

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.

Epidemiology

It is estimated that 240 million people estimated to be living with Hepatitis B with 0.9 million new infections each year.¹. 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.

Biomaterial Characterization

Recognition by a commercial CLIA HBsAg assay

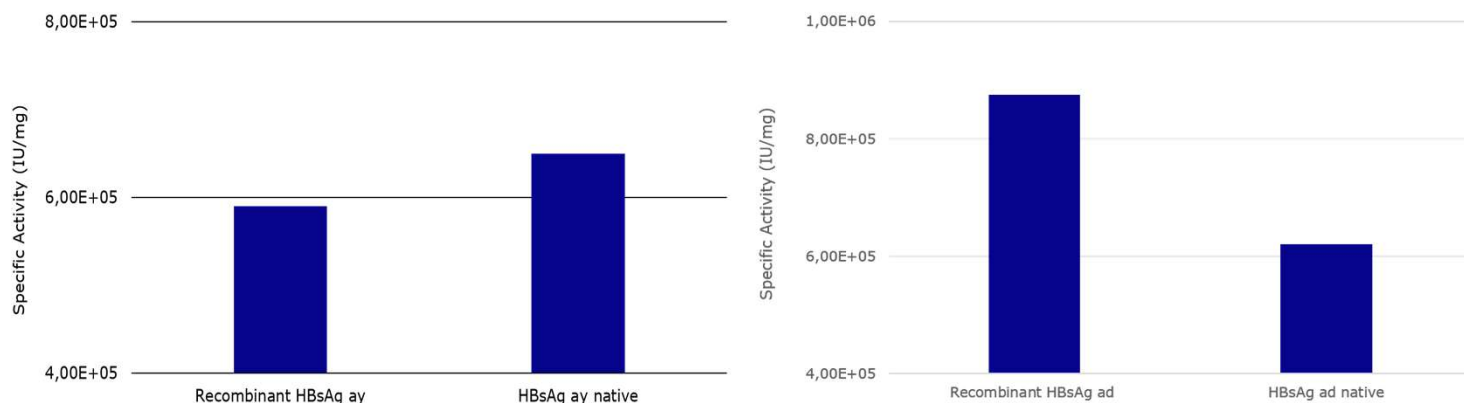


Figure 1. Recombinant HBsAg ad & ay and Native HBsAg ad & ay were analyzed as sample with a commercial HBsAg CLIA assay

1 B. WHO Factsheet. July 2026. Accessed September 2026. <https://www.who.int/news-room/fact-sheets/detail/hepatitis-b>

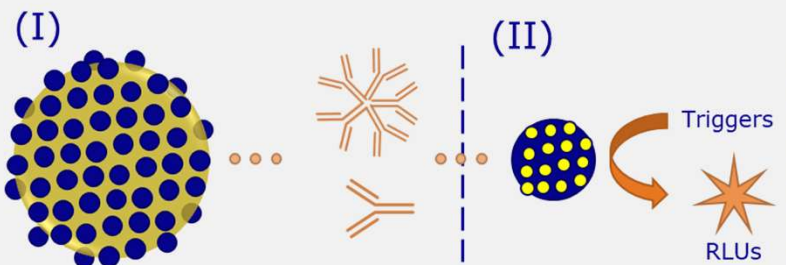
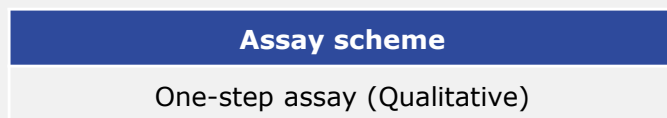
2. Hepatitis guidelines on Hepatitis B and C testing. WHO. February 2017

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

Anti-HBs CLIA

Assay Scheme

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



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

Performance of Recombinant HBsAg ad & ay CLIA Pre-prototype

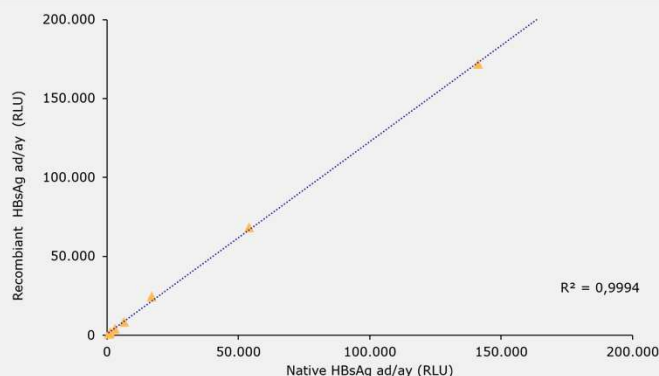


Figure 2. Comparison aHBs CLIA pre-prototype with recombinant HBsAg ad/ay vs aHBs CLIA prototype with native HBsAg ad/ay. Dilutions of the aHBs international standard were analyzed both with aHBs CLIA pre-prototype with Recombinant HBsAg ad/ay in the microparticles and with aHBs CLIA prototype with Native HBsAg ad/ay in microparticles.

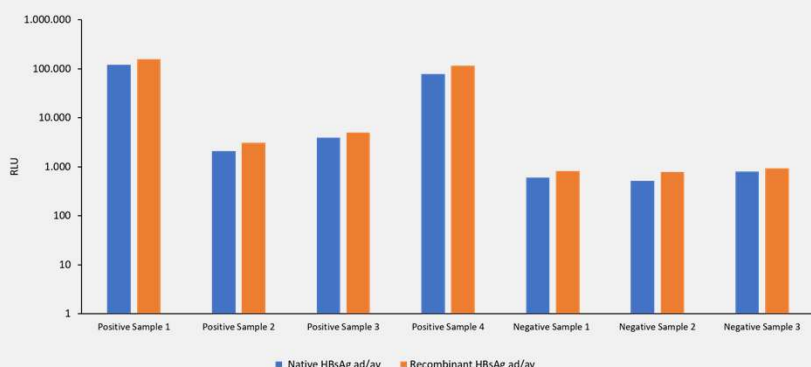


Figure 3 Comparison aHBs CLIA pre-prototype with recombinant HBsAg ad/ay vs aHBs CLIA prototype with native HBsAg ad/ay. 4 positive aHBs and 3 negative samples were analyzed with both assays

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

Recombinant HBsAg ad

(ref 3000-7082)

Storage: -70°C

Source: CHO

Storage buffer: HEPES, NaCl pH 8

Purification method: Immunoaffinity Chromatography

Protein concentration: 0.5- 1 mg/mL

Preservative: None

Recombinant HBsAg ay (3000-7069) and Recombinant HBsAg ad (3000-7082) products are 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