



CERTIFICATE OF ANALYSIS

STP pHox Ultra/CCX Cal Cartridge 1 w/Creat
Lot Number 16272038

Ref Number 48836
Exp Date 2017-09-19
Date of Manufacture 2016-09-19

Cal A	L/N	16265014	Cal B	L/N	16265014	Cal C	L/N	16265014
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	16265014	Flush	L/N	16265014	Reference	L/N	16265014
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

10/6/2016
Date