

Contemporary Cardiac Troponin I and T Assay Analytical Characteristics Designated by Manufacturer

IFCC Committee on Clinical Applications of Cardiac Bio-Markers (C-CB) v012019

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	Specimen Type	99 th Percentile (µg/L)	Percent Normals Measured ≥ LoD	Statistic Used to Calc 99 th Percentile	Epitopes Recognized by Antibodies	Country of Package Insert: Version Date
Abbott /ARCHITECT i systems/ ARCHITECT STAT Troponin-I	≤ 0.01	0.009	14%	NP	0.032	Overall n = 449 18-63y F: 225 18-62y M: 224 18-63y	Serum, heparin plasma	Overall: 0.028 F: 0.013 M: 0.033	2%	Robust	C: 87-91, 24-40 D: 41-49	US only: G1- 0467/ R11, revised June 2015
Beckman/Access 2 /AccuTnl+3, US	<0.01	0.01	20%	0.02	0.04	Overall n = 527 18-94y 59.8% Female	Lithium heparin plasma	0.02	NP	Non- Parametric	C: 41-49 D: 24-40	US B16315 2013
Beckman/Dxl/ AccuTnl+3, US	<0.01	0.01	20%	0.03	0.04	Overall n = 527 18-94y 59.8% Female	Lithium heparin plasma	<0.03	NP	Non- Parametric	C: 41-49 D: 24-40	US B16316 2013
Beckman/Access 2 /AccuTnl+3, OUS	<0.01	0.01	10%	0.02	0.04	Overall n = 998 >40y 56.6% Female	Serum	0.04	NP	Non- Parametric	C: 41-49 D: 24-40	OUS A90435 2013
Beckman/Dxl/ AccuTnl+3, OUS	<0.01	0.01	10%	0.02	0.04	Overall n = 998 >40y 56.6% Female	Serum	0.04	NP	Non- Parametric	C: 41-49 D: 24-40	OUS B00495 2013
Ortho/VITROS/ Immunodiagnostic Troponin I ES	0.007	0.012	10%	0.012	0.034	>10,000	Serum, plasma (Li heparin, EDTA)	0.034	4%	Non- Parametric	C: 24-40 41-49; D: 87-91	USA: Version 7; 2016-01-06
Philips Electronics Nederland BV/Minicare I-20 /Minicare cTnl	0.008	0.018	18.6%	0.038	NP	Overall n = 750 18-86y F: 377 M: 373	Li-heparin whole blood, capillary whole blood, Li-heparin plasma	0.043	5.1% for capillary	Non- Parametric	C: 41-49 D: 20-100, cTnC MAb	IFU cTnl EN Issue #512230 12922*2017- 03 Doc.t v3.0
Radiometer AQT90 FLEX Tnl	NP	0.009	12.3%	NP	0.027	Overall n = 231 F: 106 M: 128	EDTA & heparinized whole blood and plasma	0.023	NP	Non- Parametric	C:41-49, 190-196 D:137-149	990-872 OUS 201608X

Radiometer AQT90 FLEX TnT	NP	0.008	15.2%	NP	0.026	Overall n = 260 F: 132 M: 128	EDTA & heparinized whole blood and plasma	0.017	NP	Non-Parametric	C:125-131 D:136-147	995-639 OUS 201608H
Roche cobas e411*/ Roche E170/ cobas e601/602 /cobas e801 cTnI (18 min & STAT) *STAT only	0.1	0.16	NP	NP	0.30	Overall n = 839 20-79 y	Serum, plasma (EDTA/heparin)	0.16	1.0%	NP	C: 87-91, 190-196 D: 23-29, 27-43	EU
Roche cobas e411*/ Roche E170/ cobas e601/602 cTnI (18 min & STAT) *STAT only	<0.30	<0.30	NP	NP	0.30	Overall n = 839 20-79 y	Serum, plasma (EDTA/heparin)	<0.3	1.0%	NP	C: 87-91, 190-196 D: 23-29, 27-43	US
Roche cobas e411/ Roche E170/ cobas e601/602 cTnT (18 min STAT)	NP	0.010	NP	NP	0.03	Overall n = 1951	Serum, plasma (EDTA, heparin, citrate)	<0.010	NP	NP	C: 125-131 D:136-147	US
Siemens Atellica TnI-Ultra	0.007	0.015	<10%	0.015	< 0.020	Overall n = 1974 22-91 y F: 993 M: 981	Serum, plasma (EDTA, Li-Hep)	0.020	NP	NP	C: 41-49, 87-89 D: 27-40	CE 10995428_EN Rev. 01, 2017-05
Siemens ADVIA Centaur Systems TnI-Ultra	0.006	NP	<8%	0.017	0.03	Overall n = 648 17-91 y	Serum, plasma (EDTA, Li-Hep)	0.040	NP	NP	C: 41-49, 87-89 D: 27-40	CE 10629901_EN Rev. L, 2014-08
Siemens Dimension Vista Systems LOCI cTnI	0.015	NP	<10%	NP	<0.04	Overall n = 199	Serum, Li-Hep plasma	0.045	NP	NP	C: 27-32 D: 41-56	CE 2015-03-27 E PN 781421.001
Siemens Dimension EXL Systems LOCI cTnI	0.010	0.017	<10%	NP	0.05	Overall n = 241	Serum, plasma (EDTA, Li-Hep)	0.056	NP	NP	C: 27-32 D: 41-56	CE 2015-02-09 D PN 741621.001
Tosoh AIA cTnI 3rd Gen	0.008	0.02	<20%	0.01	0.035	Overall n = 343 Asian	Serum, plasma (EDTA/heparin)	0.04	NP	NP	NP	EU rev.cTNI-011111

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; OUS, outside United States. 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.