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Evaluation of the Analytical Performance of the Total Antibodies to Hepatitis B Core Antigen Assay on the Atellica CI Analyzer

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Background

Hepatitis B virus (HBV) causes major liver disease and despite widespread vaccination, HBV infection, often asymptomatic, remains a global health issue. Serological detection of HBV biomarkers, including total antibodies (IgM and IgG) to hepatitis B core antigen (HBc) is recommended as a first step to assess current or past exposure to HBV. Anti-HBc assays are also part of a triple serological panel (HBsAg, hepatitis B surface antigen; anti-HBs, antibody to HBsAg; anti-HBc total) recommended for routine testing by Centers for Disease Control and Prevention (CDC) in all adults aged ≥18 years at least once during a lifetime to identify most people living with HBV infection, reduce HBV prevalence and support the goal of worldwide viral hepatitis eradication.[1]

The Atellica IM HBc Total 2 (HBcT2) assay was previously developed and commercialized for use on the Atellica IM Analyzer.[2] This assay allows the qualitative determination of total antibodies (IgM and IgG) to the core antigen of the HBV. The previous version of this assay was modified to eliminate the equivocal result zone, reducing the retest need. Results are reported using Index values and samples are classified as reactive (Index value ≥1.00) or nonreactive (Index value <1.00) based on the clinically established 1.00 Index cutoff.

For over three years, the Atellica CI Analyzer (Figure 1) has been part of the Atellica Solution portfolio, offering a reduced footprint of 1.9 square meters. It is an integrated clinical chemistry and immunoassay analyzer designed for low- to mid-volume laboratories and features the same reagents,*consumables,* and sophisticated user interface as the Atellica IM Analyzer.[3]

To evaluate the analytical performance of the Atellica IM assays using this recent analyzer, precision and method comparison (MC) were assessed as performance indicators for the Atellica IM HBcT2 assay on the Atellica CI Analyzer.

Figure 1. The Atellica CI Analyzer

Material and Methods

Precision (CLSI EP05-A3)

- Sample types: pooled and contrived native human serum samples, and quality control (QC) sample.
- One aliquot/sample; tested in duplicate; two runs/day >2 hours apart for 20 days.
- One reagent lot; two analyzers; total n = 80 replicates for each system/lot combination.
- One representative system/lot combination result across all lot and system combinations tested is shown (Table 1).
- Each testing day, new frozen aliquots were thawed and used for each run. Calibrators and QC materials were handled according to the manufacturer's instructions; two calibration events for 20-day-precision study.

Method comparison (CLSI EP12-A2)

- MC was evaluated using individual native serum samples stored frozen in aliquots at ≤-20°C. Samples were thawed and centrifugated before tested on the Atellica CI Analyzer, the ADVIA Centaur XP system (parent analyzer), and the Atellica IM Analyzer using three reagent lots.
- Samples (n=200) were acquired from Siemens approved vendors from HBV positive individuals and negative normal individuals.
- MC was completed over 4 days using a single calibration event.
- One representative system/lot combination result across all lot and system combinations tested is presented (Table 2).
- One replicate processed per sample.
- Samples were classified, using 1.00 Index cutoff, as reactive (Index ≥1.00) or nonreactive (Index <1.00) specimens for the presence of antibodies to Hepatitis B core antigen.
- Negative, positive, and overall agreement are reported and were calculated as followed:

		Atellica IM (or ADVIA Centaur XP) Result	
		Reactive	Nonreactive
Atellica CI Result	Reactive	A	B
	Nonreactive	C	D

Positive percent agreement = 100 × A / (A + C)

Negative percent agreement = 100 × D / (B + D)

Overall Percent Agreement = 100 × (A + D) / (A + B + C + D)

Results

Precision

Table 1. Precision for the Atellica IM HBcT2 assay on the Atellica CI Analyzer

Specimen Type	Mean (n=80) (Index)	Repeatability		Within-laboratory Precision	
		SD (Index)	CV (%)	SD (Index)	CV (%)
Serum A	0.30	0.003	n/a	0.016	n/a
Serum B	0.70	0.035	n/a	0.044	n/a
Serum C	1.56	0.057	3.7	0.098	6.3
Serum D	3.19	0.100	3.1	0.219	6.9
Serum E	8.52	0.396	4.6	0.772	9.1
QC 1	0.29	0.030	n/a	0.035	n/a
QC 2	2.65	0.108	4.1	0.208	7.8

**Not applicable, n/a. The results remained nonreactive throughout the study.*

The Atellica IM HBcT2 assay on the Atellica CI Analyzer demonstrated ≤4.6% repeatability CV and ≤9.1% within-laboratory precision CV across the sample interval.

Method Comparison

Table 2. Qualitative method comparison for the Atellica IM HBcT2 assay on the Atellica IM and Atellica CI Analyzers

		Atellica IM HBcT2 on the Atellica IM Analyzer		
		Reactive	Nonreactive	Total
Atellica IM HBcT2 on the Atellica CI Analyzer	Reactive	100	0	100
	Nonreactive	0	100	100
	Total	100	100	200

Positive percent agreement: 100% (100/100); 95% confidence interval: 96.30–100%

Negative percent agreement: 100% (100/100); 95% confidence interval: 96.30–100%

Overall percent agreement: 100% (200/200); 95% confidence interval: 98.20–100%

The design requirements for method comparison were met with 100% negative and 100% positive agreement when comparing the Atellica IM HBcT2 assay using the Atellica CI Analyzer to the Atellica IM Analyzer. Identical agreement results were obtained when comparing the Atellica IM HBcT2 assay using the Atellica CI Analyzer to the ADVIA Centaur HBcT2 assay using the ADVIA Centaur XP system. No discordant results were observed between the compared devices.

Additionally, a similar method comparison study was conducted between two Atellica CI Analyzers using one reagent lot. One was equipped with Sample Handler (SH, full automation with track integrated, part of Atellica Integrated Automation) and the other was configured with Rack Handler (RH, direct load for standalone analyzer). Negative percent agreement was 100% (95% CI, 96.50–100%) for the 106 nonreactive samples tested. Positive percent agreement was 99.1% (95% CI, 95.03–99.84%) for the 110 HBcT2 reactive. One borderline sample which was a contrived sample, resulted at 0.99 Index (nonreactive) with SH and 1.00 Index (reactive) with RH. These findings demonstrated that the two sample handling options offered on the Atellica CI Analyzer were equivalent.

Conclusion

All results indicate that the Atellica IM HBcT2 assay demonstrated comparable analytical performance for the serological determination of total anti-HB core antibodies when tested on the Atellica CI Analyzer. In addition, strong qualitative agreement was observed between the assay on the Atellica CI Analyzer and the Atellica IM Analyzer. Altogether, these results support that the Atellica CI Analyzer has comparable performance capability to the Atellica IM Analyzer.

References

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Not yet commercially available in the United States.

**The products/features mentioned here are not commercially available in all countries. Their future availability cannot be guaranteed.*

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