nova biomedical

CERTIFICATE OF ANALYSIS

Stat Profile Prime Ampuled Controls
Lot Number 24229010

Ref Number 52714
Exp Date 2026-02-12
Date of Manufacture 2024-08-12
UDI# (01)00385480527149(11)240812(17)260212(10)24229010

Level 1 L/N: 24225040
Level 1 Exp Date: 2026-02-12

	Spec	Pass/Fail
pH	7.110 - 7.190	Pass
pCO2 mmHg	55.0 - 65.0	Pass
pO2 mmHg	58.0 - 68.0	Pass
Hct %	32 - 36	Pass
Na+ mmol/L	161.0 - 165.0	Pass
K+ mmol/L	5.52 - 5.82	Pass
Cl- mmol/L	124.3 - 133.3	Pass
Ca++ mmol/L	1.50 - 1.58	Pass
Glu mg/dL	76 - 90	Pass
Lac mmol/L	0.8 - 1.2	Pass

Level 2 L/N: 24225041
Level 2 Exp Date: 2026-02-12

	Spec	Pass/Fail
pH	7.350 - 7.420	Pass
pCO2 mmHg	39.0 - 45.0	Pass
pO2 mmHg	97.0 - 107.0	Pass
Hct %	49 - 53	Pass
Na+ mmol/L	139.0 - 143.0	Pass
K+ mmol/L	3.64 - 3.84	Pass
Cl- mmol/L	98.0 - 106.0	Pass
Ca++ mmol/L	0.96 - 1.04	Pass
Glu mg/dL	195 - 225	Pass
Lac mmol/L	2.5 - 3.1	Pass

Level 3 L/N: 24225042
Level 3 Exp Date: 2026-02-12

	Spec	Pass/Fail
pH	7.570 - 7.650	Pass
pCO2 mmHg	18.0 - 26.0	Pass
pO2 mmHg	135.0 - 149.0	Pass
Hct %	63 - 67	Pass
Na+ mmol/L	116.0 - 120.0	Pass
K+ mmol/L	1.70 - 2.00	Pass
Cl- mmol/L	82.0- 90.0	Pass
Ca++ mmol/L	0.50 - 0.60	Pass
Glu mg/dL	297 - 347	Pass
Lac mmol/L	6.4 - 7.7	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. SO2 is traced to tonometry.

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

Awishi.M
Approval

QC Inspector
Title

10/1/2024
Date