

Diagnostic accuracy of a new commercially available HCV-antigen test

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Accuratezza diagnostica di un nuovo test commerciale per la ricerca di HCV-antigene

SUMMARY

Nowadays the diagnosis of HCV infection is based on the detection of anti-HCV antibodies (HCV-Ab) subsequently confirmed by a RIBA test and HCV-RNA test. A new chemiluminescence assay is now available allowing the detection of HCV antigen (HCV-Ag) (HCV-Ag, Abbott, USA®). The aim of the study was to investigate the diagnostic performances of this new test. We performed on 63 selected serum samples the following analyses: HCV-Ab, HCV-Ag, RIBA test and HCV-RNA.

For HCV-Ag vs HCV-RNA we found specificity of 95% and sensitivity of 100%.

Our study has highlighted the diagnostic accuracy of HCV-Ag test. This test does not require special equipments to be performed, so its strong specificity suggests its possible role in a rapid and low-cost new diagnostic protocol, particularly in a population with low incidence of HCV infection.

BACKGROUND

Hepatitis C virus (HCV) is a major public health issue and a leading cause of chronic liver disease. The World Health Organization (WHO, 2009) estimates that about 200 million people (about 3% of the world's population) are infected with HCV and 3 to 4 million persons are newly infected each year. Moreover, at least 85% of infected persons become chronically infected and about 70% develop chronic hepatitis.

The diagnosis of HCV infection in clinical practice, usually performed on asymptomatic patients, is carried out by detection of HCV antibodies (HCV-Ab) followed by confirmatory testing with additional HCV-Ab tests and/or HCV RNA detection (1). This procedure generate high numbers of false-positive results, increasing test time and costs per patient (2).

The aim of this study was to evaluate the role of HCV Ag assay (3) in a rapid and less-expensive diagnostic protocol (Figure 1).

MATERIALS AND METHODS

The study was carried out on 63 selected samples; among these patients, 14 samples showed a potential interfering factors such as Rheumatoid Factor, HBsAg, Syphilide, HIV, IgM Toxoplasmosi, IgM Citomegalovirus and Epstein Barr Virus (Table 1).

All samples serum were analyzed with:

- HCV-Ab by the automated assay on Abbott Architect Ci16200 analyzer (cut off ≥ 1.0 S/CO) [HCV-Ab, Abbott®, Diagnostic USA];
- HCV-Ag by the automated assay on Abbott Architect Ci16200 analyzer (cut off ≥ 0.2 pg/mL; sensitivity 0.06 pg/mL) [HCV-Ag, Abbott®, Diagnostic USA];
- HCV-RNA by TaqMan Cobas Roche analyzer (limit of detection 8.8 UI/mL) [TaqMan HCV Test, v 2.0 Roche® Molecular Systems, Branchburg, IL, USA];
- RIBA test (RIBA test Ortho Diagnostic, Raritan, NJ, USA).

All test were performed according manufacturer's recommendations.

RESULTS

HCV-Ag showed a specificity of 95% and a sensitivity of 100% with a predictive positive value (PPV) of was 92% and a predictive negative value (PNV) of 100%, compared to HCV-RNA

Moreover, HCV-Ab presents a specificity of 24% and a sensitivity of 100% with a PPV of 46% and a PNV of 100%,

compared to HCV-RNA (Table 2).

Table 1. Characteristics of potential interfering factors among anti-HCV negative samples.

POTENTIAL INTERFERING FACTORS	N° SAMPLES
Rheumatoid Factor	1
HbsAg_pos	6
IgM Toxoplasmosi	1
IgM Citomegalovirus	2
IgM Epstein Barr Virus	1
IgM Epstein Barr Virus and Citomegalovirus	1
HIV	1
HIV and Syphilis	1

Table 2. Results of HCV detection.

	Samples			
	25 (40%)	2 (3%)	27 (43%)	9 (14%)
HCV-RNA	+	-	-	-
HCV-Ag	+	+	-	-
HCV-Ab	+	+	+	-
RIBA test	+	Undet.	Undet.	Not avail.

CONCLUSIONS

In our study, we assessed the accuracy of HCV-Ag test for the diagnosis of HCV infection. Our preliminary data suggest that the HCV-Ag test is a rapid, less expensive and easy to perform assay. Combination of a high sensitive test (HCV-Ab) with a specific assay (HCV-Ag) could offer a rapid (less than one hour) and safe diagnostic protocol.

To reduce overestimation (false-positive) of HCV infection due to HCV-Ab, we propose to detect HCV-Ag in combination with HCV-Ab in all samples performed in routine clinical practice.

As suggested in Figure II, a patient with HCV-Ag-positive/HCV-Ab-negative is affected by an acute infection, so we can clarify the viral load by HCV RNA. On the other hand, in a patient with HCV-Ag-positive/HCV-Ab-positive we can conclude that it is a serological picture of HCV infection. In this case HCV RNA detection is useful to understand only the thorny cases, such as "grey-zone" reactivity.

This new diagnostic algorithm can reduce the molecular-biology investigation tests with a high cost-effectiveness.

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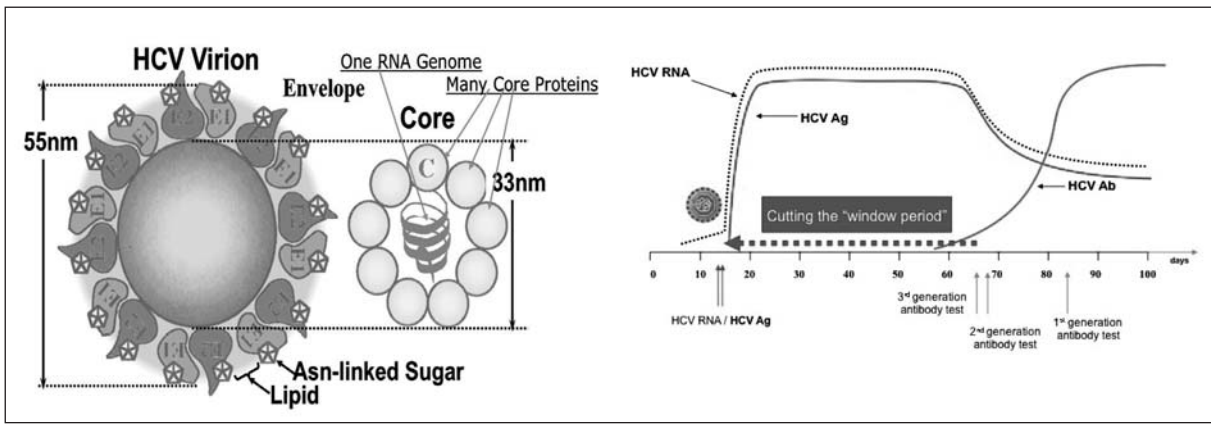


Figure I. HCV structure and the time course of markers during viral infection (by Abbott Diagnostics)

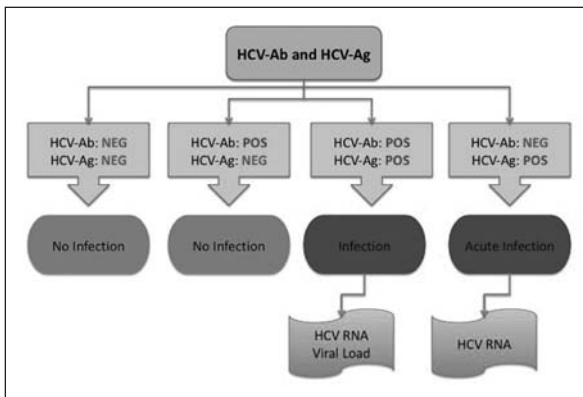


Figure II. The new diagnostic protocol.

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