



CERTIFICATE OF ANALYSIS

BioProfile FLEX 2 Chemistry Calibrator
and Reagent Cartridge HV
Lot Number 24171031

Ref Number 53937
Exp Date 2025-06-10
Date of Manufacture 2024-06-10

Chemistry Cal Cartridge L/N: 24171028 Exp Date: 2025-09-11

Cal D1 24163025

Cal D2 24166032

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: 24171024 Exp Date: 2025-06-10

PF Soln L/N 24163072

R Soln L/N 24162034

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 24162035

DF Soln L/N 24163073

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

Awishi M

Approval

QC Inspector

Title

6/27/2024

Date