Analytical Performance of Two Tumor Marker Immunoassays on the Atellica CI 1900 Analyzer

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Abstract

Background: The Atellica® CI 1900 Analyzer is an automated, high-throughput, integrated chemistry and immunoassay analyzer utilizing both Atellica® IM and Atellica® CH assays. This study was designed to evaluate the analytical performance of the Atellica CI Carcinogenic Biomarker Antigen (CEA)* and Alpha Fetoprotein (AFP) assays† on the Atellica CI 1900 Analyzer.

Methods: The Atellica CI 1900 Analyzer uses the same reagents and calibrators as the Atellica IM Analyzer. Precision and method comparison (MC) were used as performance indicators for the Atellica CI 1900 Analyzer. Precision studies were performed according to CLSI EP07-A3 using quality control, native, and contrived human serum samples. One aliquot of each sample pool was tested in duplicate in two runs per day for a total of 400 measurements per lot. For the CEA assay, six samples were tested for 6 days, two runs per day, five replicates per run, on one analyzer for a total of 306 measurements per lot. Method comparison studies were performed using a Deming regression model as indicated in Table 2.

Results: Representative precision and MC results observed for each assay across indicated sample ranges are listed in the table. Slopes determined by the Deming linear regression model were approximately equal to 1.

<table>
<thead>
<tr>
<th>Specification</th>
<th>CEA Assay</th>
<th>AFP Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproducibility</td>
<td>1.5–2.5</td>
<td>2.0–2.5</td>
</tr>
<tr>
<td>Within-laboratory precision</td>
<td>2.0–6.0</td>
<td>2.0–6.0</td>
</tr>
</tbody>
</table>

Conclusions: Evaluation of the CEA and AFP assays using the Atellica CI 1900 Analyzer demonstrated good precision and equivalent performance compared to the same assays on the Atellica IM Analyzer.

Background

Quantitative measurement of CEA and AFP in serum samples is performed in clinical laboratories to aid in the management of cancer patients in conjunction with physical examination, histology/pathology, and other clinical evaluation procedures.

Previous studies have assessed and commercialized for use on the Atellica IM Analyzer: the Carcinogenic Biomarker Antigen (CEA)* and Alpha Fetoprotein (AFP) assay†.

Recently, the Atellica CI 1900 Analyzer† (Figure 1) was added to the Atellica Solution portfolio, with a reduced footprint of 1.9 square meters. It is an integrated clinical chemistry and immunoassay analyzer designed for high- to mid-volume laboratories and features the same reagents,* consumables,* and sophisticated user interface as the Atellica IM Analyzer. The Atellica IM CEA and AFP assays on the Atellica CI 1900 Analyzer demonstrate ≤3.6% repeatability CV and ≤5.5% within-laboratory precision CV across the intervals indicated in Table 2.

To evaluate the analytical performance of the Atellica IM assays using this new analyzer, precision, method comparison, limit of quantitation (LoQ), and linearity studies were assessed as performance indicators for the Atellica IM CEA and AFP assays on the Atellica CI 1900 Analyzer.

Material and Methods

Precision evaluation was performed according to CLSI EP07-A3. Two runs were performed each day for 20 nonconsecutive days, with a minimum of 2 hours between runs. Samples were tested in duplicate, producing a total of n = 80 replicates for each system/lot combination. For each assay, one representative system/lot combination result across all lot and system combinations tested is shown in Table 3.

The Atellica IM CEA and AFP assays on the Atellica CI 1900 Analyzer demonstrated ≤3.6% repeatability CV and ≤5.5% within-laboratory precision CV across the sample interval.

Table 2. Method comparison for the Atellica IM CEA and AFP assays on the Atellica IM and Atellica CI 1900 Analyzers

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Assay</th>
<th>Reproducibility</th>
<th>Within-laboratory precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>CEA</td>
<td>1.5–2.5</td>
<td>2.0–6.0</td>
</tr>
<tr>
<td>Serum</td>
<td>AFP</td>
<td>1.5–2.5</td>
<td>2.0–6.0</td>
</tr>
</tbody>
</table>

Method Comparison

The design requirements for method comparison were met for the CEA and AFP assays. When analyzed by weighted Deming regression, each Atellica IM assay on the Atellica CI 1900 Analyzer recovered samples spanning the measuring interval, with a slope of 1.00 ± 0.10 and a correlation coefficient (r) ≥ 0.950 (CEA) and ≥ 0.980 (AFP) compared to the Atellica IM Analyzer.

Weighted Deming fit and percent difference plots on the Atellica CI 1900 Analyzer for samples ranges indicated in Table 2 are shown in Figure 2 for CEA (A) and AFP (B) assays.

Figure 2. Weighted Deming linear regression and difference plots for the Atellica IM CEA (A) and AFP (B) assays on the Atellica CI 1900 Analyzer

Conclusions

All results indicate that the Atellica IM CEA and AFP assays demonstrated analytical performance capable of measuring CEA and AFP in serum with good accuracy and precision when run on the Atellica CI 1900 Analyzer. In addition, good concordance was observed between the assays on the Atellica CI 1900 Analyzer and the Atellica IM Analyzer. Overall, these results support that the Atellica CI 1900 Analyzer when using the Atellica IM CEA and AFP assays, has performance capability comparable to the Atellica IM Analyzer as a low- to mid-volume integrated clinical chemistry and immunoassay analyzer.

References

1. Carcinogenic Biomarker Antigen (CEA) assay. Atellica IM Analyzer: 19995222; Rev. 06, 2009. 2022-10
2. Alpha Fetoprotein (AFP) assay. Atellica IM Analyzer: 19992672; Rev. 06, 2010-09.
4. The products/technologies/encompassed are not commercially available in all countries. Future availability cannot be guaranteed.
5. Atellica IM/CI 1900 Analyzer is not available for use on the Atellica CI 1900 Analyzer for pending 510(k) clearance.
6. Future availability cannot be guaranteed.
7. Atellica IM/CH/CEA/CEP/CH/CEP/IM 1900 Analyzers are potential products of the respective systems.
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Published by Siemens Healthcare Diagnostics Inc.
CLS-12756-EN 07/2023
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