nova biomedical

CERTIFICATE OF ANALYSIS

Stat Profile pHOx Plus L Calibrator Cartridge C
Lot Number 24229033

Ref Number 34087
Exp Date 2026-01-23
Date of Manufacture 2024-07-23
UDI# (01)00385480340878(11)240723(17)260123(10)24229033

Cal-A L/N 24205079

	Spec	Pass/Fail
Na mmol/L	142 - 144	Pass
HCO3 mmol/L	24.42 - 25.42	Pass
K mmol/L	4.03 - 4.09	Pass
Cl mmol/L	97.2 - 98.8	Pass
Ca mmol/L	1.01 - 1.03	Pass
Glu mg/dL	39.6 - 40.4	Pass
Lac mmol/L	0.8 - 1.2	Pass

Cal-B L/N 24205080

	Spec	Pass/Fail
HCO3 mmol/L	45.90 - 47.78	Pass

Cal-C L/N 24205081

	Spec	Pass/Fail
pH @ 37C	7.332 - 7.338	Pass
Ca mmol/L	2.01 - 2.07	Pass
Na mmol/L	72.5 - 73.5	Pass
K mmol/L	10.04 - 10.20	Pass
Cl mmol/L	52.6 - 53.4	Pass
Glu mg/dL	198 - 202	Pass
Lac mmol/L	5.5 - 6.5	Pass

Cal-D L/N 24205082

	Spec	Pass/Fail
pH @ 37C	6.788 - 6.794	Pass
Glu mg/dL	990 - 1010	Pass
Lac mmol/L	10.5 - 13.5	Pass

Reference L/N 24205102

	Spec	Pass/Fail
KCl mol/L	1.8 - 2.2	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

Approval

QC Inspector
Title

8/19/2024
Date