



CERTIFICATE OF ANALYSIS

STP Prime ES Ampuled Controls
Lot Number 23355018

Ref Number 53110
Exp Date 2025-12-05
Date of Manufacture 2023-12-05
UDI# (01)00385480531108(11)231205(17)251205(10)23355018

Level 1 L/N	23339042	
Level 1 Exp Date	2025-12-05	
	<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	23339043	
Level 2 Exp Date	2025-12-05	
	<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

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Approval

QC Inspector

Title

1/12/2024