

CERTIFICATE OF ANALYSIS

Prime Cal Cartridge ES Comp 500 Sample Lot Number 24204076

D Sample Ref Number 53461 Exp Date 2026-01-08 Date of Manufacture 2024-07-08 UDI# (01)00385480534611(11)240708(17)260108(10)24204076

| Cal A L/N 24191031 | | Cal E | Cal B L/N 24191033 | | | Reference L/N 24190068 | | |
|-------------------------|-----------|------------|--------------------|-----------|-----------|------------------------|-----------|--|
| <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 0.43 - 0.53 | 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

Amishi.M

Approval

QC Inspector Title

<u>07/29/2024</u> Date