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 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 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).

*Not available for sale in the U.S. Product availability may vary from country to country and is subject to varying regulatory requirements.

siemens.com/TNIH

SIEMENS Healthineers

ADVIA Centaur High-Sensitivity Troponin I Assay

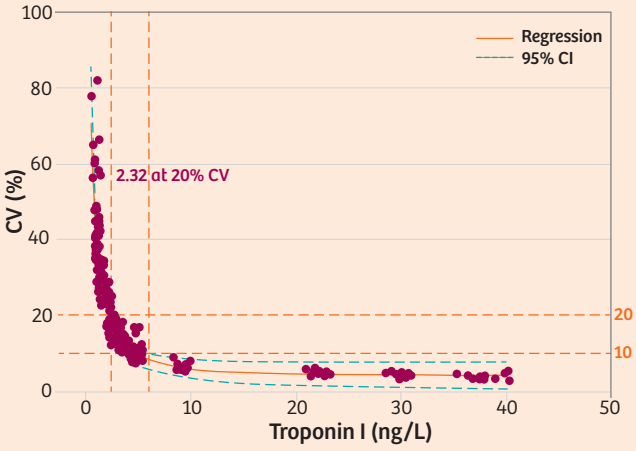
Performance Summary

ADVIA Centaur XP/XPT Systems	
Sample type	Human serum, plasma (lithium heparin)
Sample volume	100 µL
Assay range	2.50–25,000.00 pg/mL (ng/L)
Time to first result	18 minutes
Throughput	Up to 240 tests/hour
On-board stability	28 days
LoB	0.90 pg/mL (ng/L)
LoD	2.21 pg/mL (ng/L)
LoQ (20% CV)	2.50 pg/mL (ng/L)
LOQ (10% CV)	4.50 pg/mL (ng/L)
99th percentile (n=2010)	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.

Assay Precision

ADVIA Centaur XP and XPT TNIH Precision Curve (n=8640)



Ordering Information

Catalog No.	Contents	Quantity
10994774	1 ReadyPack 1 Vial High/Low Calibrator ADVIA Centaur TNIH Master Curve Card ADVIA Centaur TNIH Calibrator Assigned Value Card and barcode labels	100
10994775	5 ReadyPacks 2 Vials High/Low Calibrator ADVIA Centaur TNIH Master Curve Card ADVIA Centaur TNIH Calibrator Assigned Value Card and barcode labels	500
10994776	ADVIA Centaur TNIH Master Curve Material 5 x 1.0 mL ADVIA Centaur MCM lot-specific value sheet	

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.

Siemens Healthineers Headquarters
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany
Phone: +49 9131 84 0
siemens.com/healthineers

Local Contact Information
Siemens Healthcare Diagnostics Inc.
Laboratory Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591-5005
USA
Phone: +1 914-631-8000
siemens.com/healthineers

Order No. A91DX-CAI-170016-XC1-4A00 | 04-2017 | © Siemens Healthcare Diagnostics Inc., 2017