



CERTIFICATE OF ANALYSIS

BioProfile FLEX Gas/Electrolyte Cal Cart
Lot Number 23223054

Part Number 39543
Exp Date 2024-11

Cal A L/N 23223054

	<u>Spec</u>	<u>Pass/Fail</u>
pH	7.381 - 7.387	Pass

Cal B L/N 23223054

	<u>Spec</u>	<u>Pass/Fail</u>
pH	6.837 - 6.843	Pass
iCa++ (mM)	1.97 - 2.03	Pass

Cal C L/N 23223054

	<u>Spec</u>	<u>Pass/Fail</u>
HCO3 (mM)	19.6 - 20.4	Pass
NH4+ (mM)	0.99 - 1.01	Pass
Na+ (mM)	139.0 - 141.0	Pass
K+ (mM)	3.97 - 4.03	Pass
iCa++ (mM)	0.99 - 1.02	Pass

Cal D L/N 23223054

	<u>Spec</u>	<u>Pass/Fail</u>
HCO3 (mM)	39.2 - 40.8	Pass
NH4+ (mM)	4.95 - 5.05	Pass
Na+ (mM)	74.5 - 75.5	Pass
K+ (mM)	9.92 - 10.08	Pass

Reference L/N 23223054

	<u>Spec</u>	<u>Pass/Fail</u>
KCl (M)	1.8 - 2.2	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. The following analytes are traceable to NIST SRM Materials: Na, HCO3, pH, KCl, iCa, NH4, K.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Approval

QC Inspector

Title

9/14/2023

Date