



CERTIFICATE OF ANALYSIS

STP pHox Plus L Control Levels 1, 2, 3 - Ampules

Ref Number 34117

	Level 1 L/N:	15217010
	Level 1 Exp Date:	2017-08
	Spec	Pass/Fail
pH	7.149-7.199	Pass
pCO2 mmHg	57.0-67.0	Pass
pO2 mmHg	53.0-63.0	Pass
Na+ mmol/L	158.0-162.0	Pass
K+ mmol/L	5.35-5.65	Pass
Cl- mmol/L	118.0-127.0	Pass
Ca++ mmol/L	1.36-1.44	Pass
Glu mg/dL	260-310	Pass
Lac mmol/L	6.4-7.7	Pass

	Level 2 L/N:	15217011
	Level 2 Exp Date:	2017-08
	Spec	Pass/Fail
pH	7.355-7.395	Pass
pCO2 mmHg	37.0-43.0	Pass
pO2 mmHg	93.0-103.0	Pass
SO2 %	58.0-64.0	Pass
Hct %	33-37	Pass
Na+ mmol/L	134.0-138.0	Pass
K+ mmol/L	3.75-3.95	Pass
Cl- mmol/L	95.0-103.0	Pass
Ca++ mmol/L	0.90-0.98	Pass
Glu mg/dL	184-214	Pass
Lac mmol/L	2.6-3.2	Pass

	Level 3 L/N:	15217012
	Level 3 Exp Date:	2017-08
	Spec	Pass/Fail
pH	7.575-7.615	Pass
pCO2 mmHg	17.5-22.5	Pass
pO2 mmHg	131.0-145.0	Pass
SO2 %	88.0-96.0	Pass
Hct %	48-52	Pass
Na+ mmol/L	113.0-118.0	Pass
K+ mmol/L	2.00-2.30	Pass
Cl- mmol/L	84.0-92.0	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

9/24/2015
Date

CONFIDENTIAL