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Analytical Performance Evaluation of the Hepatitis A Total Antibodies Assay on the Atellica CI Analyzer

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Background

Hepatitis A infection, caused by the hepatitis A virus (HAV), is part of viral hepatitis global health concern. Transmission typically occurs through the fecal-oral route, either via direct person-to-person contact or through the consumption of contaminated food or water. Although most HAV infections result in lifelong immunity or can be prevented through vaccination, a small percentage of cases still lead to hepatic complications and fatalities worldwide. To diagnose HAV infection, clinical laboratories rely on serological testing, which detect serum immunoglobulin IgM and/or IgG antibodies specific to HAV (anti-HAV).[1]

The Atellica IM Hepatitis A Total (HAVT) assay was previously developed and commercialized for use on the Atellica IM Analyzer.[2] This assay allows the qualitative determination of total anti-HAV (IgM and IgG) in human neonatal, pediatric, and adult serum and plasma (EDTA, lithium heparin, and sodium heparin). Samples are classified as reactive (≥1.00 Index) or nonreactive (<1.00 Index) based on a clinically verified 1.00 Index cutoff for anti-HAV serum. This anti-HAV assay is indicated as an aid in the diagnosis of previous or ongoing hepatitis A viral infection or in the identification of HAV-susceptible individuals for vaccination.

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 the Atellica CI Analyzer, precision and method comparison (MC) were assessed as performance indicators for the Atellica IM HAVT assay.

Figure 1. The Atellica CI Analyzer

Material and Methods

Precision (CLSI EP05-A3)

- Sample types: native and pooled 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 human serum samples tested on the Atellica CI Analyzer, the ADVIA Centaur XP system (parent analyzer), and the Atellica IM Analyzer using three reagent lots.
- MC was completed in at least 3 nonconsecutive 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 as reactive (≥1.00 Index) or nonreactive (<1.00 Index) based on the 1.00 Index cutoff equivalent to 20 mIU/mL when standardized to the World Health Organization (WHO) Second International Reference Standard for Anti-Hepatitis Immunoglobulin (97/646). However, assay results cannot be considered quantitative and no clinical claims for immunity can be determined from the cut-off value.
- 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 HAVT assay on the Atellica CI Analyzer

Specimen Type	Mean (n=80) (Index)	Repeatability		Within-laboratory Precision	
		SD (Index)	CV (%)	SD (Index)	CV (%)
Serum	0.74	0.047	6.4	0.060	8.1
Serum	1.23	0.037	3.0	0.049	4.0
Serum	1.47	0.043	2.9	0.055	3.7
Serum	2.21	0.040	1.8	0.060	2.7
Serum	2.96	0.066	2.2	0.093	3.1
Serum	4.00	0.053	1.3	0.080	2.0
Positive QC	1.96	0.055	2.8	0.062	3.2

The Atellica IM HAVT assay on the Atellica CI Analyzer demonstrated ≤6.4% repeatability CV and ≤8.1% within-laboratory precision CV across the sample interval.

Method Comparison

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

1.00 Index Cutoff		Atellica IM HAVT on the Atellica IM Analyzer		
		Reactive	Nonreactive	Total
Atellica IM HAVT on the Atellica CI Analyzer	Reactive	176	1	177
	Nonreactive	0	110	110
	Total	176	111	287

Positive percent agreement: 100% (176/176); 95% confidence interval: 97.86–100%
Negative percent agreement: 99.10% (110/111); 95% confidence interval: 95.07–99.84%
Overall agreement: 99.65% (286/287); 95% confidence interval: 98.05–99.94%

The design requirements for method comparison were met for the HAVT assay. One discordant sample was a borderline sample resulting at 1.03 Index (reactive) on Atellica CI, and at 0.96 Index (nonreactive) on Atellica IM. Similar percent agreement results were obtained when comparing the Atellica IM HAVT assay using the Atellica CI Analyzer to the ADVIA Centaur HAVT assay using the ADVIA Centaur XP system (negative percent agreement = 98.18% (95% CI, 93.61–99.50; n = 110), and positive percent agreement = 98.80% (95% CI, 95.71–99.67; n = 166).

Conclusion

All results indicate that the Atellica IM HAVT assay demonstrated comparable analytical performance for the serological determination of total anti-HAV 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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**The products/features mentioned here are not commercially available in all countries. Their future availability cannot be guaranteed.*

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