Hepatitis B (anti-HBs)

Overview

Clinical

Hepatitis B, caused by the Hepatitis B Virus (HBV), poses a significant worldwide health threat. This viral infection leads to various liver diseases, encompassing acute and chronic hepatitis, cirrhosis, and primary liver cancer. Transmission occurs through contact with infected bodily fluids, including blood, saliva, vaginal secretions, and semen. Additionally, maternal transmission to newborns is a recognized route of infection[1].

In clinical environments, the quantification of Antibodies to Hepatitis B surface antigen (anti-HBs) serves as a valuable tool to evaluate the progression of recovery from Hepatitis B infection and to determine immune status[2].

Epidemiology

It is estimated that 30.4 million people (10.5% of all people estimated to be living with hepatitis B) were aware of their infection, while 6.6 million (22%) of the people diagnosed were on treatment[1].

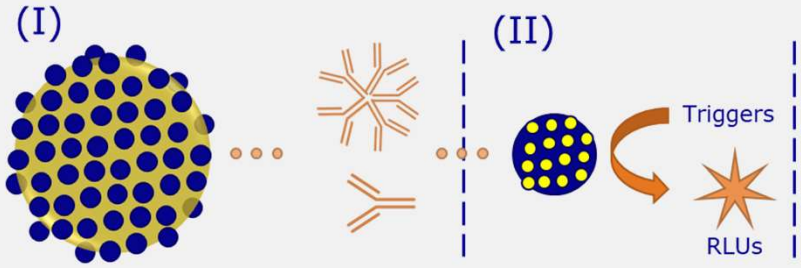
According to last US CDC recommendations, it is recommended to test all adults aged 18 years and older for HBsAg , anti-HBs and anti-HBc at least once in their lifetime[3].

Anti-HBs CLIA

Assay Scheme

Quantitative measurement of antibodies to Hepatitis B surface antigen (anti-HBs) in human serum or plasma

Assay scheme
Indirect Two-step assay (Quantitative)



PMPs	Sample	Conjugate
Magnetic Beads coated with Werfen's Hepatitis B surface Ag ad & ay subtype	Serum/Plasma With anti-HBs antibodies	Werfen Hepatitis B surface Ag-iso-luminol

1 Hepatitis B. WHO Factsheet. July 2023. Accessed March 2024. https://www.who.int/news-room/fact-sheets/detail/hepatitis-b

2. Guidelines on Hepatitis B and C testing. WHO. February 2017

3. Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations — United States, 2023. Accessed March 2024. https://www.cdc.gov/mmwr/volumes/72/rr/rr7201a1.htm?s_cid=rr7201a1_w

Evaluation of anti-HBs CLIA vs reference assay

	Reference Method		
Anti-HBs CLIA Assay	**POS**	**NEG**	**Total**
POS	**197**	**0**	197
NEG	**3**	**517**	520
Total	200	517	717

Table 2: Panel of 717 samples from different sources, including positive and negative sera for anti-HBs, was tested with CLIA anti-HBs in comparison with a commercially available EIA anti-HBs method

	Relative Sensitivity		Relative Specificity		Overall Agreement	
N	**Value**	**95% CI**	**Value**	**95% CI**	**Value**	**95% CI**
717	**98.5%**	**95.7% to 99.7%**	**100.0%**	**99.3% to 100.0%**	**99.6%**	**98.8% to 99.9%**

Table 3: Results on table 3 were obtained for relative sensitivity, specificity and overall agreement

Cross-reactivity Test with anti-HBs CLIA

Cross-reactivity	
Cross-reactant type	**Agreement**
anti-Toxoplasma *(Toxoplasma gondii)*	5/5
anti-Rubella	11/11
anti-HIV (Human Immunodeficiency Virus)	4/4
anti-HSV (Herpes Simplex Virus)	2/2
anti-HAV IgG (Hepatitis A Virus)	6/6
anti-HAV IgM (Hepatitis A Virus)	5/5
anti-HDV IgG (Hepatitis delta Virus)	2/2
anti-HEV (Hepatitis E Virus)	2/2
anti-EBV (Epstein-Barr Virus)	5/5
Anti-CMV (Cytomegalovirus)	10/11
anti-VZV (Varicella Zoster Virus)	4/4

Table 4. Cross-reactant sample testing. 57 specimens with potential cross-reactivity with the anti-HBs CLIA assay were tested against commercially available anti-HBs assay. Table above is showing the agreement between methods

Werfen's Biomaterial offering

Hepatitis B Surface Antigen (ad subtype)
(ref 3000-5200 / 3000-5201)
Storage: -20ºC
Source: Human plasma
Storage buffer: PBS pH 7,4
Purification method: Ultracentrifugation
Protein concentration: 2-3 mg/mL
Preservative: None

Hepatitis B Surface Antigen (ay subtype)
(ref 3000-5198 / 3000-5199)
Storage: -20ºC
Source: Human plasma
Storage buffer: PBS pH 7,4
Purification method: Ultracentrifugation
Protein concentration: 2-3 mg/mL
Preservative: None

The content within this brochure is provided for informational purposes.
Contact immunoassay@werfen.com for further technical information and product availability