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## Assay Data Sheet - Expected Ranges

## BioProfile® Controls - LEVEL 2

pH, PCO<sub>2</sub>, PO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, NH<sub>4</sub><sup>+</sup>, Glucose, Lactate, Osmolality, Phosphate

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Lot. No. 716331

Exp. Date 2018 - 12

Instrument Appareils Strumentazione	Constituent Parameter Constituent Costituente	Units Einheiten Unità	Mean Mittlerwert Moyenne Media	Expected Range Bereich Limites Intervallo	±3 SD Expected Range Bereich Limites Intervallo	Units Einheiten Unità	Mean Mittlerwert Moyenne Media	Expected Range Bereich Limites Intervallo	±3 SD Expected Range Bereich Limites Intervallo
Conventional Units of Measure					Other Units				
BioProfile 100	pH		7.00	6.95 - 7.05	6.92 - 7.08				
	Glucose	g/L	5.00	4.25 - 5.75	3.88 - 6.12	mmol/L	27.8	23.6 - 31.9	21.5 - 34.0
	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 <sub>4</sub> <sup>+</sup>	mmol/L	4.75	3.85 - 5.65	3.40 - 6.10	g/L	0.086	0.069-0.102	0.061-0.110
	Na <sup>+</sup>	mmol/L	130.2	121.0 - 139.4	*				
	K <sup>+</sup>	mmol/L	4.00	3.58 - 4.42	*				
BioProfile 400	pH		6.975	6.925 - 7.025	6.900 - 7.050				
	PO <sub>2</sub>	mmHg	106.5	96.5 - 116.5	91.5 - 121.5	kPa	14.2	12.9 - 15.5	12.2 - 16.2
	PCO <sub>2</sub>	mmHg	44.2	39.8 - 48.6	37.7 - 50.7	kPa	5.9	5.3 - 6.5	5.0 - 6.8
	Glucose	g/L	5.00	4.25 - 5.75	3.87 - 6.13	mmol/L	27.8	23.6 - 31.9	21.5 - 34.0
	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 <sub>4</sub> <sup>+</sup>	mmol/L	4.75	3.85 - 5.65	3.35 - 6.15	g/L	0.086	0.069-0.102	0.060-0.111
	Na <sup>+</sup>	mmol/L	131.7	122.5 - 140.9	*				
	K <sup>+</sup>	mmol/L	4.00	3.58 - 4.42	*				
BioProfile 100 Plus	pH		6.975	6.925 - 7.025	6.900 - 7.050				
	Glucose	g/L	5.00	4.25 - 5.75	3.87 - 6.13	mmol/L	27.8	23.6 - 31.9	21.5 - 34.0
	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 <sub>4</sub> <sup>+</sup>	mmol/L	4.75	3.85 - 5.65	3.35 - 6.15	g/L	0.086	0.069-0.102	0.060-0.111
	Na <sup>+</sup>	mmol/L	131.7	122.5 - 140.9	*				
	K <sup>+</sup>	mmol/L	4.00	3.58 - 4.42	*				
BioProfile Basic 2	Glucose	g/L	5.00	4.25 - 5.75	3.87 - 6.13	mmol/L	27.8	23.6 - 31.9	21.5 - 34.0
	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
BioProfile FLEX	pH		6.949	6.899 - 6.999	6.874 - 7.024				
	PO <sub>2</sub>	mmHg	109.0	99.0 - 119.0	94.0 - 124.0	kPa	14.5	13.2 - 15.9	12.5 - 16.5
	PCO <sub>2</sub>	mmHg	41.0	36.6 - 45.4	34.5 - 47.5	kPa	5.5	4.9 - 6.1	4.6 - 6.3
	Glucose	g/L	5.00	4.25 - 5.75	3.87 - 6.13	mmol/L	27.8	23.6 - 31.9	21.5 - 34.0
	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 <sub>4</sub> <sup>+</sup>	mmol/L	4.75	3.85 - 5.65	3.35 - 6.15	g/L	0.086	0.069-0.102	0.060-0.111
	Na <sup>+</sup>	mmol/L	131.7	122.5 - 140.9	*				
	K <sup>+</sup>	mmol/L	4.00	3.58 - 4.42	*				
	Ca <sup>++</sup>	mmol/L	0.80	0.67 - 0.93	*	mg/dL	3.21	2.69 - 3.73	*
	PO <sub>4</sub>	mmol/L	0.97	0.77 - 1.17	*	mg/L	92.1	73.1 - 111.1	*
	P	mg/L	30.1	23.9 - 36.3	*	ppm	30.1	23.9 - 36.3	*
	Osmolality	mOsm/kg H <sub>2</sub> O	403	397 - 409	*				
	BioProfile FLEX 2	pH		6.932	6.882 - 6.982	6.857 - 7.007			
PO <sub>2</sub>		mmHg	107.5	95.9 - 119.1	90.1 - 124.9	kPa	14.3	12.8 - 15.9	12.0 - 16.7
PCO <sub>2</sub>		mmHg	44.3	39.9 - 48.7	37.8 - 50.8	kPa	5.9	5.3 - 6.5	5.0 - 6.8
Glucose		g/L	5.00	4.25 - 5.75	3.87 - 6.13	mmol/L	27.8	23.6 - 31.9	21.5 - 34.0
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 <sub>4</sub> <sup>+</sup>		mmol/L	4.88	3.98 - 5.78	3.48 - 6.28	g/L	0.088	0.072-0.104	0.063-0.113
Na <sup>+</sup>		mmol/L	131.5	122.3 - 140.7	*				
K <sup>+</sup>		mmol/L	4.00	3.58 - 4.42	*				
Ca <sup>++</sup>		mmol/L	0.82	0.69 - 0.95	*	mg/dL	3.29	2.77 - 3.81	*
Osmolality		mOsm/kg H <sub>2</sub> O	403	397 - 409	*				
BioProfile pHOx	pH		6.951	6.901 - 7.001	6.876 - 7.026				
	PCO <sub>2</sub>	mmHg	39.6	35.2 - 44.0	33.1 - 46.1	kPa	5.28	4.69 - 5.87	4.41 - 6.15
	PO <sub>2</sub>	mmHg	100.6	90.6 - 110.6	85.6 - 115.6	kPa	13.41	12.08 - 14.74	11.41 - 15.41

\* 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

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## 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.

<b>Level 1 (Blue)</b>	Catalog No. 22600
<b>Level 2 (Green)</b>	Catalog No. 22601
<b>Level 3 (Red)</b>	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.