

7

Assay Data Sheet - Expected Ranges

BioProfile® Controls - LEVEL 7

7

pH, Na⁺, K⁺, NH₄⁺, Glucose, Lactate, Acetate, Phosphate/Glycerol

Instrument Instrument Appareils Strumentazione	Constituent Parameter Constituant Costituente	Units Einheiten Unités Unità	Mean Mittelwert Moyenne Media	Expected Range Bereich Limites Intervallo	Units Einheiten Unités Unità	Mean Mittelwert Moyenne Media	Expected Range Bereich Limites Intervallo
		Conventional Units of Measure			Other Units		
BioProfile 300	pH		6.88	6.83 - 6.93			
	Gluc	g/L	10.00	8.00 - 12.00	mmol/L	55.5	44.40 - 66.61
	Ace	mmol/L	100.0	80.0 - 120.0	g/L	5.90	4.72 - 7.08
	PO ₄	mmol/L	4.00	3.40 - 4.60	mg/L	388.4	330.1 - 446.7
	P	mg/L	124.0	105.0 - 143.0	ppm	124.0	105.0 - 143.0
	Gly	g/L	5.00	4.25 - 5.75	mmol/L	54.3	46.1 - 62.4
	NH ₄ ⁺	mmol/L	10.0	8.0 - 12.0	g/L	0.18	0.14 - 0.22
	Na ⁺	mmol/L	95	85 - 105			
	K ⁺	mmol/L	10.0	8.5 - 11.5			
	Lactate	g/L	3.00	2.50 - 3.50	mmol/L	33.3	27.8 - 38.9

Lot #/Serien Nr./No. de lot/
Lotto No.:Expiration Date/Verfallsdatum/
Date de péremption/Data scadenza:

811373

**Item No./Best. Nr./
Code produit/ Cat.No.:**
33837

2010-05

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LPN 34474B

BioProfile® Controls

Product Information

NOVA BIOPROFILE CONTROLS — An assayed aqueous quality control material intended for monitoring the measurement of pH, sodium, potassium, phosphate, glycerol, acetate, ammonium, lactate and glucose on Nova Biomedical analyzers ONLY.

Ingredients: These controls are formulated from a buffered solution, each with a known pH and containing known levels of sodium, potassium, glucose, lactate, acetate, glycerol, phosphate and ammonium. The volume of each ampule is 1.7 mL.

Level 6 (Blue)

Catalog No. 33836

Level 7 (Grey)

Catalog No. 33837

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.

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

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