



CERTIFICATE OF ANALYSIS

BioProfile FLEX 2 Chemistry Calibrator
and Reagent Cartridge LV
Lot Number 25344050

Ref Number 58003
Exp Date 2026-11-20
Date of Manufacture 2025-11-20

Chemistry Cal Cartridge L/N: 25344046 Exp Date: 2027-02-18

Cal D1 25322006

Cal D2 25324010

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.

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Chemistry Reagent Cartridge L/N: 25344043 Exp Date: 2026-11-20

PF Soln L/N 25328011

R Soln L/N 25324011

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

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

DP Soln L/N 25324009

DF Soln L/N 25325012

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

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

1/27/2026

Date