



## CERTIFICATE OF ANALYSIS

BioProfile FLEX 2 Chemistry Calibrator  
and Reagent Cartridge HV  
Lot Number 25066033

Ref Number 53937  
Exp Date 2026-02-18  
Date of Manufacture 2025-02-18

Chemistry Cal Cartridge L/N: 25066030

Exp Date: 2026-05-18

Cal D1 25049012

Cal D2 25062022

|             | <u>Spec</u>   | <u>Result</u> |
|-------------|---------------|---------------|
| Gln mmol/L  | 0.90 - 1.10   | Pass          |
| Glu mmol/L  | 0.45 - 0.55   | Pass          |
| Gluc g/L    | 0.90 - 1.10   | Pass          |
| Lac g/L     | 0.90 - 1.10   | Pass          |
| NH4 mmol/L  | 1.90 - 1.98   | Pass          |
| Na+ mmol/L  | 139.0 - 143.0 | Pass          |
| K+ mmol/L   | 3.95 - 4.07   | Pass          |
| Ca++ mmol/L | 0.90 - 0.96   | Pass          |

|             | <u>Spec</u>  | <u>Result</u> |
|-------------|--------------|---------------|
| Gln mmol/L  | 4.50 - 5.50  | Pass          |
| Glu mmol/L  | 1.75 - 2.25  | Pass          |
| Gluc g/L    | 4.80 - 5.80  | Pass          |
| Lac g/L     | 2.50 - 3.10  | Pass          |
| NH4 mmol/L  | 9.93 - 10.33 | Pass          |
| Na+ mmol/L  | 65.7 - 67.7  | Pass          |
| K+ mmol/L   | 9.86 - 10.18 | Pass          |
| Ca++ mmol/L | 4.50 - 4.84  | Pass          |

Chemistry Reagent Cartridge L/N: 25066026

Exp Date: 2026-02-18

PF Soln L/N 25057065

R Soln L/N 25049011

|    | <u>Spec</u> | <u>Result</u> |
|----|-------------|---------------|
| pH | 6.85 - 7.05 | Pass          |

  

|         | <u>Spec</u> | <u>Pass/Fail</u> |
|---------|-------------|------------------|
| NaOCl % | 0.43 - 0.73 | Pass             |

|           | <u>Spec</u> | <u>Pass/Fail</u> |
|-----------|-------------|------------------|
| KCl mol/L | 1.8 - 2.2   | Pass             |

  

|    | <u>Spec</u> | <u>Pass/Fail</u> |
|----|-------------|------------------|
| pH | 6.90 - 7.10 | 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: pH.

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

*Awishi M*

Approval

QC Inspector  
Title

3/13/2025  
Date