

Assay Data Sheet – Expected Ranges

BioProfile® FLEX2™ pH/Gas Auto QC Cartridge

Lot No. 25038026

Exp. Date 2026-08-03

| Level 1 | | | |
|------------------|-------------------------|-------|----------------|
| Constituent | Units | Mean | Expected Range |
| pH | | 6.684 | 6.634 - 6.734 |
| PO ₂ | mmHg | 61.7 | 54.1 - 69.3 |
| PO ₂ | kPa | 8.2 | 7.2 - 9.2 |
| PCO ₂ | mmHg | 68.5 | 61.7 - 75.3 |
| PCO ₂ | kPa | 9.1 | 8.2 - 10.0 |
| Osmolality | mOsm/kgH ₂ O | 201 | 196 - 206 |

| Level 2 | | | |
|------------------|-------------------------|-------|----------------|
| Constituent | Units | Mean | Expected Range |
| pH | | 7.323 | 7.273 - 7.373 |
| PO ₂ | mmHg | 149.7 | 134.1 - 165.3 |
| PO ₂ | kPa | 19.9 | 17.8 - 22.0 |
| PCO ₂ | mmHg | 19.3 | 16.1 - 22.5 |
| PCO ₂ | kPa | 2.6 | 2.1 - 3.0 |
| Osmolality | mOsm/kgH ₂ O | 609 | 601 - 617 |

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BioProfile® FLEX2™ pH/Gas Auto QC Cartridge

Product Information

NOVA BIOPROFILE FLEX2 pH/Gas CONTROLS — An assayed aqueous quality control material intended for monitoring the measurement of pH, PO_2 , PCO_2 , and Osmolality on Nova Biomedical analyzers ONLY. The Nova controls are formulated at 2 levels.

Level 1 – Acidosis, low osmolality

Level 2 – Alkalosis, high osmolality

Ingredients: BioProfile FLEX2 pH/Gas Controls contain no constituents of human origin, however, good laboratory practice should be followed during handling of these materials. (REF. NCCLS DOCUMENT M29-T2.) These controls are formulated from a buffered bicarbonate solution, each with a known pH. The solutions are equilibrated with known levels of oxygen, carbon dioxide and nitrogen. Mold Inhibited.

Storage: Controls should be refrigerated at 2 - 8°C (37 - 48°F). Do not freeze the product. It is critical to follow the room temperature equilibration instructions prior to use as described in "Directions for Use." Each control cartridge has a lot number and expiration date printed on the label.

Directions for Use: BIOPROFILE Auto QC CARTRIDGE are intended for *in vitro* Diagnostic Use. Controls must be stored at approximately 25°C (77°F) for at least 24 hours before opening. The Auto QC Cartridge pack should be mixed by gently inverting the pack for several seconds.

Assigned Values: The EXPECTED RANGE for each analyte was determined at Nova by performing multiple determinations at 37°C (98.6°F) on multiple instruments using multiple runs of each level of control. The EXPECTED RANGE indicates the maximum deviations from the mean value which may be expected under differing laboratory conditions from instruments which are operating according to specifications. Users may wish to determine MEAN VALUES and EXPECTED RANGES in their own laboratory. Please verify that the lot number appearing on the Assay Data Sheet agrees with the lot number appearing on the control material being analyzed.

Limitations: The values appearing in the Assay Data Table are specific for instruments and reagents manufactured by Nova Biomedical.

Once installed, each BioProfile FLEX2 pH/Gas Auto QC Cartridge Pack may be used for a maximum of 35 days from the date of initial installation on the system at which time the system will indicate that the Cartridge is Invalid.

Each BioProfile FLEX2 pH/Gas Auto QC Cartridge Pack may be inserted and removed from the BioProfile FLEX2 Analyzer a maximum of 6 times.

BioProfile FLEX2 pH/Gas Auto QC Cartridge packs contain 2 levels. **Catalog No. 56073.**

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