

CERTIFICATE OF ANALYSIS

Prime Cal Cartridge ES Comp 400 Sample Lot Number 24169027 Ref Number 53460 Exp Date 2025-12-10

Date of Manufacture 2024-06-10

UDI# (01)00385480534604(11)240610(17)251210(10)24169027

Cal A L/N 24162050		Cal E	Cal B L/N 24162051			Reference L/N 24162052	
<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 - 10.2	0 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 0.42 - 0.52	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

Auishi.M

06/20/2024 Date