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Assay Data Sheet - Expected Ranges

BioProfile® Controls - LEVEL 3

pH, PCO₂, PO₂, Na⁺, K⁺, Ca⁺⁺, NH₄⁺, Glucose, Lactate

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Lot. No. 413713

Exp. Date 2025-05

Instrument	Constituent	Units	Mean	Expected Range	±3 SD	Units	Mean	Expected Range	±3 SD
Instrument	Parameter	Einheiten	Mittlerwert	Bereich	Expected Range	Einheiten	Mittlerwert	Bereich	Expected Range
Appareils	Constituant	Unités	Mittlerwert	Limites	Limites	Unités	Mittlerwert	Limites	Limites
Strumentazione	Costituente	Unita	Media	Intervallo	Intervallo	Unita	Media	Intervallo	Intervallo
Conventional Units of Measure						Other Units			
BioProfile 400	pH		7.441	7.391 - 7.491	7.366 - 7.516				
	PO ₂	mmHg	141.2	126.9 - 155.5	119.8 - 162.6	kPa	18.8	16.9 - 20.7	15.9 - 21.6
	PCO ₂	mmHg	21.0	17.8 - 24.2	16.2 - 25.8	kPa	2.8	2.4 - 3.2	2.1 - 3.4
	Glucose	g/L	15.00	12.75 - 17.25	11.62 - 18.38	mmol/L	83.3	70.8 - 95.7	64.5 - 102.0
	Lactate	g/L	5.00	4.25 - 5.75	3.87 - 6.13	mmol/L	55.5	47.2 - 63.8	43.0 - 68.1
	NH ₄ ⁺	mmol/L	10.18	8.68 - 11.68	7.93 - 12.43	g/L	0.190	0.162 - 0.218	0.148 - 0.232
	Na ⁺	mmol/L	185.0	166.7 - 203.3	*				
	K ⁺	mmol/L	6.20	5.55 - 6.85	*				
BioProfile 100 Plus	pH		7.441	7.391 - 7.491	7.366 - 7.516				
	Glucose	g/L	15.00	12.75 - 17.25	11.62 - 18.38	mmol/L	83.3	70.8 - 95.7	64.5 - 102.0
	Lactate	g/L	5.00	4.25 - 5.75	3.87 - 6.13	mmol/L	55.5	47.2 - 63.8	43.0 - 68.1
	NH ₄ ⁺	mmol/L	10.18	8.68 - 11.68	7.93 - 12.43	g/L	0.190	0.162 - 0.218	0.148 - 0.232
	Na ⁺	mmol/L	185.0	166.7 - 203.3	*				
	K ⁺	mmol/L	6.20	5.55 - 6.85	*				
BioProfile Basic 2	Glucose	g/L	15.00	12.75 - 17.25	11.62 - 18.38	mmol/L	83.3	70.8 - 95.7	64.5 - 102.0
	Lactate	g/L	5.00	4.25 - 5.75	3.87 - 6.13	mmol/L	55.5	47.2 - 63.8	43.0 - 68.1
BioProfile FLEX	pH		7.364	7.314 - 7.414	7.289 - 7.439				
	PO ₂	mmHg	142.4	128.1 - 156.7	121.0 - 163.8	kPa	18.9	17.0 - 20.8	16.1 - 21.8
	PCO ₂	mmHg	17.8	14.6 - 21.0	13.0 - 22.6	kPa	2.4	1.9 - 2.8	1.7 - 3.0
	Glucose	g/L	15.00	12.75 - 17.25	11.62 - 18.38	mmol/L	83.3	70.8 - 95.7	64.5 - 102.0
	Lactate	g/L	5.00	4.25 - 5.75	3.87 - 6.13	mmol/L	55.5	47.2 - 63.8	43.0 - 68.1
	NH ₄ ⁺	mmol/L	9.74	8.24 - 11.24	7.49 - 11.99	g/L	0.182	0.154 - 0.210	0.140 - 0.224
	Na ⁺	mmol/L	185.0	166.7 - 203.3	*				
	K ⁺	mmol/L	6.20	5.55 - 6.85	*				
	Ca ⁺⁺	mmol/L	2.55	2.25 - 2.85	*				
	Osmolality	mOsm/kg H ₂ O	612	604 - 620	*				
BioProfile FLEX 2	pH		7.362	7.312 - 7.412	7.287 - 7.437				
	PO ₂	mmHg	143.5	127.9 - 159.1	120.1 - 166.9	kPa	19.1	17.0 - 21.2	16.0 - 22.2
	PCO ₂	mmHg	18.2	15.0 - 21.4	13.4 - 23.0	kPa	2.4	2.0 - 2.9	1.8 - 3.1
	Glucose	g/L	15.00	12.75 - 17.25	11.62 - 18.38	mmol/L	83.3	70.8 - 95.7	64.5 - 102.0
	Lactate	g/L	5.00	4.25 - 5.75	3.87 - 6.13	mmol/L	55.5	47.2 - 63.8	43.0 - 68.1
	NH ₄ ⁺	mmol/L	9.78	8.28 - 11.28	7.53 - 12.03	g/L	0.183	0.155 - 0.211	0.141 - 0.225
	Na ⁺	mmol/L	183.0	164.7 - 201.3	*				
	K ⁺	mmol/L	6.00	5.35 - 6.65	*				
	Ca ⁺⁺	mmol/L	2.58	2.28 - 2.88	*				
	Osmolality	mOsm/kg H ₂ O	610	602 - 618	*				
BioProfile pHOx	pH		7.334	7.284 - 7.384	7.259 - 7.409				
	PCO ₂	mmHg	18.0	14.8 - 21.2	13.2 - 22.8	kPa	2.40	1.97 - 2.82	1.76 - 3.03
	PO ₂	mmHg	138.3	124.0 - 152.6	116.9 - 159.7	kPa	18.40	16.49 - 20.30	15.55 - 21.24

* Expected Range includes all values to be seen for these parameters.

NOTE: It is recommended that each laboratory establish their own range of acceptable values, based on the allowed variation in the value of the parameter being measured.

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BioProfile® Controls

Product Information

NOVA BIOPROFILE® CONTROLS — An assayed aqueous quality control material intended for monitoring the measurement of pH, PCO_2 , PO_2 , sodium, potassium, ionized calcium, ammonium, lactate and glucose on Nova Biomedical analyzers ONLY.

Ingredients: These controls are formulated from a buffered bicarbonate solution, each with a known pH and containing known levels of sodium, potassium, glucose, lactate, calcium and ammonium. The solutions are equilibrated with known levels of oxygen, carbon dioxide and nitrogen. The volume of each ampule is 1.7 mL.

Level 1 (Blue)	Catalog No. 22600
Level 2 (Green)	Catalog No. 22601
Level 3 (Red)	Catalog No. 22602

BioProfile® Controls contain no constituents of human origin, however, good laboratory practice should be followed during handling of these materials. (REF. NCCLS DOCUMENT M29-T2)

Storage: Controls should be stored at 15-30°C. Each control has a lot number and expiration date printed on the label.

Directions for Use:

Ampules must be stored at approximately 25°C for at least 24 hours before opening. Shake the ampule for about 10 seconds. Snap open ampule (protecting fingers with gauze or gloves), and within 30 SECONDS from opening, aspirate liquid from the ampule to the analyzer, following the manufacturer's recommended technique. Any delay in measuring may cause contamination with room air and alteration of stated values.

Assigned Values: The EXPECTED RANGE for each analyte was determined at Nova by performing multiple determinations at 37°C on multiple instruments using multiple runs of each level of control. The EXPECTED RANGE indicates the maximum deviations from the mean value which may be expected under differing laboratory conditions from instruments which are operating according to specifications.

Users may wish to determine MEAN VALUES and EXPECTED RANGES in their own laboratory. Please verify that the lot number appearing on the Assay Data Sheet agrees with the lot number appearing on the control material being analyzed.

PO_2 values vary inversely with temperature, approximately 1%/°C

Limitations: The values appearing in the Assay Data Table are specific for instruments and reagents manufactured by Nova Biomedical.

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