

CERTIFICATE OF ANALYSIS

Nova 16 Calibrator Pack Lot Number 419447 Ref Number 17289 Exp Date 2025-04-12 Date of Manufacture 2024-07-12 UDI# (01)00385480172899(11)240712(17)250412(10)419447

| Cal A L/N | 24194047 | | Cal B L/N | 24194047 | | Cal C L/N | 24194047 | |
|-------------|---------------|---------------|-------------|---------------|---------------|-------------|-------------|---------------|
| | <u>Spec</u> | <u>Result</u> | | <u>Spec</u> | <u>Result</u> | | <u>Spec</u> | <u>Result</u> |
| 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 | Cl 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 | L/N 24194047 | | Reference L/N | | 24194047 | | |
| | | Spec | Result | | | <u>Spec</u> | Result | |
| | Aqueous N/A | | Present | | KCI mol/L | 1.8 - 2.2 | Pass | |
| | Salt Solution | | | | | | | |

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.

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Approval

QC Inspector Title

<u>9/11/2024</u> Date