



CERTIFICATE OF ANALYSIS

BioProfile FLEX 2 Chemistry Calibrator
and Reagent Cartridge LV
Lot Number 25287065

Ref Number 58003
Exp Date 2026-08-22
Date of Manufacture 2025-08-22

Chemistry Cal Cartridge L/N: 25287062 Exp Date: 2026-11-26

Cal D1 25238037

Cal D2 25238038

Table with 3 columns: Analyte, Spec, Result. Rows include Gln mmol/L, Glu mmol/L, Gluc g/L, Lac g/L, NH4 mmol/L, Na+ mmol/L, K+ mmol/L, Ca++ mmol/L.

Table with 3 columns: Analyte, Spec, Result. Rows include Gln mmol/L, Glu mmol/L, Gluc g/L, Lac g/L, NH4 mmol/L, Na+ mmol/L, K+ mmol/L, Ca++ mmol/L.

Chemistry Reagent Cartridge L/N: 25287059 Exp Date: 2026-08-22

PF Soln L/N 25238042

R Soln L/N 25237014

Table with 3 columns: Analyte, Spec, Result. Row includes pH 6.85 - 7.05 Pass.

Table with 3 columns: Analyte, Spec, Pass/Fail. Row includes KCl mol/L 1.8 - 2.2 Pass.

DP Soln L/N 25234029

DF Soln L/N 25238039

Table with 3 columns: Analyte, Spec, Pass/Fail. Row includes NaOCl % 0.43 - 0.73 Pass.

Table with 3 columns: Analyte, Spec, Pass/Fail. Row includes 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

Handwritten signature of P. Hernandez

Approval

QC Inspector

Title

10/20/2025

Date