

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

IFCC Task Force on Clinical Applications of Cardiac Bio-Markers (TF-CB) v060617

Company/Platform/Assay	LoB, µg/L	LoD, µg/L	% CV at 99 th percentile	Conc at 20% CV µg/L	Conc at 10% CV µg/L	Reference Population N, Ages, Sex	99 th Percentile, µg/L	Percent Normals Measure > LoD	Statistic Used to Calc 99 th Percentile	Specimen Type	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	Overall: 0.08	NP	NP	Sodium and lithium heparinized whole blood and plasma	NP	US: Rev. Date: 01-Jul-13
Alere Triage Cardiac Panel	NP	0.050	NP	16.3% at 0.120	NP	Overall n = 323 F: 168 M: 155	NP	NP	NP	EDTA whole blood or plasma	NP	USA, 2014, rev. D
Alere Triage SOB	NP	0.050	NP	16.3% at 0.120	NP	Overall n = 323 F: 168 M: 155	NP	NP	NP	EDTA whole blood or plasma	NP	USA, 2014, rev. D
Alere Triage Cardio	0.002	0.01	NP	0.020	0.040	Overall n = 989 males and females	Overall: 0.020	Overall: 11.8%	Non-parametric	EDTA whole blood or plasma	NP	USA, 2014, rev. D
LSI Medience (former Mitsubishi) PATHFAST cTnI	NP	0.001	< 6%	0.002	0.003	Overall n = 474 18-86y M: 238 F: 236	Overall: 0.015 M:0.017 F:0.011	Overall: 76.3%	Non-Parametric	Whole blood, plasma	C:41-49, D: 71-116, 163-209	WW except USA & Japan: Ver.6,2017.10
LSI Medience (former Mitsubishi) PATHFAST cTnI cTNI-II	0.003	0.005	6.1%	0,004	0,015	Overall n = 490 18-78y	Overall: 0.029	NP	Non-parametric	Whole blood, plasma	C: 41-49, D: 71-116, 163-209	USA : Ver.4,2015.3 Japan: Ver.5,2014.4
Philips Electronics Nederland BV/Minicare I-20/Minicare cTnI	0.0085	0.018	18.6%	0.038	NP	Overall n =750 18-86y M: 373 F: 377	Overall: 0.043	Overall: 5.1% for capillary	Non-Parametric	Li-heparin whole blood, capillary whole blood and plasma	C: 41-49 D: 20-100 anti cTnC MAb	IFU cTnI EN Issue #5122300 12922*2017-03 Document version 3.0
Radiometer AQT90 FLEX TnI	NP	0.009	12.3%	NP	0.027	Overall n = 231 M: 128 F: 106	Overall: 0.023	NP	Non-Parametric	EDTA and heparinized whole blood and plasma	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 M: 128 F: 132	Overall: 0.017	NP	Non-Parametric	EDTA and heparinized whole blood and plasma	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	Overall: <0.10	NP	NP	Only EDTA whole blood	NP	Eu IFU 90012-1.2
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	NP	NP	NP	Heparinized whole blood	D: 125-131 C: 136-147	EU, 2016-05
Siemens Stratus CS Acute Care cTnI test pack	<0.03	NP	8.2%	0.03	0.06	Overall n=101 No age No sex	Overall: 0.07	NP	NP	Whole blood (Li or NP heparin) or plasma Li or Na heparin	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.