

## **CERTIFICATE OF ANALYSIS**

STP pHOx Ultra/CCX Cal Cartridge 1 w/Creat
Lot Number 16272040
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 Lac mmol/L	Spec 7.351-7.357 13.5-16.5	Pass/Fail Pass Pass	pH @ 37C Na mmol/L K mmol/L CI mmol/L Ca mmol/L Mg mmol/L	Spec 6.822-6.828 69.5-70.5 9.9-10.1 39.7-40.3 1.97-2.03 1.48-1.52	Pass/Fail Pass Pass Pass Pass Pass Pass Pass	Na mmol/L K mmol/L CI mmol/L BUN mg/dl Glu mg/dl Lac mmol/L Ca mmol/L Mg mmol/L Creat mg/dl HCO3 mmol/L	Spec 139-141 3.97-4.03 118.0-120.0 9.9-10.1 78.8-81.2 1.8-2.2 0.98-1.02 0.49-0.51 0.98-1.02 18.34-19.08	Pass/Fail Pass Pass Pass Pass Pass Pass Pass Pas
Cal D L/N	16265014		Flush L/N	16265015		Reference L/N	16265015	
BUN mg/dl Glu mg/dl Lac mmol/L Creat mg/dl HCO3 mmol/L	Spec 49.4-50.6 197-203 5.5-6.5 9.8-10.2 36.68-38.18	Pass/Fail Pass Pass Pass Pass Pass	Aqueous Salt Solution	Spec N/A	Result Present	KCI mol/L	Spec 1.8-2.2	Pass/Fail 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 ansara Approval

QC Supervisor

Title

10/21/2016

Date