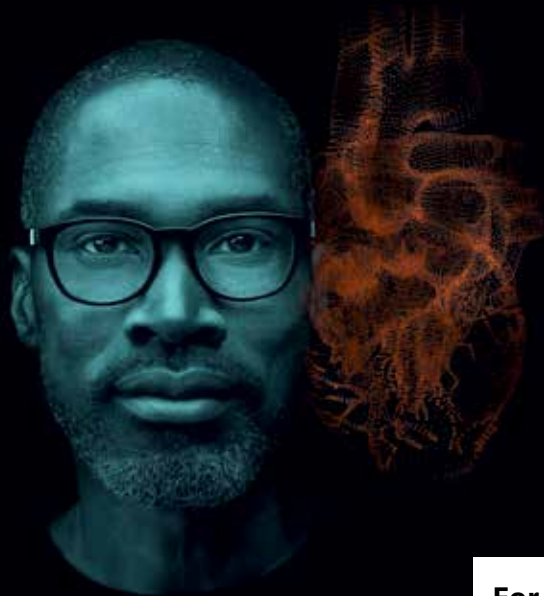


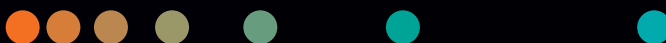
Atellica Solution

Cardiac Assays

siemens-healthineers.com/atellicsolution



For use
outside
the U.S.



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. According to the World Health Organization (WHO), CVD is the number-one cause of death globally. 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

*Atellica® IM High-Sensitivity Troponin I Assay.

Siemens Healthineers provides a comprehensive and expanding menu of assays for conditions that impact chest pain patients

- Features a proven, true high-sensitivity cardiac troponin I 10-minute assay, enabling clinicians to quickly triage chest pain patients.
- Offers fast, accurate, and actionable results to leverage faster protocols.
- Provides confidence in results due to minimal assay interferences (<10% bias from biotin [up to 3500 ng/mL] or hemolysis [up to 500 mg/dL]).*
- Gives your clinicians the power to choose NT-proBNP and BNP by expanding your B-type natriuretic peptides menu on the Atellica® IM System.

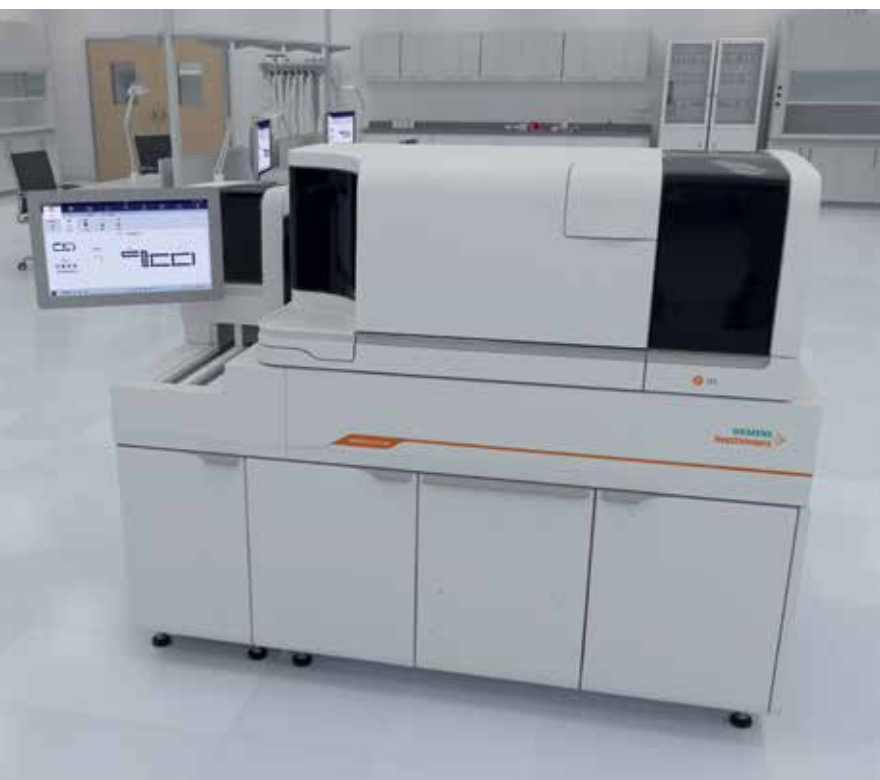
The Atellica Solution provides a broad and expanding menu to help your lab drive better clinical and business outcomes. The Atellica® IM Analyzer uses proven advanced Acridinium Ester (AE) technology, with over 50 patents granted or pending.

Assay Characteristics

Assay	Sample Type	Sample Volume (µL)	Time to First Result (min)	Measuring Interval	Detection Capabilities	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	2.50–25,000.00 pg/mL (ng/L)	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

Method Comparison

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 (ug/L)	13.79–975.67 ng/mL (ug/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



Ordering Information

Assay	SMN No.	Tests per Kit	Contents
BNP			
Atellica IM BNP	10995471	100	1 Atellica IM BNP ReadyPack® primary reagent pack
	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			
Atellica IM CKMB	10995530	100	1 Atellica IM CKMB ReadyPack primary reagent pack
	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			
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
	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			
Atellica IM MYO	10995649	50	1 Atellica IM MYO ReadyPack primary reagent pack
	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			
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
	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

At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey toward expanding precision medicine, transforming care delivery, and improving patient experience, all made possible by digitalizing healthcare.

An estimated 5 million patients globally benefit every day from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics, and molecular medicine, as well as digital health and enterprise services.

We are a leading medical technology company with over 120 years of experience and 18,000 patents globally. Through the dedication of more than 50,000 colleagues in 75 countries, we will continue to innovate and shape the future of healthcare.

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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. Apple F., Sandoval Y., Jaffe A., and 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 Biomarkers. *Clinical Chemistry* 63:01

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