



CERTIFICATE OF ANALYSIS

STP Prime ES Ampuled Controls

Ref Number 53110

Level 1 L/N	15240045		Level 2 L/N	15240046	
Level 1 Exp Date	2017-08		Level 2 Exp Date	2017-08	
	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	2.25-3.13	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

10/29/2015

Date