



CERTIFICATE OF ANALYSIS

BioProfile FLEX 2 Chemistry Calibrator
and Reagent Cartridge LV
Lot Number 25204008

Ref Number 58003
Exp Date 2026-07-07
Date of Manufacture 2025-07-07

Table with 2 main columns for Cal D1 (25189008) and Cal D2 (25198010). Each column has sub-headers for Spec and Result, and lists 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: 25204001. Each column has sub-headers for Spec/Result or Spec/Pass/Fail, and lists reagent solutions like PF Soln, R Soln, DP Soln, and DF Soln with their respective parameters and Pass/Fail status.

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

8/22/2025
Date