



CERTIFICATE OF ANALYSIS

BioProfile FLEX 2 Chemistry Calibrator
and Reagent Cartridge HV
Lot Number 25085067

Ref Number 53937
Exp Date 2026-03-12
Date of Manufacture 2025-03-12

Chemistry Cal Cartridge L/N: 25085064

Exp Date: 2026-06-13

Cal D1 25072010

Cal D2 25083075

	<u>Spec</u>	<u>Result</u>
Gln mmol/L	0.90 - 1.10	Pass
Glu mmol/L	0.45 - 0.55	Pass
Gluc g/L	0.90 - 1.10	Pass
Lac g/L	0.90 - 1.10	Pass
NH4 mmol/L	1.90 - 1.98	Pass
Na+ mmol/L	139.0 - 143.0	Pass
K+ mmol/L	3.95 - 4.07	Pass
Ca++ mmol/L	0.90 - 0.96	Pass

	<u>Spec</u>	<u>Result</u>
Gln mmol/L	4.50 - 5.50	Pass
Glu mmol/L	1.75 - 2.25	Pass
Gluc g/L	4.80 - 5.80	Pass
Lac g/L	2.50 - 3.10	Pass
NH4 mmol/L	9.93 - 10.33	Pass
Na+ mmol/L	65.7 - 67.7	Pass
K+ mmol/L	9.86 - 10.18	Pass
Ca++ mmol/L	4.50 - 4.84	Pass

Chemistry Reagent Cartridge L/N: 25085060

Exp Date: 2026-03-12

PF Soln L/N 25083039

R Soln L/N 25071046

	<u>Spec</u>	<u>Result</u>
pH	6.85 - 7.05	Pass

	<u>Spec</u>	<u>Pass/Fail</u>
NaOCl %	0.43 - 0.73	Pass

	<u>Spec</u>	<u>Pass/Fail</u>
KCl mol/L	1.8 - 2.2	Pass

	<u>Spec</u>	<u>Pass/Fail</u>
pH	6.90 - 7.10	Pass

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U.S.A in accordance with ISO 13485:2016 Medical Devices Quality Management Systems Requirements, Medical Device Single Audit Program (MDSAP), and conforms to the indicated test specifications. The following analytes are traceable to NIST SRM Materials: pH.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Approval

QC Inspector
Title

4/1/2025
Date