High-Sensitivity Cardiac Troponin I and T Assay Analytical Characteristics Designated by Manufacturer
IFCC Committee on Clinical Applications of Cardiac Bio-Markers (C-CB) v072026

Company	Platform	Assay	Point-of-care assay	LoB (ng/L)	LoD (ng/L)	Measuring interval (ng/L)	%CV at 99th percentile	Concentration at 20% CV (ng/L)	Concentration at 10% CV (ng/L)	Reference population ages, sex (n)	99th percentile Overall, sex (ng/L)	% normals measured ≥ LoD Overall, sex	Statistic used to calculate 99th 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	3.2-50,000	Overall 4.0% Females 5.3% Males 3.5%	2.1	3.7	Overall n = 1531 21-75y Females n = 764 21-75y Males n = 766 21-73y	Overall 26.2 Females 15.6 Males 34.2	>50%	Robust	Serum, plasma (heparin, EDTA)	NP	NP	OUS (2021)	/
	Alinity	hs-cTnI (US)	No	0.0	0.9	2.7-3,600	Overall 4.1% Females 3.9% Males 4.5%	2.7	3.7[1]	Overall n = 1531 21-75y Females n = 763 21-75y Males n = 766 21-73y	Overall 26.2 Females 15.6 Males 34.2	>50%	Robust	Plasma (heparin)	NP	NP	US (2022)	/
	ARCHITECT	hs-cTnI (OUS)	No	0.7-1.3	1.1-1.9	3.2-50,000	Overall 4.0% Females 5.3% Males 3.5%	1.3	4.7	Overall n = 1531 21-75y Females n = 764 21-75y Males n = 766 21-73y	Overall 26.2 Females 15.6 Males 34.2	>50%	Robust	Serum, plasma (heparin, EDTA)	NP	NP	OUS (2021)	/
	ARCHITECT	hs-cTnI (US)	No	0.9	1.7	3.5-5000	Overall 4.8% Females 5.0% Males 4.6%	2.3	NP	Overall n = 1531 21-75y Females n = 765 21-75y Males n = 766 21-73y	Overall 28 Females 17 Males 35	>50%	Robust	Plasma (EDTA)	NP	NP	OUS (2019)	/
	i-STAT 1 System POC	hs-cTnI (US)	Yes	Whole blood 0.78 Plasma 0.57	Whole blood 1.61 Plasma 1.05	2.9-1,000	Whole blood 5.2% Plasma 4.9%[1]	Whole blood 2.90 Plasma 1.18	Whole blood 6.88 Plasma 3.70	Overall n = 895 18-87y Females n = 490 Males n = 404	Overall 21 Females 13 Males 28	>50%	Non-parametric[1]	Whole blood, plasma (heparin)	NP	NP	US (2025)	/
Autobio Diagnostics Co	AutoLumo A2000 Plus, A1000, A1820, A1860, A6200, A6600, S900, S920, S960, S980	hs-cTnT	No	3	5	10-10,000	<10%	NP	10	Overall n = 686 2-88y Females n = 334 7-74y Males n = 352 2-88y	Overall 14 Females 10.3 Males 16.2	Overall 63.4% Females 59.9% Males 66.8%	Non-parametric[1]	Serum, plasma (heparin), citrate	Troponin T	C: 120-130 D: 131-145[1]	OUS (2025)	/

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Beckman Coulter	Access 2	hs-cTnI (US)	No	0.8	2.0	2.0-27,027	**Plasma** Overall 3.7% Females 4.2% Males 3.6% **Serum** Overall 6.0% Females 6.9% Males 5.8%	2.0	4.1	**Plasma** Overall n = 1089 21-99y Females n = 595 Males n = 494 **Serum** Overall n = 1088 21-99y Females n = 595 Males n = 493	**Plasma** Overall 17.5 Females 11.6 Males 19.8 **Serum** Overall 18.2 Females 11.8 Males 19.7	Overall 100% Females 99.7% Males 100%	Non-parametric	Serum, plasma (heparin)	Recombinant cTnI complex	NP	US (2024)	Christenson RH, et al. 2020
	UniCel Dxl	hs-cTnI (US)	No	1.7	2.3	2.3-27,027	**Plasma** Overall 5.2% Females 5.6% Males 5.0% **Serum** Overall 6.2% Females 6.5% Males 6.1%	2.3	5.6	**Plasma** Overall n = 1089 21-99y Females n = 593 Males n = 495 **Serum** Overall n = 1085 21-99 years Females n = 592 Males n = 493	**Plasma** Overall 17.9 Females 14.9 Males 19.8 **Serum** Overall 18.1 Females 13.6 Males 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	Overall 3.7% Females 4.2% Males 3.6%	2.3	5.6	Overall n = 1089 21-99y Females n = 595 Males n = 494	Overall 17.5 Females 11.6 Males 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	**Plasma** Overall 3.1% Females 3.9% Males 3.0% **Serum** Overall 3.7% Females 4.0% Males 3.7%	0.8	2.4	**Plasma** Overall n = 1089 21-99y Females n = 595 Males n = 494 **Serum** Overall n = 1088 21-99y Females n = 595 Males n = 493	**Plasma** Overall 17.5 Females 11.6 Males 19.8 **Serum** Overall 18.2 Females 11.8 Males 19.7	>50%	Non-parametric	Serum, plasma (heparin)	Recombinant cTnI complex	NP	OUS (2024) US (2024)	/

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Getein Biotech	MAGICL 6000, 6000i, 6100, 6200, 6800, 8200, 8500, 8800	hs-cTnI	No	0.8	1.0	1.0-80,000	Overall 3.6% Females 5.0% Males 3%	4.0	1.0-2.8	Overall n = 1306 21-82y[1] Females n = 638 21-82y[1] Males n = 668 25-76y[1]	Overall 26.4 Females 15.1 Males 34.0	Overall 87.1% Females 84.5% Males 89.5%	Non-parametric[1]	Serum, plasma, whole blood (heparin, EDTA)	hs-cTnI Calibrator: Recombinant Cardiac Troponin I-C	C: 87-89 41-49[1] D: 24-40[1]	OUS (2022) China (2016)	/
Guangzhou Wondfo Biotech Co	SmarLumiTM	hs-cTnI	No	0.6	1.0	1-28,000	Overall 3.0%-3.4%[1] Females 3.4-3.7%[1] Males 2.8-3.3%[1]	2.4	NP	Overall n = 946 18-83y Females n = 486 18-81y Males n = 460 19-83y	Overall 17.7 Females 11.8 Males 19.9	Overall 95.6%[1] Females 92.2%[1] Males 99.0%[1]	Non-parametric	Serum, plasma (heparin, EDTA)	NP	NP	OUS (2025) China (2025)	/
Lifotronic	eCL8000, eCL8000i, eCL8000p, eCL8000x, eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p, eCL9000, eCL9600, eCL9900, eCL9900i	hs-cTnI STAT (OUS)	No	0.5	1.5	1.5-50,000	Overall 3.23% Females 3.14% Males <4%	2.0	3.4	Overall n = 623 18-94y Females n = 306 18-94y Males n = 317 18-88y	Overall 26.2 Females 15.6 Males 34.2	Overall 89.5% Females 88.2% Males 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	5-10,000	Overall <4% Females 3.26% Males <4%	2.0	3.7	Overall n = 564 18-88y Females n = 284[2] 18-88y Males n = 280[2] 18-83y	Overall 14.1 Females 9.1 Males 16.8	Overall 89.2% Females 86.5% Males 93.5%	Non-parametric	Serum, plasma (EDTA, heparin)	NP	NP	OUS (2025)	/
Mindray	CL-series	hs-cTnI (OUS)	No	0.1-0.5	0.5-0.7	2.4-25,000	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

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PHC Corporation	PATHFAST	hs-cTnI (OUS)	Yes	1.23	2.33	2.33-50,000	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[1]	Whole blood, plasma (EDTA, heparin)	Human cardiac I-T-C complex[1]	C:41-49 D: 71-116, 163-209[1]	WW except US and Japan: (2024)	/
	PATHFAST	hs-cTnI-II (US)	Yes	1.47	3.02	4.1-50,000	6.1%	4.1	19[1]	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[1]	Whole blood, plasma (EDTA, heparin)	Human cardiac I-T-C complex	C:41-49 D: 71-116, 163-209	US (2024)	/
QuidelOrtho	Triage	hs-cTnI (OUS)	Yes	Plasma 0.4 Whole blood 0.8	Plasma 1.6 Whole blood 1.9	0.1-1,000	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	Overall 20.5 Males 25.7 Females 14.4	Overall 72%[1]	Non-parametric[1]	Whole blood, plasma (EDTA)	Recombinant cTn complex	NP	OUS (2020)	Boeddinghaus J, et al. 2020
	VITROS ECi/ECiQ	hs-cTnI (OUS)	No	0.51	0.86	1.50-30,000	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 cTnI in human serum/buffer matrix containing EDTA	NP	OUS (2022)	/
	VITROS XT 7600	hs-cTnI (OUS)	No	0.14	0.42	1.50-30,000	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 cTnI in human serum/buffer matrix containing EDTA	NP	OUS (2022)	/
	VITROS 3600, 5600, XT 7600	hs-cTnI (US)	No	NP	0.59	2.25-30,000	Overall 4.5% Females 4.5% Males 4.7%	2.25	ND	Overall n = 952 22-91y Females n: 486 22-91y Males n: 466 22-91y	Overall 11 Females 9 Males 12	>50%	Non-parametric	Plasma (heparin)	Human cTnI in human troponin-stripped	NP	US (2025)	/

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QuidelOrtho	VITROS 5600	hs-cTnI (OUS)	No	0.23	0.43	1.50-30,000	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 cTnI in human serum/buffer matrix containing EDTA	NP	OUS (2022)	/
	VITROS 3600	hs-cTnI (OUS)	No	0.19	0.39	1.50-30,000	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 cTnI in human serum/buffer matrix containing EDTA	NP	OUS (2022)	/
RealMind Biotech	ACL2800, ACL2800S, MCL60, A6I	hs-cTnI (OUS)	No	1.00	1.80	1-75,000	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 cTnI antigen	D: 83-93 C: 24-42	OUS (2025)	/
	ACL2800, ACL2800S, MCL60, A6I	hs-cTnT (OUS)	No	0.40	0.70	0.7-10,000	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 Diagnostics	Cobas e601, e602	Elecsys hs-cTnT 18 min (OUS)	No	2.53	3.16	3-10,000	4.7%	1.72	3.94	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 18 min (OUS)	No	1.58	2.54	3-10,000	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	3-10,000	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

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Roche Diagnostics	Cobas e411	Elecsys hs-cTnT 9 min (OUS)	No	2.14	3.25	3-10,000	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
	Cobas e801, e402	Elecsys hs-cTnT Gen 6 (OUS)	No	1.0	1.5	1.5-9,500	Overall 2.99% Females 3.26% Males 2.92%	1.5	3.0	Overall n = 4147 20-88y Females n = 2176 20-88y Males n = 1971 20-88y	Overall 27 Females 18 Males 32	Overall 89.7% Females 81.0% Males 99.2%	Non-parametric	Serum, plasma	Recombinant human cTnT	C: 125-131 D: 136-147	OUS (2025)	/
	Cobas e601, e602	hs-cTnT Gen 5 STAT (US)	No	2.5	3	6-10,000	3.6%	6	11	Overall n = 1301 21-89y Females n = 656 Males n = 645	Overall 19 Females 14 Males 22	Overall 90.2% Females 83.3% Males 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	6-10,000	<10%	6	11	Overall n = 1301 21-89y Females n = 656 Males n = 645	Overall 19 Females 14 Males 22	Overall 90.2% Females 83.3% Males 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	3-10,000	6.7%	2.30	5.40	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 e801, e402	Elecsys hs-cTnT 9 min (OUS)	No	1.91	2.72	3-10,000	5.4%	1.00	3.22	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 e801, e402	Elecsys hs-cTnT 9 min (US)	No	2.5	3	6-10,000	4.2%	6	11	Overall n = 1301 21-89y Females n = 656 Males n = 645	Overall 19 Females 14 Males 22	Overall 90.2% Females 83.3% Males 96.9%	NP	Plasma (heparin)	Recombinant human cTnT	C: 125-131 D: 136-147	OUS (2024)	Giannitsis E. et al, 2020

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Shanghai Medconn Biotechnology Co.	MI mini 90, MI mini 90e	hs-cTnI	No	1.8	3.7	3.7-50,000	Plasma <10% Serum <10% Whole blood <10%	Plasma 6.32 Serum 6.51 Whole blood 6.46	Plasma 12.38 Serum 12.69 Whole blood 12.57	Overall n = 808 21-83y Males n = 403 21-83y[1] Females n = 405 21-83y[1]	Overall 32.3 Females 26.5 Males 34.9	>50%	Non-parametric	Whole blood, serum, plasma	ALP-coated magnetic beads	C: 24-40, 83-93[1] D: NP	OUS (2026)	/
Shenzhen Drawray Biotech	iStar 500	hs-cTnI (OUS)	Yes	0.3	0.6	2-50,000	Overall: 2.90% Females: 3.05% Males: 2.99%	0.86	1.88	Overall n = 648 20-89y[1] Females n = 345 20-88y[1] Males n = 303 20-89y[1]	Overall 16.91 Males 18.51 Females 11.22	Overall 93.36% Males 96.37% Females 90.72%	Non-parametric[1]	Serum, whole blood, plasma (EDTA, heparin)	Recombinant antigen	NP	OUS (2024)	/
Shenzhen Tisenc Medical Devices Co.	ACCRE series	hs-cTnI	Yes	2.0	3.0	3-25,000	Overall 4.0%-4.1%[1] Females 5.0%[1] Males 3.8%[1]	5	NP	Overall n = 936 18-83y Females n = 481 18-81y Males n = 455 19-83y	Overall 19.5 Males 22.5 Females 12.6	Overall 88%[1] Females 83.2%[1] Males 92.9%[1]	Non-parametric	Serum, whole blood, plasma (EDTA, heparin)	NP	NP	OUS (2025)	/
	ACCRE series	hs-cTnT	Yes	2.0	3.0	3-10,000	Overall 3.7%-3.9%[1] Females 4.8%-5.4%[1] Males 3.3%-3.5%[1]	1.1-1.9	3.2-4.5	Overall n = 981 18-86y Females n = 483 18-86y Males n = 498 19-85y	Overall 14.4 Males 16.9 Females 9.7	Overall 87.4%[1] Females 82.0%[1] Males 92.9%	Non-parametric	Serum, whole blood, plasma (EDTA, heparin)	NP	NP	OUS (2026)	/
Siemens Healthineers	Atellica IM	hs-cTnI (TnIH OUS)	No	0.50	1.6	2.5-25,000	Plasma <5.0% Serum 3.9%	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 71% Females 59% Males 84%	Non-parametric	Serum, plasma (heparin)	NP	C: 41-50, 171-190 D: 29-34	OUS (2024)	Christenson RH. et al, 2019

Company	Platform	Assay	Point-of-care assay	LoB (ng/L)	LoD (ng/L)	Measuring interval (ng/L)	%CV at 99th percentile	Concentration at 20% CV (ng/L)	Concentration at 10% CV (ng/L)	Reference population ages, sex (n)	99th percentile Overall, sex (ng/L)	% normals measured ≥ LoD Overall, sex	Statistic used to calculate 99th percentile	Specimen type	Calibrator material	Epitopes recognized by antibodies	Country of Package Insert: version date	Other references
Siemens Healthineers	Atellica IM	hs-cTnI (TnIH US)	No	0.50	1.6	2.5-25,000	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	2.5-25,000	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[1]	OUS (2024)	/
	Atellica CI	hs-cTnI (TnIH US)	No	0.50	1.6	2.5-25,000	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	>50%	Non-parametric	Serum, plasma (heparin)	NP	C: 41-50, 171-190 D: 29-34[1]	US (2024)	/
	Atellica VTLi[3]	hs-cTnI (OUS)	Yes	0.55	Plasma 1.3 Whole blood 1.6	Plasma 1.2-1,250 Whole blood 1.6-1,250	<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 99th percentile	Concentration at 20% CV (ng/L)	Concentration at 10% CV (ng/L)	Reference population ages, sex (n)	99th percentile Overall, sex (ng/L)	% normals measured ≥ LoD Overall, sex	Statistic used to calculate 99th 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	2.5-25,000	Plasma <4.3% Serum <3.7%	2.50	6.0	**Plasma** Overall n = 2010 22-91y Females n = 1012 Males n = 998 **Serum** Overall n = 1990 22-91y Females n = 1006 Males n = 984	**Plasma** Overall 47.3 Females 37.0 Males 57.3 **Serum** Overall 46.5 Females 39.6 Males 58.1	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
	ADVIA Centaur XP/XPT	hs-cTnI (TNIH US)	No	0.50	1.6	2.5-25,000	Plasma <4.9% Serum <5.4%	2.50	NP	**Plasma** Overall n = 2010 22-91y Females n = 1012 Males n = 998 **Serum** Overall n = 1990 22-91y Females n = 1006 Males n = 984	**Plasma** Overall 47.3 Females 37.0 Males 57.3 **Serum** Overall 46.5 Females 39.6 Males 58.1	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
	ADVIA Centaur CP	hs-cTnI (TNIH OUS)	No	0.50	1.6	2.5-25,000	Plasma <4.0% Serum <3.8%	2.50	<6.0	**Plasma** Overall n = 2010 22-91y Females n = 1012 Males n = 998 **Serum** Overall n = 1990 22-91y Females n = 1006 Males n = 984	**Plasma** Overall 47.3 Females 37.0 Males 57.3 **Serum** Overall 46.5 Females 39.6 Males 58.1	Overall 93%[1] Females 88%[1] Males 98%[1]	Non-parametric	Serum, plasma (heparin)	NP	C: 41-50, 171-190 D: 29-34[1]	OUS (2024)	/

Company	Platform	Assay	Point-of-care assay	LoB (ng/L)	LoD (ng/L)	Measuring interval (ng/L)	%CV at 99th percentile	Concentration at 20% CV (ng/L)	Concentration at 10% CV (ng/L)	Reference population ages, sex (n)	99th percentile Overall, sex (ng/L)	% normals measured ≥ LoD Overall, sex	Statistic used to calculate 99th percentile	Specimen type	Calibrator material	Epitopes recognized by antibodies	Country of Package Insert: version date	Other references
Siemens Healthineers	ADVIA Centaur CP	hs-cTnI (TNIH US)	No	0.50	1.6	2.5-25,000	Plasma <4.0% Serum <3.8%	2.50	NP	**Plasma** Overall n = 2010 22-91y Females n = 1012 Males n = 998 **Serum** Overall n = 1990 22-91y Females n = 1006 Males n = 984	**Plasma** Overall 47.3 Females 37.0 Males 57.3 **Serum** Overall 46.5 Females 39.6 Males 58.1	Overall 93%[1] Females 88%[1] Males 98%[1]	Non-parametric	Serum, plasma (heparin)	NP	C: 41-50, 171-190 D: 29-34[1]	US (2024)	/
	Dimension VISTA	hs-cTnI (TNIH US)	No	1.0	2.0	4-25,000	<6.0%	3.0	10.0	Overall n = 2021 22-91y Females n = 1017 Males n = 1004	Overall 58.9 Females 53.7 Males 78.5	Overall 98.8% Females 97.8% Males 99.8%	Non-parametric	Plasma (heparin)	NP	D: 41-50 171-190 C: 29-34	US (2019)	Apple FS. et al, 2020
	Dimension VISTA	hs-cTnI (TNIH OUS)	No	1.0	2.0	4-25,000	<6.0%	3.0	10.0	**Plasma** Overall n = 2021 22-91y Females n = 1017 Males n = 1004 **Serum** Overall n = 2014 22-91y Females n = 1013 Males n = 1002	**Plasma** Overall 58.9 Females 53.7 Males 78.5 **Serum** Overall 57.9 Females 74.9 Males 51.1	Overall 98.8% Females 97.8% Males 99.8%	Non-parametric	Serum, plasma (heparin)	NP	D: 41-50 171-190 C: 29-34	OUS (2019)	Apple FS. et al, 2020
	Dimension EXL	hs-cTnI (TNIH OUS)	No	1.1	2.7	4-25,000	<6.0%	4.0	12.0	**Plasma** Overall n = 2020 22-91y Females n = 1017 Males n = 1003 **Serum** Overall n = 2014 22-91y Females n = 1014 Males n = 1001	**Plasma** Overall 60.4 Females 51.4 Males 76.2 **Serum** Overall 58.2 Females 47.8 Males 71.8	Overall 73%[1] Females 59%[1] Males 86%[1]	Non-parametric	Serum, plasma (heparin)	NP	D: 41-50 171-190 C: 29-34	OUS (2019)	/

Company	Platform	Assay	Point-of-care assay	LoB (ng/L)	LoD (ng/L)	Measuring interval (ng/L)	%CV at 99th percentile	Concentration at 20% CV (ng/L)	Concentration at 10% CV (ng/L)	Reference population ages, sex (n)	99th percentile Overall, sex (ng/L)	% normals measured ≥ LoD Overall, sex	Statistic used to calculate 99th percentile	Specimen type	Calibrator material	Epitopes recognized by antibodies	Country of Package Insert: version date	Other references
Siemens Healthineers	Dimension EXL	hs-cTnI (TNIH US)	No	1.1	2.7	4-25,000	<6.0%	4.0	12.0	Overall n = 2020 22-91y Females n = 1017 Males n = 1003	Overall 60.4 Females 51.4 Males 76.2	Overall 73%[1] Females 59%[1] Males 86%[1]	Non-parametric	Plasma (heparin)	NP	D: 41-50 171-190 C: 29-34	US (2019)	/
Snibe Diagnostic	Biolumi CX8, MAGLUMI X8, X3, X6	hs-cTnI	No	0.5	1.0	2.0-50,000	6.3%	3.0	5.2	Overall n = 617 Females n = 304 Males n = 313	Overall 17.5 Females 11.8 Males 20.1	Overall 87.2% Females 82.6% Males 91.7%	Non-parametric	Serum, plasma (EDTA, heparin)	Cardiac troponin I antigen	NP	OUS (2026) China (2026)	Zhang Y, et al. 2025
Tosoh	AIA-CL	hs-cTnI	No	0.97[1]	1.61	2-60,000	<10%	2.3	5.6	Overall n = 1391 Males n = 723 Females n = 688	Overall 27 Males 27 Females 23.3	>50%	Non-parametric	Serum, plasma (EDTA, heparin)	SRM 2927[1]	NP	OUS (2026)	Massoti S, et al. 2019
YHLO	iFlash-series	hs-cTnI (OUS)	No	0.3	0.6	0.6-50,000	Overall 2.73% Females 3.50% Males 2.57%	≤ 1.0	≤ 2.0	Overall n = 878 20-89y Females n = 442 Males n = 436	Overall 16.8 Males 18.5 Females 11.1	Overall 93.51% Females 90.50% Males 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	2.1-50,000	Overall 4.2% Females 4.4% Males 4.0%	2.1	6.1[1]	Overall n = 654 20-86y[1] Females n = 335 Males n = 319	Overall 28.2 Males 30.3 Females 25.3	>50%	Non-parametric[1]	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 99th percentile and b) ≥ 50% measurable concentrations ≥ LoD for both males AND females in independent evaluations.

[1] Information not reported in a Package Insert or a published manuscript. For more information, please contact the manufacturer.

[2] Note that less than 300 males and 300 females were used to determine the 99th percentile.

[3] No longer commercially available.