

CERTIFICATE OF ANALYSIS

Prime Cal Cartridge ES Comp 500 Sample Lot Number 25014054

D Sample Ref Number 53461 Exp Date 2026-05-27 Date of Manufacture 2024-11-27 UDI# (01)00385480534611(11)241127(17)260527(10)25014054

Cal A L/N 24332021		Cal E	Cal B L/N 24332020			Reference L/N 24332013		
<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	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

Kumanu Sehta

Approval

QC Inspector Title

<u>02/03/2025</u> Date