

## **CERTIFICATE OF ANALYSIS**

STP Prime Plus Reference Cartridge Lot Number 23145042 Ref Number 57823 Exp Date 2024-11-25

Date of Manufacture 2023-05-25

UDI# (01)00385480578233(11)230525(17)241125(10)23145042

Internal QC Level 4	<u>Spec</u>	Pass/Fail
Na, mmol/L	137.7 - 145.7	Pass
K, mmol/L	3.71 - 4.21	Pass
CL, mmol/L	122.8 - 131.8	Pass
External QC Level 4	<u>Spec</u>	Pass/Fail
External QC Level 4 Na, mmol/L	<u>Spec</u> 134.3 - 142.3	Pass/Fail Pass
Na, mmol/L	134.3 - 142.3	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

Lumanu Lehter

Title

6/27/2023 Date