

Manufacturer and Product Information

Mission Diagnostics
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Intended Use: MISSION CONTROL™ Blood Gas and Electrolyte Control is an assayed quality control material intended for monitoring the measurements of pH pCO₂, pO₂ in blood gas analyzers and sodium, potassium, chloride, lithium, ionized calcium and total carbon dioxide in ISE electrolyte analyzers.

Product Description: This control material is provided for monitoring analyzer performance. It is packaged in sealed glass ampules, each containing approximately 2 ml of solution. Ampules are packaged 10 per tray with each box containing 3 trays, for a total of 30 ampules per box.

Active Ingredients: MISSION CONTROL™ is a buffered solution of electrolytes (Na⁺, K⁺, Cl⁻, Ca⁺⁺, Li⁺, HCO₃⁻/CO₃⁻²). It has been equilibrated with specific levels of CO₂, O₂, and N₂. This control contains no human-based materials.

For in vitro diagnostics use.**Directions for Use**

The control should be brought to a temperature of 20-23°C before use (see instructions regarding Expected Ranges). Allow at least four (4) hours for ampules to equilibrate to this temperature prior to testing.

For pH/blood gas values, the control should be analyzed within one (1) minute of opening. For electrolyte measurements, this product is stable for up to one (1) hour after opening.

Follow the procedures listed below:

1. Before use, hold the ampule at the top and bottom (with forefinger and thumb) and shake 15-20 times (about 10 seconds) to mix the solution. Tap the ampule to restore the liquid to the bottom on the ampule.
2. Open the ampule by snapping off the tip at the score. Use gauze, tissue, gloves, or an appropriate ampule opener to protect fingers from cuts.
3. Immediately introduce the liquid from the ampule to the analyzer. Follow the manufacturer's instructions for sampling a control material. Depending on the sampling procedure chosen, the following instructions apply:
 - a. Direct Aspiration: Sample the control directly from the ampule.
 - b. Syringe Transfer:
 - i. Use a clean, gas-tight syringe attached to a clean, blunt syringe needle (if available).
 - ii. Prime the syringe by slowly aspirating a small amount (0.2-0.3 ml) of solution from the ampule.
 - iii. Discard this liquid, leaving the dead space of the syringe filled with the control.
 - iv. Aspirate the control from the ampule into the primed syringe. Be careful that air is not drawn in with the liquid. Expel 1 to 2 drops, detach the needle and immediately inject the control into the analyzer sample port.
 - c. Ampule Injector/Dispenser: Assemble and fill the ampule injector following the manufacturer's instructions. Expel one or two drops to rinse the outlet tip and inject the control into the analyzer sample port.
 - d. Capillary Mode:
 - i. Install the appropriate adapter for micro sampling onto the instrument.
 - ii. Sample the contents of the ampule following the recommendations of the instrument manufacturer. Be certain to keep the sampling tip of the adapter below the surface of the liquid during aspiration.

Limitations**Limitation:**

1. This control is sensitive to many instrument related factors that affect analytical results. Because it is not a blood-based material, it may not detect certain malfunctions, which would affect the testing of blood.
2. This product is intended for use as a quality control material and can assist in evaluating the performance of laboratory instruments. It is not for use as a calibration standard and its use should not replace other aspects of a complete quality control program.

Storage:

Store at 18-25°C. Avoid freezing and exposure to temperatures greater than 30°C. You may also store at 4-25°C without adverse effect.

Expected Ranges:

The values for each control analyte on the enclosed Expected Ranges Chart are based on multiple determinations performed on randomly selected samples from each lot. The listing for each instrument represents the expected range for these ampules when tested at 23°C. (Note: pO₂ values will vary inversely by about one percent (1%) per degree C that the temperature of the ampules varies from 23°C.

The Expected Ranges are provided as a guide in evaluating analyzer performance. Since instrument design and operating conditions may vary, each laboratory should establish its own expected values and control limits. The mean value established should fall within the Expected Ranges shown on the chart.

