ADVIA Centaur
High-Sensitivity Troponin I Assay

Key Benefits

• Offer improved cardiac patient care with a true high-sensitivity troponin I assay that meets the current guideline recommendations.1-3

• Have confidence in patient results at the low end of the assay range with precision that provides the ability to measure slight, yet critical, changes between serial troponin I values.

• Ensure reliable results from a proven, trusted technology coupled with three new monoclonal antibodies.

Assay Description

The Siemens Healthineers ADVIA Centaur TNIH assay is a 3-site sandwich immunoassay using direct chemiluminometric technology. The solid phase reagent is magnetic latex particles conjugated with streptavidin with two bound biotinylated capture monoclonal antibodies each recognizing a unique cTnI epitope. The lite reagent comprises a conjugate whose architecture consists of a proprietary acridinium ester and a recombinant anti-human cTnI sheep Fab covalently attached to bovine serum albumin (BSA) for chemiluminescent detection. The accumulated light signal is directly related to the sample cTnI concentration.

• Siemens Healthineers ADVIA Centaur TNIH assay utilizes recombinant ahu cTnI antibody fragment attached to BSA carrier with multiple TSPAE (trisulfopropyl AE), to achieve low assay interference and signal amplification (signal/binding event), respectively.

• The new TNIH assay delivers approximately 10-fold improved low-end precision and sensitivity in part due to this new high efficiency Acridinium Ester and conjugate architecture.

Intended Use

The ADVIA Centaur® High-Sensitivity Troponin I (TNIH) assay is for in vitro diagnostic use in the quantitative measurement of cardiac troponin I in human serum or plasma using the ADVIA Centaur® XP and ADVIA Centaur® XPT systems. The assay can be used to aid in the diagnosis of acute myocardial infarction (AMI).
ADVIA Centaur High-Sensitivity Troponin I Assay

Performance Summary

<table>
<thead>
<tr>
<th>System</th>
<th>Sample Type</th>
<th>Sample Volume</th>
<th>Assay Range</th>
<th>LoB (20% CV)</th>
<th>LoD (10% CV)</th>
<th>LoQ (20% CV)</th>
<th>LoQ (10% CV)</th>
<th>Onboard Stability</th>
<th>Time to First Result</th>
<th>99th percentile (n=2010)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADVIA Centaur XP/XPT</td>
<td>Human serum, plasma (lithium heparin)</td>
<td>100 μL</td>
<td>2.50–25,000.00 ng/L (pg/mL)</td>
<td>0.5 ng/L (pg/mL)</td>
<td>1.6 ng/L (pg/mL)</td>
<td>2.5 ng/L (pg/mL)</td>
<td>6.0 ng/L (pg/mL)</td>
<td>28 days</td>
<td>18 min</td>
<td>Combined: 47.34 ng/L (pg/mL)* Male: 57.27 ng/L (pg/mL) Female: 36.99 ng/L (pg/mL)</td>
</tr>
</tbody>
</table>

*99th percentile value determined using combined gender data and lithium heparin sample type.

ADVIA Centaur XP and XPT TNIIH Precision Curve

Ordering Information

<table>
<thead>
<tr>
<th>System</th>
<th>SMN No.</th>
<th>Tests per</th>
<th>Contents</th>
</tr>
</thead>
</table>
| ADVIA Centaur XP/XPT | 10994774 | 100       | • 1 ReadyPack®<sup>*</sup>  
• 1 Vial High/Low Calibrator  
• ADVIA Centaur TNIIH Master Curve Card  
• ADVIA Centaur TNIIH Calibrator Assigned Value Card and barcode labels |
|                | 10994775 | 500       | • 5 ReadyPacks  
• 2 Vials High/Low Calibrator  
• ADVIA Centaur TNIIH Master Curve Card  
• ADVIA Centaur TNIIH Calibrator Assigned Value Card and barcode labels |
|                | 10994776 |           | • ADVIA Centaur TNIIH Master Curve  
Material 5 x 1.0 mL  
• ADVIA Centaur MCM lot-specific value sheet |

ADVIA Centaur, and all associated marks are trademarks of Siemens Healthcare Diagnostics Inc., or its affiliates. All other trademarks and brands are the property of their respective owners.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

References: