

CERTIFICATE OF ANALYSIS

Prime Cal Cartridge ES Comp 200 Sample Lot Number 24291045

ample Ref Number 53362 Exp Date 2026-03-26 Date of Manufacture 2024-09-26 UDI# (01)00385480533621(11)240926(17)260326(10)24291045

Cal A L/N 24270029			Cal E	Cal B L/N 24270028			Reference	e L/N	24270027
	<u>Spec</u>	Pass/Fail		<u>Spe</u>	<u>əc</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	0.41 - 0.51	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

EPm.

Approval

QC Inspector Title

<u>10/22/2024</u> Date