



**CERTIFICATE OF ANALYSIS**

Bioprofile FLEX2 Chemistry AutoQC Cartridge  
Lot Number 25240008

Exp Date  
Date of Manufacture

Ref Number 57035  
2027-02-12  
2025-08-12

| Level 1 Lot # | 25224016    |                  | Level 2 Lot # | 25224017      |                  |
|---------------|-------------|------------------|---------------|---------------|------------------|
|               | <u>Spec</u> | <u>Pass/Fail</u> |               | <u>Spec</u>   | <u>Pass/Fail</u> |
| Gln mmol/L    | 0.85 - 1.15 | Pass             | Gln mmol/L    | 4.60 - 5.40   | Pass             |
| Glu mmol/L    | 0.40 - 0.60 | Pass             | Glu mmol/L    | 2.00 - 3.00   | Pass             |
| Gluc g/L      | 0.85 - 1.15 | Pass             | Gluc g/L      | 12.75 - 17.25 | Pass             |
| Lac g/L       | 0.85 - 1.15 | Pass             | Lac g/L       | 4.5 - 5.5     | Pass             |
| NH4 mmol/L    | 0.60 - 1.00 | Pass             | NH4 mmol/L    | 9.25 - 10.75  | Pass             |
| Na mmol/L     | 70.0 - 80.0 | Pass             | Na mmol/L     | 170.0 - 190.0 | Pass             |
| K mmol/L      | 1.95 - 2.15 | Pass             | K mmol/L      | 9.25 - 10.75  | Pass             |
| Ca mmol/L     | 0.55 - 0.70 | Pass             | Ca mmol/L     | 2.80 - 3.80   | 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. The following analytes are traceable to NIST SRM Materials: Gluc, Lac, NH4, Na, K, Ca.

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

Approval

QC Inspector  
Title

10/1/2025  
Date