



CERTIFICATE OF ANALYSIS

Bioprofile FLEX 2 pH/Gas Cal Cartridge HV
Lot Number 23334027

Part Number 54507
Exp Date 2025-05-01
Date of Manufacture 2023-11-01

Cal A L/N	23314015	
	<u>Assigned Value*</u>	<u>Result</u>
pH	7.355	N/A
pCO2 mmHg	25.0	N/A

Cal B L/N	23313079	
	<u>Spec</u>	<u>Result</u>
pH	6.837 - 6.843	Pass

Cal F L/N	23305085	
	<u>Assigned Value*</u>	<u>Result</u>
pCO2 mmHg	50.1	N/A
pO2 mmHg	98.2	N/A

Soln R L/N	23314016	
	<u>Spec</u>	<u>Result</u>
KCl mol/L	1.8 - 2.2	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: The "Assigned Values" are not to be considered specifications. They are used by the instrument for slope determination. The process of assigning these values at Nova Biomedical utilizes multiple sources of test data inputs as stipulated per the applicable procedures and therefore can result in changes from lot to lot.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Haneen Aldarwish

Approval

QC Inspector
Title

1/8/2024
Date