



CERTIFICATE OF ANALYSIS

Nova 8 Calibrator Pack
Lot Number 829242

Ref Number 15196
Exp Date 2020-04-11
Date of Manufacture 2018-10-11
UDI# (01)00385480151962(11)181011(17)200411(10)829242

Cal A	L/N	18284025	Spec	Pass/Fail	Cal B	L/N	18284040	Spec	Pass/Fail	Cal C	L/N	18284041	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	18284028	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

11/3/2018
Date