



CERTIFICATE OF ANALYSIS

STP pHOX Ultra/CCX Chemistry Controls
& Performance Check Auto-Cartridge
Lot Number 24025032

Ref Number 48905

Exp Date 2025-07-12

Date of Manufacture 2024-01-12

UDI# (01)00385480489058(11)240112(17)250712(10)24025032

Level 4			Level 5		
	<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>
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	0.57 - 0.65	Pass	Mg++ mmol/L	1.05 - 1.17	Pass
Glu mg/dL	78 - 82	Pass	Glu mg/dL	274 - 286	Pass
Lac mmol/L	1.9 - 2.1	Pass	Lac mmol/L	7.0 - 7.2	Pass
BUN mg/dL	18.5 - 19.5	Pass	BUN mg/dL	54.6 - 57.4	Pass

Level 6

QC Performance Check

	<u>Spec</u>	<u>Pass/Fail</u>
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 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

1/31/2024

Date