Hepatitis B (HBsAg)

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 settings the measurement of Hepatitis B Surface Antigen (HBsAg) is used as an aid to diagnose both acute and chronic Hepatitis B infection[2]. The presence of HBsAg indicates that the person is potentially is infectious. It could be the case that an individual may be transiently positive within 30 days after a dose of Hepatitis B Vaccine[3].

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].

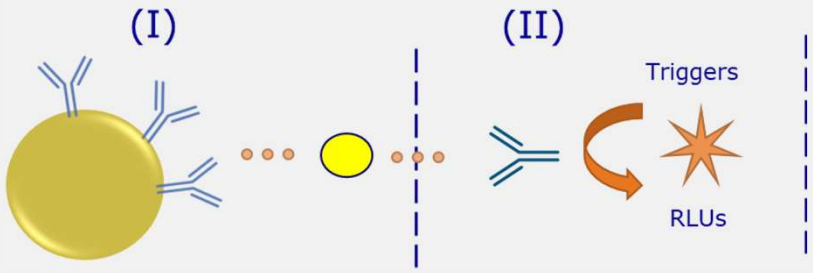
According to last US CDC recommendations, it is recommended to test all adults aged 18 years and older for HBsAg , anti-HBs and anti-HBc at least once in their lifetime[4].

HBsAg CLIA

Assay Scheme

Qualitative measurement of Hepatitis B Surface antigen (HBsAg) in human serum or plasma

Assay scheme
Two-step assay (Qualitative)



PMPs	Sample	Conjugate
Magnetic Beads coated with Werfen's Anti-Guinea Pig IgG pAb	Serum/Plasma With HBsAg	Werfen's Anti-HBs Goat IgG pAb-iso-luminol

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

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

3. Interpretation of Hepatitis B Serologic Test Results. CDC . July 2023. Accessed April 2024. https://www.cdc.gov/hepatitis/hbv/interpretationOfHepBSerologicResults.htm

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

Evaluation of HBsAg CLIA vs reference assay

HBsAg CLIA Assay	Specimens Tested	Specificity
Blood Donors	5181	99.96%
Hospitalized patients	222	99.55%

Table 2: Specificity assessment was based upon testing unselected blood door serum samples, including first time donors and hospitalized patients. Specificity was calculated with the results shown in the table above

Sample Group	Specimens Tested	Specificity
Non-subtyped	537	100%
Subtype ad	26	100%
Subtype ay	25	100%

Table 3: A panel of samples from different sources with verified HBsAg positivity was tested with our HBsAg CLIA assay. This panel includes 29 fresh same day samples (≤ 1 day after sampling). Then sensitivity was calculated for each group of samples, with the results shown in the following table above.

Cross-reactivity Test with HBsAg CLIA

Cross-reactivity	
Cross-reactant type	**Agreement**
anti-Toxoplasma *(Toxoplasma gondii)*	3/3
anti-Rubella	8/8
anti-HIV (Human Immunodeficiency Virus)	10/10
anti-HSV IgG (Herpes Simplex Virus)	7/7
Anti-HCV (Hepatitis C Virus)	6/6
anti-HAV IgG (Hepatitis A Virus)	6/6
anti-HAV IgM (Hepatitis A Virus)	5/5
anti-HDV IgG (Hepatitis delta Virus)	5/5
anti-HEV (Hepatitis E Virus)	4/4
anti-EBV (Epstein-Barr Virus)	4/4
Anti-CMV (Cytomegalovirus)	4/4
anti-VZV (Varicella Zoster Virus)	4/4

Table 4. Cross-reactant sample testing. 66 specimens with potential cross-reactivity with the HBsAg CLIA assay were tested against commercially available HBsAg assay. Table above is showing the agreement between methods

Werfen's Biomaterial offering

Anti-HBs Goat IgG pAb
(ref 3000-5501 / 3000-5502)
Storage: 2-8 ºC
Source: Goat serum
Storage buffer: Carbonate pH 9,5
Purification method: Immunoaffinity Chromatography
Protein concentration: 1-3 mg/mL
Preservative: None

Anti-HBs Guinea Pig IgG
(ref 3000-5264 / 3000-5265)
Storage: 2-8 ºC
Source: Guinea Pig serum
Storage buffer: PBS
Purification method: Immunoaffinity Chromatography
Protein concentration: 0.5 – 2.0 mg/mL
Preservative: < 0.1% Sodium Azide

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

Version 3 April 2025