

CERTIFICATE OF ANALYSIS

Stat Profile® pHOx Ultra™ / CCX™ BUN Membrane Kit Lot Number 24123004 Part Number 48596 Exp Date 2025-08-02

Date of manufacture 2024-05-02

UDI# (01)00385480485968(11)240502(17)250802(10)24123004

	<u>Spec</u>	Mean Result
BUN Slope	9.30 - 12.90	12.42
CCX L 4	14 - 24	19
CCXL5	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

5/20/2024 Date