

BioProfile FLEX 2 Chemistry Calibrator and Reagent Cartridge HV Lot Number 24361025 Ref Number 53937 Exp Date 2025-12-05 Date of Manufacture 2024-12-05

Chemistry Cal Cartridge L/N: 24359042 Exp Date: 2026-03-04

| Cal D1 24339022 |               |               |             | Cal D2 24346036 |        |  |
|-----------------|---------------|---------------|-------------|-----------------|--------|--|
|                 | <u>Spec</u>   | <u>Result</u> |             | <u>Spec</u>     | Result |  |
| Gln mmol/L      | 0.90 - 1.10   | Pass          | Gln mmol/L  | 4.50 - 5.50     | Pass   |  |
| Glu mmol/L      | 0.45 - 0.55   | Pass          | Glu mmol/L  | 1.75 - 2.25     | Pass   |  |
| Gluc g/L        | 0.90 - 1.10   | Pass          | Gluc g/L    | 4.80 - 5.80     | Pass   |  |
| Lac g/L         | 0.90 - 1.10   | Pass          | Lac g/L     | 2.50 - 3.10     | Pass   |  |
| NH4 mmol/L      | 1.90 - 1.98   | Pass          | NH4 mmol/L  | 9.93 - 10.33    | Pass   |  |
| Na+ mmol/L      | 139.0 - 143.0 | Pass          | Na+ mmol/L  | 65.7 - 67.7     | Pass   |  |
| K+ mmol/L       | 3.95 - 4.07   | Pass          | K+ mmol/L   | 9.86 - 10.18    | Pass   |  |
| Ca++ mmol/L     | 0.90 - 0.96   | Pass          | Ca++ mmol/L | 4.50 - 4.84     | Pass   |  |

Chemistry Reagent Cartridge L/N: 24358096 Exp Date: 2025-12-05

PF Soln L/N 24341054 R Soln L/N 24339032

 Spec
 Result
 Spec
 Pass/Fail

 pH
 6.85 - 7.05
 Pass
 KCI mol/L
 1.8 - 2.2
 Pass

DP Soln L/N 24340033 DF Soln L/N 24339034

 Spec
 Pass/Fail
 Spec
 Pass/Fail

 NaOCI %
 0.43 - 0.73
 Pass
 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

Auishi.M

Approval

QC Inspector Title

1/8/2025 Date