

CERTIFICATE OF ANALYSIS

STP Prime CCS Comp Cal Cartridge 400 Sample Lot Number 24025041

04004055

nple Ref Number 53105 Exp Date 2025-07-04 Date of Manufacture 2024-01-04 UDI# (01)00385480531054(11)240104(17)250704(10)24025041

24004055		Cal B L/N	24004056	
Assigned Value*	Result		<u>Spec</u>	Pass/Fail
7.356	N/A	рН	6.837 - 6.843	Pass
24.8	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
132.1 - 133.9	Pass	CI mmol/L	45.6 - 46.4	Pass
3.97 - 4.03	Pass	iCa mmol/L	2.17 - 2.23	Pass
105.2 - 106.8	Pass	Glu mg/dL	197 - 203	Pass
1.08 - 1.12	Pass	Lac mmol/L	9.5 - 10.5	Pass
79 - 81	Pass			
1.8 - 2.2	Pass			
24005032		Reference L/N	24004052	
Assigned Value*	Result		<u>Spec</u>	Pass/Fail
50.4	N/A	KCI	1.8 - 2.2	Pass
96.5	N/A			
	7.356 24.8 Spec 132.1 - 133.9 3.97 - 4.03 105.2 - 106.8 1.08 - 1.12 79 - 81 1.8 - 2.2 24005032 Assigned Value* 50.4	Assigned Value* Result 7.356 N/A 24.8 N/A Spec Pass/Fail 132.1 - 133.9 Pass 3.97 - 4.03 Pass 105.2 - 106.8 Pass 1.08 - 1.12 Pass 79 - 81 Pass 1.8 - 2.2 Pass 24005032 Assigned Value* Result 50.4 N/A	Assigned Value* Result 7.356 N/A pH 24.8 N/A pO2 mmHg Na mmol/L Na mmol/L Spec Pass/Fail K mmol/L 132.1 - 133.9 Pass CI mmol/L 3.97 - 4.03 Pass iCa mmol/L 105.2 - 106.8 Pass Glu mg/dL 1.08 - 1.12 Pass Lac mmol/L 79 - 81 Pass Lac mmol/L 1.8 - 2.2 Pass Reference L/N Assigned Value* Result 50.4 N/A KCI	Assigned Value* Result Spec 7.356 N/A pH 6.837 - 6.843 24.8 N/A pO2 mmHg 167.0 Na mmol/L 68.0 - 69.0 Na mmol/L 68.0 - 69.0 Na mmol/L 9.92 - 10.08 132.1 - 133.9 Pass 132.1 - 133.9 Pass CI mmol/L 45.6 - 46.4 3.97 - 4.03 Pass Glu mg/dL 2.17 - 2.23 105.2 - 106.8 Pass Glu mg/dL 197 - 203 1.08 - 1.12 Pass Lac mmol/L 9.5 - 10.5 79 - 81 Pass Pass Pass 1.8 - 2.2 Pass Reference L/N 24004052 Assigned Value* Result Spec 50.4 N/A KCI 1.8 - 2.2

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

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Approval

QC Inspector Title

02/05/2024 Date