with severe disease outcomes. HDV is transmitted through blood and body

fluids, quite similar to that of HBV. Delta hepatitis is common in some areas of the world with a high prevalence of HBV infection. It has been estimated that 5% of HBsAg carriers worldwide (approximately 15 million people) are infected with HDV. In areas of the low prevalence of HBV, those at risk of hepatitis B, particularly intravenous drug abusers, are also at risk of HDV infection.

The HDV virion is a spherical particle of about 36 nm in diameter, which contains an envelope (HBsAg) and a nucleocapsid containing an RNA genome in complex with HDAG. The outer envelope of HDV particles actually contains lipid and all three forms (S, M, and L) of HBV surface antigen (HBsAg), but predominantly the major form of HBsAg with very few middle (pre S1) and large (pre S2) proteins. This proportion (95:5:1 of S:M:L) is different from that found in HBV particles. HDV anti-genome contains a unique open reading frame that encodes two proteins, the small delta antigen (SHDAg) and large delta antigen (LHDAg). The SHDAg and LHDAg correspond respectively to the small-p24 and the large-p27 hepatitis delta proteins. The LHDAg amino acid sequence is identical to SHDAg except with the extension of 19 to 20 amino acids at the C terminus. While SHDAg is required for HDV replication, LHDAg inhibits replication and, together with hepatitis B surface antigen (HBsAg), is required for the assembly of HDV.

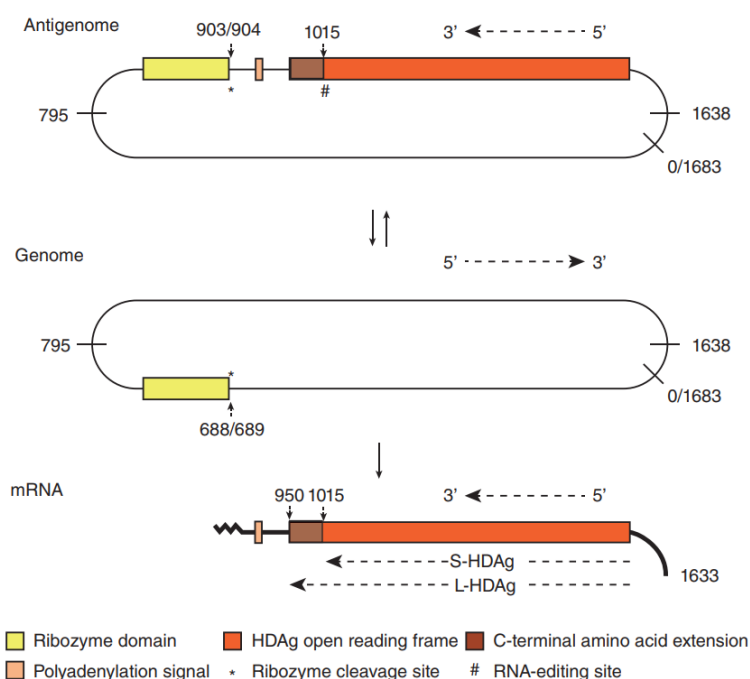


Fig. 6 Schematic representation of the HDV antigenomic and genomic RNAs, as well as of the HDAG mRNA

Hepatitis D should be considered in any individual who is HBsAg positive or has evidence of recent HBV infection. HDV infection is diagnosed by high levels of anti-HDV immunoglobulin G (IgG) and immunoglobulin M (IgM) and confirmed by detection of HDV RNA in serum. Total anti-HDV are detected by commercially available radioimmunoassay (RIA) or enzyme immunoassay (EIA) kits. The method of choice for the diagnosis of ongoing HDV infection should be RT-PCR, which can detect 10–100 copies of the HDV genome in infected serum.

HDV antibodies

Cat.	Product Name	Host	Application
CABT-CS313	Anti-HDV (Pan Genotypic) Mab	Mouse	WB, IF
CABT-CS314	Anti-HDV (Pan Genotypic) Mab	Mouse	WB, IF
CABT-NS1165	Anti-HDAg Mab, clone FD3A7	Mouse	WB, IF
CABT-NS1166	Anti-HDAg Mab, clone FD3A7	Human	WB, IF
CABT-NS1167	Anti-HDAg Mab, clone FD3A7	Rabbit	WB, IF
CABT-NS1794	Anti-HDV GP2 (linear) Mab, 24H21	Mouse	IF, IP, WB

CABT-NS1796	Anti-HDV GP2 (linear) Mab, 6H5	Mouse	IF, IP, WB
CABT-NS1795	Anti-HDV GP2 (Conformational Domain) Mab, 2H22	Mouse	IF, IP, ELISA

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HDV antigens

Cat.	Name	Host/Source	Application
DAG2297	Recombinant HDAG [His]	E. coli	ELISA, WB
DAG-P2662	Recombinant HDAG (a.a. 1-108, 151-209)	E. coli	ELISA, WB

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HDV ELISA Kits

Cat.	Product Name	Species Reactivity	Detection Sample
DEIA071	Human Anti-HDV IgG ELISA Kit, Qualitative	Human	Serum, plasma
DEIA072	Human Anti-HDV IgM ELISA Kit, Qualitative	Human	Serum, plasma
DEIA073	HDV Antigen ELISA Kit, Qualitative	Human	Serum or plasma (EDTA, heparin and Sodium Citrate)

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Hepatitis E virus (HEV)

HEV, the causative agent of human hepatitis E, what previously has been referred to as enterically transmitted non-A, non-B hepatitis or “waterborne hepatitis”, is a public health concern in many developing countries of Asia and Africa. Hepatitis E is now a recognized zoonotic disease. Besides humans, strains of HEV have also been genetically identified from swine, chickens, sika deer, mongoose, rabbits, and fish. With the identification of HEV stains from various animals, the host range and genetic diversity of HEV are rapidly expanding.

HEV, a small, non-enveloped, single-strand, positive-sense RNA virus transmitted primarily via the fecal-oral route, belongs to the family *Hepeviridae*. At least four recognized and two putative genotypes of mammalian HEV have been reported. There are three conserved open reading frames (ORFs) found in all known HEV strains: ORF1 codes for nonstructural proteins involved in virus replication, ORF2 codes for a capsid protein that elicits neutralizing antibodies and is a target for vaccine development, and ORF3 (also known as VP13) codes for a small multifunctional protein involved in virion morphogenesis and viral pathogenesis. ORF2 and ORF3 are translated from a single bicistronic messenger RNA (mRNA) and overlap each other, but neither overlap ORF1.

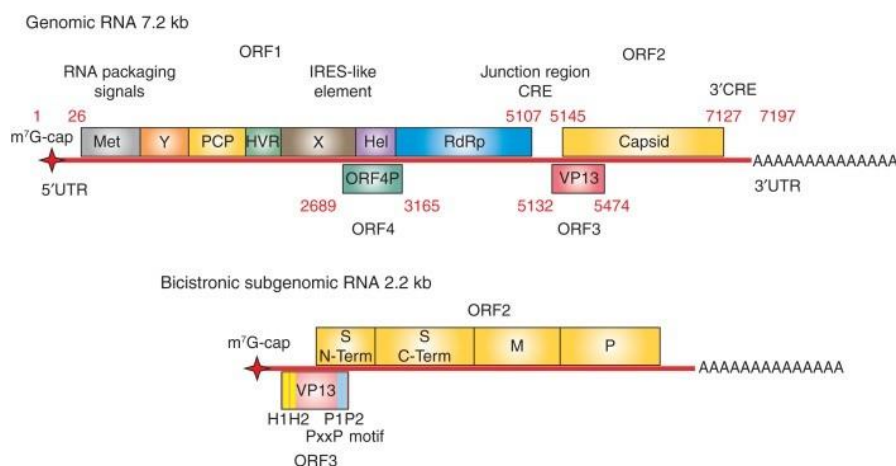


Fig. 7 Genomic organization of hepatitis E virus (HEV)

Diagnostic tests for hepatitis E have become much more widely available in the last few years. There are several commercially available enzyme immunoassays for both IgM and IgG responses to HEV as well as reliable reverse transcriptase polymerase chain reaction (RT-PCR) assays for the molecular detection of HEV RNA in serum, feces, or bile.

HEV antibodies

Cat.	Product Name	Host	Application
DMABT-Z60968	Anti-HEV Mab	Mouse	ELISA
CABT-CS095	Anti-HEV Capsid Mab	Mouse	WB, IF, IC, ELISA

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HEV antigens

Cat.	Name	Host/Source	Application
DAG-WT377	Recombinant HEV VLP	HEK293	Immunoassays
DAG578	Recombinant HEV ORF2 Protein (a.a. 633 - 659)	E. coli	LF, ELISA, WB
DAG580	Recombinant HEV ORF2 Protein (a.a. 403 - 461)	E. coli	LF, ELISA, WB
DAG2366	Recombinant HEV ORF2 Protein (a.a. 452-617) [His]	E. coli	ELISA, WB, immunogen
DAG3520	Recombinant HEV ORF2 Protein (a.a. 452-617) [GST]	E. coli	ELISA, WB
DAGC463	Recombinant HEV (genotype 3) ORF2 Protein (a.a.411-660) [His]	Yeast	ELISA
DAG-WT536	Recombinant HEV ORF2 (a.a 1-660) [His]	HEK293	ELISA, WB
DAG512	Recombinant HEV ORF2/ORF3 [GST]	E. coli	ELISA, WB
DAG579	Recombinant HEV ORF3 Protein (a.a. 92 - 123)	E. coli	LF, ELISA, WB

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HEV ELISA Kits

Cat.	Product Name	Species Reactivity	Detection Sample
DEIA076	Human Anti-HEV-Ab ELISA Kit, Qualitative	Human	Serum, plasma
DEIA1905	Human Anti-HEV IgG ELISA Kit, Qualitative	Human	Serum, plasma
DEIA1961	Human Anti-HEV IgM ELISA Kit, Qualitative	Human	Serum, plasma
DEIA077	HEV-Ag ELISA Kit, Qualitative	Human	Serum, plasma

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Contact Us

CREATIVE DIAGNOSTICS

45-1 Ramsey Road, Shirley, NY 11967, USA

Tel: 1-631-624-4882 (USA) 44-161-818-6441 (Europe)

Fax: 1-631-938-8221 | Email: info@creative-diagnostics.com

www.creative-diagnostics.com

