nova biomedical

CERTIFICATE OF ANALYSIS

STP Prime Plus Reference Cartridge
Lot Number 25094044

Ref Number 57823
Exp Date 2026-10-04
Date of Manufacture 2025-04-04
UDI# (01)00385480578233(11)250404(17)261004(10)25094044

Internal QC Level 4	Spec	Pass/Fail
Na, mmol/L	135.9 - 143.9	Pass
K, mmol/L	3.63 - 4.13	Pass
CL, mmol/L	121.5 - 130.5	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

4/29/2025
Date