



CERTIFICATE OF ANALYSIS

Stat Profile pHox Ultra / CCX BUN Membrane Kit
Lot Number 25345006

Part Number 48596
Exp Date 2027-03-11

Date of manufacture 2025-12-11

UDI# (01)00385480485968(11)251211(17)270311(10)25345006

	<u>Spec</u>	<u>Mean Result</u>
BUN Slope	9.30 - 12.90	11.75
CCX L 4	14 - 24	19
CCX L 5	49 - 63	55

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

A handwritten signature in blue ink, appearing to read "Sean Quinn".

Approval

QC Inspector

Title

12/29/2025

Date