

CERTIFICATE OF ANALYSIS

STP Prime ES Ampuled Controls Lot Number 24344035 Ref Number 53110 Exp Date 2026-11-22 Date of Manufacture 2024-11-22 UDI# (01)00385480531108(11)241122(17)261122(10)24344035

Level 1 L/N	24327069		Level 2 L/N 24327070
Level 1 Exp Date	2026-11-22		Level 2 Exp Date 2026-11-22
	<u>Spec</u>	Pass/Fail	<u>Spec</u> <u>Pass/Fail</u>
pH	7.30 - 7.40	Pass	pH 7.55 - 7.60 Pass
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
CI- mmol/L	95 - 114	Pass	CI- 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 2.44 - 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

Muyht

Approval

QC Inspector Title

<u>12/23/2024</u> Date