



CERTIFICATE OF ANALYSIS

STP pHox Ultra/CCX Blood Gas Control Auto-Cartridge
Lot Number 16168025

Ref Number 48904
Exp Date 2017-11-14
Date of Manufacture 2016-05-14

Level 1		
	Spec	Pass/Fail
pH	7.179-7.254	Pass
PCO2 mmHg	55.0-60.0	Pass
PO2 mmHg	53.0-63.0	Pass
SO2 %	55.0-61.0	Pass
Hct %	32-36	Pass

Level 2		
	Spec	Pass/Fail
pH	7.410-7.460	Pass
PCO2 mmHg	39.8-45.8	Pass
PO2 mmHg	104.0-116.0	Pass

Level 3		
	Spec	Pass/Fail
pH	7.555-7.630	Pass
PCO2 mmHg	21.5-26.5	Pass
PO2 mmHg	130.0-150.0	Pass
SO2 %	90.0-96.0	Pass
Hct %	48-52	Pass

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

6/22/2016
Date