



CERTIFICATE OF ANALYSIS

STP Prime Plus Calibrator Cartridge 300 Sample
 Lot Number 25304043

Ref Number 57827
 Exp Date 2027-04-22

Date of Manufacture 2025-10-22

UDI# (01)00385480578271(11)251022(17)270422(10)25304043

| | | | | | |
|-------------|------------------------------|-----------|--------------------------------------|---------------|------------------------------|
| Cal A L/N | 25295036 | Cal B L/N | 25295037 | Cal C L/N | 25295038 |
| | <u>Spec</u> <u>Pass/Fail</u> | | <u>Spec</u> <u>Pass/Fail</u> | | <u>Spec</u> <u>Pass/Fail</u> |
| HCO3 mmol/L | 10.78 - 11.22 Pass | pH | 6.831 - 6.837 Pass | HCO3 mmol/L | 21.56 - 22.44 Pass |
| Na mmol/L | 134.6 - 136.4 Pass | Na mmol/L | 76.5 - 77.5 Pass | Cl mmol/L | 68.4 - 69.6 Pass |
| K mmol/L | 3.97 - 4.03 Pass | K mmol/L | 9.92 - 10.08 Pass | Glu mg/dL | 197 - 203 Pass |
| Cl mmol/L | 107.1 - 108.9 Pass | Ca mmol/L | 1.89 - 1.95 Pass | Lac mmol/L | 9.0 - 11.0 Pass |
| Ca mmol/L | 1.02 - 1.06 Pass | Mg mmol/L | 1.48 - 1.52 Pass | | |
| Mg mmol/L | 0.49 - 0.51 Pass | | | | |
| Glu mg/dL | 78.8 - 81.2 Pass | | | | |
| Lac mmol/L | 1.8 - 2.2 Pass | | | | |
| | | | <u>Assigned Value*</u> <u>Result</u> | | |
| | | tHb g/dL | 15.3 N/A | | |
| Cal D L/N | 25295039 | Flush L/N | 25295010 | Reference L/N | 25295013 |
| | <u>Spec</u> <u>Pass/Fail</u> | | <u>Assigned Value*</u> <u>Result</u> | | <u>Spec</u> <u>Pass/Fail</u> |
| pH @ 37C | 7.351 - 7.357 Pass | PO2 | 105.0 N/A | KCl | 1.8 - 2.2 Pass |

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U.S.A. in accordance with ISO 13485:2016 Medical Devices Quality Management Systems Requirements, Medical Device Single Audit Program (MDSAP), and conforms to the indicated test specifications. All listed analytes are traceable to NIST SRM Materials.

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

Auishi.M

Approval

QC Inspector
 Title

12/8/2025
 Date