



CERTIFICATE OF ANALYSIS

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

Part Number 48597

Lot Number 25030017

Exp Date 2026-04-30

Date of manufacture 2025-01-30

UDI# (01)00385480485975(11)250130(17)260430(10)25030017

	<u>Spec*</u>	<u>Mean Result</u>
Slope	≥ 5.00	7.65
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

A handwritten signature in blue ink, appearing to read "C. R. S. D. A.", written over a horizontal line.

Approval

QC Inspector

Title

2/13/2025

Date