

CERTIFICATE OF ANALYSIS

STP Prime CCS Comp Cal Cartridge 300 Sample Lot Number 24355028

nple Ref Number 52427 Exp Date 2026-05-20 Date of Manufacture 2024-11-20 UDI# (01)00385480524278(11)241120(17)260520(10)24355028

| Cal A L/N | 24325037 | | Cal B L/N | 24325038 | |
|------------------------|---------------|-----------|---------------|---------------|-----------|
| Assigned Value* Result | | | | <u>Spec</u> | Pass/Fail |
| pН | 7.350 | N/A | pH | 6.837 - 6.843 | Pass |
| pCO2 mmHg | 25.3 | 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 | 24330010 | | Reference L/N | 24325039 | |
| Assigned Value* Result | | | | <u>Spec</u> | Pass/Fail |
| pCO2 mmHg | 51.3 | N/A | KCI | 1.8 - 2.2 | Pass |
| pO2 mmHg | 100.8 | 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

Amishi.M

Approval

QC Inspector Title

<u>01/03/2025</u> Date