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Analytical Performance Evaluation of the HIV Antigen/Antibody Combo Assay on the Atellica CI Analyzer

B. Belth, B. Healy, N. Riverso, G. Arrode-Bruses, H. Leipold
Siemens Healthcare Diagnostics Inc., Tarrytown, NY, U.S.

Background

Testing for human immunodeficiency virus (HIV) is essential for early detection and timely linkage to care, which are integral components of the global commitment to maintaining low HIV incidence.[1,2]

Combined HIV antigen/antibody tests, known as "fourth generation", assay can detect HIV p24 antigen and antibodies to HIV-1 and HIV-2, including group M and group O infections. These serological assays are recommended for assessing HIV infection as they offer enhanced detection of acute/early infection, which might be missed by antibody-only tests.[3]

The Atellica IM HIV Ag/Ab Combo (CHIV) assay was previously developed and commercialized for use on the Atellica IM Analyzer.[4]

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.[5]

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 CHIV assay on the Atellica CI Analyzer.

Figure 1. The Atellica CI Analyzer

Material and Methods

Assay design

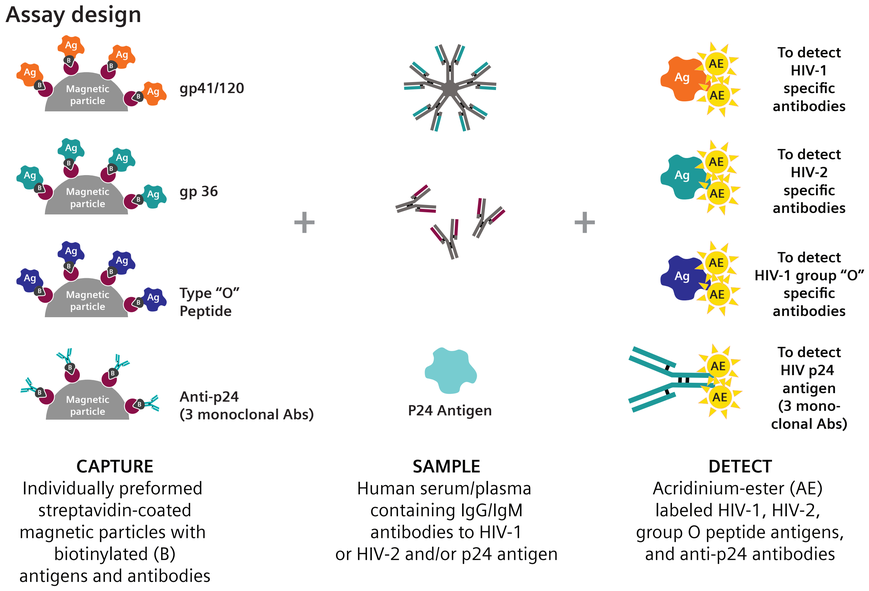

Figure 2. CHIV Combo Assay Antigen/Antibody Sandwich Format

Precision (CLSI EP05-A3)

- Sample types: native and contrived human serum pools spiked with individual human HIV-positive serum samples, and quality control (QC) samples (detailed in Table 1).
- 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 two reagent lots.
- Samples (n=215) were acquired from Siemens approved vendors from HIV-1 positive individuals and negative normal individuals.
- MC was completed over 6 nonconsecutive days using a single calibration event.
- One representative system/lot combination result across all lot and system combinations tested is presented (Table 2 & 3).
- One replicate was 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 HIV-1 (including group "O") and/or HIV-2 and/or p24 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 CHIV assay on the Atellica CI Analyzer

Specimen Type	Mean (n=80) (Index)	Repeatability		Within-laboratory Precision	
		SD (Index)	CV (%)	SD (Index)	CV (%)
Serum A	0.16	0.012	7.5*	0.014	8.8*
Serum B	0.72	0.026	3.6	0.030	4.2
Serum C	1.17	0.038	3.2	0.042	3.6
Serum D	1.48	0.023	1.6	0.045	3.0
Serum E	2.76	0.060	2.2	0.157	5.7
Serum F	2.93	0.068	2.3	0.123	4.2
Serum G	3.38	0.069	2.0	0.107	3.2
Serum H	4.92	0.077	1.6	0.152	3.1
Serum I	4.92	0.079	1.6	0.180	3.7
QC 1	0.26	0.015	5.8*	0.016	6.2*
QC 2	2.41	0.038	1.6	0.089	3.7
QC 3	2.94	0.046	1.6	0.083	2.8
QC 4	3.07	0.052	1.7	0.140	4.6
QC 5	4.99	0.097	1.9	0.120	2.4

**For information only, highest %CVs observed in samples without the analyte do not have any clinical impact as there was no change in the qualitative interpretation across all 80 negative sample results that remained nonreactive throughout the study. Serum A, Negative serum; Serum B, HIV-1 high-negative; Serum C, HIV-1 positive; Serum D, HIV-2 positive; Serum E, HIV-1 Group O positive; Serum F, HIV-p24 positive; Serum G, HIV-2 positive; Serum H, HIV-1 positive; Serum I, HIV-p24 positive. Processed human plasma nonreactive for HIV (QC 1), reactive for HIV-1 (QC 2), reactive for HIV-2 (QC 3), reactive for HIV-1 Group O (QC 4), and reactive for HIV-1 p24 antigen (QC 5).*

The Atellica IM CHIV assay on the Atellica CI Analyzer demonstrated ≤7.5% repeatability CV and ≤8.8% within-laboratory precision CV across the sample interval tested (0.16–4.99 Index).

Method Comparison

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

1.00 Index Cutoff		Atellica IM CHIV on the Atellica IM Analyzer		
		Reactive	Nonreactive	Total
Atellica IM CHIV on the Atellica CI Analyzer	Reactive	105	0	105
	Nonreactive	0	110	110
	Total	105	110	215

Positive percent agreement: 100% (105/105);
95% confidence interval: 96.47–100%
Negative percent agreement: 100% (110/110);
95% confidence interval: 96.95–100%
Overall agreement: 100% (215/215);
95% confidence interval: 98.25–100%

Table 3. Qualitative method comparison for the CHIV assay on the Atellica CI Analyzer and ADVIA Centaur XP system

1.00 Index Cutoff		ADVIA Centaur CHIV on the ADVIA Centaur XP system		
		Reactive	Nonreactive	Total
Atellica IM CHIV on the Atellica CI Analyzer	Reactive	104	0	104
	Nonreactive	0	109	109
	Total	104	109	213

Positive percent agreement: 100% (104/104);
95% confidence interval: 96.44–100%
Negative percent agreement: 100% (109/109);
95% confidence interval: 96.60–100%
Overall agreement: 100% (213/213);
95% confidence interval: 98.23–100%

Two samples out of the 215 above mentioned samples could not be evaluated on Centaur XP system due to insufficient volume.

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

Conclusion

All results indicate that the Atellica IM CHIV assay demonstrated comparable analytical performance for the serological determination of antibodies to HIV-1 (including group "O") and/or HIV-2 and/or p24 antigen 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

1. World Health Organization. Consolidated guidelines on HIV testing services. https://www.who.int/publications/i/item/978-92-4-155058-1 (Accessed on March 04, 2025).
2. Centers for Disease Control and Prevention. Estimated HIV Incidence and Prevalence in the United States, 2018–2022. HIV Surveillance Supplemental Report 2024; 29 (No. 1). Published May 2024. https://stacks.cdc.gov/view/cdc/156513 (Accessed on March 04, 2025).
3. N. W. Anderson and B. A. Parikh. The Diagnosis of HIV: Right Test, Right Interpretation, Right Away. Clinical Microbiology Newsletter, Article vol. 41, no. 22, pp. 193-202, 2019. doi: 10.1016/j.clinmicnews.2019.11.001.
4. HIV Ag/Ab Combo (CHIV) assay. Atellica IM Analyzer. 10996984_EN Rev. 04, 2024-02.
5. Technical specifications. Atellica CI Analyzer. CLS-23-3123-76. QR700003930. 12-2023.

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

Data/some data first presented at Worldlab IFCC 2025.

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