



CERTIFICATE OF ANALYSIS

STP pHox Plus L Controls Auto-Cartridge
Lot Number 16153039


Ref Number 34091
Exp Date 2017-11-06
Date of Manufacture 2016-05-06

Level 1		
	Spec	Pass/Fail
pH	7.140-7.215	Pass
pCO2 mmHg	55.0-60.0	Pass
pO2 mmHg	53.0-63.0	Pass
Na+ mmol/L	158.0-163.0	Pass
K+ mmol/L	5.47-6.07	Pass
Cl- mmol/L	119.5-128.5	Pass
Ca++ mmol/L	1.36-1.44	Pass
Glu mg/dL	270-320	Pass
Lac mmol/L	6.4-7.7	Pass

Level 2		
	Spec	Pass/Fail
pH	7.345-7.395	Pass
pCO2 mmHg	38.0-44.0	Pass
pO2 mmHg	104.0-116.0	Pass
SO2 %	58.0-64.0	Pass
Hct %	33-37	Pass
Na+ mmol/L	136.0-140.0	Pass
K+ mmol/L	3.80-4.00	Pass
Cl- mmol/L	96.0-104.0	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		
	Spec	Pass/Fail
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 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

6/15/2016
Date