

CERTIFICATE OF ANALYSIS

STP Prime CCS Comp Cal Cartridge 300 Sample Lot Number 23275025

nple Ref Number 52427 Exp Date 2025-03-15 Date of Manufacture 2023-09-15 UDI# (01)00385480524278(11)230915(17)250315(10)23275025

Assigned Value* Result Spec Pass/Fail pH 7.356 N/A pH 6.837 - 6.843 Pass pCO2 mmHg 24.9 N/A pO2 mmHg 167.0 N/A pCO2 mmHg 24.9 N/A pO2 mmHg 68.0 - 69.0 Pass Na mmol/L 132.1 - 133.9 Pass K mmol/L 9.92 - 10.08 Pass K mmol/L 3.97 - 4.03 Pass CI mmol/L 45.6 - 46.4 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 Pass Pass Pass Pass
pCO2 mmHg 24.9 N/A pO2 mmHg 167.0 N/A Na mmol/L Spec Pass/Fail Na mmol/L 68.0 - 69.0 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 Pass Pass Pass Pass
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iCa mmol/L 1.08 - 1.12 Pass Lac mmol/L 9.5 - 10.5 Pass Glu mg/dL 79 - 81 Pass
Glu mg/dL 79 - 81 Pass
5
Lac mmol/L 1.8 - 2.2 Pass
Flush L/N 23262077 Reference L/N 23258043
Assigned Value* Result Spec Pass/Fail
pCO2 mmHg 51.6 N/A KCI 1.8 - 2.2 Pass
pO2 mmHg 97.3 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

mit.

Approval

QC Inspector Title

<u>10/13/2023</u> Date