

Feasibility of Measuring Hepatitis C Virus (HCV) Core Antigen to Monitor Success of Direct Acting Antiviral (DAA) Treatment of Hepatitis C

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BACKGROUND

- In light of recent advances in HCV therapy, simplification of diagnosis confirmation, pre-treatment diagnostic workup and treatment monitoring is required to ensure broad access to interferon-free therapies.
- HCV core antigen (HCVcAg) is a serologic marker of HCV infection highly concordant with HCV RNA testing, the current standard of care.
- The aim of this study was to determine percent agreement between HCVcAg test and HCV RNA in the monitoring of patients on DAA therapy in an ongoing HCV elimination program in the country of Georgia.

Figure 1.

HCV core Ag and HCV RNA Agreement in Pre-treatment Samples				
		HCV RNA		Total
		Positive	Negative	
HCV core Ag	Positive	414	0	414
	Negative	7	0	7
Total		421	0	421

Percent Agreement: 98.3%

METHODS

- A total of 976 samples were collected at Baseline, Week 4, End of Treatment (EOT), and 12 weeks post treatment by three provider clinics in Georgia.
- HCV RNA and genotype testing was conducted at the clinics.
- Specimens were tested with the ARCHITECT HCVcAg assay at National Center for Disease Control and Public Prevention.
- Percent agreement between HCVcAg and HCV RNA results was calculated based on qualitative results.

Figure 2.

HCV core Ag and HCV RNA Agreement in Week 4 Treatment Samples				
		HCV RNA		Total
		Positive	Negative	
HCV core Ag	Positive	1	13	14
	Negative	1	331	332
Total		2	344	346

Percent Agreement: 95.9%

RESULTS

- The agreement between HCVcAg and HCV RNA in the Pre-Treatment specimens was 98.3% (414/421) (Figure 1).
- The agreement between specimens from the 4 week monitoring point was 96.5% (334/346) (Figure 2).
- At EOT and 12 weeks post treatment, the agreement between HCVcAg and HCV RNA was 98.9% (186/188) (Figure 3) and 100% (21/21), respectively, (Figure 4).

Figure 3

HCV core Ag and HCV RNA Agreement in EOT Samples				
		HCV RNA		Total
		Positive	Negative	
HCV core Ag	Positive	1	1	2
	Negative	1	185	186
Total		2	186	188

Percent Agreement: 98.9%

Figure 4

HCV core Ag and HCV RNA Agreement in SVR Samples				
		HCV RNA		Total
		Positive	Negative	
HCV core Ag	Positive	2	0	2
	Negative	0	19	9
Total		2	19	21

Percent Agreement: 100%

CONCLUSIONS

- This study indicates high agreement ($\geq 98\%$) between HCVcAg and HCV RNA in the Pre-Treatment, EOT and 12 week post treatment specimens among patients treated with DAA.
- The observed pre-treatment agreement in this study is similar to those we reported previously.
- These data suggest that the HCVcAg can be used as an alternative to HCV RNA for monitoring the DAA treatment of hepatitis C with the potential to reduce the overall cost of diagnostics.

REFERENCES

- Cloherty G. et al., **Role of Serologic and Molecular Diagnostic Assays in Identification and Management of Hepatitis C Virus Infection.** J Clin Microbiol 54:000–000. doi:10.1128/JCM.02407-15

CONFLICTS OF INTEREST

- In relation to this presentation, I declare that there are no conflicts of interest, except G. Cloherty: Assc. Research Fellow, Volwiler Society; Head Infectious Disease Research. ABBOTT Diagnostics

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