

CERTIFICATE OF ANALYSIS

Stat Profile pHOx Plus L Calibrator Cartridge A Lot Number 24110026

tridge A Ref Number 34085 Exp Date 2025-10-10 Date of Manufacture 2024-04-10 UDI# (01)00385480340854(11)240410(17)251010(10)24110026

Cal-A L/N 24101034	Cal-B L/N 24101035	Cal-C L/N 24101036
Spec Pass/Fail	Spec Pass/Fail	Spec Pass/Fail
Na mmol/L 142 - 144 Pass	HCO3 mmol/L 45.90 - 47.78 Pass	pH @ 37C 7.332 - 7.338 Pass
HCO3 mmol/L 24.42 - 25.42 Pass		Ca mmol/L 2.01 - 2.07 Pass
K mmol/L 4.03 - 4.09 Pass		Na mmol/L 72.5 - 73.5 Pass
CI mmol/L 97.2 - 98.8 Pass		K mmol/L 10.04 - 10.20 Pass
Ca mmol/L 1.01 - 1.03 Pass		CI mmol/L 52.6 - 53.4 Pass
Glu mg/dL 39.6 - 40.4 Pass		Glu mg/dL 198 - 202 Pass
Lac mmol/L 0.8 - 1.2 Pass		Lac mmol/L 5.5 - 6.5 Pass
Cal-D L/N 24101037		Reference L/N 24101033
Spec Pass/Fail		<u>Spec</u> <u>Pass/Fail</u>
pH @ 37C 6.788 - 6.794 Pass		KCI mol/L 1.8 - 2.2 Pass
Glu mg/dL 990 - 1010 Pass		
Lac mmol/L 10.5 - 13.5 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

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Approval

QC Inspector Title

4/23/2024 Date