

CERTIFICATE OF ANALYSIS

Stat Profile pHOx Ultra/CCX Calibrator Cartridge 1 Lot Number 24110053

artridge 1 Ref Number 48834 Exp Date 2025-10-04 Date of Manufacture 2024-04-04 UDI# (01)00385480488341(11)240404(17)251004(10)24110053

Cal-A L/N 24099061	Cal-B L/N 24095012	Cal-C L/N 24095013
<u>Spec</u> <u>Pass/Fail</u>	Spec Pass/Fail	Spec Pass/Fail
pH @ 37C 7.351 - 7.357 Pass	pH @ 37C 6.822 - 6.828 Pass	Na mmol/L 139.0 - 141.0 Pass
Lac mmol/L 13.5 - 16.5 Pass	Na mmol/L 69.5 - 70.5 Pass	K mmol/L 3.97 - 4.03 Pass
	K mmol/L 9.9 - 10.1 Pass	Cl mmol/L 118.0 - 120.0 Pass
	CI mmol/L 39.7 - 40.3 Pass	Ca mmol/L 0.99 - 1.02 Pass
	Ca mmol/L 1.97 - 2.03 Pass	Mg mmol/L 0.49 - 0.51 Pass
	Mg mmol/L 1.48 - 1.52 Pass	Glu mg/dL 78.8 - 81.2 Pass
		Lac mmol/L 1.8 - 2.2 Pass
		BUN mg/dL 9.9 - 10.1 Pass
		HCO3 mmol/L 18.43 - 19.19 Pass
Cal-D L/N 24095014	Flush L/N 24099053	Reference L/N 24100024
Spec Pass/Fail	Spec Pass/Fail	<u>Spec</u> <u>Pass/Fail</u>
Glu mg/dL 197 - 203 Pass	Aqueous	KCI mol/L 1.8 - 2.2 Pass
Lac mmol/L 5.5 - 6.5 Pass	Salt N/A Present	
BUN mg/dL 49.4 - 50.6 Pass	Solution	
HCO3 mmol/L 37.05 - 38.57 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. All listed analytes are traceable to NIST SRM Materials.

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

Auishi, M

Approval

QC Inspector Title

4/30/2024 Date