



CERTIFICATE OF ANALYSIS

STP pHox Plus L Controls Auto-Cartridge
Lot Number 22033058

Ref Number 34091
Exp Date 2023-07-18
Date of Manufacture 2022-01-18
(01)00385480340915(11)220118(17)230718(10)22033058

| Level 1 | | | Level 2 | | |
|-------------|---------------|------------------|-------------|---------------|------------------|
| | <u>Spec</u> | <u>Pass/Fail</u> | | <u>Spec</u> | <u>Pass/Fail</u> |
| pH | 7.140 - 7.215 | Pass | pH | 7.345 - 7.395 | Pass |
| pCO2 mmHg | 55.0 - 60.0 | Pass | pCO2 mmHg | 38.0 - 44.0 | Pass |
| pO2 mmHg | 53.0 - 63.0 | Pass | pO2 mmHg | 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 |
| Cl- mmol/L | 119.5 - 128.5 | Pass | Na+ mmol/L | 136.0 - 140.0 | Pass |
| Ca++ mmol/L | 1.36 - 1.44 | Pass | K+ mmol/L | 3.80 - 4.00 | Pass |
| Glu mg/dL | 270 - 320 | Pass | Cl- 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 | | |
|-------------|---------------|------------------|
| | <u>Spec</u> | <u>Pass/Fail</u> |
| pH | 7.575 - 7.615 | 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 |
| Cl- 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

Approval

QC Inspector
Title

2/22/2022
Date