



CERTIFICATE OF ANALYSIS

Stat Profile pHox/Basic Calibrator Cartridge D

Lot Number 24317061

Ref Number 23934

Exp Date 2026-05-01

Date of Manufacture 2024-11-01

UDI# (01)00385480239349(11)241101(17)260501(10)24317061

Cal A L/N 24311043

Cal B L/N 24311042

Cal C L/N 24309054

	<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 24309055

Reference L/N 24306015

	<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

Auishi M

Approval

QC Inspector

Title

12/18/2024

Date