



CERTIFICATE OF ANALYSIS

Stat Profile pHox Ultra/CCX Calibrator Cartridge 1
Lot Number 24156039

Ref Number 48834
Exp Date 2025-11-21

Date of Manufacture 2024-05-21

UDI# (01)00385480488341(11)240521(17)251121(10)24156039

Cal-A L/N 24142025			Cal-B L/N 24142046			Cal-C L/N 24142048		
	<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>
pH @ 37C	7.351 - 7.357	Pass	pH @ 37C	6.822 - 6.828	Pass	Na mmol/L	139.0 - 141.0	Pass
Lac mmol/L	13.5 - 16.5	Pass	Na mmol/L	69.5 - 70.5	Pass	K mmol/L	3.97 - 4.03	Pass
			K mmol/L	9.9 - 10.1	Pass	Cl mmol/L	118.0 - 120.0	Pass
			Cl mmol/L	39.7 - 40.3	Pass	Ca mmol/L	0.99 - 1.02	Pass
			Ca mmol/L	1.97 - 2.03	Pass	Mg mmol/L	0.49 - 0.51	Pass
			Mg mmol/L	1.48 - 1.52	Pass	Glu mg/dL	78.8 - 81.2	Pass
						Lac mmol/L	1.8 - 2.2	Pass
						BUN mg/dL	9.9 - 10.1	Pass
						HCO3 mmol/L	18.43 - 19.19	Pass
Cal-D L/N 24142047			Flush L/N 24150022			Reference L/N 24142024		
	<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>
Glu mg/dL	197 - 203	Pass	Aqueous			KCl mol/L	1.8 - 2.2	Pass
Lac mmol/L	5.5 - 6.5	Pass	Salt	N/A	Present			
BUN mg/dL	49.4 - 50.6	Pass	Solution					
HCO3 mmol/L	37.05 - 38.57	Pass						

This certifies that this product was manufactured and tested at Nova BiomedCal-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

Approval

QC Inspector

Title

11/29/2024

Date