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Assay Data Sheet - Expected Ranges

BioProfile® Controls - LEVEL 2

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

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Lot. No. 519731

Exp. Date 2027-01

Instrument Instrument Appareils Strumentazione	Constituent Parameter Constituant Costituente	Units Einheiten Unites Unita	Mean Mittlerwert Mittlerwert Media	Expected Range Bereich Limites Intervallo	±3 SD Expected Range Bereich Limites Intervallo	Units Einheiten Unites Unita	Mean Mittlerwert Mittlerwert Media	Expected Range Bereich Limites Intervallo	±3 SD Expected Range Bereich Limites Intervallo
Conventional Units of Measure						Other Units			
BioProfile 400	pH		----	----	----				
	PO ₂	mmHg	----	----	----	kPa	----	----	----
	PCO ₂	mmHg	----	----	----	kPa	----	----	----
	Glucose	g/L	----	----	----	mmol/L	----	----	----
	Lactate	g/L	----	----	----	mmol/L	----	----	----
	NH ₄ ⁺	mmol/L	----	----	----	g/L	----	----	----
	Na ⁺	mmol/L	----	----	*				
K ⁺	mmol/L	----	----	*					
BioProfile 100 Plus	pH		----	----	----				
	Glucose	g/L	----	----	----	mmol/L	----	----	----
	Lactate	g/L	----	----	----	mmol/L	----	----	----
	NH ₄ ⁺	mmol/L	----	----	----	g/L	----	----	----
	Na ⁺	mmol/L	----	----	*				
K ⁺	mmol/L	----	----	*					
BioProfile Basic 2	Glucose	g/L	----	----	----	mmol/L	----	----	----
	Lactate	g/L	----	----	----	mmol/L	----	----	----
BioProfile FLEX	pH		----	----	----				
	PO ₂	mmHg	----	----	----	kPa	----	----	----
	PCO ₂	mmHg	----	----	----	kPa	----	----	----
	Glucose	g/L	----	----	----	mmol/L	----	----	----
	Lactate	g/L	----	----	----	mmol/L	----	----	----
	NH ₄ ⁺	mmol/L	----	----	----	g/L	----	----	----
	Na ⁺	mmol/L	----	----	*				
	K ⁺	mmol/L	----	----	*				
	Ca ⁺⁺	mmol/L	----	----	*				
	PO ₄	mmol/L	----	----	*	mg/L	----	----	*
	P	mg/L	----	----	*	ppm	----	----	*
	Osmolality	mOsm/kg H ₂ O	----	----	*				
BioProfile FLEX 2	pH		6.926	6.876 - 6.976	6.851 - 7.001				
	PO ₂	mmHg	103.3	91.7 - 114.9	85.9 - 120.7	kPa	13.7	12.2 - 15.3	11.4 - 16.1
	PCO ₂	mmHg	44.1	39.7 - 48.5	37.6 - 50.6	kPa	5.9	5.3 - 6.4	5.0 - 6.7
	Glucose	g/L	5.13	4.38 - 5.88	4.00 - 6.26	mmol/L	28.5	24.3 - 32.6	22.2 - 34.7
	Lactate	g/L	3.00	2.55 - 3.45	2.32 - 3.68	mmol/L	33.3	28.3 - 38.3	25.8 - 40.9
	NH ₄ ⁺	mmol/L	4.88	3.98 - 5.78	3.48 - 6.28	g/L	0.091	0.074 - 0.108	0.065 - 0.117
	Na ⁺	mmol/L	131.5	122.3 - 140.7	*				
	K ⁺	mmol/L	4.00	3.58 - 4.42	*				
	Ca ⁺⁺	mmol/L	0.82	0.69 - 0.95	*				
	Osmolality	mOsm/kg H ₂ O	400	394 - 406	*				
BioProfile pHOx	pH		6.948	6.898 - 6.998	6.873 - 7.023				
	PCO ₂	mmHg	39.0	34.6 - 43.4	32.5 - 45.5	kPa	5.18	4.60 - 5.77	4.32 - 6.05
	PO ₂	mmHg	101.1	91.1 - 111.1	86.1 - 116.1	kPa	13.44	12.11 - 14.77	11.45 - 15.44

* 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.

NOVA
biomedical

200 Prospect Street Waltham, MA U.S.A. 02454
(781) 894-0800

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, glucose, osmolality and phosphate 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.