

## **CERTIFICATE OF ANALYSIS**

Nova 16 Control Levels 1 and 2

Ref Number 17452

Pass

**Pass** 

Lot Number 24232045

0.7 - 1.3

Exp Date 2026-02-13 Date of Manufacture 2024-08-13 UDI# (01)00385480174527(11)240813(17)260213(10)24232045

5.22 - 7.25

Level 1 L/N 24226071 Level 2 L/N 24226072 Level 1 Exp Date 2026-02-13 Level 2 Exp Date 2026-02-12 <u>Spec</u> Pass/Fail **Spec** Pass/Fail Na+ mmol/L 132 - 156 Pass Na+ mmol/L 109 - 128 **Pass** K+ mmol/L 3.2 - 4.0Pass K+ mmol/L 5.5 - 6.7 Pass CI- mmol/L 91 - 110 Pass CI- mmol/L 68 - 84 Pass TCO2 mmol/L 19 - 29 Pass TCO2 mmol/L 10 - 18 Pass Glu mg/dL 69 - 91 Glu mg/dL 246 - 322 Pass Pass BUN mg/dL 12 - 22 Pass BUN mg/dL 45 - 64 Pass Li+ mmol/L 0.46 - 0.76 Li+ mmol/L 1.70 - 2.40

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.

Creatinine mg/dL

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer.

Pass

Pass

Auishi. M Approval

Creatinine mg/dL

QC Inspector Title

9/30/2024

Date