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Atellica Solution

Cardiac Assays

Cardiovascular disease (CVD) is caused by disorders of the heart and blood vessels and includes coronary heart disease (heart attacks), cerebrovascular disease (stroke), elevated blood pressure (hypertension), peripheral artery disease, rheumatic heart disease, congenital heart disease, and heart failure. The major causes of cardiovascular disease are tobacco use, physical inactivity, an unhealthy diet, and harmful use of alcohol. According to the WHO (World Health Organization), CVDs are the number-one cause of death globally; more people die annually from CVDs than from any other cause. The burden of cardiovascular disease, if left unchecked, will continue to affect global financial and health care systems.¹ Help clinicians manage patients throughout the continuum of cardiovascular disease with the Atellica® Solution's expanding menu of cardiac tests.



Immunoassay

- BNP
- CKMB
- High-Sensitivity Troponin I
- Myoglobin
- NT-proBNP
- TnI-Ultra™

- Provides improved cardiac patient care with a true high-sensitivity troponin I assay that meets the current guideline recommendations.^{2,3}
- Gives your clinicians the power to choose NT-proBNP and BNP by expanding your B-type natriuretic peptides menu on the Atellica® IM System.
- Delivers fast, accurate, and reliable cardiac results that you and your clinicians can trust.

The Atellica Solution provides a broad and expanding menu to help your lab drive better clinical and business outcomes. The Atellica® IM Analyzer utilizes proven Advanced Acridinium Ester (AE) technology, with over 50 patents granted or pending.

Product availability may vary by country.

Assay Characteristics

Assay	Specimen Type	Sample Volume (µL)	Time To First Result (min)	Measuring Interval	Detection Capabilities	Reagent Onboard Stability (days)	Lot Calibration Interval (days)
BNP	EDTA plasma	100	10	2.0–5000.0 pg/mL (0.58–1445.00 pmol/L)	LoB 1.1 pg/mL LoD 2.4 pg/mL	48	61
CKMB	Serum, heparinized plasma	100	10	0.18–300.00 ng/mL (0.002–3.75 nmol/L)	LoB 0.13 ng/mL LoD 0.31 ng/mL	28	66
High-Sensitivity Troponin I	Serum, lithium heparin plasma	100	10	2.51–25,000.00 pg/mL	LoB 0.58 pg/mL LoD 1.27 pg/mL LoQ 2.51 pg/mL	31	47
Myoglobin	Serum, heparinized plasma	10	10	3.00–1000.00 ng/mL	LoB 2.56 ng/mL LoD 3.57 ng/mL	28	33
NT-proBNP	Serum, dipotassium EDTA plasma, lithium heparin plasma	20	14	35–35,000 pg/mL (4.13–4130 pmol/L)	LoB 13 pg/mL LoD 20 pg/mL LoQ 18 pg/mL	28	41
TnI-Ultra	Serum, EDTA plasma, heparinized plasma	100	10	0.006–30.000 ng/mL (µg/L)	LoB 0.007 ng/mL LoD 0.015 ng/mL Functional Sensitivity 0.015 ng/mL (µg/L)	28	66

Tables of Method Comparison Equations

Assay	Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N	r
BNP	EDTA Plasma	ADVIA Centaur® BNP	$y = 0.965x - 0.316$ pg/mL ($y = 0.965x - 0.091$ pmol/L)	2.6 - 4962.8 pg/mL (0.75 - 1434.25 pmol/L)	177	0.997
CKMB	Serum	ADVIA Centaur CKMB	$y = 1.03x + 0.25$ ng/mL ($y = 1.03x + 0.003$ nmol/L)	0.24 - 278.40 ng/mL (0.003 - 3.48 nmol/L)	122	1.000
Myoglobin	Serum	ADVIA Centaur Myoglobin	$y = 0.96x + 2.80$ ng/mL (µg/L)	13.79 - 975.67 ng/mL (µg/L)	104	1.000
NT-proBNP	Serum	ADVIA Centaur PBNP	$y = 1.07x + 10$ pg/mL ($y = 1.07x + 1.18$ pmol/L)	42 - 34,977 pg/mL (4.96 - 4127 pmol/L)	140	1.000
TnI-Ultra	Serum	ADVIA Centaur TnI-Ultra	$y = 0.97x + 0.023$ ng/mL (µg/L)	0.007 - 29.60 ng/mL (µg/L)	151	0.99
	Lithium Heparin	ADVIA Centaur TnI-Ultra	$y = 1.05x + 0.022$ ng/mL (µg/L)	0.013 - 28.8 ng/mL (µg/L)	156	0.99

Ordering Information

BNP	SMN No.	Tests per Kit	Contents
Atellica IM BNP	10995471	100	1 Atellica IM BNP ReadyPack® primary reagent pack
Atellica IM BNP	10995472	500	5 Atellica IM BNP ReadyPack primary reagent packs
Atellica IM BNP CAL	10995473		2 x 2.0 mL low calibrator 2 x 2.0 mL high calibrator

CKMB	SMN No.	Tests per Kit	Contents
Atellica IM CKMB	10995530	100	1 Atellica IM CKMB ReadyPack primary reagent pack
Atellica IM CKMB	10995531	500	5 Atellica IM CKMB ReadyPack primary reagent packs
Atellica IM CKMB CAL	10995532		2 x 2.0 mL low calibrator 2 x 2.0 mL high calibrator

High Sensitivity Troponin I	SMN No.	Tests per Kit	Contents
Atellica IM TnIH	10997840	100	1 Atellica IM TnIH ReadyPack primary reagent pack 1 vial Atellica IM TnIH CAL low-calibrator 1 vial Atellica IM TnIH CAL high calibrator
Atellica IM TnIH	10997841	500	5 Atellica IM TnIH ReadyPack primary reagent packs 2 vials Atellica IM TnIH CAL low-calibrators 2 vials Atellica IM TnIH CAL high calibrators

Myoglobin	SMN No.	Tests per Kit	Contents
Atellica IM MYO	10995649	50	1 Atellica IM MYO ReadyPack primary reagent pack
Atellica IM MYO	10995648	250	5 Atellica IM MYO ReadyPack primary reagent packs
Atellica IM CAL U	10995519		2 x 2.0 mL low calibrator 2 x 2.0 mL high calibrator

NT-proBNP	SMN No.	Tests per Kit	Contents
Atellica IM PBNP	11200588	100	1 Atellica IM PBNP ReadyPack primary reagent pack 1 vial Atellica IM PBNP CAL low calibrator 1 vial Atellica IM PBNP CAL high calibrator
Atellica IM PBNP	11200589	500	5 Atellica IM PBNP ReadyPack primary reagent packs 2 vials Atellica IM PBNP CAL low calibrator 2 vials Atellica IM PBNP CAL high calibrator

TnI-Ultra	SMN No.	Tests per Kit	Contents
Atellica IM TnI-Ultra	10995696	100	1 Atellica IM TnI-Ultra ReadyPack primary reagent pack 1 vial lyophilized low calibrator 1 vial lyophilized high calibrator
Atellica IM TnI-Ultra	10995697	500	5 Atellica IM TnI-Ultra ReadyPack primary reagent packs 2 vials lyophilized low calibrator 2 vials lyophilized high calibrator

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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. <https://www.sciencedaily.com/releases/2017/02/170214162750.htm>
2. Roffi M, et al./Task Force. Eur Heart J. 2015 ;37:267-315
3. Amsterdam EA, et al. Circulation. 2014 ;130 :e344-426 | 3) Apple FS, et al. Clin Biochem.

Siemens Healthineers Headquarters

Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen, Germany
Phone: +49 913184-0
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