



CERTIFICATE OF ANALYSIS

Stat Profile pHox Plus L Calibrator Cartridge A
Lot Number 24060043

Ref Number 34085
Exp Date 2025-08-23

Date of Manufacture 2024-02-23

UDI# (01)00385480340854(11)240223(17)250823(10)24060043

Cal-A L/N 24054002				Cal-B L/N 24054003				Cal-C L/N 24054004			
	<u>Spec</u>		<u>Pass/Fail</u>		<u>Spec</u>		<u>Pass/Fail</u>		<u>Spec</u>		<u>Pass/Fail</u>
Na mmol/L	142 - 144		Pass	HCO3 mmol/L	45.90 - 47.78		Pass	pH @ 37C	7.332 - 7.338		Pass
HCO3 mmol/L	24.42 - 25.42		Pass					Ca mmol/L	2.01 - 2.07		Pass
K mmol/L	4.03 - 4.09		Pass					Na mmol/L	72.5 - 73.5		Pass
Cl mmol/L	97.2 - 98.8		Pass					K mmol/L	10.04 - 10.20		Pass
Ca mmol/L	1.01 - 1.03		Pass					Cl mmol/L	52.6 - 53.4		Pass
Glu mg/dL	39.6 - 40.4		Pass					Glu mg/dL	198 - 202		Pass
Lac mmol/L	0.8 - 1.2		Pass					Lac mmol/L	5.5 - 6.5		Pass

Cal-D L/N 24054005				Reference L/N 24054001			
	<u>Spec</u>		<u>Pass/Fail</u>		<u>Spec</u>		<u>Pass/Fail</u>
pH @ 37C	6.788 - 6.794		Pass	KCl mol/L	1.8 - 2.2		Pass
Glu mg/dL	990 - 1010		Pass				
Lac mmol/L	10.5 - 13.5		Pass				

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

3/5/2024
Date