Assessment Of The Hepatitis E Virclia® System For The Detection Of IgM And IgG Antibodies Against HEV

P-0564

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BACKGROUND AND PURPOSE

❖ Hepatitis E Virus (HEV) is transmitted to humans through the faecal–oral route, mainly by the consumption of contaminated water or undercooked meat from infected animals.

❖ Diagnosis of acute hepatitis E infection is based on the detection of specific IgM antibodies to the virus in serum.

❖ Additional tests include RT-PCR to detect the HEV RNA. The IgG detection is used to define prior contact and sometimes to confirm seroconversion, for follow-up of acute cases.

❖ The aim of this study is the assessment of a new serological method that focuses in sensitivity and it is compared to other methods previously assessed.

MATERIAL AND METHODS

❖ Samples have been processed in VIRCLIA equipment of Chemiluminescent CLIA, based on the capture of IgM present in the sample by antiinmunoglobuline antibodies and IgG, by antigens attached to the surface of polystyrene.

❖Two different panels have been configured:

✓IgM Panel: 52 samples including 13 serum samples from patients with acute hepatitis and genotype-3 virus infection (confirmed by Immunoblot and molecular methods) and their serial dilutions 1:10, 1:100 and 1:1000.

✓IgG Panel: 40 samples including 10 serum samples from seroconversion-phase patients after acute infection and their serial dilutions 1:10, 1:100 and 1:1000.

❖These panels have been used to evaluate other screening methods (Wantai Biological Pharmacy, Euro-Immun Medizinische, MP biomedicals, Dia.Pro diagnostics bioprobes, DSI S.R.L., Saronno, Mikrogen GmbH Neuried and HEVTOP All Diag), which results have already been published[1].

RESULTS

❖Anti HEV-IgM: All tested specimens had positive results in undiluted specimens and in 1:10 and 1:100 dilutions, 77% (40/52) from the total.(Table 1)

❖Anti HEV-IgG: All tested specimens had positive results in undiluted samples and in 1:10 dilution. 7 of them also reached the 1:100 dilution. Of all, 77.5% samples were positive (31/40). (Table 2)

Table 1. IgM Panel (Anti HEV-IgM)

Samples (n=52)	52
Positive Results	40 (40/52)
-Sensitivity (undiluted samples)	100% (13/13)
-Sensitivity (all samples)	77% (40/52)
-Sensitivity (diluted 1:10)	100% (13/13)
-Sensitivity (diluted 1:100)	100% (13/13)
-Sensitivity (diluted 1:1000)	15% (2/13)

Table 2. IgG Panel (Anti HEV-IgG)

Samples (N=40)	40
Positive Results	31 (31/40)
-Sensitivity (undiluted samples):	100% (10/10)
-Sensitivity (all samples)	77,5%
-Sensitivity (diluted 1:10)	100% (10/10)
-Sensitivity (diluted 1:100)	70% (7/10)
-Sensitivity (diluted 1:1000)	40% (4/10)

CONCLUSIONS

❖ **Compared to other methods[1] The HEV-IgM VirClia® System has greater sensitivity and it is only exceeded by the DSI system.**

❖**The HEV-IgG VirClia® System has greater sensitivity with the exception of the Dia.pro system, which has the same sensitivity.**

❖ **The Chemiluminescence VIRCLIA® method is presented as a reliable serological method for the screening of acute infection by HEV in clinical specimens.**

REFERENCES

1-Avellón A et al. Comparative Sensitivity of Commercial Tests for Hepatitis E Genotype 3 Virus Antibody Detection. J. Med. Virol 2015;87:1934-9