



CERTIFICATE OF ANALYSIS

Stat Profile CCX Calibrator Cartridge 4
Lot Number 23305059

Ref Number 37164
Exp Date 2025-04-11

Date of Manufacture 2023-10-11

UDI# (01)00385480371643(11)231011(17)250411(10)23305059

Cal-A L/N 23285064			
	<u>Spec</u>	<u>Pass/Fail</u>	
pH @ 37C	7.351 - 7.357	Pass	
Lac mmol/L	13.5 - 16.5	Pass	

Cal-B L/N 23284023			
	<u>Spec</u>	<u>Pass/Fail</u>	
pH @ 37C	6.822 - 6.828	Pass	
Na mmol/L	69.5 - 70.5	Pass	
K mmol/L	9.9 - 10.1	Pass	
Cl mmol/L	39.7 - 40.3	Pass	
Ca mmol/L	1.97 - 2.03	Pass	
Mg mmol/L	1.48 - 1.52	Pass	

Cal-C L/N 23284024			
	<u>Spec</u>	<u>Pass/Fail</u>	
Na mmol/L	139.0 - 141.0	Pass	
K mmol/L	3.97 - 4.03	Pass	
Cl mmol/L	118.0 - 120.0	Pass	
Ca mmol/L	0.99 - 1.02	Pass	
Mg mmol/L	0.49 - 0.51	Pass	
Glu mg/dL	78.8 - 81.2	Pass	
Lac mmol/L	1.8 - 2.2	Pass	
BUN mg/dL	9.9 - 10.1	Pass	
HCO3 mmol/L	18.43 - 19.19	Pass	

Cal-D L/N 23284025			
	<u>Spec</u>	<u>Pass/Fail</u>	
Glu mg/dL	197 - 203	Pass	
Lac mmol/L	5.5 - 6.5	Pass	
BUN mg/dL	49.4 - 50.6	Pass	
HCO3 mmol/L	37.1 - 38.57	Pass	

Flush L/N 23286051			
	<u>Spec</u>	<u>Pass/Fail</u>	
Aqueous			
Salt	N/A	Present	
Solution			

Reference L/N 23285065			
	<u>Spec</u>	<u>Pass/Fail</u>	
KCl mol/L	1.8 - 2.2	Pass	

This certifies that this product was manufactured and tested at Nova BiomedCal-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

Awishi-M

Approval

QC Inspector

Title

11/21/2023

Date