



CERTIFICATE OF ANALYSIS

BioProfile FLEX 2 Chemistry Calibrator
and Reagent Cartridge HV
Lot Number 24361026

Ref Number 53937
Exp Date 2025-12-05
Date of Manufacture 2024-12-05

Chemistry Cal Cartridge L/N: 24359044 Exp Date: 2026-03-04

Cal D1 24339022

Cal D2 24352023

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 for both Cal D1 and Cal D2.

Chemistry Reagent Cartridge L/N: 24358097 Exp Date: 2025-12-05

PF Soln L/N 24341054

R Soln L/N 24339032

Table with 3 columns: Analyte, Spec, Result/Pass/Fail. Rows include pH for PF Soln and KCl mol/L for R Soln.

DP Soln L/N 24340033

DF Soln L/N 24339033

Table with 3 columns: Analyte, Spec, Result/Pass/Fail. Row includes NaOCl % for DP Soln and pH for DF Soln.

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 and the word 'Approval' below it.

QC Inspector
Title

12/31/2024
Date