




CERTIFICATE OF ANALYSIS

Nova 14 Calibrator Pack
Lot Number 706939

Ref Number 14609
Exp Date 2017-12-10
Date of Manufacture 2017-03-10
UDI# (01)00385480146098(11)170310(17)171210(10)706939

Cal A L/N	17069039		Cal B L/N	17069039		Cal C L/N	17069039	
	Spec	Pass/Fail		Spec	Pass/Fail		Spec	Pass/Fail
Na mmol/L	139.0-141.0	Pass	Na mmol/L	69.3-70.7	Pass	Na mmol/L	98.0-102.0	Pass
K mmol/L	3.97-4.03	Pass	K mmol/L	9.8-10.2	Pass	Cl mmol/L	87.2-90.8	Pass
Cl mmol/L	112.1-113.9	Pass	Cl mmol/L	57.4-58.6	Pass	NH4	0.88-0.92	Pass
BUN mg/dl	9.7-10.3	Pass	BUN mg/dl	49.4-50.6	Pass			
Glu mg/dl	79.2-83.2	Pass	Glu mg/dl	196-204	Pass			
Cal J L/N	17069039		Flush L/N	17069039		Reference L/N	17069039	
	Spec	Pass/Fail		Spec	Result		Spec	Pass/Fail
Na mmol/L	98.0-102.0	Pass	Aqueous Salt	N/A	Present	KCl mol/L	1.8-2.2	Pass
Cl mmol/L	90.7-94.4	Pass	Sol'n					
NH4	4.41-4.59	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

3/20/2017
Date