



CERTIFICATE OF ANALYSIS

STP pHox Ultra/CCX Chemistry Controls

Ref Number 49184

Level 4 L/N	16223027		Level 5 L/N	16223028	
Level 4 Exp Date	2017-08-10		Level 5 Exp Date	2017-08-11	
	Spec	Pass/Fail		Spec	Pass/Fail
Na+ mmol/L	134.8-137.6	Pass	Na+ mmol/L	110.6-112.8	Pass
K+ mmol/L	3.87-3.95	Pass	K+ mmol/L	6.19-6.31	Pass
Cl- mmol/L	122.4-124.8	Pass	Cl- mmol/L	96.5-98.5	Pass
Ca++ mmol/L	0.97-0.99	Pass	Ca++ mmol/L	1.48-1.50	Pass
Mg++ mmol/L	0.54-0.66	Pass	Mg++ mmol/L	0.99-1.11	Pass
Glu mg/dL	76-80	Pass	Glu mg/dL	270-282	Pass
Lac mmol/L	1.6-2.2	Pass	Lac mmol/L	6.3-6.9	Pass
BUN mg/dL	18.5-19.5	Pass	BUN mg/dL	56.6-59.5	Pass
Creatinine mg/dL	1.08-1.12	Pass	Creatinine mg/dL	6.27-6.53	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

8/22/2016
Date