



CERTIFICATE OF ANALYSIS

BioProfile FLEX 2 Chemistry Calibrator
and Reagent Cartridge HV
Lot Number 24296027

Ref Number 53937
Exp Date 2025-09-26
Date of Manufacture 2024-09-26

Chemistry Cal Cartridge L/N: 24290080

Exp Date: 2025-12-25

Cal D1 24269033

Cal D2 24277048

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: 24290076

Exp Date: 2025-09-26

PF Soln L/N 24270093

R Soln L/N 24268022

Table with 3 columns: Analyte, Spec, Result. Row includes pH.

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

DP Soln L/N 24270057

DF Soln L/N 24268023

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

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

Handwritten signature

Approval

QC Inspector
Title

10/23/2024
Date