

## **CERTIFICATE OF ANALYSIS**

Prime Cal Cartridge ES Comp 200 Sample Lot Number 25014053

ample Ref Number 53362 Exp Date 2026-05-27 Date of Manufacture 2024-11-27 UDI# (01)00385480533621(11)241127(17)260527(10)25014053

| Cal A L/N 24332021 |               |           | Cal E      | Cal B L/N 24332020 |           |           | e L/N     | 24332013  |
|--------------------|---------------|-----------|------------|--------------------|-----------|-----------|-----------|-----------|
|                    | <u>Spec</u>   | Pass/Fail |            | Spec               | Pass/Fail |           | Spec      | 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

Approval

QC Inspector

Title

01/20/2025

Date