

Nova Stat Profile Prime CCS Analyzer					
Expected Ranges					
		LOT 25016017 LEVEL 1 min - \bar{x} - max	LOT 25013008 LEVEL 2 min - \bar{x} - max	LOT 25014019 LEVEL 3 min - \bar{x} - max	LOT 25015021 LEVEL 4 min - \bar{x} - max
pH		6.751 - 6.801 - 6.851	7.054 - 7.104 - 7.154	7.386 - 7.426 - 7.466	7.681 - 7.731 - 7.781
H ⁺	nmol/L	177.58 - 158.27 - 141.05	88.31 - 78.71 - 70.15	41.09 - 37.48 - 34.18	20.84 - 18.58 - 16.56
PCO ₂	mmHg	109.3 - 127.3 - 145.3	57.6 - 67.6 - 77.6	27.6 - 32.6 - 37.6	10.1 - 14.1 - 18.1
PCO ₂	kPa	14.57 - 16.97 - 19.37	7.68 - 9.01 - 10.34	3.68 - 4.35 - 5.01	1.34 - 1.87 - 2.41
PO ₂	mmHg	15.6 - 25.6 - 35.6	81.5 - 91.5 - 101.5	133.4 - 143.4 - 153.4	442.5 - 502.5 - 562.5
PO ₂	kPa	2.08 - 3.41 - 4.74	10.87 - 12.20 - 13.53	17.79 - 19.12 - 20.45	58.99 - 66.99 - 74.99
Na ⁺	mmol/L	86.2 - 91.2 - 96.2	117.4 - 122.4 - 127.4	142.9 - 147.9 - 152.9	162.7 - 167.7 - 172.7
K ⁺	mmol/L	1.28 - 1.53 - 1.78	2.39 - 2.89 - 3.39	4.56 - 5.06 - 5.56	8.86 - 11.36 - 13.86
Cl ⁻	mmol/L	59.0 - 64.0 - 69.0	87.9 - 92.9 - 97.9	106.2 - 111.2 - 116.2	124.5 - 129.5 - 134.5
iCa	mmol/L	1.92 - 2.42 - 2.92	1.23 - 1.38 - 1.53	0.66 - 0.81 - 0.96	0.33 - 0.43 - 0.53
iCa	mg/dL	7.68 - 9.68 - 11.68	4.92 - 5.52 - 6.12	2.63 - 3.23 - 3.83	1.33 - 1.73 - 2.13
Glu	mg/dL	390 - 440 - 490	277 - 307 - 337	85 - 105 - 125	25 - 35 - 45
Glu	mmol/L	21.6 - 24.4 - 27.2	15.4 - 17.1 - 18.7	4.7 - 5.8 - 6.9	1.4 - 2.0 - 2.5
Lac	mmo/L	0.2 - 0.5 - 0.8	1.5 - 2.0 - 2.5	8.1 - 10.6 - 13.1	14.5 - 18.0 - 21.5
Lac	mg/dL	2.03 - 4.70 - 7.37	13.29 - 17.74 - 22.19	72.33 - 94.58 - 116.83	128.93 - 160.08 - 191.23

Nova Stat Profile Prime ABG Analyzer					
Expected Ranges					
		LOT 25016017 LEVEL 1 min - \bar{x} - max	LOT 25013008 LEVEL 2 min - \bar{x} - max	LOT 25014019 LEVEL 3 min - \bar{x} - max	LOT 25015021 LEVEL 4 min - \bar{x} - max
pH		6.756 - 6.796 - 6.836	7.060 - 7.100 - 7.140	7.386 - 7.426 - 7.466	7.701 - 7.741 - 7.781
H ⁺	nmol/L	175.22 - 159.81 - 145.75	87.02 - 79.37 - 72.38	41.13 - 37.51 - 34.21	19.91 - 18.16 - 16.56
PCO ₂	mmHg	120.1 - 132.1 - 144.1	62.6 - 69.6 - 76.6	27.9 - 32.9 - 37.9	10.1 - 14.1 - 18.1
PCO ₂	kPa	16.02 - 17.62 - 19.22	8.34 - 9.27 - 10.21	3.72 - 4.38 - 5.05	1.35 - 1.88 - 2.41
PO ₂	mmHg	6.3 - 21.3 - 36.3	81.2 - 91.2 - 101.2	135.1 - 145.1 - 155.1	521.3 - 581.3 - 641.3
PO ₂	kPa	0.84 - 2.84 - 4.84	10.82 - 12.16 - 13.49	18.01 - 19.35 - 20.68	69.50 - 77.50 - 85.50

Nova Stat Profile Prime Plus Analyzer					
Expected Ranges					
		LOT 25016017 LEVEL 1 min - \bar{x} - max	LOT 25013008 LEVEL 2 min - \bar{x} - max	LOT 25014019 LEVEL 3 min - \bar{x} - max	LOT 25015021 LEVEL 4 min - \bar{x} - max
pH		6.682 - 6.732 - 6.782	7.024 - 7.074 - 7.124	7.397 - 7.437 - 7.477	7.735 - 7.785 - 7.835
H ⁺	nmol/L	207.97 - 185.35 - 165.20	94.61 - 84.33 - 75.16	40.10 - 36.57 - 33.35	18.41 - 16.41 - 14.63
PCO ₂	mmHg	99.6 - 117.6 - 135.6	50.9 - 60.9 - 70.9	21.8 - 26.8 - 31.8	10.5 - 14.5 - 18.5
PCO ₂	kPa	13.24 - 15.64 - 18.03	6.78 - 8.11 - 9.44	2.90 - 3.57 - 4.23	1.40 - 1.93 - 2.46
PO ₂	mmHg	8.9 - 23.9 - 38.9	82.8 - 92.8 - 102.8	132.5 - 142.5 - 152.5	503.2 - 563.2 - 623.2
PO ₂	kPa	1.18 - 3.18 - 5.17	11.02 - 12.35 - 13.68	17.63 - 18.96 - 20.29	66.92 - 74.90 - 82.88
Na ⁺	mmol/L	82.2 - 88.2 - 94.2	118.3 - 123.3 - 128.3	143.1 - 148.1 - 153.1	164.5 - 169.5 - 174.5
K ⁺	mmol/L	1.25 - 1.55 - 1.85	2.45 - 2.95 - 3.45	4.77 - 5.27 - 5.77	9.81 - 12.31 - 14.81
Cl ⁻	mmol/L	53.5 - 58.5 - 63.5	86.7 - 91.7 - 96.7	107.2 - 112.2 - 117.2	127.7 - 132.7 - 137.7
iCa	mmol/L	1.87 - 2.37 - 2.87	1.26 - 1.41 - 1.56	0.69 - 0.84 - 0.99	0.35 - 0.45 - 0.55
iCa	mg/dL	7.51 - 9.52 - 11.52	5.07 - 5.67 - 6.27	2.77 - 3.37 - 3.97	1.40 - 1.81 - 2.21
iMg	mmol/L	1.20 - 1.40 - 1.60	0.96 - 1.16 - 1.36	0.49 - 0.59 - 0.69	0.17 - 0.25 - 0.33
iMg	mg/dL	2.91 - 3.40 - 3.88	2.34 - 2.83 - 3.31	1.19 - 1.44 - 1.68	0.41 - 0.60 - 0.80
Glu	mg/dL	395 - 445 - 495	290 - 320 - 350	83 - 103 - 123	23 - 33 - 43
Glu	mmol/L	21.9 - 24.7 - 27.5	16.1 - 17.8 - 19.4	4.6 - 5.7 - 6.8	1.3 - 1.8 - 2.4
Lac	mmo/L	0.1 - 0.4 - 0.7	1.3 - 1.8 - 2.3	7.6 - 10.1 - 12.6	13.5 - 17.0 - 20.5
Lac	mg/dL	1.29 - 3.96 - 6.63	11.14 - 15.59 - 20.04	67.34 - 89.59 - 111.84	120.09 - 151.24 - 182.39



Nova Stat Profile pHox Ultra/CCX Analyzers					
Expected Ranges					
		25016017	25013008	25014019	25015021
		2026-07-16	2026-07-13	2026-07-14	2026-07-15
		LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4
		min - \bar{x} - max	min - \bar{x} - max	min - \bar{x} - max	min - \bar{x} - max
pH		6.735 - 6.785 - 6.835	7.044 - 7.094 - 7.144	7.390 - 7.430 - 7.470	7.710 - 7.760 - 7.810
H ⁺	nmol/L	183.92 - 163.92 - 146.09	90.39 - 80.56 - 71.80	40.78 - 37.19 - 33.92	19.50 - 17.38 - 15.49
PCO ₂	mmHg	99.6 - 117.6 - 135.6	55.9 - 65.9 - 75.9	24.4 - 29.4 - 34.4	10.5 - 14.5 - 18.5
PCO ₂	kPa	13.25 - 15.64 - 18.04	7.43 - 8.76 - 10.09	3.24 - 3.91 - 4.57	1.40 - 1.93 - 2.46
PO ₂	mmHg	8.8 - 23.8 - 38.8	80.3 - 90.3 - 100.3	129.2 - 139.2 - 149.2	493.5 - 553.5 - 613.5
PO ₂	kPa	1.18 - 3.17 - 5.17	10.68 - 12.01 - 13.34	17.18 - 18.51 - 19.84	65.63 - 73.61 - 81.59
Na ⁺	mmol/L	83.7 - 89.7 - 95.7	117.3 - 122.3 - 127.3	141.5 - 146.5 - 151.5	163.5 - 168.5 - 173.5
K ⁺	mmol/L	1.29 - 1.59 - 1.89	2.45 - 2.95 - 3.45	4.76 - 5.26 - 5.76	9.44 - 11.94 - 14.44
Cl ⁻	mmol/L	58.8 - 63.8 - 68.8	87.0 - 92.0 - 97.0	106.0 - 111.0 - 116.0	125.0 - 130.0 - 135.0
iCa	mmol/L	1.93 - 2.43 - 2.93	1.23 - 1.38 - 1.53	0.65 - 0.80 - 0.95	0.36 - 0.46 - 0.56
iCa	mg/dL	7.70 - 9.70 - 11.70	4.91 - 5.51 - 6.11	2.60 - 3.20 - 3.80	1.45 - 1.85 - 2.25
iMg	mmol/L	1.19 - 1.39 - 1.59	0.78 - 0.98 - 1.18	0.37 - 0.47 - 0.57	0.10 - 0.18 - 0.26
iMg	mg/dL	2.85 - 3.33 - 3.81	1.87 - 2.35 - 2.83	0.89 - 1.13 - 1.37	0.25 - 0.44 - 0.63
Glu	mg/dL	385 - 435 - 485	262 - 292 - 322	80 - 100 - 120	25 - 35 - 45
Glu	mmol/L	21.4 - 24.1 - 26.9	14.6 - 16.2 - 17.9	4.4 - 5.6 - 6.7	1.4 - 1.9 - 2.5
Lac	mmo/L	0.2 - 0.5 - 0.8	1.4 - 1.9 - 2.4	7.6 - 10.1 - 12.6	13.8 - 17.3 - 20.8
Lac	mg/dL	1.82 - 4.49 - 7.16	12.46 - 16.91 - 21.36	67.79 - 90.04 - 112.29	122.75 - 153.90 - 185.05

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.