



CERTIFICATE OF ANALYSIS

Stat Profile pHox Ultra/CCX Calibrator Cartridge 1
Lot Number 23275058

Ref Number 48834
Exp Date 2025-03-13
Date of Manufacture 2023-09-13
UDI# (01)00385480488341(11)230913(17)250313(10)23275058

Cal-A L/N	23261012		
	<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	23257049		
	<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	23257050		
	<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	23257051		
	<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	23263014		
	<u>Spec</u>		<u>Pass/Fail</u>
Aqueous			
Salt	N/A		Present
Solution			

Reference L/N	23256059		
	<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

10/17/2023

Date