

CERTIFICATE OF ANALYSIS

STP CCX Cal Cartridge 3 Lot Number 23297085 Ref Number 36640 Exp Date 2025-04-02 Date of Manufacture 2023-10-02 UDI# (01)00385480366403(11)231002(17)250402(10)23297085

Cal A L/N	23276090		Cal B L/N	23275037		Cal C L/N	23275038	
	Spec	Pass/Fail		<u>Spec</u>	Pass/Fail		Spec	Pass/Fail
pH @ 37C	7.351 - 7.357	Pass	pH @ 37C	6.822 - 6.828	Pass	Na mmol/L	139.0 - 141.0	Pass
Lac mmol/L	13.5 - 16.5	Pass	Na mmol/L	69.5 - 70.5	Pass	K mmol/L	3.97 - 4.03	Pass
			K mmol/L	9.9 - 10.1	Pass	CI mmol/L	118.0 - 120.0	Pass
			CI mmol/L	39.7 - 40.3	Pass	BUN mg/dl	9.9 - 10.1	Pass
			Ca mmol/L	1.97 - 2.03	Pass	Glu mg/dl	78.8 - 81.2	Pass
			Mg mmol/L	1.48 - 1.52	Pass	Lac mmol/L	1.8 - 2.2	Pass
						Ca mmol/L	0.99 - 1.02	Pass
						Mg mmol/L	0.49 - 0.51	Pass
						HCO3 mmol/L	18.43 - 19.19	Pass
Cal D L/N	23275039		Flush L/N	23277041		Reference L/N	23275027	
	<u>Spec</u>	Pass/Fail		<u>Spec</u>	Result		<u>Spec</u>	Pass/Fail
BUN mg/dl	49.4 - 50.6	Pass	Aqueous Salt	N/A	Present	KCI mol/L	1.8 - 2.2	Pass
Glu mg/dl	197 - 203	Pass	Solution					
Lac mmol/L	5.5 - 6.5	Pass						

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

HCO3 mmol/L 37.05 - 38.57 Pass

Approval

QC Inspector Title

<u>11/29/2023</u> Date