

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 | |
| | | | | | | |