



CERTIFICATE OF ANALYSIS

BioProfile FLEX 2 Chemistry Calibrator
and Reagent Cartridge HV
Lot Number 25183043

Ref Number 53937
Exp Date 2026-05-27
Date of Manufacture 2025-05-27

Table with 2 main columns for Cal D1 (25149009) and Cal D2 (25149010). Each column has sub-headers for Spec and Result, listing various analytes like Gln, Glu, Gluc, Lac, NH4, Na+, K+, and Ca++ with their respective ranges and Pass/Fail status.

Table with 2 main columns for Chemistry Reagent Cartridge L/N: 25183036. Sub-headers include PF Soln L/N (25148091), DP Soln L/N (25147055), R Soln L/N (25147056), and DF Soln L/N (25149011). Analytes include pH and NaOCl % with their respective specifications and Pass/Fail results.

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

7/11/2025
Date