



CERTIFICATE OF ANALYSIS

Nova 12 Calibrator Pack
Lot Number 416628

Ref Number 15650
Exp Date 2025-02-15
Date of Manufacture 2024-05-15
UDI# (01)00385480156509(11)240515(17)250215(10)416628

Cal A L/N 24136082	Spec	Pass/Fail
Na mmol/L	139.0 - 141.0	Pass
K mmol/L	3.97 - 4.03	Pass
Cl mmol/L	112.1 - 113.9	Pass
HCO3 mmol/L	19.2 - 20.8	Pass
BUN mg/dl	9.7 - 10.3	Pass
Glu mg/dl	79.2 - 83.2	Pass

Cal B L/N 24136083	Spec	Pass/Fail
Na mmol/L	69.3 - 70.7	Pass
K mmol/L	9.8 - 10.2	Pass
Cl mmol/L	57.4 - 58.6	Pass
HCO3 mmol/L	9.8 - 10.4	Pass
BUN mg/dl	49.4 - 50.6	Pass
Glu mg/dl	196 - 204	Pass

Cal C L/N 24138009	Spec	Pass/Fail
Na mmol/L	98.0 - 102.0	Pass
Cl mmol/L	87.2 - 90.8	Pass
NH4	0.88 - 0.92	Pass

Cal J L/N 24137038	Spec	Pass/Fail
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 24138010	Spec	Result
Aqueous Salt Solution	N/A	Present

H L/N 24137011	Spec	Result
CO2 Releasing Agent	N/A	Present

Reference L/N 24137037	Spec	Pass/Fail
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.

Awishi M

Approval

QC Inspector
Title

6/18/2024
Date