Analytical Performance Evaluation of Assays Measuring Acetaminophen and Ethanol on the Atellica CI 1900 Analyzer


Abstract

Background: The Atellica CI 1900 Analyzer is a new mid-volume method-comparability automated analyzer designed to provide mid-volume laboratories with an accurate and precise alternative to existing chemistry analyzers. The system features the same reagents, consumables, and user interface as the Atellica CH 930 Analyzer. The design requirements for method comparison were met for Ethyl Alcohol (ETOH) and Acetaminophen (Acet) assays.

Material and Methods

Precision evaluation was performed according to CLSI EP06-ED2. High and low analyte samples, prepared from native and spiked patient samples, were included for each run. For each assay, one representative system/lot combination result across all lot and system combinations tested is shown. For linearity studies, the Linear Interval (LI) for ETOH and Acet CH assays were established on the Atellica CI 1900 Analyzer according to CLSI EP06-D3. High and low analytic samples, prepared from native and spiked patient samples, were analyzed in various concentrations to create nine concentrations and assayed for each assay using three reagent lots (Table 4).

Results

Precision Table 1. Precision for the Atellica CH ETOH and Acet assays on the Atellica CI 1900 Analyzer

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Assay</th>
<th>Replicates</th>
<th>Mean (mg/dL)</th>
<th>Reproducibility</th>
<th>Within-laboratory Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum QC</td>
<td>ETOH</td>
<td>80</td>
<td>93.5</td>
<td>1.14</td>
<td>1.2</td>
</tr>
<tr>
<td>Serum QC</td>
<td>Acet</td>
<td>80</td>
<td>83.5</td>
<td>1.14</td>
<td>1.2</td>
</tr>
</tbody>
</table>

The Atellica CI ETOH assay on the Atellica CI 1900 Analyzer demonstrated good precision and equivalent performance compared to the Atellica CH 930 Analyzer. In addition, good precision and equivalent performance compared to the same assays on the Atellica CH 930 Analyzer.

Conclusions

All results indicate that the Atellica CH ETOH and Acet assays demonstrated analytical performance capable of measuring ETOH and Acet in serum with good accuracy and precision when run on the Atellica CH 930 Analyzer. In addition, good concordance was observed between the assays on the Atellica CI 1900 Analyzer and the Atellica CH 930 Analyzer. Additionally, these results suggest that the Atellica CH 930 Analyzer has performance capability comparable to the Atellica CH 930 Analyzer as a low to mid-volume integrated chemistry and immunoassay analyzer.

References

5. The products/features mentioned herein are not commercially available in all countries. Their/their availability cannot be guaranteed.

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