



CERTIFICATE OF ANALYSIS

STP pHox Ultra/CCX Cal Cartridge 1 w/Creat
Lot Number 16362029

Exp Date 2017-12-16
Date of Manufacture 2016-12-16
Ref Number 48836

Cal A	L/N	16355016	Cal B	L/N	16355016	Cal C	L/N	16355016
pH @ 37C	Spec	Pass/Fail	pH @ 37C	Spec	Pass/Fail	Na mmol/L	Spec	Pass/Fail
Lac mmol/L	7.351-7.357	Pass	Na mmol/L	6.822-6.828	Pass	K mmol/L	139-141	Pass
	13.5-16.5	Pass	K mmol/L	69.5-70.5	Pass	Cl mmol/L	3.97-4.03	Pass
			Cl mmol/L	9.9-10.1	Pass	BUN mg/dl	118.0-120.0	Pass
			Ca mmol/L	39.7-40.3	Pass	Glu mg/dl	9.9-10.1	Pass
			Mg mmol/L	1.97-2.03	Pass	Lac mmol/L	78.8-81.2	Pass
				1.48-1.52	Pass	Ca mmol/L	1.8-2.2	Pass
						Mg mmol/L	0.98-1.02	Pass
						Creat mg/dl	0.49-0.51	Pass
						HCO3 mmol/L	0.98-1.02	Pass
							18.34-19.08	Pass
Cal D	L/N	16355016	Flush	L/N	16355016	Reference	L/N	16355016
BUN mg/dl	Spec	Pass/Fail	Aqueous Salt	Spec	Result	KCl mol/L	Spec	Pass/Fail
Glu mg/dl	49.4-50.6	Pass	Solution	N/A	Present		1.8-2.2	Pass
Lac mmol/L	197-203	Pass						
Creat mg/dl	5.5-6.5	Pass						
HCO3 mmol/L	9.8-10.2	Pass						
	36.68-38.18	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

1/10/2017
Date