

Hepatitis B (anti-HBs)

Overview

Clinical

Hepatitis B, caused by the Hepatitis B Virus (HBV). This viral infection leads to various liver diseases, encompassing acute and chronic hepatitis, cirrhosis, and primary liver cancer¹. Measuring antibodies to the Hepatitis B surface antigen (anti-HBs) helps assess a patient's recovery from Hepatitis B infection. It is also used to determine whether an individual is immune to the virus².

Anti-HBs CLIA

Assay Scheme

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

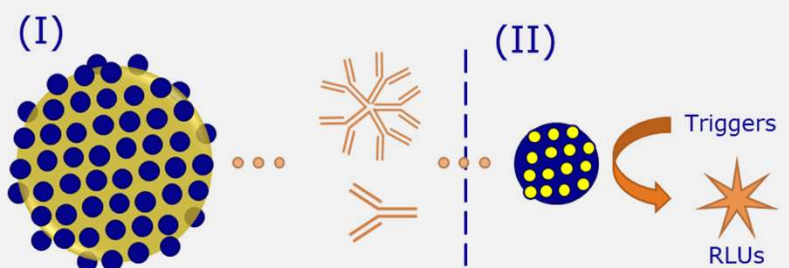
Epidemiology

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 treatment¹.

According to last US CDC recommendations, it is advised to test all adults aged 18 years and older for HBsAg, anti-HBs and anti-HBc at least once in their lifetime³.

Assay scheme

One-step assay (Quantitative)



PMPs

Magnetic Beads coated with Werfen's Recombinant HBsAg ay and Native HBsAg ad

Sample

Serum/Plasma With anti-HBs antibodies

Conjugate

Werfen Native Hepatitis B surface Ag-iso-luminol

Dose-Response of recombinant HBsAg ay CLIA Prototype

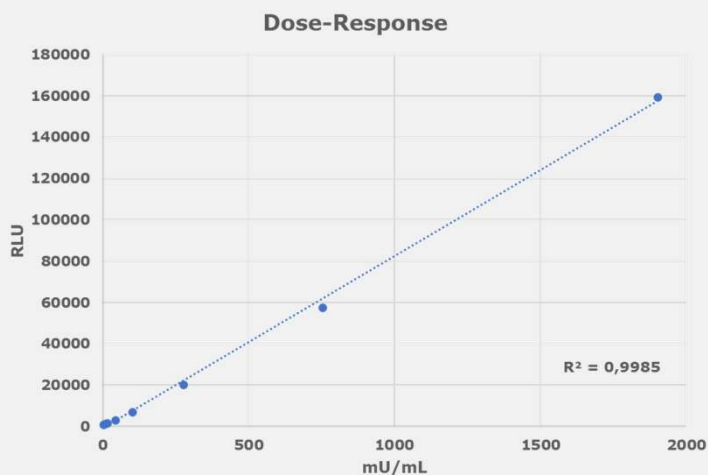


Figure 1. Recombinant HBsAg ay was coated in paramagnetic particles. Native HBsAg ay and ad were conjugated to iso-luminol to be used as tracer. Dose response curve shows reactivity of the different assay Standard plotted against the concentration obtained with a reference method (measured in mU/mL).

Standard Dilutions	mU/mL*	RLU's
S0	0	825
S1	5	1019
S2	12	1480
S3	40	2837
S4	100	6909
S5	275	20028
S6	750	57516
S7	1900	159440

*Concentration of dilutions of the Anti-Hepatitis B Surface antigen antibodies WHO International standard

Table 1. Numerical results dose-response calibration curve. Signal-to-noise and assay range performance evaluation.

Method Comparison Recombinant HBsAg ay vs Native HBsAg ay

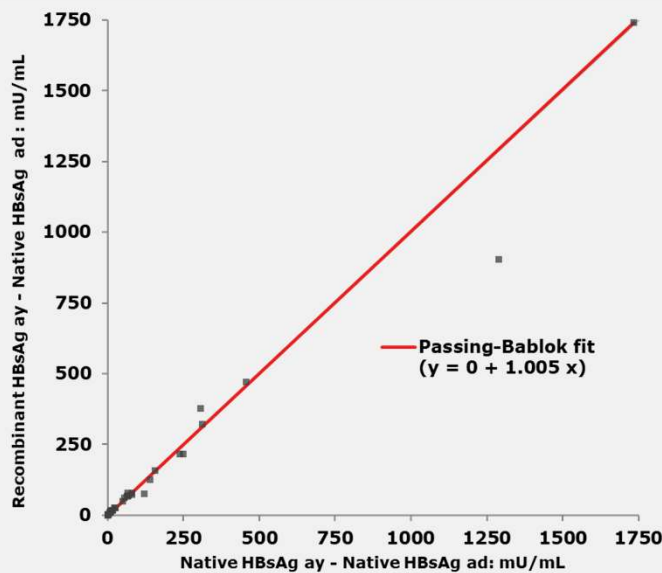


Figure 2. Method Comparison. 48 samples (aHBs positive and aHBs negative) were tested with a CLIA prototype containing Recombinant HBsAg ay and native HBsAg ad and CLIA prototype with native HBsAg ay and native HBsAg ad.

Evaluation of anti-HBs Prototype CLIA vs reference assay

Anti-HBs Prototype CLIA	Reference Assay		Total
	POS	NEG	
POS	26	2	28
NEG	2	20	22
Total	28	22	50

Table 2: Panel of 50 samples from different sources, including positive and negative sera for anti-HBs, was tested with Prototype CLIA anti-HBs using recombinant HBsAg ay and native HBsAg ad in comparison with a commercially available ECLIA anti-HBs method

N	Relative Sensitivity		Relative Specificity	
	Value	95% CI	Value	95% CI
50	93%	77% - 98%	91%	72% - 97%

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

Werfen’s Biomaterial offering

Recombinant HBsAg ay (ref 3000-7069) Storage: -70°C Source: CHO Storage buffer: Phosphate buffer , NaCl pH 8 Purification method: Immunoaffinity Chromatography Protein concentration: 0.5- 1 mg/mL Preservative: None	Hepatitis B Surface Antigen (ad subtype) (ref 3000-5200 / 3000-5201) Storage: -20°C Source: Human plasma Storage buffer: PBS pH 7.4 Purification method: Ultracentrifugation Protein concentration: 2-3 mg/mL Preservative: None
---	---

Recombinant HBsAg ay (3000-7069) product is in R&D Stage. The content within this brochure is provided for informational purposes.

Contact immunoassay@werfen.com for further technical information and product availability

1 Hepatitis B. WHO Factsheet. July 2025. Accessed September 2025. <https://www.who.int/news-room/fact-sheets/detail/hepatitis-b>

2 Hepatitis guidelines on Hepatitis B and C testing. WHO. February 2017. <https://www.afro.who.int/sites/default/files/2017-06/9789241549981-eng.pdf> . Accessed January 2026

3. Connors EE, Panagiotakopoulos L, Hofmeister MG, et al. Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations — United States, 2023. MMWR Recomm Rep 2023;72(No. RR-1):1–25. DOI: <http://dx.doi.org/10.15585/mmwr.rr7201a1>. https://www.cdc.gov/mmwr/volumes/72/rr/rr7201a1.htm?s_cid=rr7201a1_w Accessed January 2026