



CERTIFICATE OF ANALYSIS

STAT PROFILE® pHox Ultra™/CCX™ Na Sensor
Lot Number 23256039

Ref Number 48579
Exp Date 2025-03-13
Date of Manufacture 2023-09-13
UDI# (01)00385480485791(11)230913(17)250313(10)23256039

| | <u>Spec</u> | <u>Pass/Fail</u> |
|----------|-----------------|------------------|
| Slope | 9.30 - 11.00 | Pass |
| Std C mV | -10.00 - +70.00 | Pass |
| L4 CtL | 136.0 - 144.0 | Pass |
| L5 CtL | 110.5 - 118.5 | 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.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Approval

QC Inspector

Title

9/29/2023

Date