Hepatitis B (anti-HBc)

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 Antibodies to Hepatitis B core antigen (anti-HBc) is used as an aid to assess both acute and chronic Hepatitis B infection[2]. People who have immunity to hepatitis B from a vaccine do not develop anti-HBc[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].

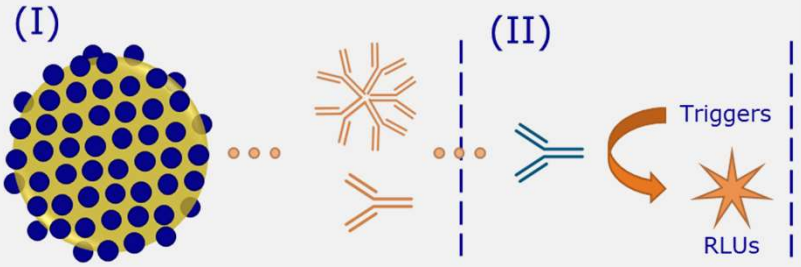
According to last US CDC recommendations, it is recommended to test all adults aged 18 years and older for HBsAg , anti-HBs and anti-HBc at least once in their lifetime[4].

Anti-HBc CLIA

Assay Scheme

Qualitative measurement of total antibodies to Hepatitis B Core antigen (anti-HBc) in human serum or plasma

Assay scheme
Indirect Two-step assay (Quantitative)



PMPs	Sample	Conjugate
Magnetic Beads coated with Werfen's recombinant Hepatitis B core antigen	Serum/Plasma With anti-HBc antibodies	Anti-HBcAg rabbit IgG-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. Interpretation of Hepatitis B Serologic Test Results. CDC . July 2023. Accessed March 2024. https://www.cdc.gov/hepatitis/hbv/interpretationOfHepBSerologicResults.htm

4. 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-HBc CLIA vs reference assay

Anti-HBc CLIA Assay	Specimens Tested	Specificity
Blood Donors	5097	99.9%
NEG	210	100%

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

Anti-HBc CLIA Assay	Specimens Tested	Specificity
EIA method	400	100%
CLIA method	205	100%

Table 3: A panel of samples from different sources with verified anti-HBc positivity was tested with our anti-HBc CLIA assay in comparison with commercially available EIA and CLIA anti-HBc methods. The sensitivity results are shown in the table above.

Cross-reactivity Test with anti-HBc CLIA

Cross-reactivity	
Cross-reactant type	**Agreement**
anti-Toxoplasma *(Toxoplasma gondii)*	4/4
anti-Rubella	10/10
anti-HIV (Human Immunodeficiency Virus)	7/7
anti-HSV (Herpes Simplex Virus)	5/5
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)	6/6
anti-VZV (Varicella Zoster Virus)	5/5

Table 4. Cross-reactant sample testing. 61 specimens with potential cross-reactivity with the anti-HBc CLIA assay were tested against commercially available anti-HBc assay. Table above is showing the agreement between methods

Werfen's Biomaterial offering

Recombinant HBc Antigen (ref 3000-5100 / 3000-5102)
Storage: -20ºC
Source: *Escherichia coli*
Storage buffer: PBS, pH 7.4
Protein concentration: 0.2 – 1.0 mg/mL
Preservative: None

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

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