

High Sensitivity* 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 ng/L	LoD, ng/L	% CV at 99th percentile	Conc at 20% CV ng/L	Conc at 10% CV ng/L	Reference Population N, Ages, Sex	99th percentile Overall/M/F ng/L	Specimen Type	Percent Normals Measured ≥ LoD Overall/M/F	Statistic Used to Calc 99 th Percentile	% RCV	Epitopes Recognized by Antibodies	Country of Package Insert: Version Date
Abbott/ ARCHITECT i systems/ ARCHITECT STAT High Sensitive Troponin-I; commercial	0.7 to 1.3	1.1	Overall: 4.0% F: 5.3% M: 3.5%	1.3	4.7	Overall n =1531 21-75y F: 764 21-75y M: 766 21-73y	Overall: 26.2 F: 15.6 M: 34.2	Lithium heparin (with/without separator), K2 EDTA, K3 EDTA, serum (with/without separator), serum with thrombin- based clot activator	Overall: 85% F: 78% Male: 92%	Robust	NP	NP	OUS only: G5-6634/R01 April 2015
bioMérieux VIDAS High Sensitive Troponin I; commercial	1.9	3.2	7.0%	4.9	NP	Overall n = 815 41-80y F: 368: 41-80y M: 447 41-80y	Overall: 19 F: 11 M: 25 F: 11	Serum or heparin plasma	NP	NP	NP	C: 41-49, 24-40 D: 87-95	France Dec 23rd 2015
ET Healthcare Pylon hs Tnl assay; research	0.8	1.2 to 1.4	10%	2	10	Overall n =763 F: 437 M: 281 15-91y (AACC Universal Sample Bank)	Overall: 26 F: 19 M: 28	EDTA plasma, EDTA whole blood, serum	Overall: 90% F: 94% M: 86%	NP	NP	C: 27-40 D: 41-49	ChiNP, 2017
LSI Medience (former Mitsubishi) PATHFAST cTnl; commercial	NP	1	< 6%	2	3.1	Overall n =474 F: 236 M: 238 18-86y	Overall: 15.48 M: 16.91 F: 11.46	Whole blood, plasma	Overall: 76.3%	Non- Parametric	NP	C: 41-49, D: 71-116, 163-209	WW except US & Japan: Ver.6,2017.10

Ortho/VITROS/Immunodiagnostic hs Troponin I preliminary data; research	0.3	1.0	<10%	1.7	4.3	Overall n =480 F: 236 M: 244 16-88y	Overall: 21 F: 9 M: 26	Serum; Lithium heparin plasma	NP	Non-parametric	NP	C: 87-91 D: 24-40; 41-49	Not Available yet-in development
Roche cTnT-hs 18-min on cobas e 601, 602, E170; commercial	1.36 2.16 for e411	2.05; 4.72 for e411	<10%	2.20	4.49	Overall n =533 F: 49.7% 20-71y	Overall: 14 F: 9 M: 16	Serum, plasma: EDTA, heparin	Overall: 71.5%	Non-parametric	NP	C: 125-131 D: 136-147	EU (upcoming PI version)
Roche cTnT-hs STAT on cobas e 601, 602, E170; commercial	2.26 2.57 for e411	2.85; 4.88 for e411	<10%	2.81	5.03	Overall n =533 F: 49.7% 20-71y	Overall: 14 F: 9 M: 16	Serum, plasma: EDTA, heparin	Overall: 58.9%	Non-parametric	NP	C: 125-131 D: 136-147	EU (upcoming PI version)
Roche TnT Gen 5 STAT on cobas e 601, 602, E170 *specified value; ** including e 411 data; commercial	2.5* 3 for e411	3* 5 for e411	<10%	6*	11**	Overall n =1301 F: 50.4% 21-89y	Overall: 19 M: 22 F: 14	Plasma heparin	Overall: 55.1%	Non-parametric	NP	C: 125-131 D: 136-147	USA, v1
Siemens ADVIA Centaur High-Sensitivity TnI (TNIH), OUS; commercial	0.90	1.10 to 2.21	<4.2%	<2.5	4.46	Overall 2010 ¹ /1990 ² F: 1012 ¹ /1006 ² M: 998 ¹ /984 ² 22-91y	Overall: 47.3 ¹ F: 37.0 ¹ M: 57.3 ¹ Overall: 46.5 ² F: 39.6 ² M: 58.0 ²	Li Hep ¹ Serum ²	Overall: >63% M: NP F: NP	NP	NP	C: 30-35, 171-190 D: 41-56	CE-marked March 2017
Singulex Clarity cTnI; commercial	0.02	0.08	2.39%	0.14	0.53	Overall n =536 F: 262 M: 274 18-84y	Overall: 8.67 M: 9.23 F: 8.76	EDTA plasma	Overall: 99% M: 100% F: 99%	Non-parametric	NP	C: 41-49, 24 - 40 D: 190-196, 86 - 90	European Union. Version 1

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; RCV, reference change value. All data have been listed as provided by the manufacturer. *Please note manufacturers may have submitted assays they claim to be 'high sensitivity' that do not meet the IFCC requirements of: a) $\leq 10\%$ CV at the 99th percentile and b) $\geq 50\%$ measurable concentrations \geq LoD.