

CERTIFICATE OF ANALYSIS

Stat Profile® pHOx Ultra™ / CCX™ BUN Membrane Kit Lot Number 24178011 Part Number 48596 Exp Date 2025-09-26

Date of manufacture 2024-06-26

UDI# (01)00385480485968(11)240626(17)250926(10)24178011

	<u>Spec</u>	Mean Result
BUN Slope	9.30 - 12.90	12.24
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

7/29/2024 Date