nova biomedical

CERTIFICATE OF ANALYSIS

STP Prime Plus Reference Cartridge — Ref Number 57823
Lot Number 25259069 — Exp Date 2027-03-16
Date of Manufacture 2025-09-16
UDI# (01)00385480578233(11)250916(17)270316(10)25259069

Internal QC Level 4	Spec	Pass/Fail
Na, mmol/L	137.2 - 145.2	Pass
K, mmol/L	3.67 - 4.17	Pass
CL, mmol/L	122.5 - 131.5	Pass

External QC Level 4	Spec	Pass/Fail
Na, mmol/L	134.3 - 142.3	Pass
K, mmol/L	3.73 - 4.23	Pass
CL, mmol/L	118.9 - 127.9	Pass

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U. S. A. in accordance with 21 CFR-Part 820, Quality System Regulation (QSR), Current Good Manufacturing Practice (cGMP) and EN ISO 13485:2016, Medical Devices, Quality Management Systems for in Vitro Diagnostic devices, and conforms to the indicated test specifications.

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

Approval

QC Inspector
Title

9/26/2025
Date