ADVIA Centaur Immunoassay System

High-Sensitivity Troponin I Assay

siemens-healthineers.com/TNIH

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/XPT Immunoassay Systems. The assay can be used to aid in the diagnosis of acute myocardial infarction (AMI).

Assay Description
The Siemens Healthineers ADVIA Centaur TNIH Assay is a three-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 antihuman 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 offers a proven, true high-sensitivity cardiac troponin I assay with fast, accurate, and actionable test results:

- Demonstrates clinical proof that the ADVIA Centaur High-Sensitivity Troponin I Assay is a true high-sensitivity troponin I assay according to the IFCC guidelines.¹
- Offers fast, accurate, and actionable results that enable use of faster protocols.
- Provides confidence in results due to high tolerance to common interferents:

<table>
<thead>
<tr>
<th>Hemolysis visible at naked eye</th>
<th>Biotin (ng/mL) supplementation level</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10% bias</td>
<td>&lt;10% bias</td>
</tr>
<tr>
<td>500 mg/dL Hb</td>
<td>3500 ng/mL</td>
</tr>
</tbody>
</table>
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</th>
<th>LoD</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 pg/mL (ng/L)</td>
<td>0.50 pg/mL (ng/L)</td>
<td>1.60 pg/mL (ng/L)</td>
<td>2.50 pg/mL (ng/L)</td>
<td>6.0 pg/mL (ng/L)</td>
<td>28 days 18 min</td>
<td>Combined: 47.34 pg/mL (ng/L)* Male: 57.27 pg/mL (ng/L) Female: 36.99 pg/mL (ng/L)</td>
<td></td>
</tr>
</tbody>
</table>

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

ADVIA Centaur XP and XPT TNIH Assay Precision Curve

Ordering Information

<table>
<thead>
<tr>
<th>System</th>
<th>SMN No.</th>
<th>Tests per Kit</th>
<th>Contents</th>
</tr>
</thead>
</table>
| ADVIA Centaur XP/XPT | 10994774     | 100           | • 1 ReadyPack®  
• 1 vial High/Low Calibrator  
• ADVIA Centaur TNIH Master Curve Card  
• ADVIA Centaur TNIH Calibrator Assigned Value Card and bar-code labels |
| 10994775   | 500           |               | • 5 ReadyPacks  
• 2 vials High/Low Calibrator  
• ADVIA Centaur TNIH Master Curve Card  
• ADVIA Centaur TNIH Calibrator Assigned Value Card and bar-code labels |
| 10994776   |               |               | • ADVIA Centaur TNIH Master Curve Material, 5 x 1.0 mL  
• ADVIA Centaur MCM lot-specific value sheet |

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

Reference:

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