

# Contemporary 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/<br>Assay                                      | LoB<br>(µg/L) | LoD<br>(µg/L) | % CV at<br>99 <sup>th</sup><br>Percentile | Conc at<br>20% CV<br>(µg/L) | Conc at<br>10% CV<br>(µg/L) | Reference<br>Population N,<br>Ages, Sex                                      | Specimen<br>Type                                   | 99 <sup>th</sup><br>Percentile<br>(µg/L)      | Percent<br>Normals<br>Measured<br>≥ LoD | Statistic<br>Used to<br>Calc 99 <sup>th</sup><br>Percentile | Epitopes<br>Recognized by<br>Antibodies | Country of<br>Package<br>Insert:<br>Version Date   |
|-----------------------------------------------------------------|---------------|---------------|-------------------------------------------|-----------------------------|-----------------------------|------------------------------------------------------------------------------|----------------------------------------------------|-----------------------------------------------|-----------------------------------------|-------------------------------------------------------------|-----------------------------------------|----------------------------------------------------|
| Abbott /ARCHITECT<br>i systems/<br>ARCHITECT STAT<br>Troponin-I | ≤ 0.01        | 0.009         | 14%                                       | NP                          | 0.032                       | Overall<br>n = 449<br>18-63y<br><br>F: 225<br>18-62y<br><br>M: 224<br>18-63y | Serum, heparin<br>plasma                           | Overall:<br>0.028<br><br>F: 0.013<br>M: 0.033 | 2%                                      | Robust                                                      | C: 87-91, 24-40<br>D: 41-49             | US only: G1-<br>0467/ R11,<br>revised June<br>2015 |
| Beckman/Access 2<br>/AccuTnI+3, US                              | <0.01         | 0.01          | 20%                                       | 0.02                        | 0.04                        | Overall<br>n = 527<br>18-94y<br><br>59.8% Female                             | Lithium heparin<br>plasma                          | 0.02                                          | NP                                      | Non-<br>Parametric                                          | C: 41–49<br>D: 24–40                    | US B16315<br>2013                                  |
| Beckman/ Dxl /<br>AccuTnI+3, US                                 | <0.01         | 0.01          | 20%                                       | 0.03                        | 0.04                        | Overall<br>n = 527<br>18-94y<br><br>59.8% Female                             | Lithium heparin<br>plasma                          | <0.03                                         | NP                                      | Non-<br>Parametric                                          | C: 41–49 D:<br>24–40                    | US B16316<br>2013                                  |
| Beckman/Access 2<br>/AccuTnI+3, OUS                             | <0.01         | 0.01          | 10%                                       | 0.02                        | 0.04                        | Overall<br>n = 998<br>>40y<br><br>56.6% Female                               | Serum                                              | 0.04                                          | NP                                      | Non-<br>Parametric                                          | C: 41–49 D:<br>24–40                    | OUS A90435<br>2013                                 |
| Beckman/Dxl/<br>AccuTnI+3, OUS                                  | <0.01         | 0.01          | 10%                                       | 0.02                        | 0.04                        | Overall<br>n = 998<br>>40y<br><br>56.6% Female                               | Serum                                              | 0.04                                          | NP                                      | Non-<br>Parametric                                          | C: 41–49 D:<br>24–40                    | OUS B00495<br>2013                                 |
| Ortho/VITROS/<br>Immunodiagnostic<br>Troponin I ES              | 0.007         | 0.012         | 10%                                       | 0.012                       | 0.034                       | >10,000                                                                      | Serum, plasma<br>(Li heparin,<br>EDTA)             | 0.034                                         | 4%                                      | Non-<br>Parametric                                          | C: 24-40 41-49;<br>D: 87-91             | USA: Version<br>7; 2016-01-06                      |
| Radiometer AQT90<br>FLEX TnI                                    | NP            | 0.009         | 12.3%                                     | NP                          | 0.027                       | Overall<br>n = 231<br><br>F: 106<br>M: 128                                   | EDTA &<br>heparinized<br>whole blood<br>and plasma | 0.023                                         | NP                                      | Non-<br>Parametric                                          | C:41-49,<br>190-196<br>D:137-149        | 990-872<br>OUS<br>201608X                          |
| Radiometer AQT90<br>FLEX TnT                                    | NP            | 0.008         | 15.2%                                     | NP                          | 0.026                       | Overall<br>n = 260<br><br>F: 132<br>M: 128                                   | EDTA &<br>heparinized<br>whole blood<br>and plasma | 0.017                                         | NP                                      | Non-<br>Parametric                                          | C:125-131<br>D:136-147                  | 995-639<br>OUS<br>201608H                          |

| Company/Platform/<br>Assay                                                                               | LoB<br>(µg/L) | LoD<br>(µg/L) | % CV at<br>99 <sup>th</sup><br>Percentile | Conc at<br>20% CV<br>(µg/L) | Conc at<br>10% CV<br>(µg/L) | Reference<br>Population N,<br>Ages, Sex                | Specimen<br>Type                             | 99 <sup>th</sup><br>Percentile<br>(µg/L) | Percent<br>Normals<br>Measured<br>≥ LoD | Statistic<br>Used to<br>Calc 99 <sup>th</sup><br>Percentile | Epitopes<br>Recognized by<br>Antibodies | Country of<br>Package<br>Insert:<br>Version Date |
|----------------------------------------------------------------------------------------------------------|---------------|---------------|-------------------------------------------|-----------------------------|-----------------------------|--------------------------------------------------------|----------------------------------------------|------------------------------------------|-----------------------------------------|-------------------------------------------------------------|-----------------------------------------|--------------------------------------------------|
| Roche cobas e411*/<br>Roche E170/ cobas<br>e601/602 /cobas<br>e801 cTnI<br>(18 min & STAT)<br>*STAT only | 0.1           | 0.16          | NP                                        | NP                          | 0.30                        | Overall<br>n = 839<br>20-79 y                          | Serum, plasma<br>(EDTA/heparin)              | 0.16                                     | 1.0%                                    | NP                                                          | C: 87-91,<br>190-196<br>D: 23-29, 27-43 | EU                                               |
| Roche cobas e411*/<br>Roche E170/ cobas<br>e601/602 cTnI<br>(18 min & STAT)<br>*STAT only                | <0.30         | <0.30         | NP                                        | NP                          | 0.30                        | Overall<br>n = 839<br>20-79 y                          | Serum, plasma<br>(EDTA/heparin)              | <0.3                                     | 1.0%                                    | NP                                                          | C: 87-91,<br>190-196<br>D: 23-29, 27-43 | US                                               |
| Roche cobas e411/<br>Roche E170/ cobas<br>e601/602 cTnT<br>(18 min STAT)                                 | NP            | 0.010         | NP                                        | NP                          | 0.03                        | Overall<br>n = 1951                                    | Serum, plasma<br>(EDTA,<br>heparin, citrate) | <0.010                                   | NP                                      | NP                                                          | C: 125-131<br>D:136-147                 | US                                               |
| Siemens<br>Atellica<br>TnI-Ultra <sup>#</sup>                                                            | 0.007         | 0.015         | <10%                                      | 0.015                       | < 0.020                     | Overall<br>n = 1974<br>22-91 y<br><br>F: 993<br>M: 981 | Serum, plasma<br>(EDTA, Li-Hep)              | 0.020                                    | NP                                      | NP                                                          | C: 41-49,<br>87-89<br>D: 27-40          | CE<br>10995428_EN<br>Rev. 04,<br>2018-07         |
| Siemens<br>ADVIA Centaur<br>Systems<br>TnI-Ultra <sup>#</sup>                                            | 0.006         | NP            | <8%                                       | 0.017                       | 0.03                        | Overall<br>n = 648<br>17-91 y                          | Serum, plasma<br>(EDTA, Li-Hep)              | 0.040                                    | NP                                      | NP                                                          | C: 41-49,<br>87-89<br>D: 27-40          | CE<br>10629901_EN<br>Rev. N,<br>2019-03          |
| Siemens<br>Dimension Vista<br>Systems<br>LOCI CTNI <sup>#</sup>                                          | 0.015         | NP            | <10%                                      | NP                          | <0.04                       | Overall<br>n = 199                                     | Serum, plasma<br>(Li-Hep, Na-<br>Hep)        | 0.045                                    | NP                                      | NP                                                          | C: 27-32<br>D: 41-56                    | CE<br>2015-03-27 E<br>PN<br>781421.001           |
| Siemens<br>Dimension EXL<br>Systems<br>LOCI TnI <sup>#</sup>                                             | 0.010         | 0.017         | <10%                                      | NP                          | 0.05                        | Overall<br>n = 241                                     | Serum, plasma<br>(Li-Hep, Na-<br>Hep)        | 0.056                                    | NP                                      | NP                                                          | C: 27-32<br>D: 41-56                    | CE<br>2015-02-09 D<br>PN<br>741621.001           |
| Tosoh AIA cTnI<br>3rd Gen                                                                                | 0.001         | 0.0016        | <10%                                      | 0.0023                      | 0.0056                      | Overall<br>n = 190<br>Caucasian                        | Serum, plasma<br>(Li-Hep)                    | 0.031                                    | >60%                                    | NP                                                          | NP                                      |                                                  |

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. <sup>#</sup> Disclaimer: The products/features mentioned herein are not commercially available in all countries. Their future availability cannot be guaranteed.