



## CERTIFICATE OF ANALYSIS

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

Part Number 48597

Lot Number 24282005

Exp Date 2026-01-08

Date of manufacture 2024-10-08

UDI# (01)00385480485975(11)241008(17)260108(10)24282005

	<u>Spec*</u>	<u>Mean Result</u>
Slope	$\geq 5.00$	10.69
CtL 4	0.7 - 1.3	0.9
CtL 5	5.2 - 7.2	6.2

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 be "J. M. Smith", written in a cursive style.

Approval

QC Inspector

Title

1/21/2025

Date