

CERTIFICATE OF ANALYSIS

STP pHOx Ultra/CCX Blood Gas Control Auto-Cartridge Lot Number 16034023

Pass

Pass

Pass

Ref Number 48903 Exp Date 2017-07

Level 1 Spec pH 7.179-7.254 PCO2 mmHg 55.0-60.0 PO2 mmHg 53.0-63.0 SO2 % 55.0-61.0 Hct % 32-36	Pass/Fail Pass Pass Pass Pass Pass	pH 7.410-7.460 P PCO2 mmHg 39.8-45.8 P	ss/Fail Pass Pass Pass
Level 3 Spec pH 7.555-7.630 PCO2 mmHg 21.5-26.5	Pass/Fail Pass Pass		

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U. S. A. in accordance with 21 CRF-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.

Joyce anair Approval

QC Supervisor

PO2 mmHg 130.0-150.0

Hct %

SO2 % 90.0-96.0

48-52

Title

2/16/2016 Date