

CERTIFICATE OF ANALYSIS

Prime Cal Cartridge ES Comp 100 Sample Lot Number 24003023

D Sample Ref Number 53103 Exp Date 2025-06-19 Date of Manufacture 2023-12-19 UDI# (01)00385480531030(11)231219(17)250619(10)24003023

Cal A L/N 23353066		Cal B L/N 23354027			Referen	Reference L/N 23353053		
<u>Spec</u>	Pass/Fail		<u>Spec</u>	<u>Pass/F</u>	ail	<u>Spec</u>	Pass/Fail	
Na mmol/L 134.1 - 13	35.9 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 - 1	0.20 Pass	6			
CI mmol/L 114.1 - 1	15.9 Pass	CI mmol/L	44.6 - 4	5.5 Pass	6			
iCa mmol/L 0.99 - 1.	01 Pass	iCa mmol/L	1.98 - 2	.02 Pass	6			
iMg mmol/L 0.38 - 0.	48 Pass	iMg mmol/L	1.48 - 1	.52 Pass	3			

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>01/10/2024</u> Date