



CERTIFICATE OF ANALYSIS

Nova 16 Control Levels 1 and 2

Ref Number 17452

Lot Number 24354018

Exp Date 2026-06-16

Date of Manufacture 2024-12-16

UDI# (01)00385480174527(11)241216(17)260616(10)24354018

Level 1 L/N 24351022

Level 2 L/N 24351023

Level 1 Exp Date 2026-06-16

Level 2 Exp Date 2026-06-16

	<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

1/9/2025

Date