

## **CERTIFICATE OF ANALYSIS**

STP Prime CCS Comp Cal Cartridge 500 Sample Lot Number 25055040

nple Ref Number 53469 Exp Date 2026-08-06 Date of Manufacture 2025-02-06 UDI# (01)00385480534697(11)250206(17)260806(10)25055040

| Cal A L/N  | 25049004        |           | Cal B L/N     | 25049005      |           |
|------------|-----------------|-----------|---------------|---------------|-----------|
|            | Assigned Value* | Result    |               | <u>Spec</u>   | Pass/Fail |
| рН         | 7.355           | N/A       | pH            | 6.837 - 6.843 | Pass      |
| pCO2 mmHg  | 24.6            | N/A       | pO2 mmHg      | 167.0         | N/A       |
|            |                 |           | Na mmol/L     | 68.0 - 69.0   | Pass      |
|            | <u>Spec</u>     | Pass/Fail | K mmol/L      | 9.92 - 10.08  | Pass      |
| Na mmol/L  | 132.1 - 133.9   | Pass      | CI mmol/L     | 45.6 - 46.4   | Pass      |
| K mmol/L   | 3.97 - 4.03     | Pass      | iCa mmol/L    | 2.17 - 2.23   | Pass      |
| CI mmol/L  | 105.2 - 106.8   | Pass      | Glu mg/dL     | 197 - 203     | Pass      |
| iCa mmol/L | 1.08 - 1.12     | Pass      | Lac mmol/L    | 9.5 - 10.5    | Pass      |
| Glu mg/dL  | 79 - 81         | Pass      |               |               |           |
| Lac mmol/L | 1.8 - 2.2       | Pass      |               |               |           |
|            |                 |           |               |               |           |
| Flush L/N  | 25037018        |           | Reference L/N | 25049006      |           |
|            | Assigned Value* | Result    |               | <u>Spec</u>   | Pass/Fail |
| pCO2 mmHg  | 51.3            | N/A       | KCI           | 1.8 - 2.2     | Pass      |
| pO2 mmHg   | 98.9            | N/A       |               |               |           |

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

03/05/2025 Date