



CERTIFICATE OF ANALYSIS

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

Table with 6 columns: Analyte, Spec, Result, 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: 24358096 Exp Date: 2025-12-05

PF Soln L/N 24341054

R Soln L/N 24339032

Table with 6 columns: Analyte, Spec, Result, Analyte, Spec, Pass/Fail. Rows include pH, NaOCl %, KCl mol/L, pH.

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

1/8/2025

Date