Performance Evaluation of the High Sensitivity Cardiac Troponin I Assay* on the ADVIA Centaur XP/XPT Immunoassay Systems

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Background
High-sensitivity troponin I assays characterized by high precision and accuracy improve the diagnostic accuracy for acute myocardial infarction. The use of absolute value changes, or “deltas,” to measure the change in cTnI concentration at 1 or 2 hours after presentation to the emergency department, when used in conjunction with other diagnostic information, may reliably rule out AMI and identify non-ST-elevated individuals whose cTnI values are below the 99th percentile at presentation but who are having an AMI.1,4

Methods

Principle of the Assay

Figure 1. The ADVIA Centaur TNIH immunoassay format.

The ADVIA Centaur® TNIH assay* is a dual-capture sandwich immunoassay using magnetic latex particles and a proprietary acridinium ester (tri-sulfo propyl acridinium ester) for chemiluminescence detection. The dual-capture monoclonal antibodies and detection recombinant Fab have Kd <10^-13. Sample is incubated with the capture magnetic latex particles and a proprietary acridinium ester (tri-sulfo propyl acridinium ester) conjugate. The ADVIA Centaur TNIH immunoassay format.

Precision

Table 1. The lower limit of reportable results for the ADVIA Centaur TNIH assay is defined as the LoQ in the U.S. LoD is in common use outside the U.S.

<table>
<thead>
<tr>
<th>LoB (pg/mL)</th>
<th>LoD (pg/mL)</th>
<th>LoQ (pg/mL) Dose at 20% CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.32</td>
<td>1.18</td>
<td>not calculated</td>
</tr>
<tr>
<td>0.51</td>
<td>1.24</td>
<td>not calculated</td>
</tr>
<tr>
<td>0.14</td>
<td>0.58</td>
<td>not calculated</td>
</tr>
<tr>
<td>≥2, ≥3</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

LoB, LoD, and LoQ

- **LoB**: Determined nonparametrically by rank order, two reagent lots, n = 160
- **LoD**: Ten low cTnI from normal serum
- **ClSI protocol EP-17-A2**
- **CLSI protocol EP6-A**
- **CLSI protocol EP5-A3**

Linearity

- **ClSI protocol EP6-A**
- **ClSI protocol EP7-A2**
- **Eight proteins tested**

Repeatability

- **Within-lab precision** is ≤3.0% at the estimated 99th percentile.
- **Repeatability** is ≤2.6%, and within-lab precision is ≤3.0% at the estimated 99th percentile.

Lot Reproducibility

- **Normal samples** having measurable cTnI values above the estimated LoDs.
- **Overall within-lab precision** is ≤3.0% at the estimated 99th percentile.

Conclusions

- **Excellent precision** was demonstrated across multiple ADVIA Centaur Immunoassay Systems and reagent lots. The repeatability and within-lab precision at the estimated 99th percentile were <3%.
- **Linearity** was demonstrated over the low and full assay range.
- **No significant cross-reactivity** to eight muscle proteins was observed.
- **LoQ** as defined by functional sensitivity was 1.32 pg/mL.
- **LoD** values of 0.58, 1.18, and 1.24 pg/mL were obtained for each of three reagent lots tested.
- **The estimated 99th percentile** was 38 pg/mL, with approximately 80 to 95% of the normal samples having measurable cTnI values above the estimated LoDs.
- The precision and accuracy of the Siemens ADVIA Centaur TNIH assay will support the measurement of cTnI changes for the early diagnosis of AMI.

References


*Under development. Not available for sale. Product availability will vary by country.

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