

## **CERTIFICATE OF ANALYSIS**

Stat Profile® pHOx Ultra™ / CCX™ BUN Membrane Kit Lot Number 23235015 Part Number 48596 Exp Date 2024-11-23

Date of manufacture 2023-08-23

UDI# (01)00385480485968(11)230823(17)241123(10)23235015

	<u>Spec</u>	Mean Result
BUN Slope	9.30 - 12.90	12.42
CCX L 4	14 - 24	19
CCX L 5	49 - 63	54

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

9/18/2023 Date