

BLOOD GAS CONTROL - LEVEL I (BG CONTROL I)

CAT. NO.	BG5001	LOT NO.	269BG
SIZE	30 x 1.8 ml	EXPIRY:	2025-01-28
GTIN:	05055273227109		

INTENDED USE

This product is intended for in vitro diagnostic use, in the quality control of Blood Gas analysis.

DEVICE DESCRIPTION

The Blood Gas Controls are supplied at 3 levels, 1, 2 and 3. Target values and ranges are supplied for the following analytes: Calcium, Chloride, Glucose, Lactate, PCO₂, pH, pO₂, Potassium, Sodium and Total CO₂.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents. Health and Safety Data Sheets are available on request.

Not suitable for instruments that do not recommend products with artificial dye.

STORAGE AND STABILITY

UNOPENED: The product is stable to expiration date when stored at +2°C to +8°C. Avoid exposure to freezing and temperatures greater than +30°C.

OPENED: For pH/blood gas values, the control should be analysed within 1 minute of opening. For electrolyte measurements, the control should be analysed within 1 hour after opening.

PREPARATION FOR USE

The Blood Gas Control should be brought to +20°C to +23°C before use. Allow at least 4 hours for ampoules to equilibrate to this temperature, prior to testing. Before use, hold the ampoule at the top and bottom (with forefinger and thumb) and shake 15 - 20 times to mix the solution. Tap the ampoule to restore the liquid to the bottom of the ampoule. Open the ampoule by snapping off the tip at the score. Use gauze, tissue, gloves or an appropriate ampoule opener to protect fingers from cuts. Immediately introduce the liquid from the ampoule to the analyser.

MATERIALS PROVIDED

Blood Gas Control - Level I 30 x 1.8 ml

ASSIGNED VALUES

Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

Each batch of Blood Gas Control is submitted to a number of external laboratories and values are assigned from a consensus of results obtained by these laboratories.

EC	REP	Radox Teoranta, Meenmore, Dungloe, Donegal, F94 TV06, Ireland
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BLOOD GAS CONTROL - LEVEL 1 (BG CONTROL 1)

Cat. No. BG5001 Lot. No. 269BG Size 30 x 1.8ml Expiry 2025-01-28

Analyte	unit	Target	Range		methods
			low	high	
Calcium	mmol/l	1.85	1.67	2.04	Ion selective electrode
	mg/dl	7.41	6.69	8.13	
	mmol/l	1.90	1.71	2.09	Colorimetric
	mg/dl	7.62	6.85	8.39	
Chloride	mmol/l	75.5	71.7	79.3	Colorimetric
	mmol/l	73.9	70.2	77.6	ISE indirect
Glucose	mmol/l	2.10	1.79	2.42	Hexokinase
	mg/dl	37.8	32.3	43.3	
	mmol/l	2.08	1.77	2.39	Enzymatic Electrode
	mg/dl	37.5	31.9	43.1	
	mmol/l	2.07	1.76	2.38	Glucose oxidase
	mg/dl	37.3	31.7	42.9	
	mmol/l	1.99	1.69	2.29	Colorimetric
	mg/dl	35.9	30.5	41.3	
Lactate	mmol/l	6.99	5.73	8.25	Enzymatic Electrode
	mg/dl	63.0	51.6	74.4	
	mmol/l	6.85	5.62	8.08	Optical Fluorescence
	mg/dl	61.7	50.6	72.8	
	mmol/l	6.53	5.35	7.71	Colorimetric
	mg/dl	58.8	48.2	69.4	
pCO ₂	kPa	10.0	8.00	12.0	Ion selective electrode
	kPa	10.3	8.24	12.4	Optical Fluorescence
pH	pH units	7.099	7.001	7.197	Ion selective electrode
	pH units	7.097	7.063	7.131	Optical Fluorescence
pO ₂	kPa	15.2	11.4	19.0	Ion selective electrode
	kPa	14.2	10.3	18.1	Optical Fluorescence
Potassium	mmol/l	2.44	2.32	2.56	ISE method - direct
Sodium	mmol/l	117	111	123	ISE method - direct
Total CO ₂	mmol/l	25.0	20.0	30.0	Ion selective electrode
	mmol/l	25.3	20.2	30.4	Calculated
	mmol/l	26.3	21.0	31.6	Optical Fluorescence
	mmol/l	25.5	20.4	30.6	Spectrophotometric