



CERTIFICATE OF ANALYSIS

Prime Sensor Card ES
Lot Number 18290063

Catalog Number 42035
Exp Date 2019-10-15
Date of Manufacture 2018-10-15
UDI# (01)10385480420355(11)181015(17)191015(10)18290063

	Slope	Pass/Fail
pH	8.50-12.00	Pass
Na	8.5-12.0	Pass
K	8.5-12.0	Pass
Cl	8.5-12.0	Pass
iCa	8.5-12.0	Pass
iMg	8.3-14.9	Pass

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U. S. A. in accordance with 21 CFR-Part 820, Quality System Regulation (QSR), Current Good Manufacturing Practice (cGMP) and EN ISO 13485:2012, Medical Devices, Quality Management Systems for in Vitro Diagnostic devices, and conforms to the indicated test specifications.

A handwritten signature in purple ink that reads "Keo Bou".

Approval

QC Inspector
Title

10/25/2018
Date