

CERTIFICATE OF ANALYSIS

STP pHOx Plus M Cal Cartridge Lot Number 22109029 Ref Number 45146 Exp Date 2023-09-23 Date of Manufacture 2022-03-23 UDI#(01)00385480451468(11)220323(17)230923(10)22109029

Cal A L/N 22088016 Cal B L/N 22088017 Cal C L/N 22101029

	<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail
Na mmol/L	136.0 - 138.0	Pass	HCO3 mmol/L	42.24 - 43.96	Pass	pH @ 37C	7.332 - 7.338	Pass
HCO3 mmol/L	21.07 - 21.93	Pass				Ca mmol/L	1.97 - 2.03	Pass
K mmol/L	3.97 - 4.03	Pass				Na mmol/L	70.5 - 71.5	Pass
Mg mmol/L	0.49 - 0.51	Pass				K mmol/L	9.92 - 10.08	Pass
Ca mmol/L	0.99 - 1.01	Pass				Mg mmol/L	1.38 - 1.42	Pass
Glu mg/dL	39.6 - 40.4	Pass				Glu mg/dL	198 - 202	Pass
Lac mmol/L	0.8 - 1.2	Pass				Lac mmol/L	5.5 - 6.5	Pass

Cal D L/N 22088019 Reference L/N 22082054

	<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail
pH @ 37C	6.788 - 6.794	Pass	KCI	1.8 - 2.2	Pass
Glu mg/dL	990 - 1010	Pass			
Lac mmol/L	10.5 - 13.5	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

Amishi.M

Approval

QC Inspector

Title

4/22/2022 Date