

CERTIFICATE OF ANALYSIS

STP Prime CCS Comp Cal Cartridge 400 Sample Lot Number 24117073

nple Ref Number 53105 Exp Date 2025-10-19 Date of Manufacture 2024-04-19 UDI# (01)00385480531054(11)240419(17)251019(10)24117073

Cal A L/N	24110045		Cal B L/N	24110046	
Assigned Value* Result				Spec	Pass/Fail
pН	7.350	N/A	рН	6.837 - 6.843	Pass
pCO2 mmHg	25.2	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			
	04440040			04440047	
Flush L/N	24110018		Reference L/N	24110047	
Assigned Value* Result				<u>Spec</u>	Pass/Fail
pCO2 mmHg	51.8	N/A	KCI	1.8 - 2.2	Pass
pO2 mmHg	94.4	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

and.

Approval

QC Inspector Title

<u>05/13/2024</u> Date