



CERTIFICATE OF ANALYSIS

BioProfile FLEX 2 Chemistry Calibrator
and Reagent Cartridge HV
Lot Number 24242070

Ref Number 53937
Exp Date 2025-07-30
Date of Manufacture 2024-07-30

Chemistry Cal Cartridge L/N: 24242067 Exp Date: 2025-10-31

Cal D1 24213070

Cal D2 24213071

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: 24242064 Exp Date: 2025-07-30

PF Soln L/N 24215012

R Soln L/N 24211047

Table with 3 columns: Analyte, Spec, Result/Pass/Fail. Rows include pH, NaOCl %.

Table with 3 columns: Analyte, Spec, Result/Pass/Fail. Rows include 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

Approval

QC Inspector
Title

9/12/2024
Date