Analytical Performance Evaluation of Four General Chemistry Assays on the Atellica CI 1900 Analyzer Used to Assess Kidney Function


Abstract

Background: The Atellica CI 1900 Analyzer is an automated, mid-throughput, integrated chemistry and immunoassay analyzer utilizing both Atellica CH and Atellica IA Assays. This study was designed to evaluate the analytical performance of the Atellica CH Creatinine (CREA_2), Enzymatic Creatinine (ECre_3), Urinary/Cerebrospinal Fluid Protein (UCFP), and Microalbumin (µALB_2) Assays on the Atellica CI 1900 Analyzer.

Methods: The Atellica CI 1900 Analyzer uses the same reagents and calibrators as the Atellica CH Analyzer. Precision and method comparison (MC) were used as performance indicators for the Atellica CI 1900 Analyzer. Precision studies were performed according to CLSI EP05-A3 using naive and conformed human urine samples. One aliquot of each sample pool was tested in duplicate in two runs per day for 2 hours on each analyzer for 20 days. MC studies were performed according to CLSI EP09-A3. Individual naive and conformed human urine samples were analyzed using the Atellica CH assays on both the Atellica CH and Atellica CI 1900 Analyzers.

Results: Representative precision and MC results derived from one reagent lot across indicated sample ranges are listed for each assay in the Table below. For the four assays tested, repeatability and within-lab %CVs were <5.1% and ≤10%, respectively. Slopes determined by Deming regression model were approximately equal to 1.

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Assay</th>
<th>Total Repeatability for Data Analysis</th>
<th>Lowest Concentration with Acceptable TE</th>
<th>LoQ Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine 1</td>
<td>CREA_2</td>
<td>0.47 mg/dL</td>
<td>3.0 mg/dL</td>
<td></td>
</tr>
<tr>
<td>Urine 2</td>
<td>CREA_2</td>
<td>0.50 mg/dL</td>
<td>3.0 mg/dL</td>
<td></td>
</tr>
<tr>
<td>Urine 1</td>
<td>UCFP</td>
<td>0.60 mg/dL</td>
<td>6.0 mg/dL</td>
<td></td>
</tr>
<tr>
<td>Urine 2</td>
<td>UCFP</td>
<td>0.2 mg/dL</td>
<td>0.3 mg/dL</td>
<td>LoQ reference</td>
</tr>
</tbody>
</table>

Although the concentrations of CREA_2, ECre_3 and UCFP at 20% MV were less than the LoQ design requirement goals for the Atellica CI 1900, the LoQs reported represent the design goal levels of 3.0 mg/dL (CREA_2), 2.0 mg/dL (ECre_3), and 0.6 mg/dL (UCFP).

For the µALB_2 assay, the LoQ is below design requirement goal for LoB and LoD so only LoB and LoD detection capability at 0.3 mg/dL is reported.

Conclusions

All tests indicate that the Atellica CH CREA_2, ECre_3, UCFP and µALB_2 Assays demonstrated analytical performance capable of measuring CREA_2, ECre_3, UCFP and µALB_2 in urine with good accuracy and precision when run on the Atellica CI 1900. In addition, good concordance was observed between the assays on the Atellica CI 1900 Analyzer and the Atellica CH Analyzer. Altogether, these results support that the Atellica CI 1900 when using the Atellica CH CREA_2, ECre_3, UCFP and µALB_2 Assays has performance capability comparable to the Atellica CH Analyzer as a low- to mid-volume integrated clinical chemistry and immunoassay analyzer.

References
