

## **CERTIFICATE OF ANALYSIS**

STP Prime CCS Comp Cal Cartridge 300 Sample Lot Number 24025041

0 | 4 | /4 | 04004055

nple Ref Number 52427 Exp Date 2025-07-04 Date of Manufacture 2024-01-04 UDI# (01)00385480524278(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

Approval

QC Inspector Title

Haneen Aldarwish

02/08/2024 Date