

BLOOD GAS CONTROL - LEVEL I (BG CONTROL I)

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|-----------------|----------------|----------------|------------|
| CAT. NO. | BG500I | LOT NO. | 273BG |
| SIZE: | 30 x 1.8 ml | EXPIRY: | 2024-03-28 |
| 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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| EC | REP | Radox Teoranta, Meenmore, Dungloe, Donegal, F94 TV06, Ireland |
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BLOOD GAS CONTROL - LEVEL 1 (BG CONTROL 1)

Cat. No. BG5001 Lot. No. 273BG Size 30 x 1.8ml Expiry 2024-03-28

| Range | | | | | |
|-----------|----------|--------|-------|-------|-------------------------|
| Analyte | unit | Target | low | high | methods |
| Calcium | mmol/l | 1.94 | 1.75 | 2.13 | Ion selective electrode |
| | mg/dl | 7.78 | 7.01 | 8.55 | |
| | mmol/l | 1.93 | 1.74 | 2.12 | Colorimetric |
| | mg/dl | 7.74 | 6.97 | 8.51 | |
| | mmol/l | 1.94 | 1.75 | 2.13 | Optical Fluorescence |
| | mg/dl | 7.78 | 7.01 | 8.55 | |
| Chloride | mmol/l | 80.6 | 74.2 | 87.0 | Colorimetric |
| | mmol/l | 78.5 | 72.2 | 84.8 | ISE indirect |
| Glucose | mmol/l | 2.05 | 1.74 | 2.36 | Enzymatic Electrode |
| | mg/dl | 36.9 | 31.4 | 42.4 | |
| | mmol/l | 2.06 | 1.75 | 2.37 | Glucose oxidase |
| | mg/dl | 37.1 | 31.5 | 42.7 | |
| | mmol/l | 1.85 | 1.57 | 2.13 | Colorimetric |
| | mg/dl | 33.3 | 28.3 | 38.3 | |
| Lactate | mmol/l | 7.18 | 5.89 | 8.47 | Enzymatic Electrode |
| | mg/dl | 64.7 | 53.1 | 76.3 | |
| | mmol/l | 6.76 | 5.54 | 7.98 | Colorimetric |
| | mg/dl | 60.9 | 49.9 | 71.9 | |
| pCO2 | kPa | 9.38 | 7.50 | 11.3 | Ion selective electrode |
| | kPa | 9.16 | 7.33 | 11.0 | Optical Fluorescence |
| pH | pH units | 7.128 | 7.017 | 7.238 | Ion selective electrode |
| pO2 | kPa | 13.8 | 11.7 | 15.9 | Ion selective electrode |
| | kPa | 12.3 | 10.5 | 14.1 | Optical Fluorescence |
| Potassium | mmol/l | 2.59 | 2.38 | 2.80 | ISE method - direct |
| Sodium | mmol/l | 124 | 118 | 130 | ISE method - direct |
| Total CO2 | mmol/l | 24.8 | 19.8 | 29.8 | Ion selective electrode |
| | mmol/l | 25.0 | 20.0 | 30.0 | Calculated |