



CERTIFICATE OF ANALYSIS

Bioprofile 100/300/400/Basic/100 Plus Lactate Sensor
Lot Number 21119036

Part Number 24449
Exp Date 04/30/2023

	<u>Spec*</u>	<u>Pass/Fail</u>
Slope	10.0 - 60.0	Pass
Biopro Ctl L 1	0.89 - 1.39	Pass
Biopro Ctl L 2	2.55 - 3.45	Pass
Biopro Ctl L 3	4.25 - 5.75	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

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

Approval

QC Inspector
Title

5/18/2021
Date