



CERTIFICATE OF ANALYSIS

Stat Profile pHox Plus M Control

Ref Number 45205

	Level 1 L/N:	16026013
	Level 1 Exp Date:	2017-07
	Spec	Pass/Fail
pH	7.110-7.190	Pass
pCO2 mmHg	55.0-65.0	Pass
pO2 mmHg	58.0-68.0	Pass
Na+ mmol/L	157.8-161.8	Pass
K+ mmol/L	5.71-6.01	Pass
Cl- mmol/L	120.0-129.0	Pass
Ca++ mmol/L	1.46-1.54	Pass
Mg++ mmol/L	0.91-1.05	Pass
Glu mg/dL	73-87	Pass
Lac mmol/L	0.8-1.2	Pass
BUN mg/dL	7-13	Pass

	Level 2 L/N:	16027027
	Level 2 Exp Date:	2017-07
	Spec	Pass/Fail
pH	7.350-7.420	Pass
pCO2 mmHg	39.0-45.0	Pass
pO2 mmHg	97.0-107.0	Pass
Na+ mmol/L	140.0-144.0	Pass
K+ mmol/L	3.76-3.96	Pass
Cl- mmol/L	94.0-102.0	Pass
Ca++ mmol/L	0.94-1.02	Pass
Mg++ mmol/L	0.52-0.60	Pass
Glu mg/dL	185-215	Pass
Lac mmol/L	2.5-3.1	Pass
BUN mg/dL	25-35	Pass

	Level 3 L/N:	16056039
	Level 3 Exp Date:	2017-08
	Spec	Pass/Fail
pH	7.570-7.650	Pass
pCO2 mmHg	18.0-26.0	Pass
pO2 mmHg	135.0-149.0	Pass
Na+ mmol/L	120.7-124.7	Pass
K+ mmol/L	1.75-2.05	Pass
Cl- mmol/L	78.0-86.0	Pass
Ca++ mmol/L	0.50-0.60	Pass
Mg++ mmol/L	0.28-0.36	Pass
Glu mg/dL	275-325	Pass
Lac mmol/L	6.4-7.7	Pass
BUN mg/dL	45-55	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.


Approval

QC Supervisor
Title

3/29/2016
Date