

Assay Data Sheet — Expected Ranges

BioProfile™ pHox® Auto-Cartridge QC

Lot. No. 811011

Exp. Date 2010-05

Level 1			
Constituent	Units	Mean	Expected Range
pH		6.708	6.658 - 6.758
H ⁺	nmol/L	195.88	219.79 - 174.58
pCO ₂	mmHg	63.5	56.7 - 70.3
pCO ₂	kPa	8.45	7.54 - 9.35
pO ₂	mmHg	64.2	58.0 - 70.4
pO ₂	kPa	8.54	7.71 - 9.36
Level 2			
Constituent	Units	Mean	Expected Range
pH		6.937	6.887 - 6.987
H ⁺	nmol/L	115.61	129.72 - 103.04
pCO ₂	mmHg	40.6	36.2 - 45.0
pCO ₂	kPa	5.40	4.81 - 5.99
pO ₂	mmHg	99.9	89.9 - 109.9
pO ₂	kPa	13.29	11.96 - 14.62
Level 3			
Constituent	Units	Mean	Expected Range
pH		7.293	7.243 - 7.343
H ⁺	nmol/L	50.93	57.15 - 45.39
pCO ₂	mmHg	19.4	15.0 - 23.8
pCO ₂	kPa	2.58	2.00 - 3.17
pO ₂	mmHg	138.3	128.3 - 148.3
pO ₂	kPa	18.39	17.06 - 19.72

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LPN 42752A

BioProfile™ pHox® Auto-Cartridge QC

Product Information

NOVA BIOPROFILE pHox CONTROLS — An assayed aqueous quality control material intended for monitoring the measurement of pH, PCO₂, and PO₂ on Nova Biomedical analyzers ONLY. The Nova controls are formulated at three clinically significant levels.

Level 1 — *Acidosis*

Level 2 — *Normal pH*

Level 3 — *Alkalosis*

Ingredients: BioProfile pHox 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°C - 8°C. 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 CARTRIDGE CONTROLS are intended for In Vitro Diagnostic Use. Controls must be stored at approximately 25°C for at least 24 hours before opening. The Auto-Cartridge QC 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 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 pHox Auto-Cartridge QC 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 pHox Auto-Cartridge QC Pack may be inserted and removed from the BioProfile pHox analyzer a maximum of six times.

BioProfile pHox Auto-Cartridge QC packs contain three levels:

3 Plus Pack, 330 QC's/Pack

Catalog No. 42751

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