nova biomedical

CERTIFICATE OF ANALYSIS

STP pHOx Ultra/CCX Cal Cartridge 1
Lot Number 16356064

Ref Number 48834
Exp Date 2017-12-08
Date of Manufacture 2016-12-08

Cal A L/N 16354014

	Spec	Pass/Fail
pH @ 37C	7.351-7.357	Pass
Lac mmol/L	13.5-16.5	Pass

Cal B L/N 16349054

	Spec	Pass/Fail
pH @ 37C	6.822-6.828	Pass
Na mmol/L	69.5-70.5	Pass
K mmol/L	9.9-10.1	Pass
Cl mmol/L	39.7-40.3	Pass
Ca mmol/L	1.97-2.03	Pass
Mg mmol/L	1.48-1.52	Pass

Cal C L/N 16354015

	Spec	Pass/Fail
Na mmol/L	139.0-141.0	Pass
K mmol/L	3.97-4.03	Pass
Cl mmol/L	118.0-120.0	Pass
BUN mg/dl	9.9-10.1	Pass
Glu mg/dl	78.8-81.2	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
HCO3 mmol/L	18.43-19.19	Pass

Cal D L/N 16354010

	Spec	Pass/Fail
BUN mg/dl	49.4-50.6	Pass
Glu mg/dl	197-203	Pass
Lac mmol/L	5.5-6.5	Pass
HCO3 mmol/L	37.05-38.57	Pass

Flush L/N 16348008

	Spec	Result
Aqueous Salt Solution	N/A	Present

Reference L/N 16343020

	Spec	Pass/Fail
KCl mol/L	1.8-2.2	Pass

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U. S. A. in accordance with 21 CRF-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.

Joyce Chiara
Approval

QC Supervisor
Title

1/10/2017
Date