



## CERTIFICATE OF ANALYSIS

STP pHoxUltra Controls

Ref Number 48935

|                   |             |
|-------------------|-------------|
| Level 1 L/N:      | 15338010    |
| Level 1 Exp Date: | 2017-12     |
| Spec              | Pass/Fail   |
| pH                | 7.180-7.220 |
| PCO2 mmHg         | 55.0-65.0   |
| PO2 mmHg          | 55.0-65.0   |
| SO2 %             | 59.0-65.0   |
| Hct %             | 32-36       |

|                   |             |
|-------------------|-------------|
| Level 2 L/N:      | 15324022    |
| Level 2 Exp Date: | 2017-11     |
| Spec              | Pass/Fail   |
| pH                | 7.395-7.435 |
| PCO2 mmHg         | 40.0-46.0   |
| PO2 mmHg          | 93.0-103.0  |

|                   |             |
|-------------------|-------------|
| Level 3 L/N:      | 15324023    |
| Level 3 Exp Date: | 2017-11     |
| Spec              | Pass/Fail   |
| pH                | 7.545-7.585 |
| PCO2 mmHg         | 22.0-27.0   |
| PO2 mmHg          | 131.0-145.0 |
| SO2 %             | 89.0-97.0   |
| Hct %             | 48-52       |

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U. S. A. in accordance with 21 CFR-Part 820, Quality System Regulation (QSR), Current Good Manufacturing Practice (cGMP) and EN ISO 13485:2012, Medical Devices, Quality Management Systems for in Vitro Diagnostic devices, and conforms to the indicated test specifications. All listed analytes are traceable to NIST SRM Materials. SO2 is traced to tonometry.

Approval

QC Supervisor

Title

1/26/2016

Date