



CERTIFICATE OF ANALYSIS

Stat Profile® pHox Ultra™ / CCX™ BUN Membrane Kit
Lot Number 23271009

Part Number 48596
Exp Date 2024-12-28

Date of manufacture 2023-09-28

UDI# (01)00385480485968(11)230928(17)241228(10)23271009

| | <u>Spec</u> | <u>Mean Result</u> |
|-----------|--------------|--------------------|
| BUN Slope | 9.30 - 12.90 | 12.40 |
| CCX L 4 | 14 - 24 | 19 |
| CCX L 5 | 49 - 63 | 53 |

This product is certified to have been 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

10/3/2023

Date