



## CERTIFICATE OF ANALYSIS

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

Part Number 48597

Lot Number 25077018

Exp Date 2026-06-18

Date of manufacture 2025-03-18

UDI# (01)00385480485975(11)250318(17)260618(10)25077018

	<u>Spec*</u>	<u>Mean Result</u>
Slope	$\geq 5.00$	8.47
CtL 4	0.7 - 1.3	0.9
CtL 5	5.2 - 7.2	6.4

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 "Sean Quinn", is written over the printed name.

Approval

QC Inspector

Title

3/25/2025

Date