

BLOOD GAS CONTROL - LEVEL I (BG CONTROL I)

CAT. NO.	BG5001	LOT NO.	186BG
SIZE:	30 x 1.8 ml	EXPIRY:	2019-09-28

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, PCO_2 , pH, pO_2 , Potassium, Sodium and Total CO_2 .

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.

STORAGE AND STABILITY

UNOPENED: The product is stable to expiration date when stored at $+2^{\circ}$ C to $+8^{\circ}$ C. Avoid exposure to freezing and temperatures greater than $+30^{\circ}$ 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 $+20^{\circ}$ C to $+23^{\circ}$ 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

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.

(s): 19 Oct 18 bm

RANDOX

Blood Gas Control LEVEL 1 (BG CONTROL 1)

Cat. No. BG5001 Lot. No. 186BG Size 30 x 1.8ml Expiry 2019-09-28						
Range						
Analyte	unit	Target	low	high	methods	
Calcium	mmol/l	1.85	1.67	2.04	Ion selective electrode	
	mg/dl	7.41	6.69	8.13		
Chloride	mmol/l	79.2	72.9	85.5	ISE indirect	
Glucose	mmol/l	2.07	1.76	2.38	Enzymatic Electrode	
	mg/dl	37.3	31.7	42.9		
	mmol/l	2.03	1.73	2.33	Glucose oxidase	
	mg/dl	36.6	31.2	42.0		
	mmol/l	2.06	1.75	2.37	Ion selective electrode	
	mg/dl	37.1	31.5	42.7		
Lactate	mmol/l	7.35	6.03	8.67	Enzymatic Electrode	
	mg/dl	66.2	54.3	78.1		
	mmol/l	7.45	6.11	8.79	Ion selective electrode	
	mg/dl	67.1	55.1	79.1		
	mmol/l	7.73	6.34	9.12	Colorimetric	
	mg/dl	69.6	57.1	82.1		
pCO2	kPa	11.0	8.80	13.2	Ion selective electrode	
	kPa	10.6	8.48	12.7	Optical Fluorescence	
рН	pH units	7.090	7.079	7.101	Ion selective electrode	
	pH units	7.071	7.067	7.075	Optical Fluorescence	
pO2	kPa	12.8	10.9	14.7	Ion selective electrode	
	kPa	10.0	8.50	11.5	Optical Fluorescence	
Potassium	mmol/l	2.50	2.30	2.70	ISE method - direct	
Sodium	mmol/l	121	115	127	ISE method - direct	
Total CO2	mmol/l	26.5	21.2	31.8	Ion selective electrode	
	mmol/l	26.4	21.1	31.7	Calculated	