



CERTIFICATE OF ANALYSIS

Stat Profile pHox Plus M Control

Ref Number 45205

Lot Number 23194046

Exp Date 2024-12-07

Date of Manufacture 2023-06-07

UDI# (01)00385480452052(11)230607(17)241207(10)23194046

Level 1 L/N: 23158002	
Level 1 Exp Date: 2024-12-07	
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: 23158003	
Level 2 Exp Date: 2024-12-07	
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: 23158004	
Level 3 Exp Date: 2024-12-07	
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

Auishi M

Approval

QC Inspector

Title

7/20/2023

Date