



CERTIFICATE OF ANALYSIS

Stat Profile pHox Ultra / CCX Creatinine Membrane Kit

Part Number 48597

Lot Number 26181003

Exp Date 2027-09-30

Date of manufacture 2026-06-30

UDI# (01)00385480485975(11)260630(17)270930(10)26181003

	<u>Spec*</u>	<u>Mean Result</u>
Slope	≥ 5.00	8.48
CtL 4	0.7 - 1.3	0.9
CtL 5	5.2 - 7.2	5.5

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 "Scott Quinn".

Approval

QC Inspector

Title

7/8/2026

Date