

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) v052023

| Company/Platform/ Assay | LoB (µg/L unless noted) | LoD (µg/L unless noted) | % CV at 99 th Percentile | Conc at 20% CV (µg/L unless noted) | Conc at 10% CV (µg/L unless noted) | Reference Population N, Ages, Sex | Specimen Type | Calibrators used | 99 th Percentile (µg/L unless noted) | Percent Normals Measured ≥ LoD | Statistic Used to Calc 99 th 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 | NP | Overall: 0.08 | NP | NP | NP | US: Rev. Date: 01-Jul-13 |
| LSI Medience PATHFAST cTnI; commercial | NP | 1 ng/L | < 6% | 2 ng/L | 3.1 ng/L | Overall n =474 18-86y F: 236 M: 238 | Heparin-Na, heparin-Li or EDTA whole blood or plasma | Human cardiac I-T- C complex | Overall: 15.48 ng/L F: 11.46 ng/L M: 16.91 ng/L | Overall: 76.3% | Non-Parametric | C: 41-49, D: 71-116, 163-209 | WW except US & Japan: Ver.6, Apr. 2021 |
| LSI Medience PATHFAST hs-cTnI /PATHFAST cTnI-II | 1.23 ng/L | 2.33 ng/L | 6.1% | 4 ng/L | 15 ng/L | Overall n=734 Age >18 F: 352 M: 382 | Heparin-Na, heparin-Li or EDTA whole blood or plasma | Human cardiac I-T- C complex | Overall: 27.9 ng/L F: 20.3 ng/L M: 29.7 ng/L | Overall: 66.3% F: 52.8% M: 78.8% | Non-Parametric | C:41-49, D: 71-116, 163-209 | hs-cTnI : WW except US Ver.3, Apr. 2021 |
| LSI Medience PATHFAST cTnI-II | NP | NP | 6.1% | NP | 0.019 | Overall n=333 | Heparin-Na, heparin-Li or EDTA whole blood or plasma | Human cardiac I-T- C complex | Overall: 0.029 | NP | Non-Parametric | C: 41-49, D: 71-116, 163-209 | US: Ver.6, Dec.2022 |
| Quidel/Alere TriageTrue hs-cTnI | 0.4 ng/L (plasma) 0.5-0.8 ng/L (whole blood) | 0.7 – 1.6 ng/L (plasma) 1.5-1.9 ng/L (whole blood) | 5.0 – 5.9% at 21 ng/L (plasma) 5.9 – 6.5% at 22 ng/L (whole blood) | 2.1 – 3.6 ng/L (plasma) 2.8 ng/L (whole blood) | 4.4 – 8.4 ng/L (plasma) 5.8 – 6.2 ng/L (whole blood) | Overall n = 789 F: 391 M: 398 | EDTA whole blood or plasma | NP | Overall: 20.5 ng/L F: 14.4 ng/L M: 25.7 ng/L | Overall: ≥ 50% | NP | NP | hs-cTnI: WW except US April 2020 |
| 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 | 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 | 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 | NP | Overall: 0.020 | Overall: 11.8% | Non-Parametric | NP | USA, 2014, rev. D |
| Radiometer AQT90 FLEX TnI | <5ng/L | <10ng/L | 12.3% | NP | 0.027 | Overall n = 231 F: 106 M: 125 | EDTA and Li- heparinized whole blood and plasma | NP | Overall: 0.023 | NP | Non-Parametric | C: 41-49, 190-196 D:137-149 | Denmark 201808Z |
| Radiometer AQT90 FLEX TnT | 5ng/L | 10ng/L | 15.2% | 30ng/L | 0.026 | Overall n = 260 F: 132 M: 128 | EDTA and Li- heparinized whole blood and plasma | NP | Overall: 0.017 | NP | Non-Parametric | C:125-131 D:136-147 | Denmark 201808Z |

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|--|----------------------------------|--|--|--|--|--|--|----|---|---|--|--|--|
| Response Biomedical RAMP Troponin I | NP | 0.03 | 20.0% | 0.10 | 0.21 | Overall n =180 | Only EDTA whole blood | NP | 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 | NP | D: 125-131 C: 136-147 | EU, 2016-05 |
| Siemens ATELLICA VT hs-cTnI [#] | 0.55 ng/L | 1.2 ng/L (plasma) 1.6 ng/L (whole blood) | 6.5% (plasma) 6.1% (whole blood) at 22.9 ng/L | 2.1 ng/L (plasma) 3.7 ng/L (whole blood) | 6.7 ng/L (plasma) 8.9 ng/L (whole blood) | Overall n = 694 F: 331 M: 363 | Li Hep whole blood and plasma, capillary blood | NP | Overall: 22.9 ng/L F: 18.5 ng/L M: 27.1 ng/L | Overall: 84% F: 80% M: 87% | Non-Parametric | C: 41-49 D: 2 Abs in range 20-100 cTnC Ab | CE, 2021-03 |
| Siemens Stratus CS Acute Care cTnI test pack [#] | <0.03 | NP | 8.2% | 0.03 | 0.06 | Overall n=101 | Whole blood (Li or NP heparin) or plasma Li or Na heparin | NP | 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. 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. [#] Disclaimer: The products/features mentioned herein are not commercially available in all countries. Their future availability cannot be guaranteed.