



## CERTIFICATE OF ANALYSIS

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

Part Number 48597

Lot Number 25119009

Exp Date 2026-07-29

Date of manufacture 2025-04-29

UDI# (01)00385480485975(11)250429(17)260729(10)25119009

	<u>Spec*</u>	<u>Mean Result</u>
Slope	$\geq 5.00$	14.56
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 be "J. M. ...", written over a horizontal line.

Approval

QC Inspector

Title

5/14/2025

Date