

Point of Care Cardiac Troponin I and T Assay Analytical Characteristics Designated by Manufacturer

IFCC Committee on Clinical Applications of Cardiac Bio-Markers (C-CB) v092021

Company/Platform/ Assay	LoB (µg/L unless noted)	LoD (µg/L unless noted)	% CV at 99 th Percentile	Conc at 20% CV (µg/L unless noted)	Conc at 10% CV (µg/L unless noted)	Reference Population N, Ages, Sex	Specimen Type	99 th Percentile (µg/L unless noted)	Percent Normals Measured ≥ LoD	Statistic Used to Calc 99 th Percentile	Epitopes Recognized by Antibodies	Country of Package Insert: Version Date
Abbott i-STAT	0.02	NP	16.5%	0.07	0.1	Overall n = 162	Sodium and lithium heparinized whole blood and plasma	Overall: 0.08	NP	NP	NP	US: Rev. Date: 01-Jul-13
LSI Medience (formerly Mitsubishi) PATHFAST cTnI; commercial	NP	1 ng/L	< 6%	2 ng/L	3.1 ng/L	Overall n =474 18-86y F: 236 M: 238	Heparin-Na, heparin-Li or EDTA whole blood or plasma	Overall: 15.48 ng/L F: 11.46 ng/L M: 16.91 ng/L	Overall: 76.3%	Non-Parametric	C: 41-49, D: 71-116, 163-209	WW except US & Japan: Ver.5, Apr. 2014
LSI Medience (formerly Mitsubishi) PATHFAST hs-cTnI /PATHFAST cTnI-II	1.23 ng/L	2.33 ng/L	6.1%	4 ng/L	15 ng/L	Overall n=734 Age >18 F: 352 M: 382	Heparin-Na, heparin-Li or EDTA whole blood or plasma	Overall: 27.9 ng/L F: 20.3 ng/L M: 29.7 ng/L	Overall: 66.3% F: 52.8% M: 78.8%	Non-Parametric	C:41-49, D: 71-116, 163-209	hs-cTnI : WW except US Ver.1, May 2018
LSI Medience (formerly Mitsubishi) PATHFAST cTnI-II	NP	NP	6.1%	NP	0.019	Overall n=333	Heparin-Na, heparin-Li or EDTA whole blood or plasma	Overall: 0.029	NP	Non-Parametric	C: 41-49, D: 71-116, 163-209	US: Ver.4, Mar.2015
Quidel/Alere TriageTrue hs-cTnI	0.4 ng/L (plasma) 0.5-0.8 ng/L (whole blood)	0.7 – 1.6 ng/L (plasma) 1.5-1.9 ng/L (whole blood)	5.0 – 5.9% at 21 ng/L (plasma) 5.9 – 6.5% at 22 ng/L (whole blood)	2.1 – 3.6 ng/L (plasma) 2.8 ng/L (whole blood)	4.4 – 8.4 ng/L (plasma) 5.8 – 6.2 ng/L (whole blood)	Overall n = 789 F: 391 M: 398	EDTA whole blood or plasma	Overall: 20.5 ng/L F: 14.4 ng/L M: 25.7 ng/L	Overall: ≥ 50%	NP	NP	hs-cTnI: WW except US April 2020
Quidel/Alere Triage Cardiac Panel	NP	0.050	NP	16.3% at 0.120	NP	Overall n = 323 F: 168 M: 155	EDTA whole blood or plasma	NP	NP	NP	NP	USA, 2014, rev. D
Quidel/Alere Triage SOB	NP	0.050	NP	16.3% at 0.120	NP	Overall n = 323 F: 168 M: 155	EDTA whole blood or plasma	NP	NP	NP	NP	USA, 2014, rev. D
Quidel/Alere Triage Cardio	0.002	0.01	NP	0.020	0.040	Overall n = 989	EDTA whole blood or plasma	Overall: 0.020	Overall: 11.8%	Non-Parametric	NP	USA, 2014, rev. D
Radiometer AQT90 FLEX TnI	NP	0.009	12.3%	NP	0.027	Overall n = 231 F: 106 M: 128	EDTA and heparinized whole blood and plasma	Overall: 0.023	NP	Non-Parametric	C: 41-49, 190-196 D:137-149	990-872 InterNptioNPI 201608X
Radiometer AQT90 FLEX TnT	NP	0.008	15.2%	NP	0.026	Overall n = 260 F: 132 M: 128	EDTA and heparinized whole blood and plasma	Overall: 0.017	NP	Non-Parametric	C:125-131 D:136-147	990-872 InterNptioNPI 201608H
Response Biomedical RAMP Troponin I	NP	0.03	20.0%	0.10	0.21	Overall n =180	Only EDTA whole blood	Overall: <0.10	NP	NP	NP	Eu IFU 90012-1.2

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Roche CARDIAC POC Troponin T – Roche cobas h 232	NP	0.04	NP	0.04 – 2.0	9.3% between 0.04 –0.2	Overall n = 302	Heparinized whole blood	NP	NP	NP	D: 125-131 C: 136-147	EU, 2016-05
Siemens ATELLICA VT hs-cTnI	0.55 ng/L	1.2 ng/L (plasma) 1.6 ng/L (whole blood)	6.5% (plasma) 6.1% (whole blood) at 22.9 ng/L	2.1 ng/L (plasma) 3.7 ng/L (whole blood)	6.7 ng/L (plasma) 8.9 ng/L (whole blood)	Overall n = 694 F: 331 M: 363	Li Hep whole blood and plasma, capillary blood	Overall: 22.9 ng/L F: 18.5 ng/L M: 27.1 ng/L	Overall: 84% F: 80% M: 87%	Non-Parametric	C: 41-49 D: 2 Abs in range 20-100 cTnC Ab	CE, 2021-03
Siemens Stratus CS Acute Care cTnI test pack	<0.03	NP	8.2%	0.03	0.06	Overall n=101	Whole blood (Li or NP heparin) or plasma Li or Na heparin	Overall: 0.07	NP	NP	C: 27-32 D: 41-56	CE, 2008-04

LoB, limit of blank; LoD, limit of detection, NP, not provided; C, capture antibody; D, detection antibody; M, male, F, female; Conc, concentration; WW worldwide. All data have been listed as provided by the manufacturer, except assays in blue were abstracted from package insert due to lack of correspondence from manufacturer.