

CERTIFICATE OF ANALYSIS

Nova Control Levels 1 and 2 Lot Number 25015023 Ref Number 18655 Exp Date 2026-12-23 Date of Manufacture 2024-12-23 UDI# (01)00385480186551(11)241223(17)261223(10)25015023

| Level 1 L/N 24358026 | | | Level 2 L/N 24358 | Level 2 L/N 24358027 | | |
|-----------------------------|-------------|-----------|------------------------|-----------------------------|--|--|
| Level 1 Exp Date 2026-12-23 | | | Level 2 Exp Date 2026- | Level 2 Exp Date 2026-12-23 | | |
| | <u>Spec</u> | Pass/Fail | <u>Spec</u> | Pass/Fail | | |
| Na+ mmol/L | 132 - 156 | Pass | Na+ mmol/L 110 - 129 | Pass | | |
| K+ mmol/L | 3.2 - 4.0 | Pass | K+ mmol/L 5.6 - 6.8 | Pass | | |
| CI- mmol/L | 95 - 114 | Pass | CI- mmol/L 76 - 92 | Pass | | |
| TCO2 mmol/L | 19 - 30 | Pass | TCO2 mmol/L 10 - 18 | Pass | | |
| Glu mg/dL | 69 - 91 | Pass | Glu mg/dL 233 - 309 | Pass | | |
| BUN mg/dL | 15 - 25 | Pass | BUN mg/dL 48 - 68 | Pass | | |
| TCa mg/dL | 5.04 - 7.24 | Pass | TCa mg/dL 7.74 - 10.91 | Pass | | |
| Ca++ mg/dL | 3.96 - 5.72 | Pass | Ca++ mg/dL 6.49 - 8.85 | Pass | | |
| Mg++ mg/dL | 0.98 - 1.74 | Pass | Mg++ mg/dL 3.38 - 4.65 | Pass | | |
| Li+ mmol/L | 0.56 - 0.87 | Pass | Li+ mmol/L 1.84 - 2.56 | Pass | | |
| pН | 7.30 - 7.40 | Pass | рН 7.55 - 7.60 | 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.

Auishi.M

Approval

QC Inspector Title

<u>2/27/2025</u> Date