

BioProfile FLEX 2 Chemistry Calibrator and Reagent Cartridge HV Lot Number 24242070 Ref Number 53937 Exp Date 2025-07-30 Date of Manufacture 2024-07-30

	Chemistry Cal Cartridge L/N: 24242067		Exp Date: 2025-10-31		
	Cal D1 24213070		Cal D2 24213071		
	<u>Spec</u>	<u>Result</u>		<u>Spec</u>	<u>Result</u>
GIn mmol/L	0.90 - 1.10	Pass	GIn mmol/L	4.50 - 5.50	Pass
Glu mmol/L	0.45 - 0.55	Pass	Glu mmol/L	1.75 - 2.25	Pass
Gluc g/L	0.90 - 1.10	Pass	Gluc g/L	4.80 - 5.80	Pass
Lac g/L	0.90 - 1.10	Pass	Lac g/L	2.50 - 3.10	Pass
NH4 mmol/L	1.90 - 1.98	Pass	NH4 mmol/L	9.93 - 10.33	Pass
Na+ mmol/L	139.0 - 143.0	Pass	Na+ mmol/L	65.7 - 67.7	Pass
K+ mmol/L	3.95 - 4.07	Pass	K+ mmol/L	9.86 - 10.18	Pass
Ca++ mmol/L	0.90 - 0.96	Pass	Ca++ mmol/L	4.50 - 4.84	Pass
Chemistry Reagent Cartridge L/N: 24242064			Exp Date: 2025-07-30		
PF Soln L/N 24215012			R Soln L/N 24211047		
	<u>Spec</u>	<u>Result</u>		<u>Spec</u>	Pass/Fail
pН	6.85 - 7.05	Pass	KCI mol/L	1.8 - 2.2	Pass
DP Soln L/N 24212068			DF Soln L/N 24212033		
	<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail
NaOCI %	0.43 - 0.73	Pass	pН	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

<u>9/12/2024</u> Date