

G-CAL

EXPECTED TARGETS AND RANGES

| | Mythic 22 | | Mythic 22 AL | |
|------------|-----------|-------|--------------|-------|
| Parameters | Mean | Range | Mean | Range |
| FSC Target | 84 | 83-85 | 81 | 80-82 |
| ALL Target | 62 | 61-63 | 63 | 62-64 |
| | | | | |

| | Mythic 60 | | Mythic 70 | |
|------------|-----------|-------|-----------|-------|
| Parameters | Mean | Range | Mean | Range |
| FSC Target | 82 | 81-83 | 83 | 82-84 |
| ALL Target | 63 | 62-64 | 63 | 62-64 |

INTENDED USE

G-CAL is designed to be used by qualified Field Service Engineers and Manufacturing Test Engineers to check the WBC position on the Mythic 22, Mythic 22AL, Mythic 60 and Mythic 70 haematology analysers.

REAGENTS

G-CAL is a blood control reagent composed of stabilized mammalian granulocytes suspended in a plasma-like fluid with preservatives.

PRECAUTION

G-CAL is intended for use only by trained personnel. All necessary maintenance regarding the instrument, especially the optical bench transverse adjustment, must be done prior to use of G-CAL.

PROCEDURE

- 1. Pull out vial from the fridge, allow vial to warm to room temperature (15 30°C) for 15 minutes before mixing.
- 2. To mix, hold a vial horizontally between the palms of the hands. **Do not pre-mix on a mechanical mixer**.
 - a) Roll the vial back and forth for 20 30 seconds; occasionally invert the vial.
 - b) Continue to mix in this manner until the cells are completely suspended. Vials stored for a long time may require extra mixing.
 - c) Gently invert the vial 8 10 times immediately before sampling.
- 3. After sampling:
 - a) If vial has been open for sampling, clean residual material from the cap and vial rim with a lint-free tissue. Replace the cap tightly.
 - b) Return vial to recommended storage temperature within 30 minutes of use.

CAUTION: Visually inspect the product before use. **Do not use if any visible cell clumps present.**

STORAGE AND STABILITY

Store G-CAL upright at 2 - 8°C when not in use. **Protect vials from overheating and freezing**. Unopened vials are stable through the expiration date if the vials are stored at 2 - 8°C. Opened vials are stable for up to 30 days the vials are stored at 2 - 8°C, provided they are handled properly.

WARNING

POTENTIAL BIOHAZARDOUS MATERIAL.

Wear protective laboratory gloves and other blood barrier protection when handling this control. Human Blood components were not used in the manufacture of this control. However, this control does contain components from non-human sources and may transmit infectious disease. When handling or disposing of product, follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (OSHA 29 CFR Part 1910.1030) or other equivalent biosafety procedures.

LIMITATIONS

The performance of this product is assured only if it is properly stored and used as described in this insert. Incomplete mixing of a tube prior to use invalidates both the sample withdrawn and any remaining material

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