Evaluation of the Performance of the TnI-Ultra Assay on the ADVIA CENTAUR® CP System

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Abstract

Objective: To evaluate the analytical performance of the TnI-Ultra assay on the ADVIA Centaur CP, a new immunoassay system that uses the same reagents and consumables as the ADVIA Centaur immunoassay system.

Materials and Methods

Precision - Assay precision was evaluated over two weeks on repeated measurements using calibrators and control materials. Within-run and total precision are expressed as % coefficients of variation (CV).

Minimum detectable concentration - MDC was estimated by calculating the concentration corresponding to the zero-dose line with two within-run standard deviations determined by running 20 replicates of the zero-Ultra standard.

Correlation - Correlation was evaluated by method comparison to the ADVIA Centaur TnI-Ultra assay using 137 lithium heparin plasma and serum samples covering the majority of TnI range.

Results:

The ADVIA Centaur CP TnI-Ultra assay exhibited minimum detectable concentration, determined by running 20 replicates of zero dose, was 0.04 ng/mL, for the ADVIA Centaur CP TnI-Ultra. The 99th percentile is 0.04 ng/mL, and we demonstrated a 10% CV at 0.03 ng/mL. The ADVIA Centaur and CP TnI-Ultra methods were compared over the dynamic range of the assay for serum and for plasma. Both serum and plasma behaved similarly, and together yielded the following linear regression relationship: ADVIA Centaur CP TnI-Ultra = 1.06 (ADVIA Centaur TnI-Ultra) - 0.015 or r = 0.999, n = 137.

Conclusion: We conclude that the ADVIA Centaur CP TnI-Ultra assay demonstrates good analytical performance and meets the precision performance criteria recommended by the joint European Society of Cardiology American College of Cardiology Committee for the Redefinition of Myocardial Infarction.

Introduction

Because physicians depend on quantitative cut-points in the diagnosis of Myocardial Infarction, the precision of Tropin assays is critical as it plays a large part in the accuracy of the result. Results obtained with recently released next generation Tropin assays show substantial improvement in the analytical performance. A Tnl-Ultra assay was developed for the ADVIA Centaur analyzer to meet the new guidelines from the European Society of Cardiology and the American College of Cardiology. The precision or total % CV at 0.01 ng/mL of a normal population should be less or equal to 10%.

The purpose of this study was to evaluate the analytical performance of the Tnl-Ultra assay on the ADVIA Centaur CP analyzer, a new immunoassay system that uses the same reagents and consumables as the ADVIA Centaur immunoassay system.

Results

Imprecision

<table>
<thead>
<tr>
<th>Product</th>
<th># Days</th>
<th># Runs</th>
<th># Reps</th>
<th>Mean (ng/mL)</th>
<th>SD</th>
<th>CV</th>
<th>SD</th>
<th>CV</th>
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</thead>
<tbody>
<tr>
<td>Cardiac Marker 1</td>
<td>12</td>
<td>12</td>
<td>43</td>
<td>0.19</td>
<td>0.04</td>
<td>4.0</td>
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<td>Cardiac Marker 2</td>
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<td>12</td>
<td>45</td>
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<td>3.5</td>
<td>0.03</td>
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<tr>
<td>Cardiac Marker 3</td>
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<td>12</td>
<td>43</td>
<td>26.43</td>
<td>0.54</td>
<td>2.0</td>
<td>0.77</td>
<td>2.6</td>
</tr>
</tbody>
</table>

Within-run Total

Minimum Detectable Concentration:

The minimum detectable dose (MDC) was calculated based on the mean plus 2 times the standard deviation of the zero level calibrator. The MDC was found to be 0.006 ng/mL for the ADVIA Centaur CP TnI-Ultra assay.

Reference range

The 95th percentile was established for Centaur using 648 healthy donors and was validated on CP and demonstrated 0.04 ng/mL as target. The potential range of results is 0.02 to 0.06 ng/mL.

Conclusions

- Within-run and total precision were < 10 % CV for low concentration control materials (0.01 ng/mL). The high precision or total % CV at 0.01 ng/mL of a normal population should be less or equal to 15%.
- The clinical performance of the ADVIA Centaur CP TnI-Ultra assay demonstrated good correlation with the ADVIA Centaur TnI-Ultra assay.
- Both plasma and serum samples can be used for routine determination.
- The ADVIA Centaur CP TnI-Ultra assay demonstrates good analytical performance and meets the performance criteria required for its utilization in the clinical laboratory.