

CERTIFICATE OF ANALYSIS

Stat Profile pHOx/Basic Calibrator Cartridge B Lot Number 25087055 Ref Number 23937 Exp Date 2026-09-06 Date of Manufacture 2025-03-06

UDI# (01)00385480239370(11)250306(17)260906(10)25087055

Cal A L/N 25069065 Cal B L/N 25069017 Cal C L/N 25065043

Spec Pass/Fail Spec Pass/Fail Spec Pass/Fail HCO3 mmol/L 20.1 - 20.9 **Pass** HCO₃ 40.2 - 41.8 **Pass** рΗ 7.342 - 7.348 **Pass** Na mmol/L 139.3 - 141.3 Pass mmol/L @ 37C

Cal D L/N 25065042 Reference L/N 25065027

Spec Pass/Fail **Spec** Pass/Fail pΗ @ 37C 6.792 - 6.798 **Pass** KCI 1.8 - 2.2 **Pass** Na mmol/L 71.5 - 72.5 **Pass** mol/L

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