

CERTIFICATE OF ANALYSIS

Prime Cal Cartridge ES Comp 600 Sample Lot Number 23289032 Ref Number 53462 Exp Date 2025-03-29

Date of Manufacture 2023-09-29

UDI# (01)00385480534628(11)230929(17)250329(10)23289032

Cal A L/N 23272028		Cal E	Cal B L/N 23272029				Reference L/N 23272027		
<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 0.39 - 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

Haneen Aldarwish

10/19/2023 Date