



CERTIFICATE OF ANALYSIS

STP Prime ES Cal Cartridge
Lot Number 16335028

Ref Number 53361
Exp Date 2017-11-14
Date of Manufacture 2016-11-14

Cal A	L/N	16319058		Cal B	L/N	16319057		Reference	L/N	16316049
		Spec	Pass/Fail			Spec	Pass/Fail			
Na mmol/L		134.1-135.9	Pass	Na mmol/L		76.2-77.8	Pass	KCl		Spec
K mmol/L		4.02-4.08	Pass	K mmol/L		9.8-10.2	Pass			1.8-2.2
Cl mmol/L		114.1-115.9	Pass	Cl mmol/L		44.6-45.5	Pass			Pass
iCa mmol/L		0.99-1.01	Pass	iCa mmol/L		1.98-2.02	Pass			
iMg mmol/L		0.46-0.48	Pass	iMg mmol/L		1.49-1.51	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

12/15/2016
Date