

## BNP, NT-proBNP, and MR-proANP Assays: Analytical Characteristics Designated by Manufacturer

### IFCC Committee on Clinical Applications of Cardiac Bio-Markers (C-CB) v062024

| Company/Platform/<br>Assay  | LoD<br>(ng/L) | %CV<br>near LoD or<br>LoQ<br>(Conc, ng/L) | Upper<br>Reference<br>Limit<br>(URL);<br>Age, Conc<br>(ng/L) | %CV at URL | Reference<br>Intervals by<br>Sex (ng/L)                  | Reference Intervals by<br>Age/Sex, N, Median<br>Conc (ng/L)   | Specimen<br>Type  | Capture<br>Antibody                     | Detection<br>Antibody   | Standard<br>Material  | POC | Package Insert:<br>Version Date  |
|---|---------------|---|--|------------|--|---|---|---|---|---|-----|--|
| Abbott /Alinity i systems/<br>Alinity i BNP                           | 1.7           | LoQ ≤20 ng/L<br>(20% CV)                  | 100  | 4.2%       | Female Non-HF<br>Median: 26<br>Male non-HF<br>Median: 14 | <p><b>Female Non-HF by age range:</b><br/>                     &lt;45y n=98 median=23<br/>                     45-54y n=75 median=23<br/>                     55-64y n=77 median=37<br/>                     65-74 n=133 median=23<br/>                     &gt;75y n=82 median=25</p> <p><b>Male Non-HF by age range:</b><br/>                     &lt;45y n=107 median=12<br/>                     45-54y n=71 median=1<br/>                     55-64y n=94 median=17<br/>                     65-74y n=115<br/>                     median=21<br/>                     &gt;75y n=38 median=37</p> | EDTA<br>plasma  | Anti-BNP (106.3)<br>mouse<br>monoclonal | Anti-BNP<br>(BC203) mouse<br>monoclonal                             | Synthetic<br>Peptide  | No  | 704-328_R04 OUS<br>only March 2018                                       |
| Abbott /Alinity i systems/<br>Alere NT-proBNP for<br>Alinity i        | 7.9           | LoQ ≤50.0<br>ng/L (20%<br>CV)             | <75y: 125<br>≥75y: 450                                       | NP         | NP   | <p><b>Non-HF by age range:</b><br/>                     &lt;45y n=112 median=43.7<br/>                     45-54y n=114<br/>                     median=57.9<br/>                     55-64y n=137<br/>                     median=74.8<br/>                     65-74y n=80<br/>                     median=161.0<br/>                     &gt;75y n=77 median=345.7</p>   | Serum<br>(SST),<br>plasma<br>(K <sub>2</sub> /K <sub>3</sub> EDTA,<br>Li-Hep) | NP                                      | NP  | NP  | No  | ABBL535R02 OUS<br>only May 2018  |
| Abbott /ARCHITECT i<br>systems/ ARCHITECT<br>BNP                      | ≤10           | NP  | 100  | ≤12%       | NP   | Non-Heart Failure<br>n = 890<br>(465 F, 425 M)<br><45 – 75+y  | EDTA<br>plasma  | Anti-BNP (106.3)<br>mouse<br>monoclonal | Anti-BNP<br>(BC203) mouse<br>monoclonal                             | NP  | No  | World Wide<br>excluding Japan /<br>608-03310/15/R05<br>revised Nov. 2015 |
| Abbott/i-STAT/BNP<br>Analytical data from CTI<br>sheet and internally | NP            | NP  | 95 <sup>th</sup> o: 50                                       | NP         | NP   | 165   | EDTA whole<br>blood or<br>Plasma  | Shinogi: BC203 <sup>2</sup>             | Diatec Mouse<br>anti-human<br>BNP clone:<br>106:3sc128 <sup>3</sup> | Synthetic BNP<br>(Peptide<br>International,<br>Louisville, KY,<br>Cat# 4212v) | Yes | US, Rev. Date:<br>01-Jul-13  |

| Company/Platform/<br>Assay  | LoD<br>(ng/L) | %CV<br>near LoD or<br>LoQ<br>(Conc, ng/L) | Upper<br>Reference<br>Limit<br>(URL);<br>Age, Conc<br>(ng/L)  | %CV at URL | Reference<br>Intervals by<br>Sex (ng/L)   | Reference Intervals by<br>Age/Sex, N, Median<br>Conc (ng/L)  | Specimen<br>Type  | Capture<br>Antibody                   | Detection<br>Antibody                       | Standard<br>Material | POC | Package Insert:<br>Version Date                       |
|---|---------------|---|---|------------|---|--|---|---------------------------------------|---|----------------------|-----|---|
| Beckman Coulter<br>/ACCESS 2, UniCel<br>Dxl600, UniCel Dxl800 /<br>ACCESS BNP | 1             | NP  | 100   | NP         | <p><b>Male Non-HF:</b><br/>(n=610)<br/>Median: 7.1</p> <p><b>Female Non-HF:</b><br/>(n=676)<br/>Median: 18.5</p>  | <p><b>Male Non-HF</b><br/>&lt;45y<br/>Median: 5.0, N=183<br/>45-54y<br/>Median: 7.2, N=196<br/>55-64y<br/>Median: 9.0, N=118<br/>65-74y<br/>Median: 15.7, N=89<br/>+75y<br/>Median: 39.0, N=24</p> <p><b>Female Non-HF</b><br/>&lt;45y<br/>Median: 11.6, N=240<br/>45-54y<br/>Median: 17.7, N=189<br/>55-64y<br/>Median: 9.0, N=111<br/>65-74y<br/>Median: 27.6, N=103<br/>+75y<br/>Median: 39.0, N=24</p>                                       | EDTA<br>Plasma  | Mouse<br>omniclonal anti-<br>human Ab | Mouse<br>monoclonal<br>anti-human<br>BNP Ab | NP                   | No  | Instructions For Use<br>C79614<br>English<br>8/1/2021 |
| Beckman Coulter / Dxl<br>9000 / NT-proBNP (OUS)                               | ≤ 10          | LoQ ≤ 10<br>(≤ 20% CV)                    | <p>&lt; 50 yrs.<br/>95% URL:<br/>118</p> <p>50-75 yrs.<br/>95% URL:<br/>273</p> <p>&gt;75 yrs.<br/>95% URL:<br/>413</p> | ≤ 8%       | <p>Clinical<br/>Performance is<br/>validated by<br/>gender at age-<br/>specific cutoffs</p> <p>Rule-out HF:<br/>All ages, &lt; 300<br/>ng/L</p> <p>Rule-in HF:<br/>&lt; 50 yrs., ≥ 450<br/>ng/L<br/>50-75 yrs., ≥ 900<br/>ng/L<br/>&gt;75 yrs., ≥ 1800<br/>ng/L</p> | <p><b>Females:</b><br/>&lt; 50 yrs. 95% URL: 152<br/>(n=135, Median = 54<br/>ng/L)</p> <p>50-75 yrs. 95% URL: 282<br/>(n=145, Median = 91<br/>ng/L)</p> <p>&gt;75 yrs. 95% URL: 443<br/>(n=89, Median = 154<br/>ng/L)</p> <p><b>Males:</b><br/>&lt; 50 yrs. 95% URL: 84<br/>(n=132, Median = 23<br/>ng/L)</p> <p>50-75 yrs. 95% URL: 188<br/>(n=111, Median = 48<br/>ng/L)</p> <p>&gt;75 yrs. 95% URL: 243<br/>(n=63, Median = 115<br/>ng/L)</p> | Serum,<br>Lithium<br>Heparin<br>Plasma,<br>EDTA<br>Plasma | Rabbit<br>monoclonal                  | Human-mouse<br>chimeric<br>monoclonal       | NP                   | No  | C99356 G: Oct 2023                                    |

| Company/Platform/<br>Assay                    | LoD<br>(ng/L) | %CV<br>near LoD or<br>LoQ<br>(Conc, ng/L) | Upper<br>Reference<br>Limit<br>(URL);<br>Age, Conc<br>(ng/L)  | %CV at URL                                 | Reference<br>Intervals by<br>Sex (ng/L)   | Reference Intervals by<br>Age/Sex, N, Median<br>Conc (ng/L)   | Specimen<br>Type   | Capture<br>Antibody   | Detection<br>Antibody                                       | Standard<br>Material         | POC | Package Insert:<br>Version Date  |
|---|---------------|---|---|--|---|---|--|---|---|------------------------------|-----|--|
| bioMerieux/VIDAS/<br>NT-proBNP                | <20           | NP  | <75y: 125<br>≥75y: 450  | NP   | NP  | Age <75y<br>n = 319<br>Mean: 204 ng/L<br>SD: 905 ng/L<br>Median: <20 ng/L<br>95 <sup>th</sup> : 174 ng/L<br>%<cutoff: 92%<br><br>Age ≥75y<br>n = 92<br>Mean: 165 ng/L<br>SD: 137 ng/L<br>Median: <120 ng/L<br>95 <sup>th</sup> : 469 ng/L<br>%<cutoff: 95%      | Serum,<br>heparin<br>plasma                                    | Sheep polyclonal<br>antibody                                | Sheep<br>polyclonal<br>antibody                             | NP                           | No  | 14708D US<br>2015/01   |
| ET Healthcare/Pylon/BNP                       | 10            | 20%                                       | 100   | 10%  | NP  | NP  | EDTA<br>plasma,<br>whole blood                                 | BNP 11-22 aa  | Single epitope  | Glycosylated<br>proBNP       | Yes | China<br>2016  |
| Fujirebio/Lumipulse G<br>G1200 and G600II/BNP | 0.307         | LoQ = 1.149<br>ng/L with CV<br>of 10%     | Sensitivity<br>&<br>specificity<br>at<br>universal<br>cut-off of<br>100 ng/L<br>calculated<br>together<br>w/assay<br>specific<br>cut-off of<br>141.06<br>ng/L | ND   | <b>Female non-HF<br/>median by age:</b><br><br>10.0<br>14.0<br>16.8<br>28.6<br>48.5<br><br><b>Male non-HF<br/>median by age:</b><br><br>6.6<br>10.5<br>13.1<br>28.2<br>57.3 | <b>Females, non-HF by<br/>age range:</b><br><br><45 yrs n= 269<br>45-54 n=254<br>55-64 n=246<br>65-74 n=250<br>>75 yrs n= 177<br><br><b>Males, non-HF by age<br/>range:</b><br><br><45 yrs n= 141<br>45-54 n=129<br>55-64 n=127<br>65-74 n=120<br>>75 yrs n= 59 | Disodium or<br>dipotassium<br>EDTA                             | NP  | NP  | NP                           | No  | English<br>FRI83445, Apr. 2018<br>Ver.02                               |
| LSI Medience/<br>Pathfast/NT-proBNP           | 5             | 21%                                       | <75y: 125<br>≥75y: 450  | 4.7% at 125<br>ng/L<br>3.4% at 450<br>ng/L | <b>Male 95%</b><br><75y: 206 ng/L<br>≥75y: 500 ng/L<br><br><b>Female 95%</b><br><75y: 330 ng/L<br>≥75y: 674 ng/L  | Overall<br>n = 578<br>(324 F, 254 M)<br><75y: 499 ng/L<br>≥75y: 79 ng/L   | Heparin-Na,<br>heparin-Li,<br>EDTA whole<br>blood or<br>plasma | NH <sub>2</sub> terminus<br>polyclonal sheep<br>AB, aa 1-21 | Central<br>molecule,<br>polyclonal<br>sheep AB, aa<br>39-50 | Synthetic NT-<br>proBNP 1-76 | Yes | WW except US and<br>Japan: 2021.04,<br>Ver.8<br><br>US: 2022.12, Ver.7 |

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|--|---------------|--|--|--|---|---|--|---|--|--|-----|--|
| LumiraDx NT ProBNP Test  | 50            | NP   | 125  | 9.4% at 100-<br>150ng/L<br>12% 800 -<br>1200ng/L | NP  | NP  | Direct<br>fingerstick,<br>Venous<br>Whole Blood<br>(Lithium<br>Heparin),<br>Plasma<br>(Lithium<br>Heparin) | Mouse<br>monoclonal   | Recombinant<br>NT-proBNP<br>monoclonal<br>antibody                             | Synthetic<br>NTproBNP 1-<br>76                     | Yes | Rev. 3 – July 2023   |
| Maccura/ i9000, i8000,<br>i6000, i3000, i3000L,<br>i3000S, i1000, i1000L,<br>i1000S, i820, i800/ BNP   | 2             | LOD=LOQ<br>2.00<br>(≤20% CV )                              | 100  | 2.31%-2.58%                                      | NP  | NP  | EDTA<br>plasma   | Sheep anti-<br>human BNP<br>antibody  | Sheep anti-<br>human BNP<br>antibody   | Recombinant<br>human B type<br>diuretic<br>peptide | No  | CE marked,<br>maccura-20220530-<br>EU1.0<br>China2022  |
| Maccura/ i9000, i8000,<br>i6000, i3000, i3000L,<br>i3000S, i1000, i1000L,<br>i1000S, i820,<br>i800/ NT-proBNP  | 20            | LOD=LOQ<br>20.00<br>(≤20% CV )                             | 125  | NP   | NP  | <b>Female, Non-HF</b><br>≤60y n=95<br>95th percentile=122.5<br>61-74y n=120<br>95th percentile=290.2<br>≥75y n=77<br>95th percentile=566.2<br><br><b>Male, Non-HF</b><br>≤60y n=109<br>95th percentile: 101.4<br>61-74y n=44<br>95th percentile=285.6<br>≥75y n=46<br>95th percentile=514.6 | Serum,<br>plasma   | Mouse anti-NT-<br>proBNP<br>monoclonal<br>antibody                            | Mouse anti-NT-<br>proBNP<br>monoclonal<br>antibody                             | Recombined<br>NT-proBNP<br>antigen                 | No  | maccura-230404-02<br>China   |
| VITROS ECi/ECiQ<br>Immunodiagnostic<br>Systems, VITROS 3600<br>Immunodiagnostic System,<br>VITROS 5600 Integrated<br>System, VITROS XT 7600<br>System NT-proBNP        | 11.1          | 20% (LoQ:<br>11.1 ng/L)                                    | <75y: 125<br>≥75y: 450                                       | <6.0%  | NP  | 242 individuals without<br>CHF<br>(147 F, 95 M)   | Serum,<br>plasma<br>(EDTA,<br>heparin)   | NH <sub>2</sub> terminus<br>polyclonal sheep<br>antibody, amino<br>acids 1-21 | Central<br>molecule,<br>polyclonal<br>sheep antibody,<br>amino acids 39-<br>50 | Synthetic NT-<br>proBNP 1-76                       | No  | GEM1315_US_EN,<br>version 8.0, 2016-<br>03-03<br>GEM1315_XUS_EN<br>, version 8.0, 2016-<br>03-03 |
| VITROS ECi/ECiQ<br>Immunodiagnostic<br>Systems, VITROS 3600<br>Immunodiagnostic<br>Systems, VITROS 5600<br>Integrated System,<br>VITROS XT 7600 System<br>NT-proBNP II | 0.49          | LoQ<br>(observed):<br>0.56 ng/L<br>LoQ<br>(claimed):<br>20 | NA   | ≤6%  | Clinical<br>performance is<br>validated by<br>gender at each<br>age-specific<br>ICON cutoff | <b>Females</b><br>22 - < 50y:<br>URI = 95.3 ng/L (n=129)<br>50 - < 75y:<br>URI = 221 ng/L<br>(n = 127)<br>> 75y:<br>URI = 296 ng/L<br>(n = 129)<br><br><b>Males</b><br>22 - < 50y:<br>URI = 125 ng/L (n=131)<br>50 - < 75y:<br>URI = 299 ng/L (n=120)<br>> 75y:<br>URI = 326 ng/L (n=123)   | Human<br>serum and<br>plasma<br>(EDTA or<br>heparin)   | Mouse<br>monoclonal   | Sheep<br>monoclonal  | Recombinant<br>NT-proBNP                           | No  | GEM1317_XUS_EN<br>Version 1.0 July<br>2019   |

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|---|---|---|--|---|--|---|--|---|---|----------------------------------|-----|---|
| VITROS ECi/ECiQ<br>Immunodiagnostic<br>Systems, VITROS 3600<br>Immunodiagnostic<br>Systems, VITROS 5600<br>Integrated System,<br>VITROS XT 7600 System<br>NT -proBNP II | LoD<br>(observed):<br>0.46<br>LoD<br>(claimed):<br>0.49 | LoQ<br>(observed):<br>0.46<br>LoQ<br>(claimed):<br>20 | NA   | <5%                                       | NP   | <b>Females</b><br>(n=129) 22 - < 50y:<br>URI = 95.3 ng/L<br>(n=127) 50-<75y:<br>URI = 221 ng/L<br>(n=129) > 75 y:<br>URI = 296 ng/L<br><br><b>Males</b><br>(n=131) 22 - < 50y:<br>URI = 125 ng/L<br>(n=120) 50 - < 75y:<br>URI = 299 ng/L<br>(n=123) > 75y:<br>URI = 326 ng/L | Human<br>serum and<br>plasma<br>(EDTA or<br>heparin)           | Mouse<br>monoclonal                             | Sheep<br>monoclonal   | Recombinant<br>NT-proBNP         | No  | GEM1318_US_EN<br>Version 1.0 Oct.<br>2021 |
| Radiometer/ AQT90 FLEX/<br>NT-proBNP  | ≤20   | 101 ng/L; 7.2<br>%                                    | 95 <sup>th</sup> : 133                                       | ≤7.2%                                     | NP   | n = 497<br>(248 F, 249 M)   | Whole Blood<br>(LiHep/<br>EDTA),<br>Plasma<br>(LiHep/<br>EDTA) | NH2 terminus<br>polyclonal sheep<br>AB, aa 1-21 | Central<br>molecule,<br>polyclonal<br>sheep AB,<br>aa 39-50 | Synthetic<br>Human NT-<br>proBNP | Yes | 994-095<br>International<br>201808S       |
| Response Biomedical/<br>Ramp/NT-proBNP  | LoB: 18   | NP  | <75y: 125<br>≥75y: 450                                       | 10% at 123<br>ng/L                        | NP   | Age: <75y<br>n = 123<br>Mean: 136.7 ng/L<br>SD: 624 ng/L<br>Median: 57 ng/L<br>95 <sup>th</sup> : 200 ng/L<br><br>Age: ≥75y<br>n = 4<br>Mean: 91.5 ng/L<br>SD: 34 ng/L<br>Median: 84 ng/L<br>95 <sup>th</sup> : 138 ng/L<br><br>% <125: 82%<br>% <450: 100%                   | EDTA<br>plasma   | NP  | NP  | NP                               | Yes | IFU2014-03,V1.4 CE                        |
| Response Biomedical/<br>Ramp/NT-proBNP  | LoD: 34<br>LoB: 27                                      | LoQ: 57   | <75y: 125<br>≥75y: 450                                       | NP  | NP   | Age: ≤75y<br>n = 340<br>Mean: 133 ng/L<br>SD: 671 ng/L<br>Median: 25 ng/L<br>95 <sup>th</sup> : 216 ng/L<br><br>Age: >75y<br>n = 30<br>Mean: 450 ng/L<br>SD: 811 ng/L<br>Median: 88 ng/L<br>95 <sup>th</sup> : 2447 ng/L<br><br>% <125: 84%<br>% <450: 74%                    | EDTA<br>plasma   | NP  | NP  | NP                               | Yes | IFU 90043-1.2<br>US only                  |
| Roche/proBNP II/<br>Modular<br>E170/e411/e601/e602<br>NT-proBNP   | 5   | NP  | 97.5 <sup>th</sup> : 196                                     | e411: 2.6%<br>E170/<br>e601/e602:<br>2.7% | Male 97.5 <sup>th</sup><br>169 ng/L<br>Female 97.5 <sup>th</sup><br>254 ng/L | n = 2264<br>(838 F, 1426 M)<br>18 – 90y   | Serum,<br>plasma<br>(Li-,NH4-<br>Hep; K2,K3<br>EDTA)           | Murine<br>monoclonal AB<br>27-31                | Sheep<br>monoclonal AB<br>42-46                             | Synthetic NT-<br>proBNP 1-76     | No  | Europe                                    |

| Company/Platform/<br>Assay  | LoD<br>(ng/L) | %CV<br>near LoD or<br>LoQ<br>(Conc, ng/L) | Upper<br>Reference<br>Limit<br>(URL);<br>Age, Conc<br>(ng/L)   | %CV at URL  | Reference<br>Intervals by<br>Sex (ng/L)  | Reference Intervals by<br>Age/Sex, N, Median<br>Conc (ng/L)  | Specimen<br>Type                                     | Capture<br>Antibody              | Detection<br>Antibody           | Standard<br>Material         | POC | Package Insert:<br>Version Date |
|---|---------------|---|--|---|--|--|--|----------------------------------|---------------------------------|------------------------------|-----|---------------------------------|
| Roche/proBNP II Elecsys<br>STAT e601/e602<br>NT-proBNP                      | 5             | NP  | 97.5 <sup>th</sup> : 196                                       | e601/e602:<br>2.5%  | Male 97.5 <sup>th</sup> :<br>169 ng/L<br>Female 97.5 <sup>th</sup> :<br>254 ng/L                     | n = 2264<br>(838 F, 1426 M)<br>18 – 90y  | Serum,<br>plasma<br>(Li-,NH4-<br>Hep; K2,K3<br>EDTA) | Murine<br>monoclonal AB<br>27-31 | Sheep<br>monoclonal AB<br>42-46 | Synthetic NT-<br>proBNP 1-76 | No  | Europe                          |
| Roche Elecsys proBNP II/<br>e801/18 min.; 9 min.<br>NT-proBNP               | 5             | NP  | 97.5 <sup>th</sup> : 196                                       | 18 min: 2.6%;<br>9 min: 1.9%  | Male 97.5 <sup>th</sup> :<br>169 ng/L<br>Female 97.5 <sup>th</sup> :<br>254 ng/L                     | n = 2264<br>(838 F, 1426 M)<br>18 – 90y  | Serum,<br>plasma<br>(Li-,NH4-<br>Hep; K2,K3<br>EDTA) | Murine<br>monoclonal AB<br>27-31 | Sheep<br>monoclonal AB<br>42-46 | Synthetic NT-<br>proBNP 1-76 | No  | Europe                          |
| Roche proBNP II Elecsys<br>2010/Modular<br>E170/e411/e601/e602<br>NT-proBNP | 5             | NP  | 95 <sup>th</sup><br><75y: 225<br>≥75y: 718                     | e411/2010<br>2.6% at 126<br>ng/L<br>1.8% at 2410<br>ng/L<br>E170/<br>e601/e602:<br>2.7% | Male 95 <sup>th</sup><br><75y: 169<br>≥75y: 852<br>Female 95 <sup>th</sup><br><75y: 252<br>≥75y: 624 | n = 1411<br>(800 F, 611 M)<br><45 and ≥75y   | Serum,<br>plasma<br>(Li-,NH4-<br>Hep; K2,K3<br>EDTA) | Murine<br>monoclonal AB<br>27-31 | Sheep<br>monoclonal AB<br>42-46 | Synthetic NT-<br>proBNP 1-76 | No  | USA                             |
| Roche proBNP II Elecsys<br>STAT e601/e602<br>NT-proBNP                      | 5             | NP  | 95 <sup>th</sup><br><75y: 225<br>≥75y: 718                     | e601/e602<br>2.5% at 142<br>ng/L<br>2.5% at 935<br>ng/L                                 | Male 95 <sup>th</sup><br><75y: 169<br>≥75y: 852<br>Female 95 <sup>th</sup><br><75y: 252<br>≥75y: 624 | n = 1411<br>(800 F, 611 M)<br><45y and ≥75 y   | Serum,<br>plasma<br>(Li-,NH4-<br>Hep; K2,K3<br>EDTA) | Murine<br>monoclonal AB<br>27-31 | Sheep<br>monoclonal AB<br>42-46 | Synthetic NT-<br>proBNP 1-76 | No  | USA                             |
| Roche<br>CARDIAC NT-proBNP<br>cobas h232                                    | 60            | NP  | 95 <sup>th</sup> :<br>Male: 238<br>ng/L<br>Female:<br>304 ng/L | Upper one-<br>sided 95%<br>confidence limit<br><9% (pooled)                             | 95 <sup>th</sup> :<br>Male: 238 ng/L<br>Female: 304<br>ng/L  | n (overall) = 4266<br>Male:<br>35-44: 90.8 ng/L<br>45-54: 121 ng/L<br>55-64: 262 ng/L<br>65-74: 486 ng/L<br>Female:<br>35-44: 202 ng/L<br>45-54: 226 ng/L<br>55-64: 284 ng/L<br>65-74: 470 ng/L    | Heparinized<br>venous<br>blood*                      | Sheep polyclonal                 | Murine<br>monoclonal            | Synthetic NT-<br>proBNP 1-76 | Yes | EU, 2023-09                     |
| Siemens<br>ATELLICA IM<br>NT-proBNP <sup>#</sup>                            | 20            | 20% CV at<br>LoQ of 18                    | <75y: 125<br>≥75y: 450   | <4%   | NP   | <b>Males, n = 348</b><br><55y: 35 ng/L<br>55-64y: 65 ng/L<br>65-74y: 73 ng/L<br>≥75y: 119 ng/L<br><b>Females, n = 203</b><br><55y: 43 ng/L<br>55-64y: 78 ng/L<br>65-74y: 52 ng/L<br>≥75y: 163 ng/L | Serum,<br>plasma<br>(Li Hep<br>EDTA)                 | Sheep<br>monoclonal              | Sheep<br>monoclonal             | NP                           | No  | CE 11200584_04<br>2019-05       |
| Siemens<br>ATELLICA IM<br>BNP <sup>#</sup>                                  | 2.4           | 20% CV at<br>LoQ of 1.5                   | 100  | <3%   | NP   | <b>Overall, n = 1521</b><br><45y: 9 ng/L<br>45-54y: 10 ng/L<br>55-64y: 14 ng/L<br>65-74y: 22 ng/L<br>≥75y: 44 ng/L   | EDTA<br>Plasma                                       | Monoclonal<br>c-terminal         | Monoclonal ring<br>structure    | NP                           | No  | CE 10995281_04,<br>2019-07      |

| Company/Platform/<br>Assay                                       | LoD<br>(ng/L) | %CV<br>near LoD or<br>LoQ<br>(Conc, ng/L) | Upper<br>Reference<br>Limit<br>(URL);<br>Age, Conc<br>(ng/L) | %CV at URL | Reference<br>Intervals by<br>Sex (ng/L) | Reference Intervals by<br>Age/Sex, N, Median<br>Conc (ng/L)  | Specimen<br>Type                              | Capture<br>Antibody                 | Detection<br>Antibody                    | Standard<br>Material                             | POC | Package Insert:<br>Version Date   |
|--|---------------|---|--|------------|---|--|---|-------------------------------------|--|--|-----|-----------------------------------|
| Siemens<br>ADVIA Centaur XP/XPT<br>NT-proBNP <sup>#</sup>        | 20            | 20% CV at<br>LoQ of <33                   | <75y: 125<br>≥75y: 450                                       | <5.0%      | NP                                      | <b>Males, n = 348</b><br><55y: 35 ng/L<br>55-64y: 64 ng/L<br>65-74y: 73 ng/L<br>≥75y: 119 ng/L<br><br><b>Females, n = 203</b><br><55y: 43 ng/L<br>55-64y: 78 ng/L<br>65-74y: 52 ng/L<br>≥75y: 163 ng/L                                   | Serum,<br>plasma<br>(Li Hep<br>EDTA)          | Sheep<br>monoclonal                 | Sheep<br>monoclonal                      | NP   | No  | CE 10998230_E,<br>2019-03         |
| Siemens<br>ADVIA Centaur CP<br>NT-proBNP <sup>#</sup>            | 14            | 20% CV at<br>LoQ of 14                    | <75y: 125<br>≥75y: 450                                       | ≤3.0%      | NP                                      | <b>Males, n = 348</b><br><55y: 35 ng/L<br>55-64y: 64 ng/L<br>65-74y: 73 ng/L<br>≥75y: 119 ng/L<br><br><b>Females, n = 203</b><br><55y: 43 ng/L<br>55-64y: 78 ng/L<br>65-74y: 52 ng/L<br>≥75y: 163 ng/L                                   | Serum,<br>plasma<br>(Li Hep<br>EDTA)          | Sheep<br>monoclonal                 | Sheep<br>monoclonal                      | NP   | No  | CE 11200078_D,<br>2019-03         |
| Siemens<br>ADVIA Centaur<br>CP/XP/XPT<br>BNP <sup>#</sup>        | <2            | LoQ 2.5                                   | 100  | <5%        | NP                                      | <b>Overall, n = 1521</b><br><45y: 9 ng/L<br>45-54y: 10 ng/L<br>55-64y: 14 ng/L<br>65-74y: 22 ng/L<br>≥75y: 44 ng/L   | EDTA<br>Plasma                                | Monoclonal<br>c-terminal            | Monoclonal ring<br>structure             | NP   | No  | CE 10629823_W<br>2019-03          |
| Siemens DIMENSION<br>VISTA PBNP (LOCI)<br>NT-proBNP <sup>#</sup> | 0.8           | LoQ <30                                   | <75y: 125<br>≥75y: 450                                       | <4.7%      | NP                                      | <b>Males, n = 155</b><br><55y: 16 ng/L<br>55-64y: 25 ng/L<br>65-74y: 123 ng/L<br>≥75y: 173 ng/L<br><br><b>Females, n = 163</b><br><55y: 39 ng/L<br>55-64y: 28 ng/L<br>65-74y: 87 ng/L<br>≥75y: 167 ng/L                                  | Serum,<br>plasma<br>(Li hep, Na<br>hep, EDTA) | Sheep<br>Monoclonal<br>(N-terminal) | Sheep<br>monoclonal                      | NP   | No  | CE<br>2019-06-07 F PN<br>10868020 |
| Siemens<br>Dimension VISTA<br>BNP (LOCI) <sup>#</sup>            | 3             | LoQ 10                                    | 100  | 3.1%       | NP                                      | <b>Males, n = 736</b><br><45y: 5 ng/L<br>45-54y: 7 ng/L<br>55-64y: 11 ng/L<br>65-74y: 17 ng/L<br>≥75y: 26 ng/L<br><br><b>Females, n = 785</b><br><45y: 10 ng/L<br>45-54y: 14 ng/L<br>55-64y: 19 ng/L<br>65-74y: 25 ng/L<br>≥75y: 54 ng/L | EDTA<br>Plasma                                | Monoclonal c-<br>terminal (27-31)   | Monoclonal ring<br>structure (14-<br>21) | Synthetic<br>human BNP<br>(amino acid<br>77-108) | No  | CE<br>2019-06-07 F PN<br>10868025 |

| Company/Platform/ Assay   | LoD (ng/L) | %CV near LoD or LoQ (Conc, ng/L) | Upper Reference Limit (URL); Age, Conc (ng/L) | %CV at URL      | Reference Intervals by Sex (ng/L)                                       | Reference Intervals by Age/Sex, N, Median Conc (ng/L)   | Specimen Type                        | Capture Antibody              | Detection Antibody      | Standard Material | POC | Package Insert: Version Date        |
|---|------------|----------------------------------|---|-----------------|---|---|--------------------------------------|-------------------------------|-------------------------|-------------------|-----|-------------------------------------|
| Siemens DIMENSION RXL PBNP (HM) NT-proBNP <sup>#</sup>              | 10         | LoQ <30                          | <75y: 125<br>≥75y: 450                        | <5.6%<br><5.1%  | NP  | <b>Males, n =145</b><br><55y: 13 ng/L<br>55-64y: 13 ng/L<br>65-74y: 76 ng/L<br>≥75y: 111 ng/L<br><b>Females, n = 163</b><br><55y: 23 ng/L<br>55-64y: 18 ng/L<br>65-74y: 59 ng/L<br>≥75y: 131 ng/L   | Serum, plasma (Li hep, Na hep, EDTA) | Sheep Monoclonal (N-terminal) | Sheep monoclonal        | NP                | No  | CE<br>2019-04-08 H PN<br>755423.002 |
| Siemens DIMENSION EXL NTP (LOCI) NT-proBNP <sup>#</sup>             | 2          | LoQ <30                          | <75y: 125<br>≥75y: 450                        | <8.9%<br><10%   | NP  | <b>Males, n = 155</b><br><55y: 16 ng/L<br>55-64y: 25 ng/L<br>65-74y: 123 ng/L<br>≥75y: 173 ng/L<br><b>Females, n = 163</b><br><55y: 39 ng/L<br>55-64y: 28 ng/L<br>65-74y: 87 ng/L<br>≥75y: 167 ng/L | Serum, plasma (Li hep, Na hep, EDTA) | Sheep Monoclonal (N-terminal) | Sheep monoclonal        | NP                | No  | CE<br>2019-05-30 E PN<br>741623.001 |
| Siemens IMMULITE/ IMMULITE 1000 Turbo NT-proBNP <sup>#</sup>        | 15         | 14.9% at 52 ng/L                 | <75y: 125<br>≥75y: 450                        | <10%<br><10%    | NP  | <b>Overall, n = 217</b><br><75y: 28 ng/L<br>≥75y: 172 ng/L<br><b>95<sup>th</sup> percentile:</b><br><75y: 110 ng/L<br>≥75y: 589 ng/L  | Heparin plasma                       | Sheep polyclonal              | Sheep polyclonal        | NP                | No  | CE<br>PINLSKNT-3[20]<br>2015-07-16  |
| Siemens IMMULITE/ IMMULITE 2000 NT-proBNP <sup>#</sup>              | 10         | 6.4% at 35 ng/L                  | <75y: 125<br>≥75y: 450                        | <5%<br><5%      | NP  | <b>Overall, n = 217</b><br><75y: 28 ng/L<br>≥75y: 172 ng/L<br><b>95<sup>th</sup> percentile:</b><br><75y: 110 ng/L<br>≥75y: 589 ng/L  | Heparin plasma                       | Sheep polyclonal              | Sheep polyclonal        | NP                | No  | CE<br>PIL2KNT-16,2015-<br>06-17     |
| Siemens/Stratus CS Acute care pBNP test Pack NT-proBNP <sup>#</sup> | ≤15        | LoQ (20%CV) at 50 ng/L           | <75y: 125<br>≥75y: 450                        | 5.3%<br><3%     | NP  | <b>Males, n = 145</b><br><55y: 15 ng/L<br>55-64y: 32 ng/L<br>65-74y: 116 ng/L<br>≥75y: 162 ng/L<br><b>Females, n = 163</b><br><55y: 36 ng/L<br>55-64y: 16 ng/L<br>65-74y: 81 ng/L<br>≥75y: 167 ng/L | Blood sample, Na or Li heparin       | Sheep monoclonal              | Sheep monoclonal        | NP                | Yes | CE<br>2008-10-30                    |
| Thermo Fisher (BRAHMS)/ Kryptor/ MR-proANP                          | 2.1 pmol/L | LoQ <10 pmol/L                   | 120 pmol/L                                    | <6.5%           | 97.5 <sup>th</sup> percentile: 85.2 pmol/L; Median 46.1 (Nonparametric) | n = 154   | Serum, plasma (heparin; EDTA)        | Sheep polyclonal antibody     | Rat monoclonal antibody | Synthetic pro-ANP | No  | IFU 25/03/2015 CE                   |
| Tosoh/AIA BNP   | 1.9        | LoQ 4                            | 26.5  | 2.9% at 27 ng/L | NP  | n = 130   | EDTA collected in plastic tubes      | NP                            | NP                      | NP                | No  | EU rev.<br>BNP-021015               |

LoD, limit of detection; LoB, limit of blank; LoQ, limit of quantitation; NP, not provided; M, male, F, female; Conc, concentration; POC, point of care; AB, antibody. Assays listed in blue were abstracted from the manufacturers' package inserts as the manufacturer did not respond to IFCC C-CB request to complete table. <sup>#</sup>Disclaimer: The products/features mentioned herein are not commercially available in all countries. Their future availability cannot be guaranteed.