

CERTIFICATE OF ANALYSIS

STP pHOx Plus L Controls Auto-Cartridge Lot Number 24058043

rols Auto-Cartridge Ref Number 34090 43 Exp Date 2025-08-02 Date of manufacture 2024-02-02 UDI# (01)00385480340908(11)240202(17)250802(10)24058043

Level 1 Level 2 Spec Pass/Fail Spec Pass/Fail 7.140 - 7.215 7.345 - 7.395 pН Pass pН Pass pCO2 mmHg 55.0 - 60.0 pCO2 mmHg Pass 38.0 - 44.0 Pass pO2 mmHg 53.0 - 63.0 pO2 mmHg Pass 104.0 - 116.0 Pass Na+ mmol/L 158.0-163.0 Pass SO2 % 58.0 - 64.0 Pass K+ mmol/L 5.65 - 5.95 Pass Hct % 33 - 37 Pass 119.5 - 128.5 136.0 - 140.0 CI- mmol/L Pass Na+ mmol/L Pass Ca++ mmol/L 1.36 - 1.44 Pass K+ mmol/L 3.80 - 4.00 Pass Glu mg/dL 270 - 320 Pass CI- mmol/L 96.0 - 104.0 Pass Lac mmol/L 6.4 - 7.7 Pass Ca++ mmol/L 0.91 - 0.99 Pass Glu mg/dL 184 - 214 Pass Lac mmol/L 2.6 - 3.2 Pass Level 3 Pass/Fail <u>Spec</u> 7.575 - 7.615 pН Pass pCO2 mmHg 19.8 - 24.8 Pass pO2 mmHg 130.0 - 150.0 Pass SO2 % 85.0 - 93.0 Pass Hct % 49 - 53 Pass Na+ mmol/L 113.0 - 118.0 Pass K+ mmol/L 1.85 - 2.15 Pass CI- mmol/L 80.0 - 88.0 Pass Ca++ mmol/L 0.53 - 0.63 Pass Glu mg/dL 77 - 91 Pass Lac mmol/L 0.9 - 1.3 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. SO2 is traced to tonometry.

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

Amishi.M

Approval

QC Inspector Title

<u>4/17/2024</u> Date