Hepatitis E Virus

Overview

Clinical

Hepatitis E is an inflammation of the liver caused by infection with the Hepatitis E Virus (HEV).

The virus is transmitted via the fecal-oral route, principally via contaminated water.

Epidemiology

Every year there are an estimated 20 million HEV infections worldwide, leading to an estimated 3.3 million symptomatic cases of Hepatitis E.

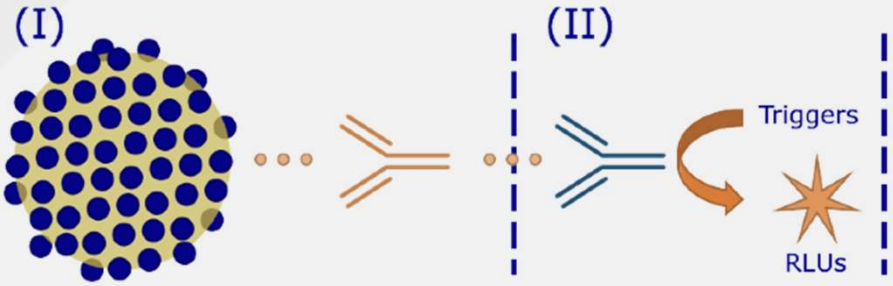
WHO estimates that hepatitis E caused approximately 44 000 deaths in 2015 (accounting for 3.3% of the mortality due to viral hepatitis)[1].

HEV IgG CLIA RUO prototype

Assay Scheme

Quantitative detection of antibodies (IgG) to Hepatitis E Virus in human serum

Assay scheme
Indirect Two-step assay (quantitative)



PMPs	Sample	Conjugate
Magnetic Beads coated with Werfen's recombinant HEV Ag	Serum/Plasma with anti-HEV IgGs	mAb a-hu-IgG-iso-luminol

Dose-response in HEV IgG RUO prototype

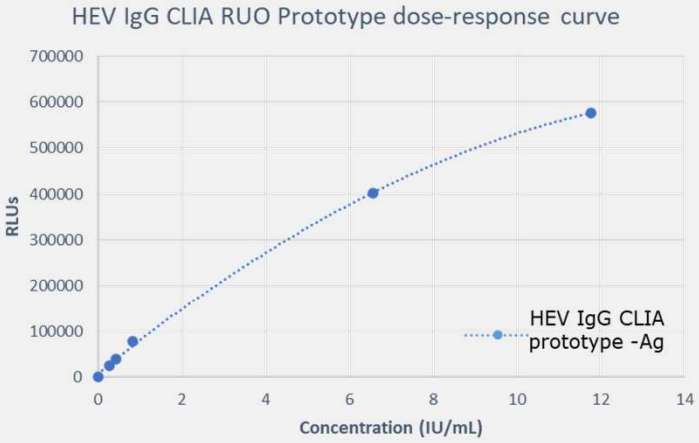


Figure 1. Calibration curve for an indirect HEV IgG CLIA RUO prototype. Recombinant HEV Ag was used for coating PMPs on CLIA RUO assay and aIgG labeled with Iso-luminol was used as a detector. A pool of POS samples diluted in NEG serum at different concentrations was used as a calibrator sample set.

Calibrator Sample	U/mL*	RLU's
S0	0	485
S1	0.26	25,110
S2	0.42	39,080
S3	0.83	77,160
S4	6.57	401,288
S5	11.77	577,319

**Concentration of the calibrator samples obtained with a reference method*

Assay Range	S5/S0	1,190

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

1 Hepatitis E. WHO Factsheet July 2023. Accessed September 2023 . https://www.who.int/news-room/fact-sheets/detail/hepatitis-e

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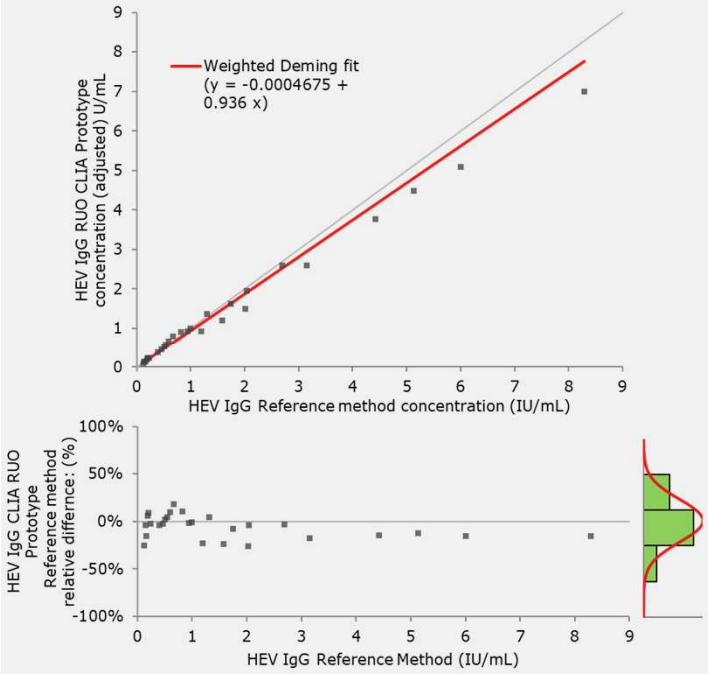
Method Comparison of HEV IgG RUO prototype vs reference assay



	HEV IgG CLIA RUO Prototype		
Ref Method	**POS**	**NEG**	**Total**
REACT	**25**	**0**	25
NR	**0**	**15**	15
Total	25	15	40

Figure 2. Method comparison for performance evaluation – HEV IgG sample from patient Testing. Quantitative correlation of HEV IgG concentration obtained in HEV IgG CLIA RUO prototype of 40 native individual native serum samples compared to the concentration determined with the reference method. reference method:

- NR=non reactive for HEV IgG
- REACT= reactive for HEV IgG

For Werfen HEV IgG RUO CLIA prototype:

- NEG = negative for HEV IgG
- POS = Positive for HEV IgG

Cross-reactivity with HEV IgG RUO prototype

Sample ID		HEV IgG Reference CLIA		HEV IgG CLIA RUO Prototype	
Cross-reactant disease type	**Sample nº**	**IU/mL**	**Status**	**Calculated concentration (U/mL)**	**Status**
Parvovirus B19	Sample 1	<<0.100	NR	0.00	NEG
	Sample 2	<<0.100	NR	0.01	NEG
EBV VCA IgG	Sample 1	<<0.100	NR	0.01	NEG
	Sample 2	<<0.100	NR	0.00	NEG
CMV IgG	Sample 1	<<0.100	NR	0.01	NEG
	Sample 2	<<0.100	NR	0.04	NEG
Hepatitis B (aHBc)	Sample 1	<<0.100	NR	0.01	NEG
	Sample 2	<<0.100	NR	0.01	NEG
Hepatitis B (HBsAg)	Sample 1	<<0.100	NR	0.01	NEG
	Sample 2	<<0.100	NR	0.01	NEG
Hepatitis C (HCV)	Sample 1	<<0.100	NR	0.01	NEG
HEV IgM	Sample 1	<<0.100	NR	0.02	NEG

Table 2. Cross-reactant sample testing. Different samples from other infectious diseases were tested for cross-reactivity towards HEV IgG Werfen RUO prototype assay. None of them show any cross-reactivity, accordingly to the results obtained with the reference method.

Werfen's Biomaterial offering

Recombinant HEV Ag (ref 3000-7065)
Storage: -70ºC
Source: *Escherichia coli*
Storage buffer: MES , NaCl pH 9.3
Purification method: Affinity chromatography
Protein concentration:1 mg/mL
Preservative: None

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