



**CERTIFICATE OF ANALYSIS**

Nova 16 Control Levels 1 and 2

Ref Number 17452

Lot Number 23198052

Exp Date 2024-12-12

Date of Manufacture 2023-06-12

UDI# (01)00385480174527(11)230612(17)241212(10)23198052

Level 1 L/N 23163059  
Level 1 Exp Date 2024-12-12

Level 2 L/N 23163060  
Level 2 Exp Date 2024-12-12

|                  | <u>Spec</u> | <u>Pass/Fail</u> |                  | <u>Spec</u> | <u>Pass/Fail</u> |
|------------------|-------------|------------------|------------------|-------------|------------------|
| Na+ mmol/L       | 132 - 156   | Pass             | Na+ mmol/L       | 109 - 128   | Pass             |
| K+ mmol/L        | 3.2 - 4.0   | Pass             | K+ mmol/L        | 5.5 - 6.7   | Pass             |
| Cl- mmol/L       | 91 - 110    | Pass             | Cl- mmol/L       | 68 - 84     | Pass             |
| TCO2 mmol/L      | 19 - 29     | Pass             | TCO2 mmol/L      | 10 - 18     | Pass             |
| Glu mg/dL        | 69 - 91     | Pass             | Glu mg/dL        | 246 - 322   | Pass             |
| BUN mg/dL        | 12 - 22     | Pass             | BUN mg/dL        | 45 - 64     | Pass             |
| Li+ mmol/L       | 0.46 - 0.76 | Pass             | Li+ mmol/L       | 1.70 - 2.40 | Pass             |
| Creatinine mg/dL | 0.7 - 1.3   | Pass             | Creatinine mg/dL | 5.22 - 7.25 | 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

7/24/2023

Date