

CERTIFICATE OF ANALYSIS

Nova 16 Calibrator Pack Lot Number 505666 Ref Number 17289 Exp Date 2025-11-25 Date of Manufacture 2025-02-25 UDI# (01)00385480172899(11)250225(17)251125(10)505666

| Cal A L/N | 25056066 | | Cal B L/N | 25056066 | | Cal C L/N | 25056066 | |
|-------------|-----------------------|------------|-------------|---------------|-----------|-------------|-------------|--------|
| | <u>Spec</u> | Result | | <u>Spec</u> | Result | | <u>Spec</u> | Result |
| HCO3 mmol/L | 19.2 - 20.8 | Pass | HCO3 mmol/L | 19.6 - 20.8 | Pass | | | |
| Na mmol/L | 139.0 - 141.0 | Pass | Na mmol/L | 79.2 - 80.8 | Pass | HCO3 mmol/L | 9.6 - 10.4 | Pass |
| K mmol/L | 3.97 - 4.03 | Pass | K mmol/L | 9.8 - 10.2 | Pass | | | |
| CI mmol/L | 112.1 - 113.9 | Pass | CI mmol/L | 57.4 - 58.6 | Pass | | | |
| Glu mg/dL | 78.4 - 81.6 | Pass | Glu mg/dL | 196 - 204 | Pass | | | |
| BUN mg/dL | 9.7 - 10.3 | Pass | BUN mg/dL | 49.4 - 50.6 | Pass | | | |
| Creat mg/dL | 0.98 - 1.02 | Pass | Creat mg/dL | 9.8 - 10.2 | Pass | | | |
| | Flush L/N | N 25056066 | | Reference L/N | | 25056066 | | |
| | | Spec | Result | | | <u>Spec</u> | Result | |
| | Aqueous Salt Solution | N/A | Present | | KCI mol/L | 1.8 - 2.2 | 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

3/27/2025

Date