

## **CERTIFICATE OF ANALYSIS**

Stat Profile® pHOx Ultra™ / CCX™ Creatinine Membrane Kit Part Number 48597

Lot Number 25024016 Exp Date 2026-04-24

Date of manufacture 2024-01-24

UDI# (01)00385480485975(11)240124(17)260424(10)25024016

	Spec*	Mean Result
Slope	<u>&gt;</u> 5.00	7.01
CtL 4	0.7 - 1.3	0.8
CtL 5	5.2 - 7.2	5.3

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

Id Lua-Rossen

Title

2/3/2025 Date