LOCI Cardiac Troponin I Assay Specifications
LOCI Troponin I Assay on the Dimension EXL and Dimension Vista Systems

Meeting the Standards for Better Cardiac Care

Use of a sensitive cardiac troponin (cTn) assay facilitates expeditious detection and assessment of change—important in the differentiation of an acute myocardial infarction (AMI) related to myocardial ischemia from other causes of myocardial necrosis. The 99th percentile of a normal population is recommended by the NACB/IFCC as the value above which a troponin level is considered elevated. Troponin assays should have a total imprecision (%CV) of ≤10% at the 99th percentile of the reference population.1,2

A third universal definition of myocardial infarction was published in 2012 by the joint European Society of Cardiology/American College of Cardiology Foundation/American Heart Association/World Heart Federation (ESC/ACCF/AHA/WHF) that integrates new knowledge and takes into account that a very small degree of myocardial injury or necrosis can be detected by cardiac troponin and/or imaging.3

The introduction of troponin assays with improved sensitivity has increased the number of chest-pain patients presenting at admission with cTn values exceeding the 99th percentile as a result of causes other than AMI. This complicates the appropriate triage of patients.4,5,6 To assist with such triage, assessing cTn kinetics with serial testing should be used in the clinical evaluation of chest-pain patients. A fast-track rule-out protocol (3 hours instead of 6 hours), recommended by the European Society of Cardiology in the 2011 guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation, advises cardiac troponin measurement at admission and then 3 hours after the time of presentation.7,8

The LOCI® Cardiac Troponin I assay on the Dimension® EXL™ and Dimension Vista® systems meets this standard of performance for accurate and rapid results required for timely AMI diagnosis.

Analytical Benefits
• Reduces the risk of interference and increases accuracy with a low sample volume
• Improves laboratory workflow with same tube Troponin testing with other STAT chemistry assays

Clinical Benefits
• Allows for earlier detection by meeting the guidelines criterion for ≤10%CV at the 99th percentile. Unique oxygen channeling technology provides greater precision and low background signal with minimal noise improves sensitivity
• Supports rapid triage of chest-pain patients and improves acute care workflow between serial measurements (6h reduced to 3h protocols)* with a time to first result in 12 minutes or less

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### LOCI Cardiac Troponin I Performance Summary

<table>
<thead>
<tr>
<th>Dimension EXL</th>
<th>Dimension Vista</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Type</td>
<td>Serum, Plasma (Na or Li Heparin)</td>
</tr>
<tr>
<td>Sample Volume</td>
<td>20 µL</td>
</tr>
<tr>
<td>Assay Range</td>
<td>17–40,000 ng/L (pg/mL)</td>
</tr>
<tr>
<td>Time to First Result</td>
<td>11 minutes</td>
</tr>
<tr>
<td>On-board Stability</td>
<td>Sealed on-board (at 2-8° C): 30 days</td>
</tr>
<tr>
<td>Open well stability</td>
<td>3 days</td>
</tr>
<tr>
<td>Calibration Interval</td>
<td>21 days</td>
</tr>
<tr>
<td>Dilution</td>
<td>Manual dilution – 1:5</td>
</tr>
<tr>
<td>Limit of Detection</td>
<td>17 ng/L (pg/mL)</td>
</tr>
<tr>
<td>10% CV (Limit of Quantitation)</td>
<td>50 ng/L (pg/mL)</td>
</tr>
<tr>
<td>99th Percentile</td>
<td>56 ng/L (pg/mL)</td>
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</tbody>
</table>

**References:**

8. Mueller C. Sensitive cardiac troponin I in the distinction of acute myocardial infarction from acute cardiac non-coronary artery disease, to be published in 2014 (APACE Study).

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