nova biomedical

CERTIFICATE OF ANALYSIS

STP pHOx Ultra/CCX Cal Cartridge 1 w/Creat
Lot Number 24254027

Ref Number 48836
Exp Date 2026-02-26
Date of Manufacture 2024-08-26
UDI# (01)00385480488365(11)240826(17)260226(10)24254027

Cal A L/N 24240045

	Spec	Pass/Fail
pH @ 37C	7.351 - 7.357	Pass
Lac mmol/L	13.5 - 16.5	Pass

Cal B L/N 24240046

	Spec	Pass/Fail
pH @ 37C	6.822 - 6.828	Pass
Na mmol/L	69.5 - 70.5	Pass
K mmol/L	9.9 - 10.1	Pass
Cl mmol/L	39.7 - 40.3	Pass
Ca mmol/L	1.97 - 2.03	Pass
Mg mmol/L	1.48 - 1.52	Pass

Cal C L/N 24255051

	Spec	Pass/Fail
Na mmol/L	139.0 - 141.0	Pass
K mmol/L	3.97 - 4.03	Pass
Cl mmol/L	118.0 - 120.0	Pass
BUN mg/dl	9.9 - 10.1	Pass
Glu mg/dl	78.8 - 81.2	Pass
Lac mmol/L	1.8 - 2.2	Pass
Ca mmol/L	0.99 - 1.02	Pass
Mg mmol/L	0.49 - 0.51	Pass
Creat mg/dl	0.98 - 1.02	Pass
HCO3 mmol/L	18.34 - 19.08	Pass

Cal D L/N 24240048

	Spec	Pass/Fail
BUN mg/dl	49.4 - 50.6	Pass
Glu mg/dl	197 - 203	Pass
Lac mmol/L	5.5 - 6.5	Pass
Creat mg/dl	9.8 - 10.2	Pass
HCO3 mmol/L	36.68 - 38.18	Pass

Flush L/N 24240044

	Spec	Result
Aqueous Salt Solution	N/A	Present

Reference L/N 24239030

	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

9/19/2024
Date