

6

Assay Data Sheet - Expected Ranges

BioProfile® Controls - LEVEL 6

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

6

Instrument Instrument Apparati Strumentazione	Constituent Parameter Constituente	Units Einheiten Unità	Mean Mittlerwert Moyenne Media	Expected Range Bereich Limites Intervallo	Units Einheiten Unità	Mean Mittlerwert Moyenne Media	Expected Range Bereich Limites Intervallo
Conventional Units of Measure				Other Units			
BioProfile 300	pH		7.580	7.530 - 7.630			
	Gluc	g/L	2.00	1.75 - 2.25	mmol/L	11.1	9.7 - 12.5
	Ace	mmol/L	19.5	13.9 - 25.1	g/L	1.15	0.82 - 1.48
	PO ₄	mmol/L	1.00	0.80 - 1.20	mg/L	95.0	76.0 - 114.0
	P	mg/L	31.0	24.8 - 37.2	ppm	31.0	24.8 - 37.2
	Gly	g/L	2.50	2.00 - 3.00	mmol/L	27.1	21.7 - 32.6
	NH ₄ ⁺	mmol/L	2.0	1.7 - 2.3	g/L	0.04	0.03 - 0.04
	Na ⁺	mmol/L	140	130 - 150			
	K ⁺	mmol/L	4.0	3.6 - 4.4			
	Lactate	g/L	1.00	0.75 - 1.25	mmol/L	11.1	8.3 - 13.9

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.

Lot #/Serien Nr./No. de lot/
Lotto No.:

429730

Item No./Best. Nr./
Code produit/ Cat.No.:
33836Expiration Date/Verfallsdatum/
Date de péremption/Data scadenza:

2026-04

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