nova biomedical

CERTIFICATE OF ANALYSIS

STP Prime Plus Reference Cartridge
Ref Number 57823
Lot Number 24331078
Exp Date 2026-05-26
Date of Manufacture 2024-11-26
UDI# (01)00385480578233(11)241126(17)260526(10)24331078

Internal QC Level 4	Spec	Pass/Fail
Na, mmol/L	139.3 - 147.3	Pass
K, mmol/L	3.73 - 4.23	Pass
CL, mmol/L	123.4 - 132.4	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

12/10/2024
Date