Assay Data Sheet — Expected Ranges BioProfile™ pHOx® Auto-Cartridge QC

Lot. No. 24355041 Exp. Date 2026-06

ituent Units Mean 6.740 nmol/L nmmHg 59.0 mmHg 59.0 kPa 7.85 mmHg 66.3 kPa 8.82 el 2 Units Mean ituent Units Mean kPa 109.24 mmHg 5.19 mmHg 107.4 kPa kPa 14.28 el 3 Units Mean ituent Units Mean kPa 7.325 nmol/L nmol/L kPa 18.6	135.2 - 155.2	2:4 <i>i</i> 145.2 19.31	mmHg kPa	pO ₂
lituent Units Mean nmol/L 182.10 nmol/L 59.0 mmHg 59.0 kPa 7.85 mmHg 66.3 kPa 8.82 lituent Units Mean kPa 109.24 mmHg 39.0 kPa 107.4 kPa 14.28 lituent Wean lituent Mean mmHg 14.28 lituent Mean	53.13 - 42.20 14.2 - 23.0 1.89 - 3.06	47.35 18.6 2.47	nmol/L mmHg kPa	pCO ₂
ittuent Units Mean 6.740 nmol/L 182.10 mmHg 59.0 KPa 7.85 mmHg 66.3 KPa 8.82 ittuent Units Mean ittuent Units Mean before the following the mol/L 109.24 mmHg 39.0 kPa 5.19 mmHg 107.4 kPa 14.28	Expected Range 7.275 - 7.375	Mean 7.325	Units	Level 3 Constituent pH
ittuent Units Mean 6.740 6.740 nmol/L 182.10 mmHg 59.0 kPa 7.85 mmHg 66.3 kPa 8.82 el 2 Units ituent Mean mmHg 6.962 nmol/L 109.24 mmHg 39.0 kPa 5.19 mmHg 107.4	12.95 - 15.61	14.28	kPa	pO ₂
ittuent Units Mean 6.740 nmol/L 182.10 mmHg 59.0 kPa 7.85 mmHg 66.3 kPa 8.82 lituent Units Mean 6.962 nmol/L 109.24 mmHg 39.0	4.60 - 5.77 97.4 - 117.4	5. 19 107.4	kPa mmHg	pCO ₂
nstituent Units Mean 6.740 nmol/L 02 mmHg 59.0 03 KPa 7.85 mmHg 66.3 kPa 8.82 pvel 2 Units Mean	122.57 - 97.36 34.6 - 43.4	109.24 39.0	nmol/L mmHg	PCO ₂
nstituent Units Mean 6.740 nmol/L 182.10 O ₂ mmHg 59.0 O ₂ kPa 7.85 mmHg 66.3 kPa 8.82 yvel 2 Units Mean	6.912 - 7.012	6.962		рН
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Instituent Units Mean 6.740 6.740 nmol/L 182.10 O ₂ mmHg 59.0 KPa 7.85		66.3	mmHg	po ₂
Instituent Units Mean 6.740 6.740 nmol/L 182.10 O, mmHg 59.0		7.85	kPa	pCO ₂
nstituent Units Mean 6.740 nmol/ 182 10	Į	59.0	mmHg	pCO,
Units Mean	6.690 - 6.790	6.740 182 10	nmol/I	PH H
	Expected Range	Mean	Units	Constituent

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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

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 Bio-Profile 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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