

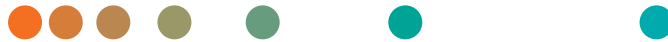
Independent Performance Evaluation

Comparison of high-throughput fully automated immunoanalyzers for detecting hepatitis B virus infection

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Archives of Pathology & Laboratory Medicine. 2020. doi: 10.5858/arpa.2019-0096-OA*

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Why it matters

- Hepatitis B virus (HBV) infection is a major global health issue leading to chronic hepatitis, cirrhosis, and hepatocellular carcinoma.
- Accurate detection of HBV infection is crucial for diagnosis and management.
- The CDC has newly recommended universal triple panel (HBsAg, anti-HBs, total anti-HBc) HBV serological testing in adults aged ≥ 18 years at least once during a lifetime to reduce U.S. HBV prevalence.¹
- High-throughput, fully automated immunoanalyzers are essential for efficient and reliable HBV “screening.” This article compares the performance of the Atellica, Abbott, and Roche assays for the detection of HBV infection.

What it covers

- Fresh serum specimens (n = 914–1055) collected and submitted for HBV serological testing from May to June 2018 at a single center (Severance Hospital, Seoul) located in Korea, a country with an HBV prevalence rate of 2–7%.
- Specimens tested on Atellica IM, Abbott ARCHITECT i2000, Abbott ALINITY i, and Roche COBAS e 801 analyzers for the serological detection of hepatitis B surface antigen (HBsAg), anti-hepatitis B surface antibody (anti-HBs), and total hepatitis B core antibody (anti-HBc).
- Concordance rate between the four tested methods.

Table 1. Hepatitis B assays evaluated for each analyzer.

Siemens Healthineers	Abbott		Roche
Atellica IM	ARCHITECT i2000	ALINITY i	COBAS e 801
HBsAgII	HBsAg Qualitative II	HBsAg Qualitative II	ELECSYS HBsAg II
aHBs2	Anti-HBs	Anti-HBs	ELECSYS Anti-HBs II
HBcT	Anti-HBc II	Anti-HBc II	ELECSYS Anti-HBc II

*The primary source for all information presented in this document, except reference 1, is the principal reference denoted here.

The highlights

- HBV serological tests on Roche COBAS, Atellica IM from Siemens Healthineers, Abbott ARCHITECT, and ALINITY analyzers performed well in comparison with each other.
- A high agreement rate (>90%) between each assay was observed.
- Atellica IM Analyzer showed total agreement ranging from 93.1% for anti-HBc with Abbott ALINITY analyzer to 99.3% for HBsAg with Abbott ARCHITECT analyzer (Table 2).
- Atellica IM Analyzer had lower anti-HBc–positive results compared to Abbott ARCHITECT and ALINITY analyzers, but the true status of HBV infection was not determined using a confirmatory method to resolve these discordant results. A negative HBsAgII assay result suggested that these samples were likely false positive on Abbott instruments.

Table 2. Agreement rate for Atellica IM analyzer.

Comparator Device	Atellica IM Total Agreement		
	HBsAg	Anti-HBs	Anti-HBc
Abbott ARCHITECT	99.3%	93.9%	93.5%
Abbott ALINITY	98.7%	94.1%	93.1%
Roche COBAS	94.3%	NA†	98.6%
	n = 932	n = 914	n = 1055

†Anti-HBs not performed on COBAS analyzer.

HBV: hepatitis B virus

HBsAg: hepatitis B surface antigen

aHBs2: anti-hepatitis B surface antigen 2

anti-HBc: hepatitis B core total antibody

anti-HBs: hepatitis B surface antibody

The “screening” term expressed throughout this paper represents solely the opinion of the authors and should not be attributed to Siemens Healthineers. All Atellica IM assays from Siemens Healthineers reported by the authors have received FDA clearance or approval. However, they are not intended for use in general screening. These assays should be used as part of a broader diagnostic process, which includes additional serological and clinical information, to diagnose acute or chronic hepatitis B infection.

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Reference:

1. Conners EE, et al. Screening and testing for hepatitis B virus infection: CDC recommendations - United States, 2023. MMWR Morb Mortal Wkly Rep. 2023;72(RR-1):1-25. doi: <http://dx.doi.org/10.15585/mmwr.rr7201a1>

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Published by

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