Hepatitis C

Overview

Clinical

Hepatitis C, caused by the Hepatitis C Virus (HCV), poses a significant threatagainst worldwide health. HCV viral infection can include the following symptoms: fever, fatigue, abdominal pain and jaundice, among others. Acute infections can be asymptomatic and not lead to major health issues while chronic infection can lead to liver cirrhosis. Transmission occurs through contact with infected blood. Additionally, maternal transmission to newborns is a recognized route of infection[1].

In clinical settings the measurement of antibodies to HCV is used as an aid to diagnose both acute and chronic Hepatitis C virus infection[2]. The presence of antibodies to HCV indicates that the individual has past or current HCV infection[3].

Epidemiology

It is estimated that 50 million people are living with hepatitis C. And every year, 2022 figures, it is estimated that 1 million people becomes infected worldwide with an estimated death toll of 240,000 people dying from Hepatitis C[3].

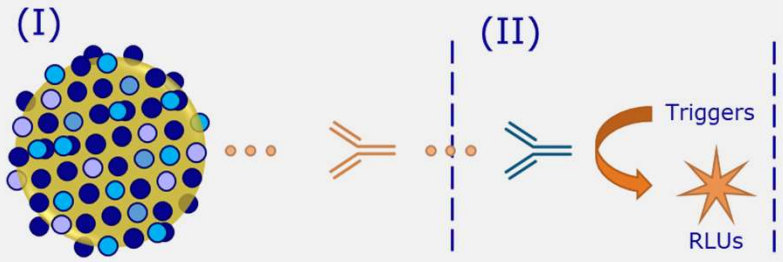
According to last US CDC, it is recommended to undergo HCV screening all adults aged 18 years and older at least once in their lifetime[4].

Anti-Hepatitis C CLIA

Assay Scheme

Qualitative measurement of IgG antibodies to Hepatitis C virus (Anti-HCV) in human serum or plasma

Assay scheme
Two-step assay (Qualitative)



PMPs	Sample	Conjugate
Magnetic Beads coated with Werfen's recombinant HCV capside Ag and NS3 Ag . Also coated with NS4 and NS5	Serum/Plasma Anti-HCV IgG	Anti-human IgG mAb-iso-luminol

1 Hepatitis C. WHO Factsheet. April 2024. Accessed April 2024. https://www.who.int/news-room/fact-sheets/detail/hepatitis-c
2. Guidelines on Hepatitis B and C testing. WHO. February 2017
3. Global hepatitis report 2024: action for access in low- and middle-income countries. WHO. April 2024
4. Clinical Screening and Diagnosis for Hepatitis C. CDC . December 2023. Accessed July 2024. https://www.cdc.gov/hepatitis-c/testing/index.html

Evaluation of Anti-Hepatitis C CLIA vs reference assay

Anti-HCV CLIA Assay	Specimens Tested	Specificity
Blood Donors	5022	99.7%
Hospitalized Patients	250	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

Sample Group	Specimens Tested	Specificity
Non-genotyped	197	100%
≤ 1 day after sampling	37	100%
Genotype 1	25	100%
Genotype 2	91	100%
Genotype 3	55	100%
Genotype 4	50	100%
Genotype 5 / 6	14 / 1	100% / 100

Table 3: A panel of samples from different sources with verified anti-HCV positivity was tested with our Anti-HCV CLIA assay. This panel includes 37 fresh same day samples (≤ 1 day after sampling).

Cross-reactivity Test with Anti-Hepatitis C CLIA

Cross-reactivity	
Cross-reactant type	**Agreement**
anti-Toxoplasma *(Toxoplasma gondii)*	6/6
anti-Rubella	6/6
anti-HIV (Human Immunodeficiency Virus)	3/3
anti-HSV 1 (Herpes Simplex Virus type 1)	5/5
anti-HBc	6/6
anti-HAV IgG (Hepatitis A Virus)	6/6
anti-HAV IgM (Hepatitis A Virus)	5/5
anti-HDV IgG (Hepatitis delta Virus)	8/8
anti-HEV (Hepatitis E Virus)	5/5
anti-EBV (Epstein-Barr Virus)	6/6
anti-CMV (Cytomegalovirus)	6/6
anti-HBs	6/6

Table 4. Cross-reactant sample testing. 68 specimens with potential cross-reactivity with the anti-HCV CLIA assay were tested against commercially available anti-HCV assay. Table above is showing the agreement between methods

Werfen's Biomaterial offering

Recombinant HCV Capsid Polypeptide
(ref 3000-5103 / 3000-5314)
Storage: -70 ºC
Source: *Escherichia coli*
Storage buffer: Acetate, NaCl, pH 5.5
Purification method: Ion Exchange Chromatography
Protein concentration: 0.5-2 mg/mL
Preservative: None

Recombinant HCV NS3 Polypeptide
(ref 3000-5104 / 3000-5105)
Storage: -70 ºC
Source: *Escherichia coli*
Storage buffer: Tris HCL, NaCL, pH 8.6
Purification method: Affinity Chromatography
Protein concentration: 0.5 – 2.0 mg/mL
Preservative: None

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

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