

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 infection¹.

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 status².

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.

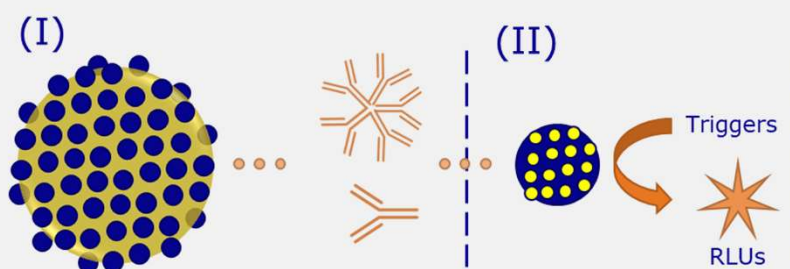
Anti-HBs CLIA

Assay Scheme

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

Assay scheme

One-step assay (Quantitative)



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

1 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

3. Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations. March 2023. Accessed September 2025.

https://www.cdc.gov/mmwr/volumes/72/rr/rr7201a1.htm?s_cid=rr7201a1_w

Dose-Response of recombinant HBsAg ay CLIA Prototype

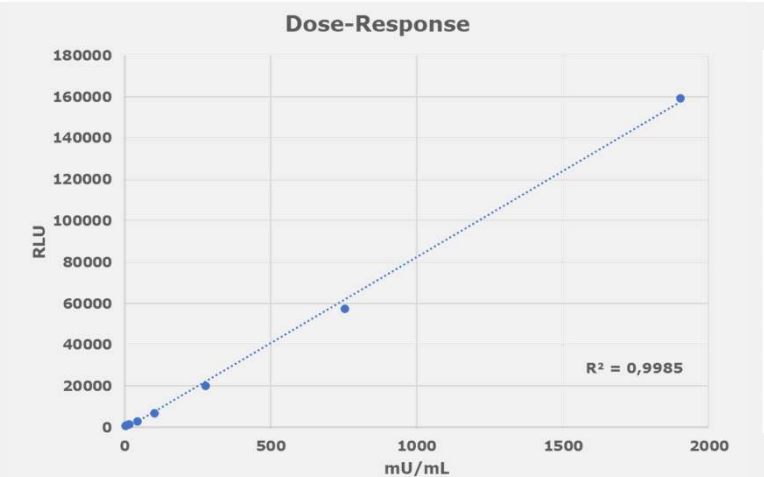


Figure 1. Recombinant HBsAg ay was coated in paramagnetic particles. Native HBsAg ay and ad were conjugated to iso-luminol to be used as tracer. Dose response curve shows reactivity of the different assay Standard plotted against the concentration obtained with a reference method (measured in mU/mL).

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

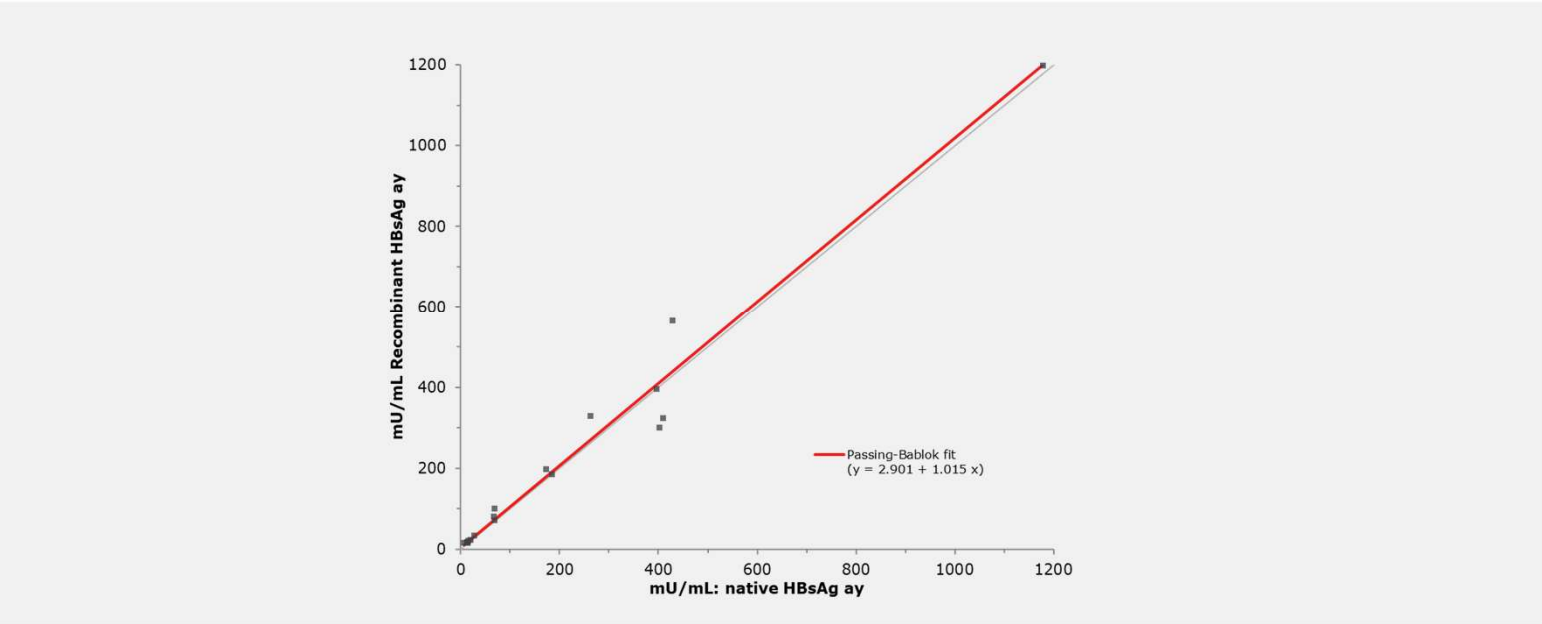


Figure 2. Method Comparison. 19 samples (aHBs positive and aHBs negative) were tested with a CLIA kit containing Recombinant HBsAg ay and CLIA kit with only native HBsAg ay.

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

