



CERTIFICATE OF ANALYSIS

STP CCX Cal Cartridge 2
Lot Number 16316053

Ref Number 36251
Exp Date 2017-11-08
Date of Manufacture 2016-11-08

Cal A L/N	16314029		Cal B L/N	16314042		Cal C L/N	16314040	
	Spec	Pass/Fail		Spec	Pass/Fail		Spec	Pass/Fail
pH @ 37C	7.351-7.357	Pass	pH @ 37C	6.822-6.828	Pass	Na mmol/L	139.0-141.0	Pass
Lac mmol/L	13.5-16.5	Pass	Na mmol/L	69.5-70.5	Pass	K mmol/L	3.97-4.03	Pass
			K mmol/L	9.9-10.1	Pass	Cl mmol/L	118.0-120.0	Pass
			Cl mmol/L	39.7-40.3	Pass	BUN mg/dl	9.9-10.1	Pass
			Ca mmol/L	1.97-2.03	Pass	Glu mg/dl	78.8-81.2	Pass
			Mg mmol/L	1.48-1.52	Pass	Lac mmol/L	1.8-2.2	Pass
						Ca mmol/L	0.98-1.02	Pass
						Mg mmol/L	0.49-0.51	Pass
						HCO3 mmol/L	18.43-19.19	Pass
Cal D L/N	16314043		Flush L/N	16314044		Reference L/N	16313005	
	Spec	Pass/Fail		Spec	Result		Spec	Pass/Fail
BUN mg/dl	49.4-50.6	Pass	Aqueous Salt	N/A	Present	KCl mol/L	1.8-2.2	Pass
Glu mg/dl	197-203	Pass	Solution					
Lac mmol/L	5.5-6.5	Pass						
HCO3 mmol/L	37.05-38.57	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

12/9/2016
Date