



CERTIFICATE OF ANALYSIS

Nova 12 Calibrator Pack
Lot Number 609625

Ref Number 15650
Exp Date 2026-12-04
Date of Manufacture 2026-03-04
UDI# (01)00385480156509(11)260304(17)261204(10)609625

Cal A L/N 26082032	Cal B L/N 26082033	Cal C L/N 26064009
<u>Spec</u> <u>Pass/Fail</u>	<u>Spec</u> <u>Pass/Fail</u>	<u>Spec</u> <u>Pass/Fail</u>
Na mmol/L 139.0 - 141.0 Pass	Na mmol/L 69.3 - 70.7 Pass	Na mmol/L 98.0 - 102.0 Pass
K mmol/L 3.97 - 4.03 Pass	K mmol/L 9.8 - 10.2 Pass	Cl mmol/L 87.2 - 90.8 Pass
Cl mmol/L 112.1 - 113.9 Pass	Cl mmol/L 57.4 - 58.6 Pass	NH4 0.88 - 0.92 Pass
HCO3 mmol/L 19.2 - 20.8 Pass	HCO3 mmol/L 9.8 - 10.4 Pass	
BUN mg/dl 9.7 - 10.3 Pass	BUN mg/dl 49.4 - 50.6 Pass	
Glu mg/dl 79.2 - 83.2 Pass	Glu mg/dl 196 - 204 Pass	

Cal J L/N 26063009
<u>Spec</u> <u>Pass/Fail</u>
Na mmol/L 98.0 - 102.0 Pass
Cl mmol/L 90.7 - 94.4 Pass
NH4 4.4 - 4.6 Pass

Flush L/N 26082025
<u>Spec</u> <u>Result</u>
Aqueous Salt Solution N/A Present

H L/N 26063047
<u>Spec</u> <u>Result</u>
CO2 Releasing Agent N/A Present

Reference L/N 26063010
<u>Spec</u> <u>Pass/Fail</u>
KCl 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

4/8/2026
Date