

REF 55229

Nova Linearity Levels 1 - 4

LOT 24032017

2025-07-23

Only 15°C → 30°C Rx

IVD

Nova Stat Profile Prime CCS Analyzer

Expected Ranges

		LOT 24023013 2025-07-23	LOT 24029001 2025-07-29	LOT 24030050 2025-07-30	LOT 24031011 2025-07-31
		LEVEL 1 min - \bar{x} - max	LEVEL 2 min - \bar{x} - max	LEVEL 3 min - \bar{x} - max	LEVEL 4 min - \bar{x} - max
pH		6.773 - 6.823 - 6.873	7.062 - 7.112 - 7.162	7.377 - 7.417 - 7.457	7.715 - 7.765 - 7.815
H ⁺	nmol/L	168.66 - 150.31 - 133.97	86.69 - 77.26 - 68.86	41.94 - 38.25 - 34.89	19.29 - 17.20 - 15.33
PCO ₂	mmHg	103.8 - 121.8 - 139.8	60.8 - 70.8 - 80.8	30.7 - 35.7 - 40.7	9.4 - 13.4 - 17.4
PCO ₂	kPa	13.84 - 16.24 - 18.64	8.11 - 9.44 - 10.78	4.09 - 4.76 - 5.42	1.25 - 1.79 - 2.32
PO ₂	mmHg	15.4 - 25.4 - 35.4	74.5 - 84.5 - 94.5	129.4 - 139.4 - 149.4	419.0 - 479.0 - 539.0
PO ₂	kPa	2.05 - 3.39 - 4.72	9.93 - 11.26 - 12.60	17.25 - 18.59 - 19.92	55.86 - 63.86 - 71.86
Na ⁺	mmol/L	85.5 - 90.5 - 95.5	116.8 - 121.8 - 126.8	142.4 - 147.4 - 152.4	162.2 - 167.2 - 172.2
K ⁺	mmol/L	1.27 - 1.52 - 1.77	2.39 - 2.89 - 3.39	4.59 - 5.09 - 5.59	8.96 - 11.46 - 13.96
Cl ⁻	mmol/L	58.3 - 63.3 - 68.3	87.5 - 92.5 - 97.5	105.7 - 110.7 - 115.7	125.5 - 130.5 - 135.5
iCa	mmol/L	1.83 - 2.33 - 2.83	1.32 - 1.47 - 1.62	0.65 - 0.80 - 0.95	0.35 - 0.45 - 0.55
iCa	mg/dL	7.34 - 9.34 - 11.34	5.28 - 5.88 - 6.48	2.60 - 3.20 - 3.80	1.41 - 1.81 - 2.21
Glu	mg/dL	394 - 444 - 494	287 - 317 - 347	87 - 107 - 127	26 - 36 - 46
Glu	mmol/L	21.9 - 24.6 - 27.4	15.9 - 17.6 - 19.2	4.9 - 6.0 - 7.1	1.4 - 2.0 - 2.5
Lac	mmo/L	0.2 - 0.5 - 0.8	1.5 - 2.0 - 2.5	8.2 - 10.7 - 13.2	14.4 - 17.9 - 21.4
Lac	mg/dL	1.36 - 4.03 - 6.70	13.05 - 17.50 - 21.95	72.56 - 94.81 - 117.06	128.56 - 159.71 - 190.86

Nova Stat Profile Prime ABG Analyzer

Expected Ranges

		LOT 24023013 2025-07-23	LOT 24029001 2025-07-29	LOT 24030050 2025-07-30	LOT 24031011 2025-07-31
		LEVEL 1 min - \bar{x} - max	LEVEL 2 min - \bar{x} - max	LEVEL 3 min - \bar{x} - max	LEVEL 4 min - \bar{x} - max
pH		6.777 - 6.817 - 6.857	7.070 - 7.110 - 7.150	7.380 - 7.420 - 7.460	7.725 - 7.765 - 7.805
H ⁺	nmol/L	167.14 - 152.43 - 139.02	85.08 - 77.59 - 70.77	41.68 - 38.02 - 34.67	18.83 - 17.18 - 15.67
PCO ₂	mmHg	115.0 - 127.0 - 139.0	65.9 - 72.9 - 79.9	29.8 - 34.8 - 39.8	8.0 - 12.0 - 16.0
PCO ₂	kPa	15.33 - 16.93 - 18.53	8.79 - 9.72 - 10.65	3.98 - 4.64 - 5.31	1.07 - 1.60 - 2.13
PO ₂	mmHg	3.3 - 18.3 - 33.3	79.2 - 89.2 - 99.2	131.4 - 141.4 - 151.4	510.9 - 570.9 - 630.9
PO ₂	kPa	0.44 - 2.44 - 4.44	10.56 - 11.89 - 13.23	17.51 - 18.85 - 20.18	68.11 - 76.11 - 84.11

Nova Stat Profile Prime Plus Analyzer

Expected Ranges

		LOT 24023013 2025-07-23	LOT 24029001 2025-07-29	LOT 24030050 2025-07-30	LOT 24031011 2025-07-31
		LEVEL 1 min - \bar{x} - max	LEVEL 2 min - \bar{x} - max	LEVEL 3 min - \bar{x} - max	LEVEL 4 min - \bar{x} - max
pH		6.695 - 6.745 - 6.795	7.035 - 7.085 - 7.135	7.394 - 7.434 - 7.474	7.784 - 7.834 - 7.884
H ⁺	nmol/L	201.62 - 179.69 - 160.15	92.29 - 82.26 - 73.31	40.35 - 36.80 - 33.56	16.44 - 14.65 - 13.06
PCO ₂	mmHg	91.9 - 109.9 - 127.9	51.1 - 61.1 - 71.1	23.6 - 28.6 - 33.6	9.3 - 13.3 - 17.3
PCO ₂	kPa	12.22 - 14.62 - 17.01	6.79 - 8.12 - 9.45	3.14 - 3.81 - 4.47	1.24 - 1.77 - 2.30
PO ₂	mmHg	4.5 - 19.5 - 34.5	78.2 - 88.2 - 98.2	129.3 - 139.3 - 149.3	490.0 - 550.0 - 610.0
PO ₂	kPa	0.60 - 2.59 - 4.59	10.41 - 11.74 - 13.07	17.20 - 18.53 - 19.86	65.17 - 73.15 - 81.13
Na ⁺	mmol/L	81.3 - 87.3 - 93.3	118.1 - 123.1 - 128.1	143.2 - 148.2 - 153.2	164.7 - 169.7 - 174.7
K ⁺	mmol/L	1.22 - 1.52 - 1.82	2.43 - 2.93 - 3.43	4.77 - 5.27 - 5.77	9.83 - 12.33 - 14.83
Cl ⁻	mmol/L	52.1 - 57.1 - 62.1	85.9 - 90.9 - 95.9	106.5 - 111.5 - 116.5	128.2 - 133.2 - 138.2
iCa	mmol/L	1.85 - 2.35 - 2.85	1.36 - 1.51 - 1.66	0.69 - 0.84 - 0.99	0.37 - 0.47 - 0.57
iCa	mg/dL	7.43 - 9.43 - 11.44	5.45 - 6.05 - 6.65	2.76 - 3.36 - 3.96	1.47 - 1.87 - 2.27
iMg	mmol/L	1.15 - 1.35 - 1.55	0.92 - 1.12 - 1.32	0.47 - 0.57 - 0.67	0.16 - 0.24 - 0.32
iMg	mg/dL	2.79 - 3.27 - 3.76	2.24 - 2.73 - 3.21	1.14 - 1.39 - 1.63	0.39 - 0.58 - 0.78
Glu	mg/dL	411 - 461 - 511	295 - 325 - 355	86 - 106 - 126	24 - 34 - 44
Glu	mmol/L	22.8 - 25.6 - 28.4	16.4 - 18.0 - 19.7	4.8 - 5.9 - 7.0	1.3 - 1.9 - 2.4
Lac	mmo/L	0.1 - 0.4 - 0.7	1.2 - 1.7 - 2.2	7.6 - 10.1 - 12.6	13.2 - 16.7 - 20.2
Lac	mg/dL	0.94 - 3.61 - 6.28	11.08 - 15.53 - 19.98	67.20 - 89.45 - 111.70	117.90 - 149.05 - 180.20

Nova Stat Profile pHox Ultra/CCX Analyzers

Expected Ranges

		24023013	2025-07-23	24029001	2025-07-29	24030050	2025-07-30	24031011	2025-07-31
		LEVEL 1	min - \bar{x} - max	LEVEL 2	min - \bar{x} - max	LEVEL 3	min - \bar{x} - max	LEVEL 4	min - \bar{x} - max
pH		6.757 - 6.807 - 6.857		7.055 - 7.105 - 7.155		7.384 - 7.424 - 7.464		7.751 - 7.801 - 7.851	
H ⁺	nmol/L	175.05 - 156.02 - 139.05		88.03 - 78.46 - 69.93		41.30 - 37.67 - 34.35		17.73 - 15.80 - 14.08	
PCO ₂	mmHg	97.4 - 115.4 - 133.4		56.8 - 66.8 - 76.8		27.1 - 32.1 - 37.1		9.2 - 13.2 - 17.2	
PCO ₂	kPa	12.95 - 15.35 - 17.74		7.55 - 8.88 - 10.21		3.61 - 4.27 - 4.94		1.22 - 1.75 - 2.29	
PO ₂	mmHg	11.1 - 26.1 - 41.1		77.5 - 87.5 - 97.5		124.9 - 134.9 - 144.9		457.4 - 517.4 - 577.4	
PO ₂	kPa	1.48 - 3.47 - 5.47		10.31 - 11.64 - 12.97		16.61 - 17.94 - 19.27		60.84 - 68.82 - 76.80	
Na ⁺	mmol/L	82.9 - 88.9 - 94.9		117.1 - 122.1 - 127.1		141.4 - 146.4 - 151.4		163.9 - 168.9 - 173.9	
K ⁺	mmol/L	1.27 - 1.57 - 1.87		2.45 - 2.95 - 3.45		4.70 - 5.20 - 5.70		9.39 - 11.89 - 14.39	
Cl ⁻	mmol/L	58.2 - 63.2 - 68.2		86.7 - 91.7 - 96.7		104.4 - 109.4 - 114.4		125.3 - 130.3 - 135.3	
iCa	mmol/L	1.81 - 2.31 - 2.81		1.28 - 1.43 - 1.58		0.65 - 0.80 - 0.95		0.40 - 0.50 - 0.60	
iCa	mg/dL	7.25 - 9.25 - 11.25		5.13 - 5.73 - 6.33		2.60 - 3.20 - 3.80		1.59 - 1.99 - 2.39	
iMg	mmol/L	1.06 - 1.26 - 1.46		0.73 - 0.93 - 1.13		0.36 - 0.46 - 0.56		0.12 - 0.20 - 0.28	
iMg	mg/dL	2.54 - 3.02 - 3.50		1.74 - 2.22 - 2.70		0.86 - 1.10 - 1.34		0.29 - 0.48 - 0.67	
Glu	mg/dL	409 - 459 - 509		278 - 308 - 338		80 - 100 - 120		30 - 40 - 50	
Glu	mmol/L	22.7 - 25.5 - 28.2		15.4 - 17.1 - 18.7		4.5 - 5.6 - 6.7		1.7 - 2.2 - 2.8	
Lac	mmo/L	0.3 - 0.6 - 0.9		1.4 - 1.9 - 2.4		7.3 - 9.8 - 12.3		13.0 - 16.5 - 20.0	
Lac	mg/dL	2.65 - 5.32 - 7.99		12.16 - 16.61 - 21.06		64.55 - 86.80 - 109.05		115.97 - 147.12 - 178.27	

EN

Product Description

A set of aqueous solutions contains pH, PCO₂, PO₂, Na⁺, K⁺, Cl⁻, iCa, iMg, Glu, and Lac. Refer to Intended Use.

Intended Use

Use for *in vitro* diagnostic use to verify calibration, analytical linearity, estimate test imprecision, and detect systematic analytical deviations that may arise from calibrator cartridge or analytical instrument variation for pH, PCO₂, PO₂, Na⁺, K⁺, Cl⁻, iCa, iMg, Glu, and Lac.

Methodology

Refer to the analyzer's Instructions for Use Manual for Methodology and Principles of the testing procedures.

Composition

A buffered bicarbonate solution, each with a known pH and known levels of Na⁺, K⁺, Cl⁻, iCa, iMg, Glu, and Lac. Solutions are equilibrated with known levels of O₂, CO₂, and N₂. Mold inhibited. Each ampule contains 1.7 mL volume. Contains no constituents of human origin, however, good laboratory practice should be followed during handling of these materials (REF. NCCLS DOCUMENT M29-T2).

Warnings and Cautions

Intended for *In Vitro* Diagnostic Use.

Cloudiness or particulate matter in the solution is an indication of possible deterioration. DO NOT FREEZE. Follow standard practices for handling laboratory reagents. Discard in accordance with local requirements.

Storage

Store at 15-30°C; DO NOT FREEZE. The expiration date is printed on each ampule container. Do not store unused opened ampules.

Directions for Use

Contents must be shaken well prior to use. Analyze the vial immediately after opening to prevent PCO₂ and PO₂ gas exchange. Solutions must be stored at approximately 24-26°C for at least 24 hours prior to opening. Linearity Standards are recommended for use as frequently as required by local regulatory and hospital requirements. There are 4 levels (1, 2, 3, 4). It is recommended that each laboratory establish the upper and lower limits of its reportable range for each sample type and devise a policy for processing patient specimens that fall outside of this range.

Limitations

Use on analyzers manufactured by Nova Biomedical. Performance characteristics have not been established for use on other manufacturers' analyzers.

Traceability of Standards

Analytes traced to NIST Standard Reference Materials.

Expected Ranges

The expected range indicates the maximum deviations from the mean value that may be expected under differing laboratory conditions for analyzers operating within specifications. The expected ranges for the analytes listed in the table above were verified using replicate determinations on the analyzers indicated.