

CERTIFICATE OF ANALYSIS

STP pHOx Plus L Cal Cartridge Lot Number 21348067 Ref Number 34086

Exp Date 2023-05-17

Date of Manufacture 2021-11-17

UDI# (01)00385480340861(11)211117(17)230517(10)21348067

Cal A L/N	21324013		Cal B L/N	21326044		Cal C L/N	21326045	
	Spec	Pass/Fail		Spec	Pass/Fail		Spec	Pass/Fail
Na mmol/L	142-144	Pass	HCO3 mmol/L	45.90-47.78	Pass	pH @ 37C	7.332-7.338	Pass
HCO3 mmol/L	24.42-25.42	Pass				Ca mmol/L	2.01-2.07	Pass
K mmol/L	4.03-4.09	Pass				Na mmol/L	72.5-73.5	Pass
CI mmol/L	97.2-98.8	Pass				K mmol/L	10.04-10.20	Pass
Ca mmol/L	1.01-1.03	Pass				CI mmol/L	52.6-53.4	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	21326040		Reference L/N	21321037				
	Spec	Pass/Fail		Spec	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

Approval

QC Inspector

<u>12/27/2021</u> Date