



CERTIFICATE OF ANALYSIS

Nova 16 Calibrator Pack
Lot Number 636439

Ref Number 17289
Exp Date 2017-09-29
Date of Manufacture 2016-12-29

Cal A L/N 16364039

Cal B L/N 16364039

Cal C L/N 16364039


	Spec	Result		Spec	Result		Spec	Result
Na mmol/L	139.0-141.0	Pass	Na mmol/L	79.2-80.8	Pass	HCO3 mmol/L	9.6-10.4	Pass
K mmol/L	3.97-4.03	Pass	K mmol/L	9.8-10.2	Pass			
Cl mmol/L	112.1-113.9	Pass	Cl mmol/L	57.4-58.6	Pass			
BUN mg/dl	9.7-10.3	Pass	BUN mg/dl	49.4-50.6	Pass			
Glu mg/dl	78.4-81.6	Pass	Glu mg/dl	196-204	Pass			
HCO3 mmol/L	19.2-20.8	Pass	HCO3 mmol/L	19.6-20.8	Pass			
Creat mg/dl	0.98-1.02	Pass	Creat mg/dl	9.8-10.2	Pass			

Flush L/N 16364039

Reference L/N 16364039

	Spec	Result		Spec	Result
Aqueous Salt Sol'n	N/A	Present	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 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

1/31/2017
Date