



CERTIFICATE OF ANALYSIS

Stat Profile® pHox Ultra™ / CCX™ Creatinine Membrane Kit

Part Number 48597

Lot Number 25107008

Exp Date 2026-07-17

Date of manufacture 2025-04-17

UDI# (01)00385480485975(11)250417(17)260717(10)25107008

| | <u>Spec*</u> | <u>Mean Result</u> |
|-------|--------------|--------------------|
| Slope | ≥ 5.00 | 14.22 |
| CtL 4 | 0.7 - 1.3 | 1.0 |
| CtL 5 | 5.2 - 7.2 | 6.1 |

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

A handwritten signature in black ink, appearing to read "P. Hernandez", written in a cursive style.

Approval

QC Inspector

Title

4/28/2025

Date