



CERTIFICATE OF ANALYSIS

Stat Profile pHox Ultra/CCX Calibrator Cartridge 1
Lot Number 23216013

Ref Number 48834
Exp Date 2024-12-19
Date of Manufacture 2023-06-19
UDI# (01)00385480488341(11)230619(17)241219(10)23216013

Cal-A L/N 23170052		
	<u>Spec</u>	<u>Pass/Fail</u>
pH @ 37C	7.351 - 7.357	Pass
Lac mmol/L	13.5 - 16.5	Pass

Cal-B L/N 23174046		
	<u>Spec</u>	<u>Pass/Fail</u>
pH @ 37C	6.822 - 6.828	Pass
Na mmol/L	69.5 - 70.5	Pass
K mmol/L	9.9 - 10.1	Pass
Cl mmol/L	39.7 - 40.3	Pass
Ca mmol/L	1.97 - 2.03	Pass
Mg mmol/L	1.48 - 1.52	Pass

Cal-C L/N 23173090		
	<u>Spec</u>	<u>Pass/Fail</u>
Na mmol/L	139.0 - 141.0	Pass
K mmol/L	3.97 - 4.03	Pass
Cl mmol/L	118.0 - 120.0	Pass
Ca mmol/L	0.99 - 1.02	Pass
Mg mmol/L	0.49 - 0.51	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 23172066		
	<u>Spec</u>	<u>Pass/Fail</u>
Glu mg/dL	197 - 203	Pass
Lac mmol/L	5.5 - 6.5	Pass
BUN mg/dL	49.4 - 50.6	Pass
HCO3 mmol/L	37.1 - 38.57	Pass

Flush L/N 23173024		
	<u>Spec</u>	<u>Pass/Fail</u>
Aqueous		
Salt Solution	N/A	Present

Reference L/N 23170050		
	<u>Spec</u>	<u>Pass/Fail</u>
KCl mol/L	1.8 - 2.2	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

Haneen Aldarwish

Approval

QC Inspector
Title

8/8/2023
Date