

CERTIFICATE OF ANALYSIS

Stat Profile® pHOx Ultra™ / CCX™ BUN Membrane Kit Lot Number 25058008 Part Number 48596 Exp Date 2026-05-27

Date of manufacture 2025-02-27

UDI# (01)00385480485968(11)250227(17)260527(10)25058008

	<u>Spec</u>	Mean Result
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

3/11/2025

Date