

CERTIFICATE OF ANALYSIS

Prime Cal Cartridge ES Comp 100 Sample Lot Number 24075014 Ref Number 53103 Exp Date 2025-09-06

Date of Manufacture 2024-03-06

UDI# (01)00385480531030(11)240306(17)250906(10)24075014

Cal A L/N 24066027		Cal E	Cal B L/N 24066028			Reference L/N 24066064		
<u>Spec</u>	Pass/Fail		Spec	<u>Pa</u>	ass/Fail		<u>Spec</u>	Pass/Fail
Na mmol/L 134.1 - 135.9	Pass	Na mmol/L	76.5 - 7	7.5	Pass	KCI mol/L	1.8 - 2.2	Pass
K mmol/L 4.02 - 4.08	Pass	K mmol/L	9.80 - 10	0.20	Pass			
CI mmol/L 114.1 - 115.9	Pass	CI mmol/L	44.6 - 4	5.5	Pass			
iCa mmol/L 0.99 - 1.01	Pass	iCa mmol/L	1.98 - 2.	.02	Pass			
iMg mmol/L 0.39 - 0.49	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

Approval

QC Inspector Title

03/21/2024 Date