



CERTIFICATE OF ANALYSIS

STP pHox Ultra/CCX Cal Cartridge 1 w/Creat
Lot Number 18113025

Exp Date 2019-10-11
Date of Manufacture 2018-04-11

Ref Number 48836

UDI# (01)00385480488365(11)180411(17)191011(10)18113025

Cal A L/N	18103006		Cal B L/N	18101029		Cal C L/N	18101040	
	Spec	Pass/Fail		Spec	Pass/Fail		Spec	Pass/Fail
pH @ 37C	7.351-7.357	Pass	pH @ 37C	6.822-6.828	Pass	Na mmol/L	139-141	Pass
Lac mmol/L	13.5-16.5	Pass	Na mmol/L	69.5-70.5	Pass	K mmol/L	3.97-4.03	Pass
			K mmol/L	9.9-10.1	Pass	Cl mmol/L	118.0-120.0	Pass
			Cl mmol/L	39.7-40.3	Pass	BUN mg/dl	9.9-10.1	Pass
			Ca mmol/L	1.97-2.03	Pass	Glu mg/dl	78.8-81.2	Pass
			Mg mmol/L	1.48-1.52	Pass	Lac mmol/L	1.8-2.2	Pass
						Ca mmol/L	0.98-1.02	Pass
						Mg mmol/L	0.49-0.51	Pass
						Creat mg/dl	0.98-1.02	Pass
						HCO3 mmol/L	18.34-19.08	Pass
Cal D L/N	18101041		Flush L/N	18107062		Reference L/N	18102009	
	Spec	Pass/Fail		Spec	Result		Spec	Pass/Fail
BUN mg/dl	49.4-50.6	Pass	Aqueous Salt	N/A	Present	KCl mol/L	1.8-2.2	Pass
Glu mg/dl	197-203	Pass	Solution					
Lac mmol/L	5.5-6.5	Pass						
Creat mg/dl	9.8-10.2	Pass						
HCO3 mmol/L	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.

Alisha Moquewin

Approval

QC inspector
Title

4/26/2018
Date