

BLOOD GAS CONTROL - LEVEL I (BG CONTROL I)

CAT. NO.	BG5001	LOT NO.	305BG
SIZE:	30 x 1.8 ml	EXPIRY:	2027-02-28
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.

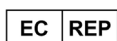
MATERIALS PROVIDED

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.



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Table of Content

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Method		Blood Gas Control - Level 1 (BG CONTROL 1)					
Lot. No: 305BG Cat. No: BG5001 Expiry: 2027/02/28							
Size: 30 x 1.8 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Calcium	mg/dl	6.73	6.06	7.40	0.335	0.670	Calculated
	mmol/l	1.68	1.51	1.85	0.085	0.170	
	mg/dl	6.81	6.13	7.49	0.340	0.680	Ion Selective Electrode
	mmol/l	1.70	1.53	1.87	0.085	0.170	
Chloride	mmol/l	73.6	67.7	79.5	2.95	5.90	ISE Indirect
Glucose	mg/dl	34.1	29.0	39.2	2.55	5.10	Colorimetric
	mmol/l	1.89	1.61	2.17	0.140	0.280	
	mg/dl	34.4	29.2	39.6	2.60	5.20	Enzymatic Electrode
	mmol/l	1.91	1.62	2.20	0.145	0.290	
	mg/dl	34.1	29.0	39.2	2.55	5.10	Glucose Oxidase
	mmol/l	1.89	1.61	2.17	0.140	0.280	
Lactate	mg/dl	65.5	53.7	77.3	5.90	11.8	Colorimetric
	mmol/l	7.27	5.96	8.58	0.655	1.31	
	mg/dl	71.4	58.5	84.3	6.45	12.9	Enzymatic Electrode
	mmol/l	7.93	6.50	9.36	0.715	1.43	
	mg/dl	65.8	54.0	77.6	5.90	11.8	Optical Fluorescence
	mmol/l	7.30	5.99	8.61	0.655	1.31	
pCO2	kPa	9.42	7.54	11.3	0.940	1.88	Ion Selective Electrode
	kPa	9.37	7.50	11.2	0.915	1.83	Optical Fluorescence
pH	pH units	7.12	7.05	7.19	0.035	0.070	Ion Selective Electrode
	pH units	7.13	7.06	7.20	0.035	0.070	Optical Fluorescence
Potassium	mmol/l	2.50	2.30	2.70	0.100	0.200	Enzymatic
	mmol/l	2.44	2.24	2.64	0.100	0.200	Ion Selective Electrode Method
Sodium	mmol/l	117	111	123	3.00	6.00	Ion Selective Electrode Method
	mmol/l	122	116	128	3.00	6.00	Optical Fluorescence
Total CO2	mmol/l	24.4	19.5	29.3	2.45	4.90	Calculated
	mmol/l	24.5	19.6	29.4	2.45	4.90	Ion Selective Electrode