<u>Q.I.medical, inc</u>

QTMicro™ System Catalog #TM6100 TSB #TM6101 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

- Single use only
- Manipulations should be performed in a controlled environment.
- Use in hospital and homecare IV pharmacy Quality Assurance & Improvement programs.
- Use aseptic technique where appropriate.
- For testing up to 120cc of liquid.
- Use for testing clear solutions, emulsions will not pass through the filter.
- 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 Female Luer cap from OUTLET Male Luer fitting. Carefully position in laminar air flow to avoid contamination of inner surface of cap.
- 4. Firmly attach a sterile needle to the OUTLET Male Luer fitting. The needle is then inserted into a sterile, empty container, that has 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 container. Pull back syringe plunger slightly and press again to transfer any solution remaining in the filter housing.
- 6. Carefully remove receiving container from the needle.

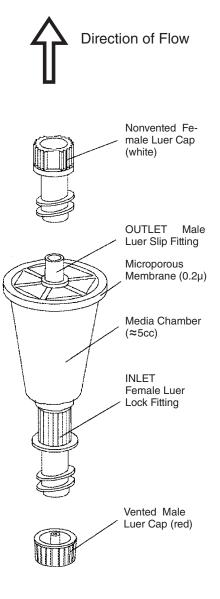
Note: QTMicro is not intended to filter-sterilize (cold sterilize) contaminated solutions or admixtures made from non-sterile ingredients.

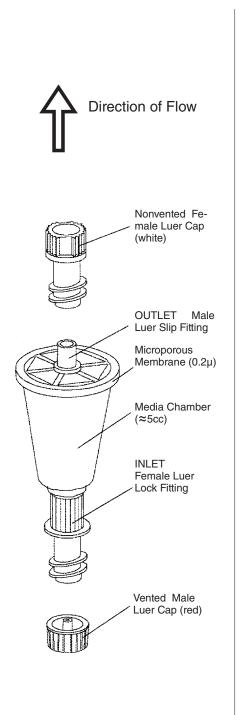
- 7. Remove needle and replace WHITE Nonvented Female Luer cap on OUTLET Male Luer fitting.
- 8. Remove empty syringe from INLET Female Luer Lock fitting.
- 9. Attach syringe containing GroMed[™] growth media to the INLET Female Luer Lock fitting.

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

- **10.** Press plunger on growth media syringe to fill chamber on QTMicro.
- NOTE: Point syringe DOWN while pressing plunger.

This will remove air from filter chamber.





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- 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.

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