



CERTIFICATE OF ANALYSIS

Prime Sensor Card CCS Comp (High Volume)
Lot Number 18306055

Catalog Number 55264

Exp Date 2019-10-15

Date of Manufacture 2018-10-15

UDI# (01)10385480552643(11)181015(17)191015(10)18306055

	Slope	Pass/Fail
pH	8.50 - 12.00	Pass
PCO2	-25.00 - 8.00	Pass
PO2	4.00 - 12.20	Pass
Na+	8.50 - 12.00	Pass
K+	8.50 - 12.00	Pass
Cl	8.50 - 12.00	Pass
Ca+	8.50 - 12.00	Pass
Glu	4.00 - 10.00	Pass
Lac	3.50 - 11.00	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.

Approval

QC Inspector

Title

11/14/2018

Date