

BioProfile® FLEX2™ Chemistry Auto QC Cartridge

Product Information

2 Chemistry Auto QC Cartridge — An assayed aqueous quality control material intended for monitoring Amine, Glutamate, Glucose, Lactate, NH_4^+ , Na^+ , K^+ , and Ca^{++} on Nova Biomedical analyzers ONLY. The Nova 2 levels.

FLEX2 Chemistry Auto QC Cartridge contain no constituents of human origin, however, good laboratory practice handling of these materials. (REF. NCCLS DOCUMENT M29-T2.) These controls are formulated from a buffer each with a known pH. The solutions contain known levels of Glutamine, Glutamate, Glucose, Lactate, NH_4^+ , and others.

Be stored frozen at or below -15°C (5°F). Prior to installation, it is critical to ensure complete thawing until the liquid state as directed in "Directions for Use." Each control cartridge has a lot number and expiration date printed on the label.

When installing the BioProfile FLEX2 Chemistry Auto QC Cartridge, prepare the Chemistry Auto QC Cartridge solution is in a liquid state. The Chemistry Auto QC Cartridge Pack should be mixed by gently inverting the BioProfile FLEX2 Chemistry Auto QC Cartridge are intended for *in vitro* Diagnostic Use.

EXPECTED RANGE for each analyte was determined at Nova by performing multiple determinations on multiple levels of each level of control.

Indicates the maximum deviations from the mean value which may be expected under differing laboratory conditions are operating according to specifications.

Use MEAN VALUES and EXPECTED RANGES in their own laboratory. Please verify that the lot number appearing on the label agrees with the lot number appearing on the control material being analyzed.

Values appearing in the Assay Data Table are specific for instruments and reagents manufactured by Nova Biomedical. The BioProfile FLEX2 Chemistry Auto QC Cartridge may be used for a maximum of 14 days from the date of initial installation at which time the system will indicate that the Cartridge is Invalid.

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

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LPN 59224B 2019-08

Assay Data Sheet – Expected Ranges

BioProfile® FLEX2™ Chemistry Auto QC Cartridge

Exp. Date 2024-09-07

Mean	Expected Range	±3SD Expected Range	Units	Mean	Expected Range	±3SD Expected Range
Conventional Units			Other Units			
0.89	0.64 - 1.14	0.51 - 1.27	g/L	0.13	0.09 - 0.17	0.07 - 0.19
0.53	0.28 - 0.78	0.15 - 0.91	g/L	0.08	0.04 - 0.11	0.02 - 0.13
0.99	0.74 - 1.24	0.61 - 1.37	mmol/L	5.49	4.11 - 6.88	3.39 - 7.60
0.93	0.68 - 1.18	0.55 - 1.31	mmol/L	10.32	7.55 - 13.10	6.11 - 14.54
0.92	0.67 - 1.17	0.54 - 1.30	g/L	0.017	0.013 - 0.022	0.010 - 0.024
75.7	67.9 - 83.5					
2.10	1.81 - 2.39					
0.59	0.47 - 0.71					

Mean	Expected Range	±3SD Expected Range	Units	Mean	Expected Range	±3SD Expected Range
Conventional Units			Other Units			
4.83	4.08 - 5.58	3.70 - 5.96	g/L	0.71	0.60 - 0.82	0.54 - 0.87
2.30	2.00 - 2.60	1.85 - 2.75	g/L	0.34	0.29 - 0.38	0.27 - 0.40
14.47	12.22 - 16.72	11.09 - 17.85	mmol/L	80.31	67.82 - 92.80	61.55 - 99.07
4.77	4.02 - 5.52	3.64 - 5.90	mmol/L	52.95	44.63 - 61.28	40.41 - 65.50
10.16	8.66 - 11.66	7.91 - 12.41	g/L	0.190	0.162 - 0.218	0.148 - 0.232
179.8	161.5 - 198.1					
10.12	9.08 - 11.16					
2.96	2.66 - 3.26					

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