IFCC Paper

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High sensitivity, contemporary and point-of-care cardiac troponin assays: educational aids developed by the IFCC Committee on Clinical Application of Cardiac Bio-Markers

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Abstract: The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) formed a Task Force on the Application of Cardiac Bio-markers (TF-CB) in 2008, re-designated in 2018 as a committee (C-CB), to produce educational materials on cardiac biomarkers. Established in June 2017, definitive tables covering the majority of high-sensitivity, contemporary and point-of-care (POC) cTn assays have been developed by the C-CB and are available on the IFCC website. These tables provide extensive information about assays' analytical characteristics and encompass information on diagnostic discriminants, particularly the 99th percentiles, as provided by the manufacturers.

Keywords: 99th percentiles; cardiac troponin; education; high sensitivity assays; myocardial injury; point-of-care.

The Global Task Force for Fourth Universal Definition of Myocardial Infarction (MI) utilizes cardiac troponin (cTn) as the standard biomarker for the detection of myocardial injury [1]. An increased cTn concentration above the upper reference limit (URL) defines myocardial injury, with cTn URLs specified as sex-specific 99th percentiles of a normal healthy reference population, defined by sex, age, racial and ethnic diversity [1–4]. Prior to 2000, the definition of MI utilized a different diagnostic discriminant, the 97.5th percentile of a reference population, for a 'cardiac enzyme', typically total creatine kinase (CK) or its MB isoenzyme (CK-MB) [5].

When first introduced into routine clinical practice, cTn assays were evaluated against the WHO diagnostic criteria for MI as the diagnostic gold standard. Using the WHO criteria as the diagnostic standard resulted in a relatively high diagnostic discriminant, typically 10–50 times the cTn 99th percentile. Shortly after, the redefinition of MI guidelines endorsed the preferred diagnostic discriminant as cTn, with a statement that cTn assays should ideally have a 10% coefficient of variation (CV) at the assay's 99th percentile URL concentration [6]. Assays were considered to be clinically acceptable if they had a %CV at the 99th percentile ≤20%, as patients would not be misclassified at this concentration [7]. Introduction of cTn assays into routine clinical use was accompanied by a range of different proposed diagnostic URLs for the diagnosis of MI, likely due to the misunderstanding of the intent and recommendations within the guidelines. Surveys of laboratory practice revealed that there was still use of a range of biomarkers other than cTn and a great deal of uncertainty as to what diagnostic URL (WHO equivalent, 10% or 20% CV concentration, or the 99th percentile) was appropriate [8].

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) formed a Task Force on the Application of Cardiac Bio-markers (TF-CB) in 2008, re-designated in 2018 as a committee (C-CB), to produce educational materials on cardiac biomarkers [3–5]. Since the 2007 survey [2–4], there has been progressive improvement in assay analytical sensitivity, culminating in the development and global clinical implementation of high-sensitivity (hs) cTn assays [2–4]. Subsequent surveys, most recently in 2016, have shown that although there has been a shift to cTn as the

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Table 1: High-sensitivity[a] cardiac troponin I and T assay analytical characteristics designated by manufacturer – IFCC Committee on Clinical Applications of Cardiac Bio-Markers (C-CB).

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, Age, Sex	99th percentile overall M/F, ng/L	Specimen type	Percent normals measured ≥LoD Overall M/F	Statistic used to calc 99th percentile	% RCV	Epitopes recognized by antibodies	Country of package insert: version date
Abbott/ ARCHITECT i Systems/ ARCHITECT STAT high sensitive troponin-I; commercial	0.7–1.3	1.1	Overall: 4.0% F: 5.3% M: 3.5%	1.3	4.7	Overall n =1531 21–75 years F: 764 21–75 years M: 766 21–73 years	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, DxI/ Access hsTnI; commercial – OUS	0.0–1.7	1.0–2.3	Overall: 3.7% F: 4.2% M: 3.6%	1.0–2.3	5.6	Overall n = 1089 21–99 years 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 hsTnI; commercial – US: LiHep plasma	0.0–0.8	1.0–2.0	Overall: 3.7% F: 4.2% M: 3.6%	0.9–2.3	4.1	Overall n = 1089 21–99 years 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 hsTnI; commercial – US: Serum	0.0–0.8	1.0–2.0	Overall: 6.0% F: 6.9% M: 5.8%	0.9–2.3	4.1	Overall n = 1088 21–99 years 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/ DxI, Access hsTnI; commercial – US: LiHep plasma	0.0–1.7	1.5–2.3	Overall: 5.2% F: 5.6% M: 5.0%	1.2–2.3	5.6	Overall n = 1088 21–99 years 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/ DxI, Access hsTnI; commercial – US: Serum	0.0–1.7	1.5–2.3	Overall: 6.2% F: 6.5% M: 6.1%	1.2–2.3	5.6	Overall n = 1085 21–99 years F: 592 M: 493	Overall: 18.1 F: 13.6 M: 19.8	Serum	>50%	Non-parametric	NP	NP	US B52699/ C09448 June 2018

Table 1 (continued)

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, Age, Sex	99th percentile overall M/F, ng/L	Specimen type	Percent normals measured ≥LoD Overall M/F	Statistic used to calc 99th percentile	% RCV	Epitopes recognized by antibodies	Country of package insert: version date
bioMérieux VIDAS High Sensitive Troponin I; commercial	1.9	3.2	7.0%	4.9	NP	Overall n = 815 41–80 years F: 368: 41–80 years M: 447 41–80 years	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 hsTnI assay; research	0.8	1.2–1.4	10%	2	10	Overall n = 763 15–91 years F: 437 M: 281 (AACC Universal Sample Bank)	Overall: 26 F: 19 M: 28	EDTA plasma, EDTA whole blood, serum	Overall: 90% F: 86% M: 94%	NP	NP	C: 27–40 D: 41–49	ChiNP, 2017
Fujirebio Lumipulse G G1200 and G600II hsTnI	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[a], dipotassium EDTA[a], 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 18–86 years 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 and Japan: Ver.6, 2017.10

Table 1 (continued)

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, Age, Sex	99th percentile overall M/F, ng/L	Specimen type	Percent normals measured ≥LoD Overall M/F	Statistic used to calc 99th percentile	% RCV	Epitopes recognized by antibodies	Country of package insert: version date
LSI Medience (former 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 and Japan Ver.1, May 2018 cTnI-II: US, ver.4 Mar 2015
Ortho/VITROS/ Immunodiagnostic hs Troponin I prelim data; research	0.3	1.0	<10%	1.7	4.3	Overall n = 480 16–88 years 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 20–71 years 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 20–71 years 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 20–71 years 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 21–89 years F: 50.4%	Overall: 19 F: 14 M: 22	Plasma heparin	Overall: 55.1%	NP	NP	C: 125–131 D: 136–147	USA, v1

Table 1 (continued)

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, Age, Sex	99th percentile overall M/F, ng/L	Specimen type	Percent normals measured ≥LoD Overall M/F	Statistic used to calc 99th percentile	% RCV	Epitopes recognized by antibodies	Country of package insert: version date
Siemens ATELLICA high-sensitivity TnI (TnIH), US and OUS; commercial	0.50	1.6	<4.0%	2.50	<6.0	Overall n = 2001 22–91 years F: 1007 M: 994	Overall: 45.4 F: 38.6 M: 53.5	Li heparin 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 TnI (TNIH), US and OUS; commercial	0.50	1.6	<4.9%	2.50	<6.0	Overall n = 1990 22–91 years F: 1006 M: 984	Overall: 46.5 F: 39.6 M: 58.0	Li heparin 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 TnI (TNIH), OUS; commercial	1.0	2.0	<5.0%	3.0	10.0	Overall n = 2014 22–91 years F: 1013 M: 1001	Overall: 57.9 F: 51.1 M: 74.9	Li heparin 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 TnI (TNIH), OUS; commercial	1.1	2.7	<5.0%	4.0	12.0	Overall n = 2014 22–91 years F: 1013 M: 1001	Overall: 58.2 F: 47.8 M: 71.8	Li heprin serum	Overall: 51.5% F: NP M: NP	Non-parametric	NP	D: 41–50 171–190 C: 29–34	CE-marked 2017
Singulex Clarity cTnI; commercial	0.02	0.08	2.39%	0.14	0.53	Overall n = 536 18–84 years 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 the United States; RCV, reference change value; n, number. All data have been listed as provided by the manufacturer. [a]Please note manufacturers may have submitted assays they claim to be 'high sensitivity' that do not meet the IFCC requirements of: a) ≤10% CV at the 99th percentile and b) ≥50% measurable concentrations ≥LOD for both males and female separately.

Table 2: Contemporary cardiac troponin I and T assay analytical characteristics designated by manufacturer – IFCC Committee on Clinical Applications of Cardiac Bio-Markers (C-CB).

Company/platform/assay	LoB, µg/L	LoD, µg/L	% CV at 99th percentile	Conc at 20% CV, µg/L	Conc at 10% CV, µg/L	Reference population n, Age, Sex	Specimen type	99th percentile, µg/L	Percent normals measured ≥LoD	Statistic used to calc 99th 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 18–63 years F: 225 18–62 years M: 224 18–63 years	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/ AccuTnI + 3, US	<0.01	0.01	20%	0.02	0.04	Overall n = 527 18–94 years 59.8% Female	Lithium heparin plasma	0.02	NP	Non-parametric	C: 41–49 D: 24–40	US B16315 2013
Beckman/DxI/ AccuTnI + 3, US	<0.01	0.01	20%	0.03	0.04	Overall n = 527 18–94 years 59.8% Female	Lithium heparin plasma	<0.03	NP	Non-parametric	C: 41–49 D: 24–40	US B16316 2013
Beckman/Access 2/ AccuTnI + 3, OUS	<0.01	0.01	10%	0.02	0.04	Overall n = 998 >40 years 56.6% Female	Serum	0.04	NP	Non-parametric	C: 41–49 D: 24–40	OUS A90435 2013
Beckman/DxI/ AccuTnI + 3, OUS	<0.01	0.01	10%	0.02	0.04	Overall n = 998 >40 years 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 The NetherlandsBV/ Minicare I-20/ Minicare cTnI	0.008	0.018	18.6%	0.038	NP	Overall n = 750 18–86 years 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 cTnI EN Issue #512230 12922*2017-03 Doc.t v3.0
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	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 and heparinized whole blood and plasma	0.017	NP	Non-parametric	C: 125–131 D: 136–147	995-639 OUS 201608H

Table 2 (continued)

Company/platform/assay	LoB, µg/L	LoD, µg/L	% CV at 99th percentile	Conc at 20% CV, µg/L	Conc at 10% CV, µg/L	Reference population n, Age, Sex	Specimen type	99th percentile, µg/L	Percent normals measured ≥LoD	Statistic used to calc 99th percentile	Epitopes recognized by antibodies	Country of package insert: version date
Roche cobas e411*/ Roche E170/cobas e601/602/cobas e801 cTnI (18 min and STAT) *STAT only	0.1	0.16	NP	NP	0.30	Overall n = 839 20–79 years	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 and STAT) *STAT only	<0.30	<0.30	NP	NP	0.30	Overall n = 839 20–79 years	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 years F: 993 M: 981	Serum, plasma (EDTA, Li-heparin)	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 years	Serum, plasma (EDTA, Li-heparin)	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-heparin 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-heparin)	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; n, number. All data have been listed as provided by the manufacturer, except Tosoh assay that was abstracted from package insert due to lack of correspondence from manufacturer.

Table 3: 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).

Company/ platform/ assay	LoB, µg/L	LoD, µg/L	% CV at 99th percentile	Conc at 20% CV, µg/L	Conc at 10% CV, µg/L	Reference population n, Age, Sex	Specimen type	99th percentile, µg/L	Percent normals measured ≥LoD	Statistic used to calc 99th 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	<6%	2	3.1	Overall n = 474 18–86 years F: 236 M: 238	Overall: 15.48 M: 16.91 F: 11.46	Whole blood, plasma	Overall: 76.3%	Non-parametric	C: 41–49, D: 71–116, 163–209	WW except US and Japan: Ver.6,2017.10
LSI Medience (former 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	C:41–49, D: 71–116, 163–209	hs-cTnI: WW except US and Japan Ver.1, May 2018 cTnI-II: US, ver.4 Mar 2015
Philips electronics The Netherlands BV/Minicare I-20/Minicare cTnI	0.0085	0.018	18.6%	0.038	NP	Overall n = 750 18–86 years F: 377 M: 373	Li-heparin whole blood, capillary whole blood and plasma	Overall: 0.043	Overall: 5.1% for capillary	Non-parametric	C: 41–49 D: 20–100 anti cTnC MAb	IFU cTnI EN Issue #5122300 12922*2017-03 Document version 3.0
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 InterNPtioNPl 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 InterNPtioNPl 201608H

Table 3 (continued)

Company/ platform/ assay	LoB, µg/L	LoD, µg/L	% CV at 99th percentile	Conc at 20% CV, µg/L	Conc at 10% CV, µg/L	Reference population n, Age, Sex	Specimen type	99th percentile, µg/L	Percent normals measured ≥LoD	Statistic used to calc 99th percentile	Epitopes recognized by antibodies	Country of package insert: version date
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
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 Stratus CS Acute care cTnI test pack	<0.03	NP	8.2%	0.03	0.06	Overall n = 101 No age No sex	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; n, number. All data have been listed as provided by the manufacturer, except Response Biomedical assay that was abstracted from package insert due to lack of correspondence from manufacturer.

preferred and primary biomarker, there remains a lack of a consistent approach to the interpretation of cTn measurements [9]. Although the IFCC C-CB has defined the analytical characteristics to define 'high sensitivity', there also continues to be confusion as to what defines an hs-cTn assay and how to optimally use hs-cTn assays clinically.

The current environment is partly due to both the rapid pace in assay development and to the legacy of the varied range of diagnostic URLs for MI. The IFCC C-CB seeks to address the broader educational needs of the laboratory and clinical community and to provide authoritative, explanatory reference documents for global widespread use. The C-CB has academic, clinical and industry membership and works collaboratively with other clinical and laboratory medicine groups, such as the European Federation of Laboratory Medicine (EFLM) and the Academy of the American Association of Clinical Chemists (AACC). To date, several peer reviewed manuscripts have been produced to explain the concept of hs-cTn assays [2, 3]. The top eight analytical and top three clinical key components for the implementation of hs-cTn assays have been summarized as educational aids on a poster and a mouse pad and are currently available for distribution (poster) from by the IFCC if desired.

Established in June 2017, definitive tables covering the majority of high-sensitivity (Table 1), contemporary (Table 2) and point-of-care (POC) (Table 3) cTn assays have been developed by the C-CB and are available on the IFCC website [10–12]. These tables provide extensive information about assays' analytical characteristics and encompass information on diagnostic discriminants, particularly the 99th percentiles, as provided by the manufacturers. In addition, a table that addresses the effects of hemolysis and biotin on cTn assays has been published [13] and posted to the IFCC website [14]. All tables will be updated on a quarterly basis. Further, tables summarizing analytical characteristics of natriuretic peptides (NP) [15] and effects of hemolysis and biotin on NP assays [16] are also found on the website. An educational document for NPs, paralleling the cTn document, is under development by the C-CB.

A series of industry sponsored workshops are being planned at major congresses, and started with the 2018 AACC annual meeting in Chicago. Most importantly, the C-CB wishes to encourage educational feedback from the laboratory and clinical communities on what they and their clinical colleagues find challenging in routine clinical use of cardiac biomarkers, specifically high sensitivity cTn assays.

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