



CERTIFICATE OF ANALYSIS

BioProfile FLEX 2 Chemistry Calibrator
and Reagent Cartridge HV
Lot Number 24192026

Ref Number 53937
Exp Date 2025-06-24
Date of Manufacture 2024-06-24

Chemistry Cal Cartridge L/N: 24192022 Exp Date: 2025-09-27

Cal D1 24179007

Cal D2 24183031

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: 24192019 Exp Date: 2025-06-24

PF Soln L/N 24190043

R Soln L/N 24176053

Table with 3 columns: Analyte, Spec, Result. Row: pH 6.85 - 7.05 Pass

Table with 3 columns: Analyte, Spec, Pass/Fail. Row: KCl mol/L 1.8 - 2.2 Pass

DP Soln L/N 24176054

DF Soln L/N 24180014

Table with 3 columns: Analyte, Spec, Pass/Fail. Row: NaOCl % 0.43 - 0.73 Pass

Table with 3 columns: Analyte, Spec, Pass/Fail. Row: pH 6.90 - 7.10 Pass

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

Haneen Aldarwish

Approval

QC Inspector

Title

7/19/2024

Date