

CERTIFICATE OF ANALYSIS

STP Prime CCS Comp Cal Cartridge 100 Sample Lot Number 23355035

nple Ref Number 52861 Exp Date 2025-05-30 Date of Manufacture 2023-11-30 UDI# (01)00385480528610(11)231130(17)250530(10)23355035

Cal A L/N	23334012		Cal B L/N	23334013	
	Assigned Value	<u>Result</u>		<u>Spec</u>	Pass/Fail
pН	7.352	N/A	pH	6.837 - 6.843	Pass
pCO2 mmHg	24.9	N/A	pO2 mmHg	167.0	N/A
			Na mmol/L	68.0 - 69.0	Pass
	<u>Spec</u>	Pass/Fail	K mmol/L	9.92 - 10.08	Pass
Na mmol/L	132.1 - 133.9	Pass	CI mmol/L	45.6 - 46.4	Pass
K mmol/L	3.97 - 4.03	Pass	iCa mmol/L	2.17 - 2.23	Pass
CI mmol/L	105.2 - 106.8	Pass	Glu mg/dL	197 - 203	Pass
iCa mmol/L	1.08 - 1.12	Pass	Lac mmol/L	9.5 - 10.5	Pass
Glu mg/dL	79 - 81	Pass			
Lac mmol/L	1.8 - 2.2	Pass			
Flush L/N	23334010		Reference L/N	23335038	
	Assigned Value*	<u>Result</u>		<u>Spec</u>	Pass/Fail
pCO2 mmHg	52.2	N/A	KCI	1.8 - 2.2	Pass
pO2 mmHg	97.2	N/A			

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

Haneen Aldarwish

Approval

QC Inspector Title

<u>01/02/2024</u> Date