## GroMed<sup>TM</sup> 10mL FTM Tubes

## Microbial Contamination Tester Catalog #GM0101

Direct transfer method of testing for microbial contamination in sterile drug products.

Store upright at 2 to 25°C, out of direct light, until ready to use.

- 1. Carefully add up to 1 milliliter of test solution or ointment into the tube of FTM. This is accomplished either by (a) injection through the needle port or by (b) unscrewing the black cap. Tighten cap if method (b) is used.
- 2. Invert tube to mix contents.
- 3. Complete information on piggyback label provided. Attach label to tube.
- 4. For maximum sensitivity, incubate at  $32.5 + /- 2.5^{\circ}$  C for not less than 14 days.
- 5. Examine the tube of FTM for turbidity. If the FTM remains clear the test is negative. If turbidity is observed, growth from microorganisms is indicated and the test is positive.
- 6. For secondary testing to detect slow growing fungal contamination, use the Q.I. Medical #GM4000, Potato Dextrose Agar slants.
- 7. At end of observation period, remove the piggyback gummed label and transfer to GroMed log. Fill out remaining information in log.
- 8. Dispose of used tube in a safe manner.

NOTE: If more than the upper one-third of the medium has acquired a pink color, the medium may be restored once by heating the containers in a water-bath or in free-flowing steam until the pink color disappears and by cooling quickly, taking care to prevent the introduction of non-sterile air into the container.





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## **GroMed**<sup>TM</sup>Log

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RESI	POSITIVE	Comments												GMI 001 H 6/14
		Organism Identified												
	NEGATIVE	Initials												
	•	Incubation Temperature												
		Media Lot #												
ey, CA 95945 ical com		Solution or Process Tested												
Grass Vall www.gimed		# pooH												
115 Whispering Pines Lane, Suite 150 • Grass Valley, CA 95945 (30) 272-8700 • FAX (530) 272-8702 • www.qimedical.com	1000	Prepared by												
		Sample #												
.15 Whisper	(20)	Test Date												