

4TH GENERATION

HEPALISA ULTRA

Microwell ELISA Test for the Detection of
Hepatitis B Surface Antigen (HBsAg) in Human Serum/Plasma



- 4th Generation HBsAg Detection Kit
- Based on Direct sandwich principle
- Detects all known 11 sub-types of HBV and also mutant strains
- Analytical Sensitivity: 0.05 ng/ml
- Ready to use conjugate
- Easy Interpretation of results
- Long Shelf Life 24 months. Storage at 2-8°C
- Excellent Specificity

CONVENIENT PACK SIZE
96
TESTS



Scan QR Code
For more product &
service information



Since 1969

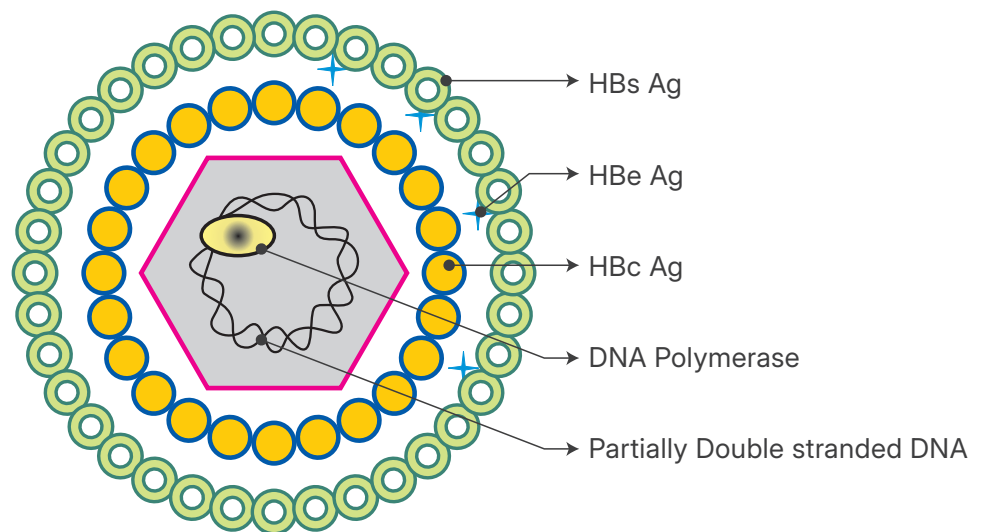
J. Mitra & Co. Pvt. Ltd.

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Hepatitis B: An Introduction

Hepatitis B is a potentially life-threatening liver infection caused by the hepatitis B virus. Originally known as serum hepatitis. It is a major global health problem and the most serious type of viral hepatitis. It can cause chronic liver disease and puts people at high risk of death from cirrhosis of the liver and liver cancer. World-wide, an estimated two billion people have been infected with the hepatitis B virus (HBV), and more than 350 million have chronic (long-term) Liver infections. The disease has caused epidemics in parts of Asia and Africa.

HBV: The silent Killer



Hepatitis B virus (HBV) is a member of the Hepadnavirus family. The virus consists of an outer lipid envelope, core and DNA polymerase. The genetic material is partially double stranded DNA. The outer envelope contains embedded proteins which are involved in viral binding of, and entry into, susceptible cells. The outer surface of the virus is composed of lipid and protein, which is called the surface antigen (HBsAg), and is produced in excess during the life cycle of the virus.

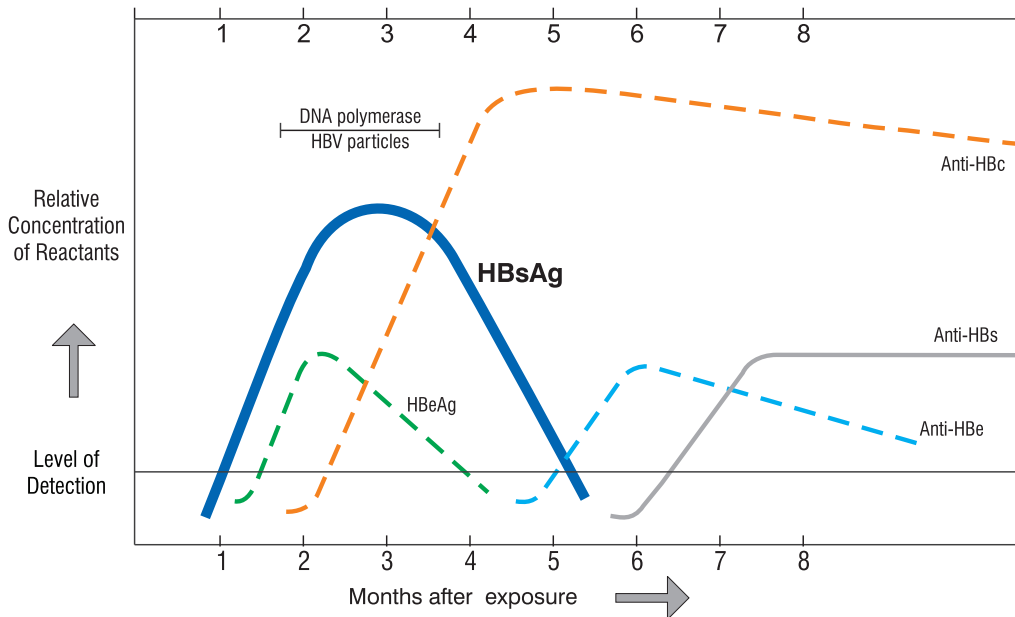
The virus is divided into 4 major serotypes (ad, adw, ayr, ayw) based on antigenic epitopes present on its envelope proteins. Due to variation in 'w' determinant, 11 subtypes are formed. There are 8 genotypes (A-H) according to overall nucleotide sequence variation of the genome.

HBsAg: An Ideal Marker

The diagnosis of Hepatitis B virus (HBV) infection was revolutionized by the discovery of Australian antigen, now called Hepatitis B Surface Antigen (HBsAg)

- It is first detected during HBV infection before appearance of symptoms.
- It is the most reliable & universal marker of HBV infection.
- It persists for more than 6 months in carrier & chronic state also produced in large quantities.
- HBsAg carrier is a highly antigenic determinant. Hence is also used to make Hepatitis B vaccine.

Serological Markers & Clinical Pattern: (During acute HEIV infection)



Hepatitis B surface antigen (HBsAg)

- It is the first detected during HBV infection before appearance of symptoms and appears within 2 weeks and disappeared within 3-4 months and persists for more than 6 months in carrier & chronic state

Hepatitis B envelope antigen (HBeAg)

- Appears within 1 week after the HBsAg and lasts for 3-6 weeks
- Disappears before HBsAg clearance and presence indicate highly infectious state presence also indicates that virus is replicating

Anti-HBs Antibody

- Produced in response to HBsAg & appears in the blood with in few weeks after HBsAg clearance
- Causing window period of about 6 months & detection of anti-HBs does not discriminate between current or previous infection
- Used as pre-vaccination screening & follow-up post-vaccination response

Anti-HBe Antibody

- Appears before clearance of HBsAg
- Temporarily in acute HBV infection & consistently during or after viral replication
- Good prognosis for the resolution of infection

IgM anti-HBc

- Present in high titre during acute HBV infection
- Low level during recovery
- Marker of recent infection and differentiate between acute and chronic infection

Anti-HBc total

- Appears at the onset of symptoms 4-10 weeks after HBsAg appearance and persists for a life or years
- The only indicator of infections in the "window period"
- Presence indicates previous & ongoing infection

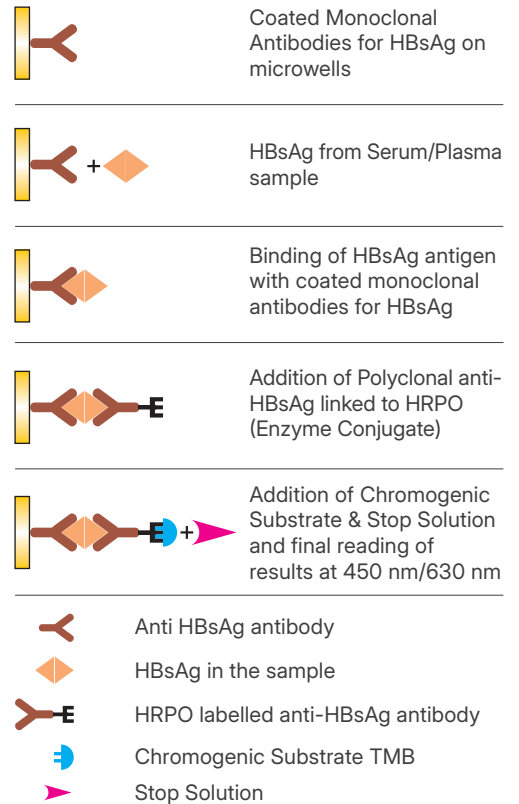
HBV DNA

- Can be detected at low level by PCR
- Diagnosis of acute/chronic/carrier state & monitoring the effect of interferon treatment

Test Procedure

Add Sample Diluent		25 µl																																																				
Add Controls & Sample		100 µl																																																				
Cover the Plate and Incubate		60 Minutes at 37°C																																																				
Add enzyme conjugate (Ready to use)		50 µl																																																				
Cover the Plate and Incubate		60 min. at 37°C																																																				
Wash		6 Cycles																																																				
Prepare Chromogenic Substrate		<table border="1"> <thead> <tr> <th>No. of strip</th> <th>1</th> <th>2</th> <th>3</th> <th>4</th> <th>5</th> <th>6</th> <th>7</th> <th>8</th> <th>9</th> <th>10</th> <th>11</th> <th>12</th> </tr> </thead> <tbody> <tr> <td>TMB</td> <td>0.5</td> <td>1.0</td> <td>1.5</td> <td>2.0</td> <td>2.5</td> <td>3.0</td> <td>3.5</td> <td>4.0</td> <td>4.5</td> <td>5.0</td> <td>5.5</td> <td>6.0</td> </tr> <tr> <td>Substrate (ml)</td> <td>0.5</td> <td>1.0</td> <td>1.5</td> <td>2.0</td> <td>2.5</td> <td>3.0</td> <td>3.5</td> <td>4.0</td> <td>4.5</td> <td>5.0</td> <td>5.5</td> <td>6.0</td> </tr> <tr> <td>TMB Diluent (ml)</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	No. of strip	1	2	3	4	5	6	7	8	9	10	11	12	TMB	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5	6.0	Substrate (ml)	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5	6.0	TMB Diluent (ml)												
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Add Working Substrate		100 µl																																																				
Incubate in Dark		30 min. at room temperature																																																				
Add Stop Solution		100 µl																																																				
Read Results		450 nm / 630 nm																																																				

Principle



Key Facts about Hepatitis-B

- Hepatitis B is a viral infection that attacks the liver and can cause both acute and chronic disease.
- The virus is transmitted through contact with the blood or other body fluids of an infected person - not through casual contact.
- About 2 billion people worldwide have been infected with the virus and about 350 million live with chronic infection. An estimated 600 000 persons die each year due to the acute or chronic consequences of hepatitis B.
- About 25% of adults who become chronically infected during childhood later die from liver cancer or cirrhosis (scarring of the liver) caused by the chronic infection.
- The hepatitis B virus is 50 to 100 times more infectious than HIV. Hepatitis B virus is an dangerous occupational hazard for health workers.
- Highest incidence of the disease is in the age group 20-49.
- HBV can survive outside the body for at least 7 days and still be capable of causing infection.



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