



CERTIFICATE OF ANALYSIS

Stat Profile pHox Plus L Calibrator Cartridge A
Lot Number 23264028

Ref Number 34085
Exp Date 2025-03-11
Date of Manufacture 2023-09-11
UDI# (01)00385480340854(11)230911(17)250311(10)23264028

Cal-A L/N 23254093				Cal-B L/N 23254098				Cal-C L/N 23254099			
	<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 23255010				Reference L/N 23254094							
	<u>Spec</u>		<u>Pass/Fail</u>		<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 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

10/2/2023
Date