

CERTIFICATE OF ANALYSIS

Prime ES Plus Cal Cartridge 600 Sample Lot Number 24352122

Sample Ref Number 62230 Exp Date 2026-05-06 Date of Manufacture 2024-11-06 UDI# (01)00385480622301(11)241106(17)260506(10)24352122

Cal A L/N 24311037			Cal E	Cal B L/N 24		038	Reference L/N 2		1312025
	<u>Spec</u>	Pass/Fail		<u>Sp</u>	<u>ec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail
Na mmol/L	134.1 - 135.9	Pass	Na mmol/L	76.5 -	77.5	Pass	KCI mol/L	1.8 - 2.2	Pass
K mmol/L	4.02 - 4.08	Pass	K mmol/L	9.80 -	10.20	Pass			
CI mmol/L	114.1 - 115.9	Pass	CI mmol/L	44.6 -	45.5	Pass			
iCa mmol/L	0.99 - 1.01	Pass	iCa mmol/L	1.98 -	2.02	Pass			
iMg mmol/L	0.38 - 0.48	Pass	iMg mmol/L	1.48 -	1.52	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

Amishi.M

Approval

QC Inspector Title

<u>12/24/2024</u> Date