



CERTIFICATE OF ANALYSIS

Stat Profile pHox Plus M Control

Ref Number 45205

Lot Number 23320028

Exp Date 2025-05-06

Date of Manufacture 2023-11-06

UDI# (01)00385480452052(11)231106(17)250506(10)23320028

Level 1 L/N:	23313022	
Level 1 Exp Date:	2025-05-09	
	Spec	Pass/Fail
pH	7.110-7.190	Pass
pCO2 mmHg	55.0-65.0	Pass
pO2 mmHg	58.0-68.0	Pass
Na+ mmol/L	157.8-161.8	Pass
K+ mmol/L	5.71-6.01	Pass
Ca++ mmol/L	1.46-1.54	Pass
Mg++ mmol/L	0.91-1.05	Pass
Glu mg/dL	73-87	Pass
Lac mmol/L	0.8-1.2	Pass

Level 2 L/N:	23310056	
Level 2 Exp Date:	2025-05-06	
	Spec	Pass/Fail
pH	7.350-7.420	Pass
pCO2 mmHg	39.0-45.0	Pass
pO2 mmHg	97.0-107.0	Pass
Na+ mmol/L	140.0-144.0	Pass
K+ mmol/L	3.76-3.96	Pass
Ca++ mmol/L	0.94-1.02	Pass
Mg++ mmol/L	0.52-0.60	Pass
Glu mg/dL	185-215	Pass
Lac mmol/L	2.5-3.1	Pass

Level 3 L/N:	23310057	
Level 3 Exp Date:	2025-05-06	
	Spec	Pass/Fail
pH	7.570-7.650	Pass
pCO2 mmHg	18.0-26.0	Pass
pO2 mmHg	135.0-149.0	Pass
Na+ mmol/L	118.0-122.0	Pass
K+ mmol/L	1.85-2.15	Pass
Ca++ mmol/L	0.50-0.60	Pass
Mg++ mmol/L	0.28-0.36	Pass
Glu mg/dL	285-325	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.

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

Approval

QC Inspector

Title

12/18/2023

Date