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Assay Data Sheet - Expected Ranges

BioProfile Controls - LEVEL 5

Glutamine (Gln), Glutamate (Glu)

5

Lot. No. 812464

Exp. Date 2010-06

Instrument Instrument Appareil 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 200/250	Gln	mmol/L	4.99	4.24 - 5.74	g/L	0.73	0.62 - 0.84
	Glu	mmol/L	1.97	1.67 - 2.27	g/L	0.29	0.24 - 0.33
BioProfile 100	Gln	mmol/L	5.16	4.41 - 5.91	g/L	0.75	0.64 - 0.86
	Glu	mmol/L	1.96	1.66 - 2.26	g/L	0.29	0.24 - 0.33
BioProfile 400/100 Plus	Gln	mmol/L	5.07	4.32 - 5.82	g/L	0.74	0.63 - 0.85
	Glu	mmol/L	1.99	1.69 - 2.29	g/L	0.29	0.25 - 0.33
BioProfile Basic	Gluc	g/L	10.06	8.06 - 12.06	mmol/L	55.8	44.7 - 66.9
	Lac	g/L	5.07	4.32 - 5.82	mmol/L	56.3	48.0 - 64.6
	Gln	mmol/L	5.07	4.32 - 5.82	g/L	0.74	0.63 - 0.85
	Glu	mmol/L	1.99	1.69 - 2.29	g/L	0.29	0.25 - 0.33
BioProfile FLEX	Gln	mmol/L	5.20	4.45 - 5.95	g/L	0.76	0.65 - 0.87
	Glu	mmol/L	2.04	1.74 - 2.34	g/L	0.30	0.26 - 0.34
	Gluc	g/L	10.18	8.18 - 12.18	mmol/L	56.5	45.4 - 67.6
	Lac	g/L	5.15	4.40 - 5.90	mmol/L	57.2	48.8 - 65.5

* 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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LPN 26691E

BioProfile Controls

Product Information

NOVA BIOPROFILE CONTROLS — An assayed aqueous quality control material intended for monitoring the measurement of glucose, lactate, glutamine and glutamate on Nova Biomedical analyzers ONLY.

Ingredients: These controls are formulated from a buffered aqueous solution, each with a known pH and containing known levels of glutamine and glutamate. The volume of each ampule is 1.7 mL.

Level 4

Catalog No. 24617

Level 5

Catalog No. 24619

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 frozen at or below -15°C. Each control has a lot number and expiration date printed on the label.

Directions for Use:

Before opening BioProfile Controls, prepare the solution by thawing to approximately 25°C, and then shake the ampules for about 10 seconds. Snap open ampule (protecting fingers with gauze or gloves), and aspirate liquid from the ampule to the analyzer, following the manufacturer's recommended technique.

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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