



CERTIFICATE OF ANALYSIS

STP pHoxUltra/CCX
Chemistry Controls & Performance Check
Auto-Cartridge W/Creatinine
Lot Number 23298027

Ref Number 48927
Exp Date 2025-04-05
Date of Manufacture 2023-10-05
UDI# (01)00385480489270(11)231005(17)250405(10)23298027

Level 4			Level 5		
	<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>
Na+ mmol/L	138.6 - 141.4	Pass	Na+ mmol/L	113.4 - 115.6	Pass
K+ mmol/L	3.93 - 4.01	Pass	K+ mmol/L	6.34 - 6.46	Pass
Cl- mmol/L	124.5 - 127.1	Pass	Cl- mmol/L	95.0 - 97.0	Pass
Ca++ mmol/L	1.10 - 1.12	Pass	Ca++ mmol/L	1.61 - 1.65	Pass
Mg++ mmol/L	0.57 - 0.65	Pass	Mg++ mmol/L	1.02 - 1.14	Pass
Glu mg/dL	78 - 82	Pass	Glu mg/dL	274 - 286	Pass
Lac mmol/L	1.9 - 2.1	Pass	Lac mmol/L	7.1 - 7.3	Pass
BUN mg/dL	18.5 - 19.5	Pass	BUN mg/dL	54.6 - 57.4	Pass
Creatinine mg/dL	0.98 - 1.02	Pass	Creatinine mg/dL	6.08 - 6.32	Pass

Performance Check

	<u>Spec</u>	<u>Pass/Fail</u>
Glu mg/dL	700 - 1500	Pass
Creatinine mg/dL	0.80 - 1.80	Pass

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U.S.A. in accordance with ISO 13485:2016 Medical Devices Quality Management Systems Requirements, Medical Device Single Audit Program (MDSAP), and conforms to the indicated test specifications. All listed analytes are traceable to NIST SRM Materials.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Haneen Aldarwish

Approval

QC Inspector

Title

11/7/2023

Date