

BioProfile FLEX 2 Chemistry Calibrator and Reagent Cartridge HV Lot Number 24113115 Ref Number 53937 Exp Date 2025-04-09 Date of Manufacture 2024-04-09

Chemistry Cal Cartridge L/N: 24113112 Exp Date: 2025-07-11

Cal D1 24102011 Cal D2 24108001 Spec Result Spec Result Gln mmol/L 0.90 - 1.10**Pass** GIn 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 - 1.10Pass 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** 9.86 - 10.18 K+ mmol/L 3.95 - 4.07Pass K+ mmol/L Pass 0.90 - 0.96 4.50 - 4.84 Ca++ mmol/L Pass Ca++ mmol/L **Pass**

Chemistry Reagent Cartridge L/N: 24113108 Exp Date: 2025-04-09

PF Soln L/N 24106056 R Soln L/N 24101014

 Spec
 Result
 Spec
 Pass/Fail

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

DP Soln L/N 24100101 DF Soln L/N 24101013

 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

Approval

QC Inspector

Haneen Aldarwish

Title

5/6/2024 Date