



CERTIFICATE OF ANALYSIS

Linearity Standard Set F
Lot Number 24197023

Ref Number 41274
Exp Date 2026-01-02
Date of Manufacture 2024-07-02
UDI# (01)00385480412742(11)240702(17)260102(10)24197023

Level 1 L/N	24184054		Level 2 L/N	24184055	
Level 1 Exp Date	2026-01-02		Level 2 Exp Date	2026-01-02	
	Spec	Pass/Fail		Spec	Pass/Fail
Na+ mmol/L	89.1-90.9	Pass	Na+ mmol/L	111.9-114.1	Pass
K+ mmol/L	1.98-2.02	Pass	K+ mmol/L	3.86-3.94	Pass
Cl- mmol/L	72.3-73.7	Pass	Cl- mmol/L	91.1-92.9	Pass
TCO2 mmol/L	8.6-9.4	Pass	TCO2 mmol/L	15.4-16.6	Pass
Glu mg/dL	490-510	Pass	Glu mg/dL	294-306	Pass
BUN mg/dL	97.5-102.5	Pass	BUN mg/dL	29.3-30.8	Pass
Creatinine mg/dL	16.7-17.3	Pass	Creatinine mg/dL	4.9-5.1	Pass
Lac mmol/L	18.2 - 18.8	Pass	Lac mmol/L	9.2 - 9.6	Pass
Level 3 L/N	24184056		Level 4 L/N	24184057	
Level 3 Exp Date	2026-01-02		Level 4 Exp Date	2026-01-02	
	Spec	Pass/Fail		Spec	Pass/Fail
Na+ mmol/L	139.6-142.4	Pass	Na+ mmol/L	189.1-192.9	Pass
K+ mmol/L	5.74-5.86	Pass	K+ mmol/L	7.62-7.78	Pass
Cl- mmol/L	110.9-113.1	Pass	Cl- mmol/L	147.5-150.5	Pass
TCO2 mmol/L	26.9-29.1	Pass	TCO2 mmol/L	36.5-39.5	Pass
Glu mg/dL	98-102	Pass	Glu mg/dL	34.3-35.7	Pass
BUN mg/dL	9.8-10.3	Pass	BUN mg/dL	5.9-6.2	Pass
Creatinine mg/dL	0.49-0.51	Pass	Lac mmol/L	0.6 - 0.8	Pass
Lac mmol/L	1.9 - 2.1	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

Haneen Aldarwish

Approval

QC Inspector
Title

07/26/2024
Date