

## **CERTIFICATE OF ANALYSIS**

STP Prime CCS Comp Cal Cartridge 100 Sample Lot Number 24212066

nple Ref Number 52861 Exp Date 2026-01-16 Date of Manufacture 2024-07-16 UDI# (01)00385480528610(11)240716(17)260116(10)24212066

| Cal A L/N              | 24198051       |                 | Cal B L/N     | 24198052      |           |
|------------------------|----------------|-----------------|---------------|---------------|-----------|
|                        | Assigned Value | * <u>Result</u> |               | Spec          | Pass/Fail |
| pН                     | 7.354          | N/A             | рН            | 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            |               |               |           |
|                        | 0.4.4.0.00.4.0 |                 |               | 0.400.40.45   |           |
| Flush L/N              | 24198049       |                 | Reference L/N | 24204045      |           |
| Assigned Value* Result |                |                 |               | <u>Spec</u>   | Pass/Fail |
| pCO2 mmHg              | 51.3           | N/A             | KCI           | 1.8 - 2.2     | Pass      |
| pO2 mmHg               | 98.0           | 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

Fra

Approval

QC Inspector Title

<u>08/08/2024</u> Date