

Independent Performance Evaluation

Comparative evaluation of Elecsys, Atellica, and Alinity assays for measuring the anti-Hepatitis C virus (HCV) antibody

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Why it matters

- Hepatitis C virus (HCV) infection is a major global health issue leading to cirrhosis, hepatocellular carcinoma, and liver-related mortality worldwide.
- Accurate detection of HCV infection is crucial for diagnosis and management.
- High-throughput, fully automated immunoanalyzers are essential for efficient and reliable HCV “screening.” This article reports the diagnostic performance of Atellica IM aHCV assay compared to Roche ELECSYS Anti-HCV II and Abbott ALINITY Anti-HCV assays.

What it covers

- Diagnostic performance evaluation of three qualitative anti-HCV assays—Atellica IM aHCV assay (Siemens Healthineers), ELECSYS Anti-HCV II assay (Roche), and ALINITY s Anti-HCV assay (Abbott)—for the serological detection of anti-HCV antibody.
- Frozen serum specimens (n = 1180) collected and submitted for HCV serological testing from January to May 2019 at a single center (Severance Hospital, Seoul) located in Korea, a country with an estimated HCV prevalence rate of 0.6–0.8%.
- Concordance rate, sensitivity, and PPV determined for each method.

*The primary source for all information presented in this document is the principal reference denoted here.

The highlights

- Atellica IM, ELECSYS, and ALINITY HCV antibody assays demonstrated good agreement (>95%). However, lower quantitative correlation was observed between the ELECSYS assay versus the Atellica IM and ALINITY assays (Table 1).
- Atellica IM and ALINITY assays had higher diagnostic sensitivities than the ELECSYS assay (Table 2), indicating potential for earlier disease detection.
- PPVs for Atellica IM and ALINITY assays were higher than for the ELECSYS assay (Table 2).

Table 1. Agreement[†] between Atellica IM aHCV and ELECSYS and ALINITY assays.

		Atellica IM aHCV					Atellica IM aHCV		
		Positive	Negative	Total			Positive	Negative	Total
ELECSYS anti-HCV	Positive	137	20	157	ALINITY s anti-HCV	Positive	158	7	165
	Negative	25	998	1023		Negative	4	1011	1015
	Total	162	1018	1180		Total	162	1018	1180
	Total Agreement	96.2% (1135/1180)				Total Agreement	99.1% (1169/1180)		

[†]True status of HCV infection was not determined using definitive reference method (RIBA) to resolve discordant results.

Table 2. Diagnostic sensitivity and PPV[‡] for HCV antibody assays tested.

	%Sensitivity (95% CI)	%PPV (95% CI)
ALINITY s	99.4 (96.63–99.98)	98.2 (94.58–99.41)
Atellica IM	97.5 (93.84–99.33)	98.1 (94.48–99.39)
ELECSYS	86.5 (80.28–91.34)	89.8 (84.37–93.50)

[‡]Calculated assuming the results of anti-HCV as “truly positive” if more than two systems designated the results as positive.

HCV: hepatitis C virus

anti-HCV: hepatitis C antibody

RIBA: recombinant immunoblot assay

PPV: positive predictive value

The “screening” term expressed throughout this paper represents solely the opinion of the authors and should not be attributed to Siemens Healthineers. Atellica IM aHCV assay reported by the authors has received FDA clearance or approval; however, it is not intended for use in general screening. This assay should be used as part of a broader diagnostic process, which includes additional serological and clinical information, to diagnose acute or chronic hepatitis C infection.

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