

BLOOD GAS CONTROL - LEVEL 2 (BG CONTROL 2)

CAT. NO.	BG5002	LOT NO.	250BG
SIZE:	30 x I.8 ml	EXPIRY:	2023-09-28

GTIN: 05055273227116

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.

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°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 2 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

Randox Teoranta, Meenmore, Dungloe, Donegal, F94 TV06, Ireland

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BLOOD GAS CONTROL - LEVEL 2 (BG CONTROL 2)

Cat. No. BG5002 Lot. No. 250BG Size 30 x 1.8ml Expiry 2023-09-28 Range methods Analyte unit Target low high Calcium mmol/l 1.10 0.990 1.21 Ion selective electrode mg/dl 4.41 3.97 4.85 Chloride 103 **ISE** indirect mmol/l 95.4 87.8 Glucose 5.97 mmol/l 5.19 4.41 Enzymatic Electrode mg/dl 93.5 79.5 108 mmol/l 5.21 4.43 5.99 Glucose oxidase 79.8 108 mg/dl 93.9 Lactate 3.16 2.59 3.73 **Enzymatic Electrode** mmol/l mg/dl 28.5 23.3 33.7 2.20 3.16 Colorimetric mmol/l 2.68 mg/dl 24.1 19.8 28.4 pCO2 kPa 5.63 4.50 6.76 Ion selective electrode kPa 4.42 6.62 **Optical Fluorescence** 5.52 pН pH units 7.392 7.324 7.461 Ion selective electrode pO2 kPa 17.0 14.5 19.6 Ion selective electrode kPa 16.5 14.0 19.0 **Optical Fluorescence** Potassium 3.77 3.47 4.07 ISE method - direct mmol/l Sodium 137 151 ISE method - direct mmol/l 144 Total CO2 mmol/l 26.6 21.3 31.9 Ion selective electrode 26.8 21.4 32.2 Calculated mmol/l