



CERTIFICATE OF ANALYSIS

STP Prime Plus Reference Cartridge
Lot Number 25059062

Ref Number 57823

Exp Date 2026-08-28

Date of Manufacture 2025-02-28

UDI# (01)00385480578233(11)250228(17)260828(10)25059062

| Internal QC Level 4 | <u>Spec</u> | <u>Pass/Fail</u> |
|---------------------|---------------|------------------|
| 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 | <u>Spec</u> | <u>Pass/Fail</u> |
| 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

3/13/2025
Date