



CERTIFICATE OF ANALYSIS

STP pHOX Ultra/CCX Chemistry Controls & Performance Check Auto-Cartridge

Ref Number 48905

Lot Number 16028021

Exp Date 2017-07

Level 4			Level 5		
	Spec	Pass/Fail		Spec	Pass/Fail
Na+ mmol/L	141.8-144.6	Pass	Na+ mmol/L	115.6-118.0	Pass
K+ mmol/L	4.01-4.09	Pass	K+ mmol/L	6.51-6.65	Pass
Cl- mmol/L	125.4-128.0	Pass	Cl- mmol/L	95.0-97.0	Pass
Ca++ mmol/L	1.10-1.12	Pass	Ca++ mmol/L	1.60-1.64	Pass
Mg++ mmol/L	0.56-0.64	Pass	Mg++ mmol/L	1.05-1.17	Pass
Glu mg/dL	83-87	Pass	Glu mg/dL	281-293	Pass
Lac mmol/L	1.9-2.1	Pass	Lac mmol/L	6.7-6.9	Pass
BUN mg/dL	18.5-19.5	Pass	BUN mg/dL	54.6-57.4	Pass
Level 6					
	Spec	Pass/Fail			
Glu mg/dL	700-1500	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

2/9/2016
Date