



## CERTIFICATE OF ANALYSIS

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

Part Number 48597

Lot Number 25085012

Exp Date 2026-06-26

Date of manufacture 2025-03-26

UDI# (01)00385480485975(11)250326(17)260626(10)25085012

	<u>Spec*</u>	<u>Mean Result</u>
Slope	$\geq 5.00$	10.00
CtL 4	0.7 - 1.3	1.0
CtL 5	5.2 - 7.2	6.3

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

Approval

QC Inspector

Title

4/8/2025

Date