



CERTIFICATE OF ANALYSIS

Nova 16 Control Levels 1 and 2

Ref Number 17452

Level 1 L/N	16082010		Level 2 L/N	16082011	
Level 1 Exp Date	2017-09		Level 2 Exp Date	2017-09	
	Spec	Pass/Fail		Spec	Pass/Fail
Na+ mmol/L	132.0-156.0	Pass	Na+ mmol/L	109.0-128.0	Pass
K+ mmol/L	3.20-4.00	Pass	K+ mmol/L	5.50-6.70	Pass
Cl- mmol/L	91.0-110.0	Pass	Cl- mmol/L	68.0-84.0	Pass
TCO2 mmol/L	19-29	Pass	TCO2 mmol/L	10-18	Pass
Glu mg/dL	69-91	Pass	Glu mg/dL	246-322	Pass
BUN mg/dL	12-22	Pass	BUN mg/dL	45-64	Pass
Li+ mmol/L	0.46-0.76	Pass	Li+ mmol/L	1.70-2.40	Pass
Creatinine mg/dL	0.7-1.3	Pass	Creatinine mg/dL	5.2-7.3	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. All listed analytes are traceable to NIST SRM Materials.

Approval

QC Supervisor

Title

5/17/2016

Date