



CERTIFICATE OF ANALYSIS

Stat Profile® pHox Ultra™ / CCX™ Creatinine Membrane Kit
Lot Number 24221013

Part Number 48597

Exp Date 2025-11-08

Date of manufacture 2024-08-08

UDI# (01)00385480485975(11)240808(17)251108(10)24221013

	<u>Spec*</u>	<u>Mean Result</u>
Slope	≥ 5.00	14.29
CtL 4	0.7 - 1.3	0.9
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

8/14/2024

Date