

Use for testing large volume IV solutions such as Total Parenteral Nutrition admixtures, for microbial contamination under the conditions of growth described in the Directions For Use and for verifying aseptic technique.

NOTES:

DIRECTIONS FOR USE

- Use in hospital and homecare IV pharmacy Quality Control programs.
 - Use aseptic technique where appropriate.
 - For testing up to 4 liters of liquid.
 - Single use only.
1. Remove and save cover from large-bore male fitting on distal end of QuickTest filter chamber.
 2. Attach large-bore female fitting on 18-inch tubing set to large-bore male fitting on distal end of filter chamber. Attach needle to male luer lock on distal end of tubing set.
 3. Remove and save cover on vented spike. Insert spike into source container. Open vent cap on spike **only** if source container is a non-vented bottle.
 4. Insert needle into septum on receiving container
 5. Hang the source container higher than the receiving container if using gravity to transfer liquid through filter.

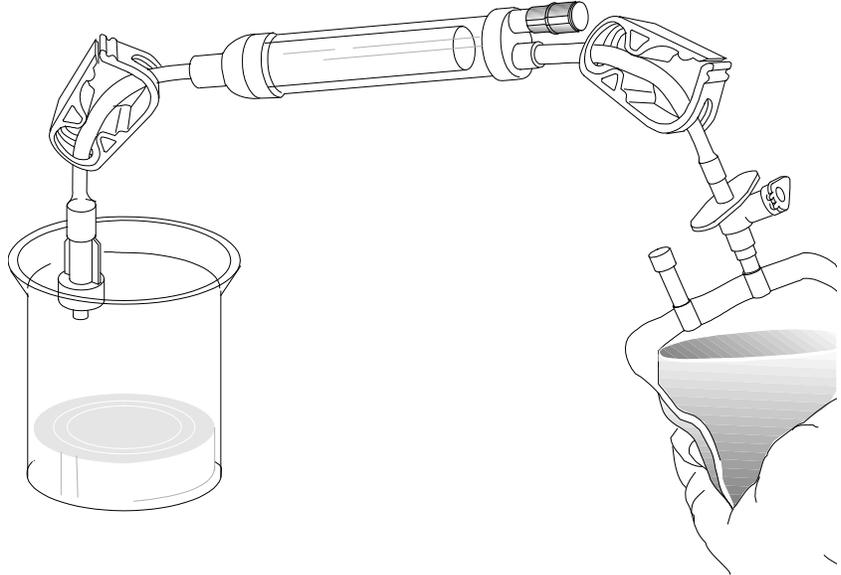
Note: Admixtures containing emulsions may require more than gravity pressure to complete the transfer. Contact your Q.I. Medical representative for details.
 6. Invert QuickTest filter chamber to purge air while priming set. It is not necessary to remove all air from QuickTest filter chamber to achieve high flow rates.
 7. Transfer contents of source container to receiving container.
 8. Close slide clamp on distal end of QuickTest. Remove needle from receiving container.

Note: QuickTest is not intended to filter-sterilize (cold sterilize) contaminated solutions or admixtures made from non-sterile ingredients. Discard filtered solution and receiving container.
 9. Disconnect and discard 18-inch transfer tubing and needle.
 10. Remove and discard empty source container. **Close vent cap** on spike if open. Insert spike into bag of GroMed™ growth media.

NOTE: The Soybean-Casein Digest Medium growth media is formulated according to USP XXVII requirements for performing microbiological sterility tests.
 11. If admixture being tested does **not** contain an emulsion, squeeze bag of growth media to fill filter chamber. Skip direction #12.

- 12. TESTING ADMIXTURES CONTAINING EMULSIONS:** (see illustration). Residual emulsion particles can partially cloud the QuickTest when growth media is added to the filter chamber. Steps a - e will remove most residual emulsion particles and make turbidity caused by microbial growth easier to visualize.

- a.** Open clamp on distal end of QuickTest. Position end of tubing in a clean beaker.



- b.** Most residual emulsion can be removed by rinsing with 40-80cc of media.
- c.** Agitating the filter chamber while rinsing will help remove emulsion particles. Purged admixture and media used for rinsing should be collected in the beaker and discarded.
- d.** Close clamp on distal end of QuickTest.
- e.** Squeeze media bag to fill QuickTest filter chamber.
- 13.** Close clamp on tubing below vented spike. Remove and discard bag of growth media. Reattach cover on spike.
- 14.** Reattach cover on large bore connector on distal end of QuickTest.
- 15.** Complete, then attach gummed label to filter chamber.
- 16.** Incubation
USP Chapter <71> Sterility Tests Method: Incubate at 22.5+/-2.5°C for not less than 14 days. Observe the media on a periodic basis for the 14 days. If the test is positive before 14 days of incubation, further incubation is not necessary.
- 17.** Remove "piggy back" gummed label from QuickTest and record results in QuickTest log.
- 18.** Discard used QuickTest filters in a safe manner.

IMPORTANT: 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.



