

CERTIFICATE OF ANALYSIS

Prime Cal Cartridge ES Comp 200 Sample Lot Number 24250055

ample Ref Number 53362 Exp Date 2026-02-27 Date of Manufacture 2024-08-27 UDI# (01)00385480533621(11)240827(17)260227(10)24250055

Cal A L/N 24240072			Cal E	Cal B L/N 24240073			nce L/N	24240034
	<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail
Na mmol/L	134.1 - 135.9	Pass	Na mmol/L	76.5 - 77.5	5 Pass	KCI mol/L	1.8 - 2.2	Pass
K mmol/L	4.02 - 4.08	Pass	K mmol/L	9.80 - 10.2	20 Pass			
CI mmol/L	114.1 - 115.9	Pass	CI mmol/L	44.6 - 45.5	5 Pass			
iCa mmol/L	0.99 - 1.01	Pass	iCa mmol/L	1.98 - 2.02	2 Pass			
iMg mmol/L	0.39 - 0.49	Pass	iMg mmol/L	1.48 - 1.52	2 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

Auishi.M

Approval

QC Inspector Title

<u>09/13/2024</u> Date