Analytical Performance Evaluation of Assays Used for Iron Studies on the Atellica® CI 1900 Analyzer


Abstract

Background: The Atellica CI 1900 Analyzer is an automated, mid-throughput, integrated chemistry and immunoassay analyzer employing both Atellica CH and Atellica IM Assays. This study was designed to evaluate the analytical performance of the Atellica CH Iron_2, TIBC, Total Iron Binding Capacity (TIBC), and Trf (Trf) Assays and the Atellica IM Ferritin (Fer) Assay on the Atellica CI 1900 Analyzer.

Methods: The Atellica CI 1900 Analyzer uses the same reagents and calibrators as the Atellica CH 930 and the Atellica IM 1600 Analyzers. Precision and method comparison (MC) were used as performance indicators for the Atellica CI 1900 Analyzer. Precision studies were performed according to CLSI EP03-A3 using native and controls human serum samples. One aliquot of each sample was tested in duplicate in two runs per day, 24 hours apart on each analyzer for 120 days. MC studies were performed according to CLSI EP03-A3 Native and historical human samples were analyzed using the Atellica CH Iron_2, TIBC, and Trf Assays on both the Atellica CH 930 and Atellica CI 1900 Analyzers. For Fer, native and controls human samples were analyzed using the Atellica IM Fer Assay on the Atellica IM 1600 and Atellica CI 1900 Analyzers.

Results: Representative precision and MC results for each assay are listed in the Table. For the four assays tested, repeatability and within-lab SD were ≤5.5% and ≤4.5%, respectively. Slopes determined by the Deming linear regression model were approximately equal to 1.

Background

Quantitative measurement of Iron_2, TIBC, Trf, and Fer in serum samples is routinely performed in clinical laboratories to assess overall iron status. These measurements are used in the diagnosis and treatment of multiple disorders such as anemias, red blood cell dyserythropoiesis, hemochromatosis, and viral hepatitis infection.

Previously, four quantitative assays were developed and commercialized for use on the Atellica Analyzers: the Atellica CH Iron_2, TIBC, Total Iron Binding Capacity (TIBC), Transferrin (Trf) Assays, and the Atellica IM Ferritin (Fer) Assay.

Recently, the Atellica CI 1900 Analyzer 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 low- to mid-throughput laboratories.

Figure 1. The Atellica CI 1900 Analyzer brings the power and possibility of the central lab to clinical laboratories of all sizes.

Material and Methods

Precision evaluation was performed according to CLSI EP03-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. Precision studies included two calibration events per assay.

For linearity studies, the linear intervals for the Atellica CH Iron_2, TIBC, and Trf Assays and the Atellica IM Fer Assay were established on the Atellica CI 1900 Analyzer according to CLSI EP60-E22. High and low analytic samples, prepared from native patient samples, were mixed in various proportions to create a minimum of nine concentrations (Table 4) and assayed for each analytic using three reagent lots.

Results

Analytical Performance Evaluation of Assays Used for Iron Studies on the Atellica® CI 1900 Analyzer

Table 3. LoQ for the Atellica CH Iron_2, TIBC, and Trf Assays, and the Atellica IM Fer Assay on the Atellica CI 1900 Analyzer

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Assay</th>
<th># of Sample Combinations Tested</th>
<th>Linearity Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Iron_2</td>
<td>2</td>
<td>y = 0.98x + 5 μg/dL</td>
</tr>
<tr>
<td>Serum</td>
<td>TIBC</td>
<td>2</td>
<td>y = 0.98x + 5 μg/dL</td>
</tr>
<tr>
<td>Serum</td>
<td>Trf</td>
<td>2</td>
<td>y = 0.98x + 5 μg/dL</td>
</tr>
<tr>
<td>Serum</td>
<td>Fer</td>
<td>2</td>
<td>y = 0.98x + 5 μg/dL</td>
</tr>
</tbody>
</table>

The Atellica CH Iron_2 Assay on the Atellica CI 1900 Analyzer demonstrated ≤6.8% repeatability CV and ≤10.7% within-laboratory precision CV across the sample interval.

The Atellica CH TIBC Assay on the Atellica CI 1900 Analyzer demonstrated ≤0.9% repeatability CV and ≤2.4% within-laboratory precision CV across the sample interval.

The Atellica CH Trf Assay on the Atellica CI 1900 Analyzer demonstrated ≤0.3% repeatability CV and ≤1.1% within-laboratory precision CV across the sample interval.

The Atellica IM Fer Assay on the Atellica CI 1900 Analyzer demonstrated ≤3.2% repeatability CV and ≤4.3% within-laboratory precision CV across the sample interval.

Conclusions

All results indicate that the Atellica CH Iron_2, TIBC, and Trf Assays and the Atellica IM Fer Assay demonstrated analytical performance capable of measuring Iron_2, TIBC, and Fer in serum with good accuracy and precision when run on the Atellica CI 1900 Analyzer. Additionally, good concordance was observed between the assays on the Atellica CH 930 and the Atellica IM 1600 Analyzers, depending on the analyte tested. Altogether, these results support that the Atellica CI 1900 Analyzer has performance capability comparable to the Atellica CH and Atellica IM Analyzers as a low- to mid-throughput integrated clinical chemistry and immunoassay analyzer.

References

1. Iron_2 Assay. Atellica Analyzer. 11:01/04 (EN_300), 2019-06.
2. Total Iron Binding Capacity (TIBC) assay. Atellica Analyzer. 11:01/04 (EN_300), 2019-06.
3. Transferrin Assay. Atellica Analyzer. 11:01/04 (EN_300), 2019-06.
4. Ferritin Assay. Atellica Analyzer. 10:01/04 (EN_300), 2019-06.