

# High-Sensitivity\* 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 (ng/L)	LoD (ng/L)	% CV at 99 <sup>th</sup> Percentile	Conc at 20% CV (ng/L)	Conc at 10% CV (ng/L)	Reference Population N, Ages, Sex	99 <sup>th</sup> Percentile Overall M / F (ng/L)	Specimen Type	Percent Normals Measured ≥ LoD Overall M / F	Statistic Used to Calc 99 <sup>th</sup> 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% M: 92%	Robust	NP	NP	OUS only: G5-6634/R01 April 2015
Beckman Coulter/ Access 2, Dxl/Access hsTnl; commercial – OUS	0.0 to 1.7	1.0 to 2.3	Overall: 3.7% F: 4.2% M: 3.6%	1.0 to 2.3	5.6	Overall n=1089 21-99y  F: 595 M: 494	Overall: 17.5  F: 11.6 M: 19.8	Heparin plasma	> 50%	Non- Parametric	NP	NP	OUS B52699/ C11140 Sept 2017
Beckman Coulter/ Access 2, /Access hsTnl; commercial – U.S.: LiHep plasma	0.0 to 0.8	1.0 to 2.0	Overall: 3.7% F: 4.2% M: 3.6%	0.9 to 2.3	4.1	Overall n=1089 21-99y  F: 595 M: 494	Overall: 17.5  F: 11.6 M: 19.8	Heparin plasma	> 50%	Non- Parametric	NP	NP	US B52699/ C09449 June 2018
Beckman Coulter/ Access 2, /Access hsTnl; commercial – U.S.: Serum	0.0 to 0.8	1.0 to 2.0	Overall: 6.0% F: 6.9% M: 5.8%	0.9 to 2.3	4.1	Overall n=1088 21-99y  F: 595 M: 493	Overall: 18.2  F: 11.8 M: 19.7	Serum	> 50%	Non- Parametric	NP	NP	US B52699/ C09449 June 2018
Beckman Coulter/ Dxl, Access hsTnl; commercial – U.S.: LiHep plasma	0.0 to 1.7	1.5 to 2.3	Overall: 5.2% F: 5.6% M: 5.0%	1.2 to 2.3	5.6	Overall n=1088 21-99y  F: 593 M: 495	Overall: 17.9  F: 14.9 M: 19.8	Heparin plasma	> 50%	Non- Parametric	NP	NP	US B52699/ C09448 June 2018

Beckman Coulter/ Dxl, Access hsTnl; commercial – U.S.: Serum	0.0 to 1.7	1.5 to 2.3	Overall: 6.2% F: 6.5% M: 6.1%	1.2 to 2.3	5.6	Overall n=1085 21-99y  F: 592 M: 493	Overall: 18.1  F: 13.6 M: 19.8	Serum	> 50%	Non-Parametric	NP	NP	US B52699/ C09448 June 2018
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	Serum or heparin plasma	NP	NP	NP	C: 41-49, 24-40 D: 87-95	France Dec 23rd 2015
ET Healthcare Pylon hsTnl assay; China FDA approved	0.8	1.2 – 1.4	10%	2	10	Overall n =863 15-91y  F: 438 M: 425 (AACC Universal Sample Bank)	Overall: 27  F: 21 M: 27	EDTA plasma, EDTA whole blood, serum	Overall: 91%  F: 89% M: 94%	Non-Parametric	NP	C: 27-40 D: 41-49	China, 2018
ET Healthcare Pylon hsTnT; research	0.4	0.8	4%	1	4	Overall n=863 15-91y  F: 438 M: 425 (AACC Universal Sample Bank)	Overall: 13  F: 13 M: 14	EDTA whole blood, EDTA plasma, serum	Overall: 94%  F: 93% M: 97%	Non-Parametric	NP	C: 119-138, D: 132-151	China, 2018
Fujirebio Lumipulse G G1200 and G600II hsTnl	1.2	2.1	≤4.6%	NP	7.3	Overall n=1018, 18-90 years  F: 428 M: 590	Overall: 28.6 F: 22.4 M: 32.9  Serum Overall: 26.9 F: 21.4 M: 29.4  Li Heparin Plasma Overall: 29.6 F: 27.8 M: 32.8	Red top serum, serum separator tube, rapid clotting tubes; Disodium EDTA*, Dipotassium EDTA*, Lithium heparin, Sodium heparin, Sodium Citrate, PST with lithium heparin	Overall: 68.3%  Serum: 68.1%  Li Heparin Plasma: 65.0%	Robust	NP	NP	English FRI0030, Feb 2017 Ver.01

LSI Medience (formerly Mitsubishi) PATHFAST cTnI; commercial	NP	1	< 6%	2	3.1	Overall n =474 18-86y F: 236 M: 238	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.5, Apr.2014
LSI Medience (formerly Mitsubishi) PATHFAST hs-cTnI /PATHFAST cTnI-II	1.23	2.33	6.1%	4	15	Overall n=734 Age >18 F: 352 M: 382	Overall: 27.9 F: 20.3 M: 29.7	Whole blood, plasma	Total: 66.3% F: 52.8% M: 78.8%	Non-Parametric	ND	C:41-49 D: 71-116, 163-209	hs-cTnI : WW except US Ver.1, May 2018
Ortho/ VITROS/ Immunodiagnostic hs Troponin I prelim data; research	0.3	1.0	<10%	1.7	4.3	Overall n =480 16-88y F: 236 M: 244	Overall: 21 F: 9 M: 26	Serum; Lithium heparin plasma	NP	Non-Parametric	NP	C: 87-91 D: 24-40, 41-49	In Development
Roche/ cobas e601, e602, E170/cTnT-hs 18-min; commercial	1.36; (2.16 for e411)	2.05; (4.72 for e411)	<10%	2.20	4.49	Overall n=533 20-71y F: 49.7%	Overall:14 F: 9 M:16	Serum, plasma: EDTA, heparin	Overall: 71.5%	NP	NP	C: 125-131 D: 136-147	EU (upcoming PI version)
Roche/ cobas e601, e602, E170/ cTnT-hs STAT; commercial	2.26; 2.57 for e411	2.85; 4.88 for e411	<10%	2.81	5.03	Overall n =533 20-71y F: 49.7%	Overall: 14 F: 9 M: 16	Serum, plasma: EDTA, heparin	Overall: 58.9%	NP	NP	C: 125-131 D: 136-147	EU (upcoming PI version)
Roche/ cobas e801/ cTnT-hs 18-min and STAT; commercial	2.5	3	<10%	6	18-min: 3.83 STAT: 5.48	Overall n =533 20-71y F: 49.7%	Overall: 14 F: 9 M: 16	Serum, plasma: EDTA, heparin	Overall: 57.4%	NP	NP	C: 125-131 D: 136-147	EU, v2
Roche/ cobas e601, e602, E170/ TnT Gen 5 STAT ^specified value; ^^including e411 data; commercial	2.5^; 3 for e411	3^; 5 for e411	<10%	6^^	11^^	Overall n =1301 21-89y F: 50.4%	Overall: 19 F: 14 M: 22	Plasma heparin	Overall: 55.1%	NP	NP	C: 125-131 D: 136-147	USA, v1
Siemens ATELLICA High-Sensitivity TnI (TnIH), US & OUS; commercial	0.50	1.6	<4.0%	2.50	<6.0	Overall n = 2001 22-91y F: 1007 M: 994	Overall: 45.4 F: 38.6 M: 53.5	Li Hep Serum	Overall: 75% F: 62% M: 89%	Non-Parametric	NP	C: 41-50, 171-190 D: 29-34	CE-marked March 2017 FDA 510k July 2018

Siemens ADVIA Centaur XP/ XPT High-Sensitivity Tnl (TNIH), US & OUS; commercial	0.50	1.6	<4.9%	2.50	<6.0	Overall n = 1990 22-91y F: 1006 M: 984	Overall: 46.5 F: 39.6 M: 58.0	Li Hep Serum	Overall: 63% F: NP M: NP	Non-Parametric	NP	C: 41-50, 171-190 D: 29-34	CE-marked March 2017 FDA 510k July 2018
Siemens Dimension VISTA High Sensitivity Tnl (TNIH), OUS; commercial	1.0	2.0	<5.0%	3.0	10.0	Overall n = 2014 22-91y F: 1013 M: 1001	Overall: 57.9 F: 51.1 M: 74.9	Li Hep Serum	Overall: 81.8% F: NP M: NP	Non-Parametric	NP	D: 41-50 171-190 C: 29-34	CE-marked 2017
Siemens Dimension ExL High Sensitivity Tnl (TNIH), OUS; commercial	1.1	2.7	<5.0%	4.0	12.0	Overall n = 2014 22-91y F: 1013 M: 1001	Overall: 58.2 F: 47.8 M: 71.8	Li Hep Serum	Overall: 51.5% F: NP M: NP	Non-Parametric	NP	D: 41-50 171-190 C: 29-34	CE-marked 2017
Singulex Clarity cTnl; commercial	0.02	0.08	2.39%	0.14	0.53	Overall n = 536 18-84y F: 262 M: 274	Overall: 8.67 F: 8.76 M: 9.23	EDTA plasma	Overall: 99% F: 99% M: 100%	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 99<sup>th</sup> percentile and b)  $\geq 50\%$  measurable concentrations  $\geq$  LoD for both males AND females.