<u>QI.medical, inc</u>

QTMicro™ System Catalog #TM6000 TSB #TM6001 FTM

Use for testing IV solutions for microbial contamination under the conditions of growth described in the Directions For Use and for verifying aseptic technique.

DIRECTIONS FOR USE

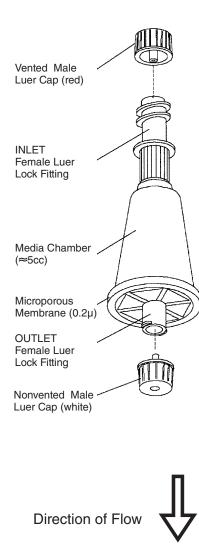
- Refer to USP General Chapter <71> Sterility Tests, www.usp.org
- Single use only
- Manipulations should be performed in a controlled environment.
- Use aseptic technique where appropriate.
- For testing up to 120cc of liquid.
- Rinsing of filter may be necessary to remove residual solution from filter.
- Use for testing clear solutions, emulsions may not pass through the filter.
- A satisfactory result only indicates that no contaminating microorganism has been found in the sample examined under the conditions of the test.
- 1. Remove and discard RED Vented Male Luer cap on INLET Female Luer Lock fitting on QTMicro.
- 2. Attach syringe containing solution to be tested to the INLET Female Luer Lock fitting.
- **3.** Remove and save WHITE Nonvented Male Luer cap from OUTLET Female Luer Lock fitting. Carefully position in laminar air flow to avoid contamination of inner surface of Male Luer cap.
- 4. Firmly attach a sterile, empty (receiving) syringe to the OUTLET Female Luer Lock. The empty syringe must have a capacity equal to or greater than the volume of solution in the syringe being tested.
- 5. Press plunger on syringe containing solution to be tested to transfer solution through QTMicro into the receiving syringe. Pull back syringe plunger slightly and press again to transfer any solution remaining in the filter housing.
- 6. Carefully remove and cap receiving syringe.

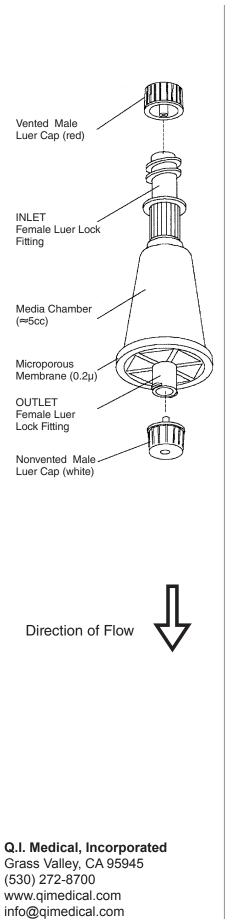
Note: QTMicro is not intended to filter-sterilize (cold sterilize) contaminated solutions or admixtures made from non-sterile ingredients.

- 7. Replace WHITE cap on OUTLET Female Luer Lock fitting.
- 8. Remove empty syringe from INLET Female Luer Lock fitting.
- 9. Attach syringe containing GroMed[™] growth media to the INLET Female Luer Lock fitting.

Note: The Soybean-Casein Digest and Fluid Thioglycollate Medium growth media are formulated according to current USP requirements for performing microbiological sterility tests.

NOTE: Point syringe DOWN while pressing plunger. This will remove air from filter chamber.





- 10. Press plunger on growth media syringe to fill chamber on QTMicro.
- 11. Leave growth media syringe attached to the QT Micro.
- **12**. Complete, then attach gummed label to GroMed syringe.
- **13.** Incubation, USP Chapter <71> Sterility Test Method

Soybean-Casein Digest Medium (TSB) Incubate at 22.5+/-2.5°C for not less than 14 days.

Fluid Thioglycollate Medium (FTM) Incubate at 32.5+/-2.5°C for not less than 14 days.

If the test is positive before 14 days of incubation, further incubation is not necessary.

- **14.** Remove "piggy back" gummed label from QTMicro and record results in QuickTest log.
- 15. Discard used QTMicro filters in a safe manner.
- IMPORTANT:Do not use to test blood, blood products, or emulsions.Do not use if protective covers are missing or not in place.Do not use for direct infusion into patient.Do not resterilize or reuse, discard after use.

Q.I. Medical, Inc. Price List

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SterilityTests Log

RESULTS	POSITIVE	Comments						
		Organism Identified						
	NEG.	Initials						
		Incubation Temp						
		Media Lot #						
v. CA 95945	com	Solution or Process Tested						
Grass Valley, CA 95	www.qimedia	# pooH						
Lane, Suite 150 • 0	(530) 272-8700 • FAX (530) 272-8702 • www.qimedical.com	Prepared by						
Vhispering Pines		Sample #						
1415 Whisp		Test Date						

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