

High-Sensitivity Cardiac Troponin I and T Assay Analytical Characteristics Designated by Manufacturer  
IFCC Committee on Clinical Applications of Cardiac Bio-Markers (C-CB) v092025

Company	Platform	Assay	Point-of-care assay	LoB (ng/L)	LoD (ng/L)	Measuring interval (ng/L)	%CV at 99 <sup>th</sup> percentile	Concentration at 20% CV (ng/L)	Concentration at 10% CV (ng/L)	Reference population ages, sex (n)	99 <sup>th</sup> percentile Overall, sex (ng/L)	% normals measured ≥ LoD Overall, sex	Statistic used to calculate 99 <sup>th</sup> percentile	Specimen type	Calibrator material	Epitopes recognized by antibodies	Country of Package Insert: version date	Other references
Abbott	Alinity	hs-cTnI (OUS)	No	0.7	1.3	3.2-50000	<u>Overall</u> 4.0% <u>Females</u> 5.3% <u>Males</u> 3.5%	2.1	3.7	<u>Overall</u> n = 1531 21-75y <u>Females</u> n = 764 21-75y <u>Males</u> n = 766 21-73y	<u>Overall</u> 26.2 <u>Females</u> 15.6 <u>Males</u> 34.2	>50%>50%	Robust	Serum, plasma (heparin, EDTA)	NP	NP	OUS (2021)	/
	Alinity	hs-cTnI (US)	No	0.0	0.9	2.7-3600	<u>Overall</u> 4.1% <u>Females</u> 3.9% <u>Males</u> 4.5%	2.7	3.7 <sup>1</sup>	<u>Overall</u> n = 1531 21-75y <u>Females</u> n = 763 21-75y <u>Males</u> n = 766 21-73y	<u>Overall</u> 26.2 <u>Females</u> 15.6 <u>Males</u> 34.2	>50%	Robust	Plasma (heparin)	NP	NP	US (2022)	/
	ARCHITECT	hs-cTnI (OUS)	No	0.7-1.3	1.1-1.9	3.2-50000	<u>Overall</u> 4.0% <u>Females</u> 5.3% <u>Males</u> 3.5%	1.3	4.7	<u>Overall</u> n = 1531 21-75y <u>Females</u> n = 764 21-75y <u>Males</u> n = 766 21-73y	<u>Overall</u> 26.2 <u>Females</u> 15.6 <u>Males</u> 34.2	>50%	Robust	Serum, plasma (heparin, EDTA)	NP	NP	OUS (2021)	/
	ARCHITECT	hs-cTnI (US)	No	0.9	1.7	3.5-5000	<u>Overall</u> 4.8% <u>Females</u> 5.0% <u>Males</u> 4.6%	2.3	NP	<u>Overall</u> n = 1531 21-75y <u>Females</u> n = 765 21-75y <u>Males</u> n = 766 21-73y	<u>Overall</u> 28 <u>Females</u> 17 <u>Males</u> 35	>50%	Robust	Plasma (EDTA)	NP	NP	OUS (2019)	/
	i-STAT 1 System POC	hs-cTnI (US)	Yes	<u>Whole blood</u> 0.78 <u>Plasma</u> 0.57	<u>Whole blood</u> 1.61 <u>Plasma</u> 1.05	2.9-1000	<u>Whole blood</u> 5.2% <u>Plasma</u> 4.9% <sup>1</sup>	<u>Whole blood</u> 2.90 <u>Plasma</u> 1.18	<u>Whole blood</u> 6.88 <u>Plasma</u> 3.70	<u>Overall</u> n = 895 18-87 years <u>Females</u> n = 490 <u>Males</u> n = 404	<u>Overall</u> 21 <u>Females</u> 13 <u>Males</u> 28	>50%	Non-parametric <sup>1</sup>	Whole blood, plasma (heparin)	NP	NP	US (2025)	/
Beckman Coulter	Access 2	hs-cTnI (US)	No	0.8	2.0	2.0-27,027	<u>Plasma</u> <u>Overall</u> 3.7% <u>Females</u> 4.2% <u>Males</u> 3.6% <u>Serum</u> <u>Overall</u> 6.0% <u>Females</u> 6.9% <u>Males</u> 5.8%	2.0	4.1	<u>Plasma</u> <u>Overall</u> n = 1089 21-99y <u>Females</u> n = 595 <u>Males</u> n = 494 <u>Serum</u> <u>Overall</u> n = 1088 21-99y <u>Females</u> n = 595 <u>Males</u> n = 493	<u>Plasma</u> <u>Overall</u> 17.5 <u>Females</u> 11.6 <u>Males</u> 19.8 <u>Serum</u> <u>Overall</u> 18.2 <u>Females</u> 11.8 <u>Males</u> 19.7	<u>Overall</u> 100% <u>Females</u> 99.7% <u>Males</u> 100%	Non-parametric	Serum, plasma (heparin)	Recombinant cTnI complex	NP	US (2024)2024)	Christenson RH, et al. 2020

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Beckman Coulter	UniCel Dxl	hs-cTnI (US)	No	1.7	2.3	2.3-27,027	<u>Plasma</u> <u>Overall</u> 5.2% <u>Females</u> 5.6% <u>Males</u> 5.0% <u>Serum</u> <u>Overall</u> 6.2% <u>Females</u> 6.5% <u>Males</u> 6.1%	2.3	5.6	<u>Plasma</u> <u>Overall</u> n = 1089 21-99y <u>Females</u> n = 593 <u>Males</u> n = 495 <u>Serum</u> <u>Overall</u> n = 1085 21-99 years <u>Females</u> n = 592 <u>Males</u> n = 493	<u>Plasma</u> <u>Overall</u> 17.9 <u>Females</u> 14.9 <u>Males</u> 19.8 <u>Serum</u> <u>Overall</u> 18.1 <u>Females</u> 13.6 <u>Males</u> 19.8	>50%	Non-parametric	Serum, plasma (heparin)	Recombinant cTnI complex	NP	US (2024)	/
	Access 2, UniCel Dxl	hs-cTnI (OUS)	No	1.7	2.3	2.3-27,027	<u>Overall</u> 3.7% <u>Females</u> 4.2% <u>Males</u> 3.6%	2.3	5.6	<u>Overall</u> n = 1089 21-99y <u>Females</u> n = 595 <u>Males</u> n = 494	<u>Overall</u> 17.5 <u>Females</u> 11.6 <u>Males</u> 19.8	>50%	Non-parametric	Serum, plasma	Recombinant cTnI complex	NP	OUS (2024)	/
	Dxl 9000	hs-cTnI	No	0.5	0.8	2.0-27,027	<u>Plasma</u> <u>Overall</u> 3.1% <u>Females</u> 3.9% <u>Males</u> 3.0% <u>Serum</u> <u>Overall</u> 3.7% <u>Females</u> 4.0% <u>Males</u> 3.7%	0.8	2.4	<u>Plasma</u> <u>Overall</u> n = 1089 21-99y <u>Females</u> n = 595 <u>Males</u> n = 494 <u>Serum</u> <u>Overall</u> n = 1088 21-99y <u>Females</u> n = 595 <u>Males</u> n = 493	<u>Plasma</u> <u>Overall</u> 17.5 <u>Females</u> 11.6 <u>Males</u> 19.8 <u>Serum</u> <u>Overall</u> 18.2 <u>Females</u> 11.8 <u>Males</u> 19.7	>50%	Non-parametric	Serum, plasma (heparin)	Recombinant cTnI complex	NP	OUS (2024) US (2024)	/
Lifotronic	eCL8000, eCL8000i, eCL8000p, eCL8000x, eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p, eCL9000, eCL9600, eCL9900, eCL9900i	hs-cTnI STAT (OUS)	No	0.5	1.5	1.5-50000	<u>Overall</u> 3.23% <u>Females</u> 3.14% <u>Males</u> <4%	2.0	3.4	<u>Overall</u> n = 623 18-94 years <u>Females</u> n = 306 18-94 years <u>Males</u> n = 317 18-88 years	<u>Overall</u> 26.2 <u>Females</u> 15.6 <u>Males</u> 34.2	<u>Overall</u> 89.5% <u>Females</u> 88.2% <u>Males</u> 91.0%	Non-parametric	Serum, plasma (EDTA, heparin)	Recombinant Cardiac Troponin I-C	NP	OUS (2025)	/
	eCL8000, eCL8000i, eCL8000p, eCL8000x, eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p, eCL9000, eCL9600, eCL9900, eCL9900i	hs-cTnT STAT (OUS)	No	0.5	1.5	5-10000	<u>Overall</u> <4% <u>Females</u> 3.26% <u>Males</u> <4%	2.0	3.7	<u>Overall</u> n = 564 18-88 years <u>Females</u> n = 284 <sup>2</sup> 18-88 years <u>Males</u> n = 280 <sup>2</sup> 18-83 years	<u>Overall</u> 14.1 <u>Females</u> 9.1 <u>Males</u> 16.8	<u>Overall</u> 89.2% <u>Females</u> 86.5% <u>Males</u> 93.5%	Non-parametric	Serum, plasma (EDTA, heparin)	NP	NP	OUS (2025)	/

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Mindray	CL-series	hs-cTnl (OUS)	No	0.1-0.5	0.5-0.7	2.4-25000	Overall: 2.4% Females: 1.9% Males: 2.0%	0.25	0.51	Overall: n = 832 21-87y Females: n = 407 21-87y Males: n = 424 21-83y	Overall 24.2 Females 15.3 Males 31.3	Overall 87% Females 77% Males 97%	Non-parametric	Serum, plasma (heparin)	Recombinant Cardiac Troponin I-C	C: 24-40, 41-49* D: cTn complex*	EU (2023) China (2023)	Li L. et al, 2023  Fabre-Estremera B. et al, 2024
PHC Corporation	PATHFAST	hs-cTnl (OUS)	Yes	1.23	2.33	2.33-50000	6.6%	NP	14.2	Overall n = 734 >18y Females n: 352 >18y Males n: 382 >18y	Overall 27.9 Females 20.3 Males 29.7	Overall 66.3% Females 52.8% Males 78.8%	Non-parametric <sup>1</sup>	Whole blood, plasma (EDTA, heparin)	Human cardiac I-T-C complex <sup>1</sup>	C:41-49 D: 71-116, 163-209 <sup>1</sup>	WW except US and Japan: (2024)	/
	PATHFAST	hs-cTnl-II (US)	Yes	1.47	3.02	4.1-50000	6.1%	4.1	19 <sup>1</sup>	Overall n= 734 18-91y Females n = 352 18-91y Males n = 382 18-75y	Overall 29 Females 20.3 Males 29.7	Overall 66.3% Females 52.8% Males 78.8%	Non-parametric <sup>1</sup>	Whole blood, plasma (EDTA, heparin)	Human cardiac I-T-C complex	C:41-49 D: 71-116, 163-209	US (2024)	/
QuidelOrtho	Triage	hs-cTnl (OUS)	Yes	Plasma 0.4 Whole blood 0.8	Plasma 1.6 Whole blood 1.9	0.1-1000	Plasma 5.9% Whole blood 6.5%	Plasma 3.6 Whole blood 2.8	Plasma 8.4 Whole blood 6.2	Overall n = 789 Males n = 398 Females n = 391	Whole blood, plasma (EDTA)	Overall 20.5 Males 25.7 Females 14.4	Overall 72% <sup>1</sup>	Recombinant cTn complex	Non-parametric <sup>1</sup>	NP	OUS (2020)	Boeddinghaus J, et al. 2020
	VITROS ECi/ECiQ	hs-cTnl (OUS)	No	0.51	0.86	1.50-30000	7.4%	1.23	1.99	Overall n = 952 22-91y Females n: 486 22-91y Males n: 466 22-91y	Plasma Overall 11 Females 9 Males 13 Serum Overall 11 Females 9 Males 12	>50%	Non-parametric	Serum, plasma (heparin)	Human cTnl in human serum/buffer matrix containing EDTA	NP NP	OUS (2022)	/
	VITROS XT 7600	hs-cTnl (OUS)	No	0.14	0.42	1.50-30000	8.5%	1.23	1.99	Overall n = 952 22-91y Females n: 486 22-91y Males n: 466 22-91y	Overall 11 Females 9 Males 13	>50%	Non-parametric	Serum, plasma (heparin)	Human cTnl in human serum/buffer matrix containing EDTA	NP NP	OUS (2022)	/

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QuidelOrtho	VITROS 5600	hs-cTnl (OUS)	No	0.23	0.43	1.50-30000	6.1%	1.23	1.99	Overall n = 952 22-91y  Females n: 486 22-91y  Males n: 466 22-91y	Overall 11  Females 9  Males 13	>50%	Non-parametric	Serum, plasma (heparin)	Human cTnl in human serum/buffer matrix containing EDTA	NP NP	OUS (2022)	/
	VITROS 3600	hs-cTnl (OUS)	No	0.19	0.39	1.50-30000	6.7%	1.23	1.99	Overall n = 952 22-91y  Females n: 486 22-91y  Males n: 466 22-91y	Overall 11  Females 9  Males 13	>50%	Non-parametric	Serum, plasma (heparin)	Human cTnl in human serum/buffer matrix containing EDTA	NP NP	OUS (2022)	/
RealMind Biotech	ACL2800, ACL2800S, MCL60, A6I	hs-cTnl (OUS)	No	1.00	1.80	1-75000	Overall 4.2% Females 5.6% Males 3.8%	1.80	4.80	Overall n = 879 18-88y Females n = 433 18-88y Males N = 446 18-88y	Overall 26.2 Females 15.6 Males 34.2	Overall 92.6% Females 90.1% Males 95.1%	Non-parametric	Whole blood (EDTA), serum, plasma (EDTA, heparin)	Recombinant cTnl antigen	D: 83-93 C: 24-42	OUS (2025)	/
	ACL2800, ACL2800S, MCL60, A6I	hs-cTnT (OUS)	No	0.40	0.70	0.7-10000	Overall 3.0% Females 2.8% Males 4.0%	0.7	2.5	Overall n=1603 18-70y Females n = 824 18-70y Males N = 779 18-70y	Overall 14 Females 9 Males 15	Overall 94.6% Females 89.9% Males 99.4%	Non-parametric	Whole blood (EDTA), serum, plasma (EDTA, heparin)	Recombinant cTnT antigen	NP	OUS (2025)	/
Roche	Cobas e601, e602	Elecsys hs-cTnT 18 min (OUS)	No	2.53	3.16	3-10000	4.7%	1.72	3.94	Overall n = 533 20-71y Females n = 265 Males	Overall 14 Females 9 Males 17	Overall 90.2% Females 83.3% Males 96.9%	Non-parametric	Serum, plasma (heparin, EDTA)	Recombinant human cTnT	C: 125-131 D: 136-147	OUS (2024)	Giannitsis E. et al, 2020
	Cobas e411	Elecsys hs-cTnT 18 min (OUS)	No	1.58	2.54	3-10000	7.9%	4.01	7.45	Overall n = 533 20-71y Females n = 265 Males n = 268	Overall 14 Females 9 Males 17	Overall 90.2% Females 83.3% Males 96.9%	Non-parametric	Serum, plasma (heparin, EDTA)	Recombinant human cTnT	C: 125-131 D: 136-147	OUS (2024)	Giannitsis E. et al, 2020
	Cobas e601, e602	Elecsys hs-cTnT 9 min (OUS)	No	2.36	2.85	3-10000	5.5%	1.21	2.92	Overall n = 533 20-71y Females n = 265 Males n = 268	Overall 14 Females 9 Males 17	Overall 90.2% Females 83.3% Males 96.9%	Non-parametric	Serum, plasma (heparin, EDTA)	Recombinant human cTnT	C: 125-131 D: 136-147	OUS (2024)	Giannitsis E. et al, 2020
	Cobas e411	Elecsys hs-cTnT 9 min (OUS)	No	2.14	3.25	3-10000	3.7%	2.88	6.74	Overall n = 533 20-71y Females n = 265 Males n = 268	Overall 14 Females 9 Males 17	Overall 90.2% Females 83.3% Males 96.9%	Non-parametric	Serum, plasma (heparin, EDTA)	Recombinant human cTnT	C: 125-131 D: 136-147	OUS (2024)	Giannitsis E. et al, 2020

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Roche	Cobas e601, e602	hs-cTnT Gen 5 STAT (US)	No	2.5	3	6-10000	3.6%	6	11	<u>Overall</u> n = 1301 21-89y <u>Females</u> n = 656 <u>Males</u> n = 645	<u>Overall</u> 19 <u>Females</u> 14 <u>Males</u> 22	<u>Overall</u> 90.2% <u>Females</u> 83.3% <u>Males</u> 96.9%	NP	Plasma (heparin)	Recombinant human cTnT	C: 125-131 D: 136-147	OUS (2024)	Giannitsis E. et al, 2020
	Cobas e411	hs-cTnT Gen 5 STAT (US)	No	3	5	6-10000	<10%	6	11	<u>Overall</u> n = 1301 21-89y <u>Females</u> n = 656 <u>Males</u> n = 645	<u>Overall</u> 19 <u>Females</u> 14 <u>Males</u> 22	<u>Overall</u> 90.2% <u>Females</u> 83.3% <u>Males</u> 96.9%	NP	Plasma (heparin)	Recombinant human cTnT	C: 125-131 D: 136-147	OUS (2024)	Giannitsis E. et al, 2020
	Cobas e801, e402	Elecsys hs-cTnT 18 min (OUS)	No	2.21	2.97	3-10000	6.7%	2.30	5.40	<u>Overall</u> n = 533 20-71y <u>Females</u> n = 265 <u>Males</u> n = 268	<u>Overall</u> 14 <u>Females</u> 9 <u>Males</u> 17	<u>Overall</u> 90.2% <u>Females</u> 83.3% <u>Males</u> 96.9%	Non-parametric	Serum, plasma (heparin, EDTA)	Recombinant human cTnT	C: 125-131 D: 136-147	OUS (2024)	Giannitsis E. et al, 2020
	Cobas e801, e402	Elecsys hs-cTnT 9 min (OUS)	No	1.91	2.72	3-10000	5.4%	1.00	3.22	<u>Overall</u> n = 533 20-71y <u>Females</u> n = 265 <u>Males</u> N = 268	<u>Overall</u> 14 <u>Females</u> 9 <u>Males</u> 17	<u>Overall</u> 90.2% <u>Females</u> 83.3% <u>Males</u> 96.9%	Non-parametric	Serum, plasma (heparin, EDTA)	Recombinant human cTnT	C: 125-131 D: 136-147	OUS (2024)	Giannitsis E. et al, 2020
	Cobas e801, e402	Elecsys hs-cTnT 9 min (US)	No	2.5	3	6-10000	4.2%	6	11	<u>Overall</u> n = 1301 21-89y <u>Females</u> n = 656 <u>Males</u> n = 645	<u>Overall</u> 19 <u>Females</u> 14 <u>Males</u> 22	<u>Overall</u> 90.2% <u>Females</u> 83.3% <u>Males</u> 96.9%	NP	Plasma (heparin)	Recombinant human cTnT	C: 125-131 D: 136-147	OUS (2024)	Giannitsis E. et al, 2020
Shenzhen Drawray Biotech	iStar 500	hs-cTnl (OUS)	Yes	0.3	0.6	2-50000	<u>Overall:</u> 2.90% <u>Females:</u> 3.05% <u>Males:</u> 2.99%	0.86	1.88	<u>Overall</u> n = 648 20-89y <sup>1</sup> <u>Females</u> n = 345 20-88y <sup>1</sup> <u>Males</u> n = 303 20-89y <sup>1</sup>	<u>Overall</u> 16.91 <u>Males</u> 18.51 <u>Females</u> 11.22	<u>Overall</u> 93.36% <u>Males</u> 96.37% <u>Females</u> 90.72%	Non-parametric <sup>1</sup>	Serum, whole blood, plasma (EDTA, heparin)	Recombinant antigen	NP	OUS (2024)	/
Siemens Healthineers	Atellica IM	hs-cTnl (TnlH OUS)	No	0.50	1.6	2.5-25000	<u>Plasma</u> <5.0% <u>Serum</u> 3.9%	2.50	6.0	<u>Plasma</u> <u>Overall</u> n = 2007 22-91y <u>Females</u> n = 1007 <u>Males</u> n = 1000 <u>Serum</u> <u>Overall</u> n = 2001 22-91y <u>Females</u> n = 1007 <u>Males</u> n = 994	<u>Plasma</u> <u>Overall</u> 45.2 <u>Females</u> 34.1 <u>Males</u> 53.5 <u>Serum</u> <u>Overall</u> 45.4 <u>Females</u> 38.6 <u>Males</u> 53.5	<u>Overall</u> 71% <u>Females</u> 59% <u>Males</u> 84%	Non-parametric	Serum, plasma (heparin)	NP	C: 41-50, 171-190 D: 29-34	OUS (2024)	Christenson RH. et al, 2019

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Siemens Healthineers	Atellica IM	hs-cTnI (TnIH US)	No	0.50	1.6	2.5-25000	Plasma <5.3% Serum <4.7%	2.50	NP	Plasma Overall n = 2007 22-91y  Females n = 1007  Males n = 1000  Serum Overall n = 2001 22-91y  Females n = 1007  Males n = 994	Plasma Overall 45.2  Females 34.1  Males 53.5  Serum Overall 45.4  Females 38.6  Males 53.5	Overall 71% Females 59% Males 84%	Non-parametric	Serum, plasma (heparin)	NP	C: 41-50, 171-190 D: 29-34	US (2024)	Christenson RH. et al, 2019
	Atellica CI	hs-cTnI (TnIH OUS)	No	0.50	1.6	2.5-25000	Plasma <5.1% Serum <3.0%	2.50	6.0	Plasma Overall n = 2007 22-91y  Females n = 1007  Males n = 1000  Serum Overall n = 2001 22-91y  Females n = 1007  Males n = 994	Plasma Overall 45.2  Females 34.1  Males 53.5  Serum Overall 45.4  Females 38.6  Males 53.5	Overall >50% Females >50% Males >50%	Non-parametric	Serum, plasma (heparin)	NP	C: 41-50, 171-190 D: 29-34 <sup>1</sup>	OUS (2024)	/
	Atellica CI	hs-cTnI (TnIH US)	No	0.50	1.6	2.5-25000	Plasma <5.1% Serum <3.0%	2.50	NP	Plasma Overall n = 2007 22-91y  Females n = 1007  Males n = 1000  Serum Overall n = 2001 22-91y  Females n = 1007  Males n = 994	Plasma Overall 45.2  Females 34.1  Males 53.5  Serum Overall 45.4  Females 38.6  Males 53.5	Overall >50%	Non-parametric	Serum, plasma (heparin)	NP	C: 41-50, 171-190 D: 29-34 <sup>1</sup>	US (2024)	/
	Atellica VTli	hs-cTnI (OUS)	Yes	0.55	Plasma 1.3 Whole blood 1.6	Plasma 1.2-1250 Whole blood 1.6-1250	<10%	Plasma 2.1 Whole blood 3.7	Plasma 6.7 Whole blood 8.9	Overall n = 693 18-91y  Females n = 330  Males n = 363	Overall 22.9  Females 18.5  Males 27.1	Overall 84% Females 80% Males 87%	Non-parametric	Whole blood, plasma (heparin), capillary blood	NP	C: 41-49 D: 23-29, 87-91,cTnC	OUS (2023)	Apple FS. et al, 2021 Christenson RH. et al, 2022

Company	Platform	Assay	Point-of-care assay	LoB (ng/L)	LoD (ng/L)	Measuring interval (ng/L)	%CV at 99 <sup>th</sup> percentile	Concentration at 20% CV (ng/L)	Concentration at 10% CV (ng/L)	Reference population ages, sex (n)	99 <sup>th</sup> percentile Overall, sex (ng/L)	% normals measured ≥ LoD Overall, sex	Statistic used to calculate 99 <sup>th</sup> percentile	Specimen type	Calibrator material	Epitopes recognized by antibodies	Country of Package Insert: version date	Other references
Siemens Healthineers	ADVIA Centaur XP/XPT	hs-cTnI (TNIH OUS)	No	0.50	1.6	2.5-25000	Plasma <4.3% Serum <3.7%	2.50	6.0	Plasma Overall n = 2010 22-91y	Plasma Overall 47.3	Overall 93% Females 88% Males 98%	Non-parametric	Serum, plasma (heparin)	NP	C: 41-50, 171-190 D: 29-34	OUS (2024)	Christenson RH. et al, 2019
										Females n = 1012	Females 37.0							
										Males n = 998	Males 57.3							
										Serum Overall n = 1990 22-91y	Serum Overall 46.5							
	ADVIA Centaur XP/XPT	hs-cTnI (TNIH US)	No	0.50	1.6	2.5-25000	Plasma <4.9% Serum <5.4%	2.50	NP	Plasma Overall n = 2010 22-91y	Plasma Overall 47.3	Overall 93% Females 88% Males 98%	Non-parametric	Serum, plasma (heparin)	NP	C: 41-50, 171-190 D: 29-34	US (2024)	Christenson RH. et al, 2019
										Females n = 1012	Females 37.0							
										Males n = 998	Males 57.3							
										Serum Overall n = 1990 22-91y	Serum Overall 46.5							
	ADVIA Centaur CP	hs-cTnI (TNIH OUS)	No	0.50	1.6	2.5-25000	Plasma <4.0% Serum <3.8%	2.50	<6.0	Plasma Overall n = 2010 22-91y	Plasma Overall 47.3	Overall 93% <sup>1</sup> Females 88% <sup>1</sup> Males 98% <sup>1</sup>	Non-parametric	Serum, plasma (heparin)	NP	C: 41-50, 171-190 D: 29-34 <sup>1</sup>	OUS (2024)	/
										Females n = 1012	Females 37.0							
										Males n = 998	Males 57.3							
										Serum Overall n = 1990 22-91y	Serum Overall 46.5							
	ADVIA Centaur CP	hs-cTnI (TNIH US)	No	0.50	1.6	2.5-25000	Plasma <4.0% Serum <3.8%	2.50	NP	Plasma Overall n = 2010 22-91y	Plasma Overall 47.3	Overall 93% <sup>1</sup> Females 88% <sup>1</sup> Males 98% <sup>1</sup>	Non-parametric	Serum, plasma (heparin)	NP	C: 41-50, 171-190 D: 29-34 <sup>1</sup>	US (2024)	/
										Females n = 1012	Females 37.0							
										Males n = 998	Males 57.3							
										Serum Overall n = 1990 22-91y	Serum Overall 46.5							

Company	Platform	Assay	Point-of-care assay	LoB (ng/L)	LoD (ng/L)	Measuring interval (ng/L)	%CV at 99 <sup>th</sup> percentile	Concentration at 20% CV (ng/L)	Concentration at 10% CV (ng/L)	Reference population ages, sex (n)	99 <sup>th</sup> percentile Overall, sex (ng/L)	% normals measured ≥ LoD Overall, sex	Statistic used to calculate 99 <sup>th</sup> percentile	Specimen type	Calibrator material	Epitopes recognized by antibodies	Country of Package Insert: version date	Other references
Siemens Healthineers										<u>Plasma</u> <u>Overall</u> n = 2021 22-91y  <u>Females</u> n = 1017  <u>Males</u> n = 1004  <u>Serum</u> <u>Overall</u> n = 2014 22-91y  <u>Females</u> n = 1013  <u>Males</u> n = 1002	<u>Plasma</u> <u>Overall</u> 58.9  <u>Females</u> 53.7  <u>Males</u> 78.5  <u>Serum</u> <u>Overall</u> 57.9  <u>Females</u> 74.9  <u>Males</u> 51.1	<u>Overall</u> 98.8%  <u>Females</u> 97.8%  <u>Males</u> 99.8%	Non-parametric	Serum, plasma (heparin)	NP	D: 41-50 171-190 C: 29-34	OUS (2019)	Apple FS. et al, 2020
	Dimension VISTA	hs-cTnI (TNIH OUS)	No	1.0	2.0	4-25000	<6.0%	3.0	10.0									
										<u>Overall</u> n = 2021 22-91y  <u>Females</u> n = 1017  <u>Males</u> n = 1004	<u>Overall</u> 58.9  <u>Females</u> 53.7  <u>Males</u> 78.5	<u>Overall</u> 98.8%  <u>Females</u> 97.8%  <u>Males</u> 99.8%	Non-parametric	Plasma (heparin)	NP	D: 41-50 171-190 C: 29-34	US (2019)	Apple FS. et al, 2020
										<u>Plasma</u> <u>Overall</u> n = 2020 22-91y  <u>Females</u> n = 1017  <u>Males</u> n = 1003  <u>Serum</u> <u>Overall</u> n = 2014 22-91y  <u>Females</u> n = 1014  <u>Males</u> n = 1001	<u>Plasma</u> <u>Overall</u> 60.4  <u>Females</u> 51.4  <u>Males</u> 76.2  <u>Serum</u> <u>Overall</u> 58.2  <u>Females</u> 47.8  <u>Males</u> 71.8	<u>Overall</u> 73% <sup>1</sup>  <u>Females</u> 59% <sup>1</sup>  <u>Males</u> 86% <sup>1</sup>	Non-parametric	Serum, plasma (heparin)	NP	D: 41-50 171-190 C: 29-34	OUS (2019)	/
	Dimension EXL	hs-cTnI (TNIH US)	No	1.1	2.7	4-25000	<6.0%	4.0	12.0									
										<u>Overall</u> n = 2020 22-91y  <u>Females</u> n = 1017  <u>Males</u> n = 1003	<u>Overall</u> 60.4  <u>Females</u> 51.4  <u>Males</u> 76.2	<u>Overall</u> 73% <sup>1</sup>  <u>Females</u> 59% <sup>1</sup>  <u>Males</u> 86% <sup>1</sup>	Non-parametric	Plasma (heparin)	NP	D: 41-50 171-190 C: 29-34	US (2019)	/
YHLO	iFlash-series	hs-cTnI (OUS)	No	0.3	0.6	0.6-50000	<u>Overall</u> 2.73% <u>Females</u> 3.50% <u>Males</u> 2.57%	≤ 1.0	≤ 2.0	<u>Overall</u> n = 878 20-89 years  <u>Females</u> n = 442  <u>Males</u> n = 436	<u>Overall</u> 16.8  <u>Males</u> 18.5  <u>Females</u> 11.1	<u>Overall</u> 93.51%  <u>Females</u> 90.50%  <u>Males</u> 96.56%	Non-parametric	Serum, plasma (heparin, EDTA)	cTnI protein	NP	OUS (2023)	/
Zybio Inc.	EXI CLIA System	hs-cTnI (China)	No	0.8	1.1	2.1-50000	<u>Overall</u> 4.2% <u>Females</u> 4.4% <u>Males</u> 4.0%	2.1	6.1 <sup>1</sup>	<u>Overall</u> n = 654 20-86 years <sup>1</sup>  <u>Females</u> n = 335  <u>Males</u> n = 319	<u>Overall</u> 28.2  <u>Males</u> 30.3  <u>Females</u> 25.3	<u>Overall</u> >50%	Non-parametric <sup>1</sup>	Serum, plasma (heparin, EDTA)	Natural Cardiac Troponin I-C-T antigen	C: 24-40, 81-100 D: cTn complex	China (2024)	/

LoB, limit of blank; LoD, limit of detection; NP, not provided; C, capture antibody; D, detection antibody; WW, worldwide; OUS, outside United States. All data have been listed as provided by the manufacturer and should unless otherwise is noted reported in the Package insert or a peer-reviewed publication. Please note that the IFCC has not performed an independent evaluation demonstrating 'high sensitivity' at the IFCC requirements of: a) ≤10% CV at the 99<sup>th</sup> percentile and b) ≥ 50% measurable concentrations ≥ LoD for both males AND females in independent evaluations.

<sup>1</sup>Information not reported in a Package Insert or a published manuscript. For more information, please contact the manufacturer.

<sup>2</sup> Note that less than 300 males and 300 females were used to determine the 99<sup>th</sup> percentile.