

CERTIFICATE OF ANALYSIS

STP pHOx Ultra/CCX Glucose Membrane Lot Number 24352021

Membrane Part Number 48552 Exp Date 2026-03-17 Date of Manufacture 2024-12-17 UDI# (01)00385480485524(11)241217(17)260317(10)24352021

| | Spec* | <u>Mean Result</u> |
|-----------------------|---------------|--------------------|
| Slope | 11.00 - 45.00 | 36.75 |
| pHOx Ultra/CCX Ctl L4 | 73 - 87 | 80 |
| pHOx Ultra/CCX Ctl L5 | 255 - 305 | 284 |

This certifies that this product was 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

<u>12/30/2024</u> Date