

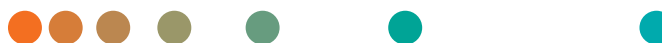


## ADVIA Centaur Immunoassay System

# High-Sensitivity Troponin I Assay



[siemens-healthineers.com/TNIH](https://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.<sup>1</sup>
- Offers fast, accurate, and actionable results that enable use of faster protocols.
- Provides confidence in results due to high tolerance to common interferents:

#### ADVIA Centaur TNIH

Hemolysis visible at naked eye	Biotin (ng/mL) supplementation level
<10% bias 500 mg/dL Hb	<10% bias 3500 ng/mL

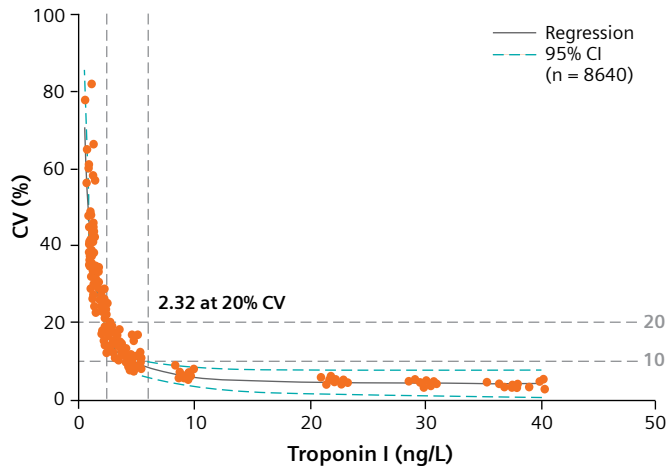
# ADVIA Centaur High-Sensitivity Troponin I Assay

## Performance Summary

System	Sample Type	Sample Volume	Assay Range	LoB	LoD	LoQ (20% CV)	LoQ (10% CV)	Onboard Stability	Time to First Result	99th percentile (n = 2010)
ADVIA Centaur XP/XPT	Human serum, plasma (lithium heparin)	100 µL	2.50–25,000.00 pg/mL (ng/L)	0.50 pg/mL (ng/L)	1.60 pg/mL (ng/L)	2.50 pg/mL (ng/L)	6.0 pg/mL (ng/L)	28 days	18 min	Combined: 47.34 pg/mL (ng/L)* Male: 57.27 pg/mL (ng/L) Female: 36.99 pg/mL (ng/L)

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

## ADVIA Centaur XP and XPT TNIH Assay Precision Curve



## Ordering Information

System	SMN No.	Tests per Kit	Contents
ADVIA Centaur XP/XPT	10994774	100	<ul style="list-style-type: none"> <li>• 1 ReadyPack®</li> <li>• 1 vial High/Low Calibrator</li> <li>• ADVIA Centaur TNIH Master Curve Card</li> <li>• ADVIA Centaur TNIH Calibrator Assigned Value Card and bar-code labels</li> </ul>
	10994775	500	<ul style="list-style-type: none"> <li>• 5 ReadyPacks</li> <li>• 2 vials High/Low Calibrator</li> <li>• ADVIA Centaur TNIH Master Curve Card</li> <li>• ADVIA Centaur TNIH Calibrator Assigned Value Card and bar-code labels</li> </ul>
	10994776		<ul style="list-style-type: none"> <li>• ADVIA Centaur TNIH Master Curve Material, 5 x 1.0 mL</li> <li>• ADVIA Centaur MCM lot-specific value sheet</li> </ul>

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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:

1. Apple F, Sandoval Y, Jaffe A, Ordonez-Llanos J. Cardiac troponin assays: guide to understanding analytical characteristics and their impact on clinical care. Report of the IFCC Task Force on Clinical Applications of Cardiac Bio-Markers. Clinical Chemistry. 2016 Oct 10;63(1):73-81.

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