



# CERTIFICATE OF ANALYSIS

BioProfile FLEX 2 Chemistry Calibrator  
and Reagent Cartridge LV

Ref Number 58003

Lot Number 18337010

Exp Date 2019-10-11  
Date of Manufacture 2018-10-11

| Chemistry Cal Cartridge L/N: 18330074 |             |        | Exp Date: 2020-01-11 |            |        |
|---------------------------------------|-------------|--------|----------------------|------------|--------|
| Cal D1                                | 18284004    |        | Cal D2               | 18285022   |        |
|                                       | Spec        | Result |                      | Spec       | 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: 18325042 |           |           | Exp Date: 2019-10-11 |           |           |
|-------------------------------------------|-----------|-----------|----------------------|-----------|-----------|
| DF Soln L/N                               | 18291082  |           | PF Soln L/N          | 18333008  |           |
|                                           | Spec      | Pass/Fail |                      | Spec      | Result    |
| pH                                        | 6.90-7.10 | Pass      | pH                   | 6.85-7.05 | Pass      |
|                                           |           |           | R Soln L/N           | 18274033  |           |
| DP Soln L/N                               | 18284013  |           |                      | Spec      | Pass/Fail |
|                                           | Spec      | Pass/Fail | KCl mol/L            | 1.8-2.2   | Pass      |
| NaOCl %                                   | 0.43-0.73 | Pass      |                      |           |           |

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U. S. A. in accordance with ISO 9001:2008, Quality Management System Requirements and current Good Manufacturing Practices (cGMP) , and conforms to the indicated test specifications. The following analytes are traceable to NIST SRM Materials: pH.

*Alisha Moquewin*

Approval

QC Inspector  
Title

12/5/2018  
Date