

CERTIFICATE OF ANALYSIS

Stat Profile pHOx Plus L Calibrator Cartridge C Lot Number 24110028

tridge C Ref Number 34087 Exp Date 2025-10-10 Date of Manufacture 2024-04-10 UDI# (01)00385480340878(11)240410(17)251010(10)24110028

| Cal-A L/N 24101034 | Cal-B L/N 24101035 | Cal-C L/N 24101036 |
|--------------------------------|--------------------------------|------------------------------|
| <u>Spec</u> <u>Pass/Fai</u> | 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 |
| <u>Spec</u> <u>Pass/Fai</u> | | <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

Approval

QC Inspector Title

<u>4/23/2024</u> Date