

CERTIFICATE OF ANALYSIS

Prime Cal Cartridge ES Comp 500 Sample Lot Number 24250057 Ref Number 53461 Exp Date 2026-02-27

Date of Manufacture 2024-08-27

UDI# (01)00385480534611(11)240827(17)260227(10)24250057

| Cal A L/N 24240072 | | Cal E | Cal B L/N 24240073 | | | | Reference L/N 24240034 | | |
|-------------------------|-----------|------------|--------------------|-----------|-----------|-----------|------------------------|-----------|--|
| <u>Spec</u> | Pass/Fail | | Sp. | <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

Auishi.M

Approval

QC Inspector Title

09/16/2024 Date