

CERTIFICATE OF ANALYSIS

Stat Profile® pHOx Ultra™ / CCX™ BUN Membrane Kit Lot Number 25106008 Part Number 48596 Exp Date 2026-07-16

Date of manufacture 2025-04-16

UDI# (01)00385480485968(11)250416(17)260716(10)25106008

	<u>Spec</u>	Mean Result
BUN Slope	9.30 - 12.90	12.31
CCX L 4	14 - 24	19
CCX L 5	49 - 63	56

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

4/28/2025

Date