



CERTIFICATE OF ANALYSIS

Stat Profile® pHox Ultra™ / CCX™ Creatinine Membrane Kit
Lot Number 23319013

Part Number 48597

Exp Date 2025-02-15

Date of manufacture 2023-11-15

UDI# (01)00385480485975(11)231115(17)250215(10)23319013

	<u>Spec*</u>	<u>Mean Result</u>
Slope	≥ 5.00	7.51
CtL 4	0.7 - 1.3	0.9
CtL 5	5.2 - 7.2	6.0

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

11/21/2023

Date