BLOOD GAS CONTROL - LEVEL 3 (BG CONTROL 3)

CAT. NO.	BG5003	**LOT NO.**	295BG
SIZE:	30 x 1.8 ml	**EXPIRY:**	2025-07-28
GTIN:	05055273227123		

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.

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 3 30 x 1.8 ml

ASIGNED 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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RANDOX

Table of Content

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RANDOX

Method

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Lot. No: 295BG Cat. No: BG5003 Expiry: 2025-07-28

Size: 30 x 1.8 ml

			Range				
Analyte	**Unit**	**Target**	**Low**	**High**	**1SD**	**2SD**	**Method**
Calcium	mmol/l	0.672	0.605	0.739	0.034	0.067	Colorimetric
	mg/dl	2.69	2.42	2.96	0.135	0.270	
	mmol/l	0.698	0.628	0.768	0.035	0.070	Ion Selective Electrode
	mg/dl	2.80	2.52	3.08	0.140	0.280	
Chloride	mmol/l	123	113	133	5.00	10.0	Colorimetric
	mmol/l	120	110	130	5.00	10.0	ISE, indirect
Glucose	mmol/l	14.6	12.4	16.8	1.10	2.20	Colorimetric
	mg/dl	263	224	302	19.5	39.0	
	mmol/l	14.7	12.5	16.9	1.10	2.20	Enzymatic Electrode
	mg/dl	265	225	305	20.0	40.0	
	mmol/l	14.6	12.4	16.8	1.10	2.20	Glucose oxidase
	mg/dl	263	224	302	19.5	39.0	
	mmol/l	14.4	12.2	16.6	1.10	2.20	Hexokinase
	mg/dl	259	220	298	19.5	39.0	
Lactate	mmol/l	0.981	0.804	1.16	0.090	0.179	Colorimetric
	mg/dl	8.84	7.25	10.4	0.780	1.56	
	mmol/l	1.04	0.853	1.23	0.095	0.190	Enzymatic Electrode
	mg/dl	9.37	7.68	11.1	0.865	1.73	
	mmol/l	1.01	0.828	1.19	0.090	0.180	Optical Fluorescence
	mg/dl	9.10	7.46	10.7	0.800	1.60	
pCO2	kPa	2.86	2.29	3.43	0.285	0.570	Ion Selective Electrode
	kPa	2.80	2.24	3.36	0.280	0.560	Optical Fluorescence
pH	pH units	7.58	7.50	7.66	0.040	0.080	Ion Selective Electrode
	pH units	7.59	7.51	7.67	0.040	0.080	Optical Fluorescence
pO2	kPa	20.4	17.3	23.5	1.55	3.10	Ion Selective Electrode
	kPa	20.6	17.5	23.7	1.55	3.10	Optical Fluorescence
Potassium	mmol/l	6.23	5.73	6.73	0.250	0.500	ISE method - direct
Sodium	mmol/l	163	155	171	4.00	8.00	ISE method - direct
total CO2	mmol/l	21.1	16.9	25.3	2.10	4.20	Calculated
	mmol/l	21.3	17.0	25.6	2.15	4.30	Ion Selective Electrode
	mmol/l	21.4	17.1	25.7	2.15	4.30	Spectrophotometric

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All enzyme values are quoted to a temperature of 37°C, unless otherwise stated