



CERTIFICATE OF ANALYSIS

STP Prime ES Ampuled Controls
Lot Number 23278085

Ref Number 53110
Exp Date 2025-09-13
Date of Manufacture 2023-09-13
UDI# (01)00385480531108(11)230913(17)250913(10)23278085

Level 1 L/N	23256044		
Level 1 Exp Date	2025-09-13		
	<u>Spec</u>	<u>Pass/Fail</u>	
pH	7.30 - 7.40	Pass	
Na+ mmol/L	132 - 156	Pass	
K+ mmol/L	3.2 - 4.0	Pass	
Cl- mmol/L	95 - 114	Pass	
iCa mg/dL	3.96 - 5.72	Pass	
iMg mg/dL	0.98 - 1.74	Pass	

Level 2 L/N	23256045		
Level 2 Exp Date	2025-09-13		
	<u>Spec</u>	<u>Pass/Fail</u>	
pH	7.55 - 7.60	Pass	
Na+ mmol/L	110 - 129	Pass	
K+ mmol/L	5.6 - 6.8	Pass	
Cl- mmol/L	76 - 92	Pass	
iCa mg/dL	6.49 - 8.85	Pass	
iMg mg/dL	2.44 - 3.66	Pass	

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U.S.A. in accordance with ISO 13485:2016 Medical Devices Quality Management Systems Requirements, Medical Device Single Audit Program (MDSAP), and conforms to the indicated test specifications. All listed analytes are traceable to NIST SRM Materials.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Approval

QC Inspector
Title

10/31/2023