



CERTIFICATE OF ANALYSIS

Stat Profile pHox Plus M Calibrator Cartridge A
Lot Number 23206033

Ref Number 45714
Exp Date 2024-12-07

Date of Manufacture 2023-06-07

UDI# (01)00385480457149(11)230607(17)241207(10)23206033

Cal-A L/N 23158068				Cal-B L/N 23158069				Cal-C L/N 23158070			
	Spec		Pass/Fail		Spec		Pass/Fail		Spec		Pass/Fail
Na mmol/L	136	- 138	Pass	HCO3 mmol/L	42.24	- 43.96	Pass	pH @ 37C	7.332	- 7.338	Pass
HCO3 mmol/L	21.07	- 21.93	Pass					Ca mmol/L	1.97	- 2.03	Pass
K mmol/L	3.97	- 4.03	Pass					Na mmol/L	70.5	- 71.5	Pass
Mg mmol/L	0.49	- 0.51	Pass					K mmol/L	9.92	- 10.08	Pass
Ca mmol/L	0.99	- 1.01	Pass					Cl mmol/L	1.38	- 1.42	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 23158071				Reference L/N 23158067			
	Spec		Pass/Fail		Spec		Pass/Fail
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

7/28/2023
Date