

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

IFCC Committee on Clinical Applications of Cardiac Bio-Markers (C-CB) v092021

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

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bioMerieux/VIDAS/ NT-proBNP	<20	NP	<75y: 125 ≥75y: 450	NP	NP	Age <75y n = 319 Mean: 204 ng/L SD: 905 ng/L Median: <20 ng/L 95 th : 174 ng/L %<cutoff: 92% Age ≥75y n = 92 Mean: 165 ng/L SD: 137 ng/L Median: <120 ng/L 95 th : 469 ng/L %<cutoff: 95%	Serum, heparin plasma	Sheep polyclonal antibody	Sheep polyclonal antibody	NP	No	14708D US 2015/01
ET Healthcare/Pylon/BNP	10	20%	100	10%	NP	NP	EDTA plasma, whole blood	BNP 11-22 aa	Single epitope	Glycosylated proBNP	Yes	China 2016
Fujirebio/Lumipulse G G1200 and G600II/BNP	0.307	LoQ = 1.149 ng/L with CV of 10%	Sensitivity & specificity at universal cut-off of 100 ng/L calculated together w/assay specific cut-off of 141.06 ng/L	ND	Female non-HF median by age: 10.0 14.0 16.8 28.6 48.5 Male non-HF median by age: 6.6 10.5 13.1 28.2 57.3	Females, non-HF by age range: <45 yrs n= 269 45-54 n=254 55-64 n=246 65-74 n=250 >75 yrs n= 177 Males, non-HF by age range: <45 yrs n= 141 45-54 n=129 55-64 n=127 65-74 n=120 >75 yrs n= 59	Disodium or dipotassium EDTA	NP	NP	NP	No	English FRI83445, Apr. 2018 Ver.02
Medience (Mitsubishi)/ Pathfast/NT-proBNP	5	21%	<75y: 125 ≥75y: 450	4.7% at 125 ng/L 3.4% at 450 ng/L	Male 95% <75y: 206 ng/L ≥75y: 500 ng/L Female 95% <75y: 330 ng/L ≥75y: 674 ng/L	Overall n = 578 (324 F, 254 M) <75y: 499 ng/L ≥75y: 79 ng/L	Heparin-Na, heparin-Li, EDTA whole blood or plasma	NH ₂ terminus polyclonal sheep AB, aa 1-21	Central molecule, polyclonal sheep AB, aa 39-50	Synthetic NT- proBNP 1-76	Yes	WW except US and Japan: 2016.3, Ver.7 US: 2014.8, Ver.5
VITROS ECi/ECiQ Immunodiagnostic Systems, VITROS 3600 Immunodiagnostic System, VITROS 5600 Integrated System, VITROS XT 7600 System NT-proBNP	11.1	20% (LoQ: 11.1 ng/L)	<75y: 125 ≥75y: 450	<6.0%	NP	242 individuals without CHF (147 F, 95 M)	Serum, plasma (EDTA, heparin)	NH ₂ terminus polyclonal sheep antibody, amino acids 1-21	Central molecule, polyclonal sheep antibody, amino acids 39- 50	Synthetic NT- proBNP 1-76	No	GEM1315_US_EN, version 8.0, 2016- 03-03 GEM1315_XUS_EN , version 8.0, 2016- 03-03

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VITROS ECi/ECiQ Immunodiagnostic Systems, VITROS 3600 Immunodiagnostic Systems, VITROS 5600 Integrated System, VITROS XT 7600 System NT-proBNP II	0.49	LoQ (observed): 0.56 ng/L LoQ (claimed): 20 ng/L	NA	≤6%	Clinical performance is validated by gender at each age-specific ICON cutoff	Females 22 - < 50y: URI = 95.3 ng/L (n=129) 50 - < 75y: URI = 221 ng/L (n = 127) > 75y: URI = 296 ng/L (n = 129) Males 22 - < 50y: URI = 125 ng/L (n=131) 50 - < 75y: URI = 299 ng/L (n=120) > 75y: URI = 326 ng/L (n=123)	Human serum and plasma (EDTA or heparin)	Mouse monoclonal	Sheep monoclonal	Recombinant NT-proBNP	No	GEM1317_XUS_EN Version 1.0 July 2019
Quidel/Alere	Data Not Provided											
Radiometer/ AQT90 FLEX/ NT-proBNP	≤20	NP	95 th : 133	≤7.2%	NP	n = 497 (248 F, 249 M)	Whole Blood (LiHep/ EDTA), Plasma (LiHep/ EDTA)	NH2 terminus polyclonal sheep AB, aa 1-21	Central molecule, polyclonal sheep AB, aa 39-50	Synthetic Human NT- proBNP	Yes	994-095 International 201507P
Response Biomedical/ Ramp/NT-proBNP	LoB: 18	NP	<75y: 125 ≥75y: 450	10% at 123 ng/L	NP	Age: <75y n = 123 Mean: 136.7 ng/L SD: 624 ng/L Median: 57 ng/L 95 th : 200 ng/L Age: ≥75y n = 4 Mean: 91.5 ng/L SD: 34 ng/L Median: 84 ng/L 95 th : 138 ng/L % <125: 82% % <450: 100%	EDTA plasma	NP	NP	NP	Yes	IFU2014-03,V1.4 CE
Response Biomedical/ Ramp/NT-proBNP	LoD: 34 LoB: 27	LoQ: 57	<75y: 125 ≥75y: 450	NP	NP	Age: ≤75y n = 340 Mean: 133 ng/L SD: 671 ng/L Median: 25 ng/L 95 th : 216 ng/L Age: >75y n = 30 Mean: 450 ng/L SD: 811 ng/L Median: 88 ng/L 95 th : 2447 ng/L % <125: 84% % <450: 74%	EDTA plasma	NP	NP	NP	Yes	IFU 90043-1.2 US only
Roche/proBNP II/ Modular E170/e411/e601/e602 NT-proBNP	5	NP	97.5 th : 196	e411: 2.6% E170/ e601/e602: 2.7%	Male 97.5 th 169 ng/L Female 97.5 th 254 ng/L	n = 2264 (838 F, 1426 M) 18 – 90y	Serum, plasma (Li-,NH4- Hep; K2,K3 EDTA)	Murine monoclonal AB 27-31	Sheep monoclonal AB 42-46	Synthetic NT- proBNP 1-76	No	Europe

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Roche/proBNP II Elecsys STAT e601/e602 NT-proBNP	5	NP	97.5 th : 196	e601/e602: 2.5%	Male 97.5 th : 169 ng/L Female 97.5 th : 254 ng/L	n = 2264 (838 F, 1426 M) 18 – 90y	Serum, plasma (Li-,NH4- Hep; K2,K3 EDTA)	Murine monoclonal AB 27-31	Sheep monoclonal AB 42-46	Synthetic NT- proBNP 1-76	No	Europe
Roche Elecsys proBNP II/ e801/18 min.; 9 min. NT-proBNP	5	NP	97.5 th : 196	18 min: 2.6%; 9 min: 1.9%	Male 97.5 th : 169 ng/L Female 97.5 th : 254 ng/L	n = 2264 (838 F, 1426 M) 18 – 90y	Serum, plasma (Li-,NH4- Hep; K2,K3 EDTA)	Murine monoclonal AB 27-31	Sheep monoclonal AB 42-46	Synthetic NT- proBNP 1-76	No	Europe
Roche proBNP II Elecsys 2010/Modular E170/e411/e601/e602 NT-proBNP	5	NP	95 th <75y: 225 ≥75y: 718	e411/2010 2.6% at 126 ng/L 1.8% at 2410 ng/L E170/ e601/e602: 2.7%	Male 95 th <75y: 169 ≥75y: 852 Female 95 th <75y: 252 ≥75y: 624	n = 1411 (800 F, 611 M) <45 and ≥75y	Serum, plasma (Li-,NH4- Hep; K2,K3 EDTA)	Murine monoclonal AB 27-31	Sheep monoclonal AB 42-46	Synthetic NT- proBNP 1-76	No	USA
Roche proBNP II Elecsys STAT e601/e602 NT-proBNP	5	NP	95 th <75y: 225 ≥75y: 718	e601/e602 2.5% at 142 ng/L 2.5% at 935 ng/L	Male 95 th <75y: 169 ≥75y: 852 Female 95 th <75y: 252 ≥75y: 624	n = 1411 (800 F, 611 M) <45y and ≥75 y	Serum, plasma (Li-,NH4- Hep; K2,K3 EDTA)	Murine monoclonal AB 27-31	Sheep monoclonal AB 42-46	Synthetic NT- proBNP 1-76	No	USA
Roche CARDIAC NT-proBNP cobas h232	6*	NP	97.5 th : 196*	<15% *	Male 97.5 th 169 ng/L Female 97.5 th 254 ng/L*	n = 2264 (838 F, 1426 M) 18-90y*	Heparinized venous blood*	Sheep polyclonal	Murine monoclonal	Synthetic NT- proBNP 1-76	Yes	EU, 2013-10
Siemens ATELLICA IM NT-proBNP	20	20% CV at LoQ of 18	<75y: 125 ≥75y: 450	<4%	NP	Males, n = 348 <55y: 35 ng/L 55-64y: 65 ng/L 65-74y: 73 ng/L ≥75y: 119 ng/L Females, n = 203 <55y: 43 ng/L 55-64y: 78 ng/L 65-74y: 52 ng/L ≥75y: 163 ng/L	Serum, plasma (Li Hep EDTA)	Sheep monoclonal	Sheep monoclonal	NP	No	CE 11200584_04 2019-05
Siemens ATELLICA IM BNP	2.4	20% CV at LoQ of 1.5	100	<3%	NP	Overall, n = 1521 <45y: 9 ng/L 45-54y: 10 ng/L 55-64y: 14 ng/L 65-74y: 22 ng/L ≥75y: 44 ng/L	EDTA Plasma	Monoclonal c-terminal	Monoclonal ring structure	NP	No	CE 10995281_04, 2019-07
Siemens ADVIA Centaur XP/XPT NT-proBNP	20	20% CV at LoQ of <33	<75y: 125 ≥75y: 450	<5.0%	NP	Males, n = 348 <55y: 35 ng/L 55-64y: 64 ng/L 65-74y: 73 ng/L ≥75y: 119 ng/L Females, n = 203 <55y: 43 ng/L 55-64y: 78 ng/L 65-74y: 52 ng/L ≥75y: 163 ng/L	Serum, plasma (Li Hep EDTA)	Sheep monoclonal	Sheep monoclonal	NP	No	CE 10998230_E, 2019-03

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Siemens ADVIA Centaur CP NT-proBNP	14	20% CV at LoQ of 14	<75y: 125 ≥75y: 450	≤3.0%	NP	Males, n = 348 <55y: 35 ng/L 55-64y: 64 ng/L 65-74y: 73 ng/L ≥75y: 119 ng/L Females, n = 203 <55y: 43 ng/L 55-64y: 78 ng/L 65-74y: 52 ng/L ≥75y: 163 ng/L	Serum, plasma (Li Hep EDTA)	Sheep monoclonal	Sheep monoclonal	NP	No	CE 11200078_D, 2019-03
Siemens ADVIA Centaur CP/XP/XPT BNP	<2	LoQ 2.5	100	<5%	NP	Overall, n = 1521 <45y: 9 ng/L 45-54y: 10 ng/L 55-64y: 14 ng/L 65-74y: 22 ng/L ≥75y: 44 ng/L	EDTA Plasma	Monoclonal c-terminal	Monoclonal ring structure	NP	No	CE 10629823_W 2019-03
Siemens DIMENSION VISTA PBNP (LOCI) NT-proBNP	0.8	LoQ <30	<75y: 125 ≥75y: 450	<4.7%	NP	Males, n = 155 <55y: 16 ng/L 55-64y: 25 ng/L 65-74y: 123 ng/L ≥75y: 173 ng/L Females, n = 163 <55y: 39 ng/L 55-64y: 28 ng/L 65-74y: 87 ng/L ≥75y: 167 ng/L	Serum, plasma (Li hep, Na hep, EDTA)	Sheep Monoclonal (N-terminal)	Sheep monoclonal	NP	No	CE 2019-06-07 F PN 10868020
Siemens Dimension VISTA BNP (LOCI) (OUS only)	3	LoQ 10	100	3.1%	NP	Males, n = 736 <45y: 5 ng/L 45-54y: 7 ng/L 55-64y: 11 ng/L 65-74y: 17 ng/L ≥75y: 26 ng/L Females, n = 785 <45y: 10 ng/L 45-54y: 14 ng/L 55-64y: 19 ng/L 65-74y: 25 ng/L ≥75y: 54 ng/L	EDTA Plasma	Monoclonal c- terminal (27-31)	Monoclonal ring structure (14- 21)	Synthetic human BNP (amino acid 77-108)	No	CE 2019-06-07 F PN 10868025
Siemens DIMENSION RXL PBNP (HM) NT-proBNP	10	LoQ <30	<75y: 125 ≥75y: 450	<5.6% <5.1%	NP	Males, n = 145 <55y: 13 ng/L 55-64y: 13 ng/L 65-74y: 76 ng/L ≥75y: 111 ng/L Females, n = 163 <55y: 23 ng/L 55-64y: 18 ng/L 65-74y: 59 ng/L ≥75y: 131 ng/L	Serum, plasma (Li hep, Na hep, EDTA)	Sheep Monoclonal (N-terminal)	Sheep monoclonal	NP	No	CE 2019-04-08 H PN 755423.002

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Siemens DIMENSION EXL NTP (LOCI) NT-proBNP	2	LoQ <30	<75y: 125 ≥75y: 450	<8.9% <10%	NP	Males, n = 155 <55y: 16 ng/L 55-64y: 25 ng/L 65-74y: 123 ng/L ≥75y: 173 ng/L Females, n = 163 <55y: 39 ng/L 55-64y: 28 ng/L 65-74y: 87 ng/L ≥75y: 167 ng/L	Serum, plasma (Li hep, Na hep, EDTA)	Sheep Monoclonal (N-terminal)	Sheep monoclonal	NP	No	CE 2019-05-30 E PN 741623.001
Siemens IMMULITE/ IMMULITE 1000 Turbo NT-proBNP	15	14.9% at 52 ng/L	<75y: 125 ≥75y: 450	<10% <10%	NP	Overall, n = 217 <75y: 28 ng/L ≥75y: 172 ng/L 95 th percentile: <75y: 110 ng/L ≥75y: 589 ng/L	Heparin plasma	Sheep polyclonal	Sheep polyclonal	NP	No	CE PINLSKNT-3[20] 2015-07-16
Siemens IMMULITE/ IMMULITE 2000 NT-proBNP	10	6.4% at 35 ng/L	<75y: 125 ≥75y: 450	<5% <5%	NP	Overall, n = 217 <75y: 28 ng/L ≥75y: 172 ng/L 95 th percentile: <75y: 110 ng/L ≥75y: 589 ng/L	Heparin plasma	Sheep polyclonal	Sheep polyclonal	NP	No	CE PIL2KNT-16,2015- 06-17
Siemens/Stratus CS Acute care pBNP test Pack NT-proBNP	≤15	LoQ (20%CV) at 50 ng/L	<75y: 125 ≥75y: 450	5.3% <3%	NP	Males, n = 145 <55y: 15 ng/L 55-64y: 32 ng/L 65-74y: 116 ng/L ≥75y: 162 ng/L Females, n = 163 <55y: 36 ng/L 55-64y: 16 ng/L 65-74y: 81 ng/L ≥75y: 167 ng/L	Blood sample, Na or Li heparin	Sheep monoclonal	Sheep monoclonal	NP	Yes	CE 2008-10-30
Thermo Fisher (BRAHMS)/ Kryptor/ MR-proANP	2.1 pmol/L	LoQ <10 pmol/L	120 pmol/L	<6.5%	97.5 th 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. 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.