



CERTIFICATE OF ANALYSIS

Stat Profile pHox/Basic Calibrator Cartridge D

Lot Number 25087054

Ref Number 23934

Exp Date 2026-09-06

Date of Manufacture 2025-03-06

UDI# (01)00385480239349(11)250306(17)260906(10)25087054

Cal A L/N 25069065

Cal B L/N 25069017

Cal C L/N 25065043

	<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 25065042

Reference L/N 25065027

	<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

Approval

QC Inspector
Title

04/14/2025
Date