



CERTIFICATE OF ANALYSIS

Stat Profile® pHox Ultra™ / CCX™ Creatinine Membrane Kit
Lot Number 24081012

Part Number 48597

Exp Date 2025-06-21

Date of manufacture 2024-03-21

UDI# (01)00385480485975(11)240321(17)250621(10)24081012

| | <u>Spec*</u> | <u>Mean Result</u> |
|-------|--------------|--------------------|
| Slope | ≥ 5.00 | 10.56 |
| CtL 4 | 0.7 - 1.3 | 0.9 |
| CtL 5 | 5.2 - 7.2 | 5.8 |

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

4/12/2024

Date