



CERTIFICATE OF ANALYSIS

Stat Profile pHox/Basic Calibrator Cartridge C
Lot Number 24262030

Ref Number 23936
Exp Date 2026-03-06
Date of Manufacture 2024-09-06
UDI# (01)00385480239363(11)240906(17)260306(10)24262030

Cal A L/N 24253055

Cal B L/N 24254028

Cal C L/N 24253052

	<u>Spec</u>	<u>Pass/Fail</u>
HCO ₃ mmol/L	20.1 - 20.9	Pass
Na mmol/L	139.3 - 141.3	Pass

	<u>Spec</u>	<u>Pass/Fail</u>
HCO ₃ mmol/L	40.2 - 41.8	Pass

	<u>Spec</u>	<u>Pass/Fail</u>
pH @ 37C	7.342 - 7.348	Pass

Cal D L/N 24253059

Reference L/N 24250051

	<u>Spec</u>	<u>Pass/Fail</u>
pH @ 37C	6.792 - 6.798	Pass
Na mmol/L	71.5 - 72.5	Pass

	<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 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

09/24/2024
Date