



CERTIFICATE OF ANALYSIS

Stat Profile® pHox Ultra™ / CCX™ BUN Membrane Kit
Lot Number 25219001

Part Number 48596
Exp Date 2026-11-07

Date of manufacture 2025-08-07

UDI# (01)00385480485968(11)250807(17)261107(10)25219001

	<u>Spec</u>	<u>Mean Result</u>
BUN Slope	9.30 - 12.90	12.05
CCX L 4	14 - 24	19
CCX L 5	49 - 63	58

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

8/27/2025

Date