



CERTIFICATE OF ANALYSIS

STP Prime ES Ampuled Controls

Ref Number 53110

Level 1 L/N	15314027		Level 2 L/N	15342020	
Level 1 Exp Date	2017-11		Level 2 Exp Date	2017-12	
	Spec	Pass/Fail		Spec	Pass/Fail
Na+ mmol/L	132-156	Pass	Na+ mmol/L	110-129	Pass
K+ mmol/L	3.2-4.0	Pass	K+ mmol/L	5.6-6.8	Pass
Cl- mmol/L	95-114	Pass	Cl- mmol/L	76-92	Pass
iCa mg/dL	3.96-5.72	Pass	iCa mg/dL	6.49-8.85	Pass
iMg mg/dL	0.98-1.74	Pass	iMg mg/dL	2.24-3.12	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

4/4/2016

Date