



CERTIFICATE OF ANALYSIS

Prime Cal Cartridge ES Comp 400 Sample
Lot Number 23289032

Ref Number 53460
Exp Date 2025-03-29
Date of Manufacture 2023-09-29
UDI# (01)00385480534604(11)230929(17)250329(10)23289032

Cal A L/N 23272028			Cal B L/N 23272029			Reference L/N 23272027		
	<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>
Na mmol/L	134.1 - 135.9	Pass	Na mmol/L	76.5 - 77.5	Pass	KCl mol/L	1.8 - 2.2	Pass
K mmol/L	4.02 - 4.08	Pass	K mmol/L	9.80 - 10.20	Pass			
Cl mmol/L	114.1 - 115.9	Pass	Cl mmol/L	44.6 - 45.5	Pass			
iCa mmol/L	0.99 - 1.01	Pass	iCa mmol/L	1.98 - 2.02	Pass			
iMg mmol/L	0.39 - 0.49	Pass	iMg mmol/L	1.48 - 1.52	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

Approval

QC Inspector
Title

10/19/2023
Date