



CERTIFICATE OF ANALYSIS

Nova 8 Calibrator Pack
Lot Number 814237

Ref Number 15196
Exp Date 2019-11-16
Date of Manufacture 2018-05-16
UDI# (01)00385480151962(11)180516(17)191116(10)814237

| Cal A L/N | 18136041 | Spec | Pass/Fail | Cal B L/N | 18136030 | Spec | Pass/Fail | Cal C L/N | 18136046 | Spec | Pass/Fail |
|------------|-------------|------|-----------|------------|-------------|------|-----------|------------|-------------|------|-----------|
| Na mmol/L | 139.0-141.0 | | Pass | Na mmol/L | 74.5-75.5 | | Pass | Na mmol/L | 139.0-141.0 | | Pass |
| K mmol/L | 3.97-4.03 | | Pass | K mmol/L | 9.8-10.2 | | Pass | K mmol/L | 3.97-4.03 | | Pass |
| iCa mmol/L | 0.99-1.01 | | Pass | iCa mmol/L | 1.98-2.02 | | Pass | iCa mmol/L | 0.99-1.01 | | Pass |
| iMg mmol/L | 0.495-0.505 | | Pass | iMg mmol/L | 0.495-0.505 | | Pass | iMg mmol/L | 1.48-1.52 | | Pass |
| pH @ 37C | 7.274-7.294 | | Pass | pH @ 37C | 6.730-6.750 | | Pass | pH @ 37C | 7.374-7.394 | | Pass |

| Reference L/N | 18137066 | Spec | Pass/Fail |
|---------------|----------|------|-----------|
| KCl mol/L | 1.8-2.2 | | 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 ISO EN 13485:2012, Medical Devices, Quality Management Systems for in Vitro Diagnostic devices, and conforms to the indicated test specifications. All listed analytes are traceable to NIST SRM Materials.

Approval

QC Inspector
Title

5/29/2018
Date