

CERTIFICATE OF ANALYSIS

Nova 16 Calibrator Pack Lot Number 419447 Ref Number 17289 Exp Date 2025-04-12 Date of Manufacture 2024-07-12 UDI# (01)00385480172899(11)240712(17)250412(10)419447

Cal A L/N	24194047		Cal B L/N	24194047		Cal C L/N	24194047	
	<u>Spec</u>	<u>Result</u>		<u>Spec</u>	<u>Result</u>		<u>Spec</u>	<u>Result</u>
HCO3 mmol/L	19.2 - 20.8	Pass	HCO3 mmol/L	19.6 - 20.8	Pass			
Na mmol/L	139.0 - 141.0	Pass	Na mmol/L	79.2 - 80.8	Pass	HCO3 mmol/L	9.6 - 10.4	Pass
K mmol/L	3.97 - 4.03	Pass	K mmol/L	9.8 - 10.2	Pass			
CI mmol/L	112.1 - 113.9	Pass	Cl mmol/L	57.4 - 58.6	Pass			
Glu mg/dL	78.4 - 81.6	Pass	Glu mg/dL	196 - 204	Pass			
BUN mg/dL	9.7 - 10.3	Pass	BUN mg/dL	49.4 - 50.6	Pass			
Creat mg/dL	0.98 - 1.02	Pass	Creat mg/dL	9.8 - 10.2	Pass			
	Flush L/N	L/N 24194047		Reference L/N		24194047		
		Spec	Result			<u>Spec</u>	Result	
	Aqueous N/A		Present		KCI mol/L	1.8 - 2.2	Pass	
	Salt Solution							

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.

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Approval

QC Inspector Title

<u>9/11/2024</u> Date