

# Assay Data Sheet – Expected Ranges

## BioProfile® FLEX2™ Chemistry Auto QC Cartridge

**Lot No.** 25240008

**Exp. Date** 2027-02-12

Level 1								
Constituent	Units	Mean	Expected Range	±3SD Expected Range	Units	Mean	Expected Range	±3SD Expected Range
Conventional Units					Other Units			
Gln	mmol/L	0.99	0.74 - 1.24	0.61 - 1.37	g/L	0.14	0.11 - 0.18	0.09 - 0.20
Glu	mmol/L	0.54	0.29 - 0.79	0.16 - 0.92	g/L	0.08	0.04 - 0.12	0.02 - 0.14
Gluc	g/L	1.01	0.76 - 1.26	0.63 - 1.39	mmol/L	5.61	4.22 - 6.99	3.50 - 7.71
Lac	g/L	0.97	0.72 - 1.22	0.59 - 1.35	mmol/L	10.77	7.99 - 13.54	6.55 - 14.99
NH <sub>4</sub> <sup>+</sup>	mmol/L	0.92	0.67 - 1.17	0.54 - 1.30	g/L	0.017	0.013 - 0.022	0.010 - 0.024
Na <sup>+</sup>	mmol/L	79.6	71.8 - 87.4					
K <sup>+</sup>	mmol/L	2.14	1.85 - 2.43					
Ca <sup>++</sup>	mmol/L	0.62	0.50 - 0.74					

Level 2								
Constituent	Units	Mean	Expected Range	±3SD Expected Range	Units	Mean	Expected Range	±3SD Expected Range
Conventional Units					Other Units			
Gln	mmol/L	5.12	4.37 - 5.87	3.99 - 6.25	g/L	0.75	0.64 - 0.86	0.58 - 0.91
Glu	mmol/L	2.38	2.08 - 2.68	1.93 - 2.83	g/L	0.35	0.31 - 0.39	0.28 - 0.42
Gluc	g/L	14.63	12.38 - 16.88	11.25 - 18.01	mmol/L	81.20	68.71 - 93.68	62.44 - 99.96
Lac	g/L	5.48	4.73 - 6.23	4.35 - 6.61	mmol/L	60.83	52.51 - 69.16	48.29 - 73.38
NH <sub>4</sub> <sup>+</sup>	mmol/L	10.38	8.88 - 11.88	8.13 - 12.63	g/L	0.194	0.166 - 0.222	0.152 - 0.236
Na <sup>+</sup>	mmol/L	179.6	161.3 - 197.9					
K <sup>+</sup>	mmol/L	10.21	9.17 - 11.25					
Ca <sup>++</sup>	mmol/L	3.01	2.71 - 3.31					

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LPN 59224B 2019-08

# BioProfile® FLEX2™ Chemistry Auto QC Cartridge

## Product Information

**NOVA BIOPROFILE FLEX2 Chemistry Auto QC Cartridge** — An assayed aqueous quality control material intended for monitoring the measurement of Glutamine, Glutamate, Glucose, Lactate,  $\text{NH}_4^+$ ,  $\text{Na}^+$ ,  $\text{K}^+$ , and  $\text{Ca}^{++}$  on Nova Biomedical analyzers ONLY. The Nova controls are formulated at 2 levels.

**Level 1 – Low**

**Level 2 – High**

**Ingredients:** BioProfile FLEX2 Chemistry Auto QC Cartridge contain no constituents of human origin, however, good laboratory practice should be followed during handling of these materials. (REF. NCCLS DOCUMENT M29-T2.) These controls are formulated from a buffered bicarbonate solution, each with a known pH. The solutions contain known levels of Glutamine, Glutamate, Glucose, Lactate,  $\text{NH}_4^+$ ,  $\text{Na}^+$ ,  $\text{K}^+$ ,  $\text{Ca}^{++}$ , and mold inhibited.

**Storage:** Controls should be stored frozen at or below  $-15^\circ\text{C}$  ( $5^\circ\text{F}$ ). Prior to installation, it is critical to ensure complete thawing until the control solution is in a liquid state as directed in “Directions for Use.” Each control cartridge has a lot number and expiration date printed on the label.

**Directions for Use:** Before installing the BioProfile FLEX2 Chemistry Auto QC Cartridge, prepare the Chemistry Auto QC Cartridge by thawing until the control solution is in a liquid state. The Chemistry Auto QC Cartridge Pack should be mixed by gently inverting the pack for several seconds. BioProfile FLEX2 Chemistry Auto QC Cartridge are intended for *in vitro* Diagnostic Use.

**Assigned Values:** The EXPECTED RANGE for each analyte was determined at Nova by performing multiple determinations 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. Once installed, each BioProfile FLEX2 Chemistry Auto QC Cartridge may be used for a maximum of 14 days from the date of initial installation on the system at which time the system will indicate that the Cartridge is Invalid.

BioProfile FLEX2 Chemistry Auto QC Cartridge contain 2 levels: **Catalog No. 57035.**

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