

## **CERTIFICATE OF ANALYSIS**

Prime Cal Cartridge ES Comp 300 Sample Lot Number 24291045

D Sample Ref Number 53102 Exp Date 2026-03-26 Date of Manufacture 2024-09-26 UDI# (01)00385480531023(11)240926(17)260326(10)24291045

| Cal A L/N 24270029      |           | Cal E      | Cal B L/N 24270028 |           |           | Reference L/N 24270027 |           |  |
|-------------------------|-----------|------------|--------------------|-----------|-----------|------------------------|-----------|--|
| <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 0.41 - 0.51  | 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

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Approval

QC Inspector Title

<u>10/22/2024</u> Date