

CERTIFICATE OF ANALYSIS

Stat Profile pHOx Plus M Calibrator Cartridge A Lot Number 23244003

tridge A Ref Number 45714 Exp Date 2025-02-15 Date of Manufacture 2023-08-15 UDI# (01)00385480457149(11)230815(17)250215(10)23244003

Cal-A L/N 23234094	Cal-B L/N 23227092	Cal-C L/N 23230034
Spec Pass/Fail	Spec Pass/Fail	Spec Pass/Fail
Na mmol/L 136 - 138 Pass	HCO3 mmol/L 42.24 - 43.96 Pass	pH @ 37C 7.332 - 7.338 Pass
HCO3 mmol/L 21.07 - 21.93 Pass		Ca mmol/L 1.97 - 2.03 Pass
K mmol/L 3.97 - 4.03 Pass		Na mmol/L 70.5 - 71.5 Pass
Mg mmol/L 0.49 - 0.51 Pass		K mmol/L 9.92 - 10.08 Pass
Ca mmol/L 0.99 - 1.01 Pass		CI mmol/L 1.38 - 1.42 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 23227094		Reference L/N 23227089
Spec Pass/Fail		Spec Pass/Fail
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

<u>9/6/2023</u> Date