



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 TSPAЕ (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).

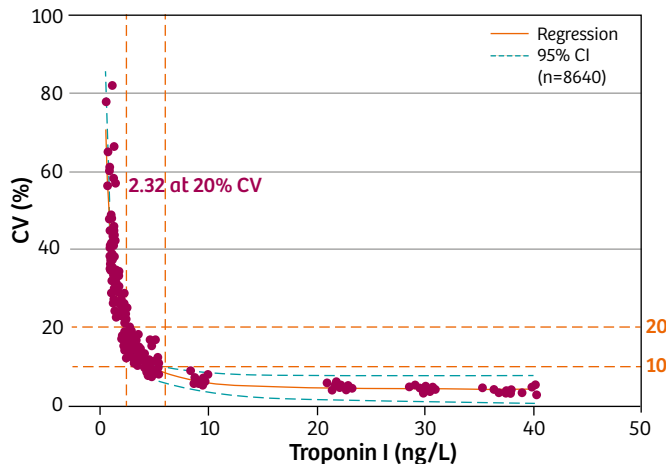
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Performance Summary

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 ng/L (pg/mL)	0.5 ng/L (pg/mL)	1.6 ng/L (pg/mL)	2.5 ng/L (pg/mL)	6.0 ng/L (pg/mL)	28 days	18 min	Combined: 47.34 ng/L (pg/mL)* Male: 57.27 ng/L (pg/mL) Female: 36.99 ng/L (pg/mL)

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

ADVIA Centaur XP and XPT TNIH Precision Curve



Ordering Information

System	SMN No.	Tests per	Contents
ADVIA Centaur XP/XPT	10994774	100	<ul style="list-style-type: none"> 1 ReadyPack® 1 Vial High/Low Calibrator ADVIA Centaur TNIH Master Curve Card ADVIA Centaur TNIH Calibrator Assigned Value Card and barcode labels
	10994775	500	<ul style="list-style-type: none"> 5 ReadyPacks 2 Vials High/Low Calibrator ADVIA Centaur TNIH Master Curve Card ADVIA Centaur TNIH Calibrator Assigned Value Card and barcode labels
	10994776		<ul style="list-style-type: none"> 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.

References:

1. Roffi M, et al./Task Force. Eur Heart J. 2015 ;37:267-315.
2. Amsterdam EA, et al. Circulation. 2014 ;130 :e344-426.
3. Apple FS, et al. Clin Biochem. 2015 ;48 :201-3.

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