



CERTIFICATE OF ANALYSIS

STP® pHox Ultra™ / CCX™ Glucose Sensor
Lot Number 21161012

Part Number 48551
Exp Date 2023-06-10
Date of Manufacture 2021-06-10
UDI# (01)00385480485517(11)210610(17)230610(10)21161012

	<u>Spec</u>	<u>Pass/Fail</u>
Slope	11.00 - 45.00	Pass
pHox Ctl L3	77- 91	Pass
Set A L1	≥ 470	Pass

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: The process for assigning values to Nova Biomedical Quality Control and Linearity Solutions utilizes multiple sources of test data inputs to establish the ranges for each analyte in each lot, which may result in small lot-to-lot variation in insert range values.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Approval

QC Inspector
Title

6/23/2021
Date