

QuickTest[®] System Catalog #QT2000

Aseptic Process Validation Test Kit for Large Volume Parenterals
 Including "3 in 1" TPN and Emulsions

Use for testing large volume IV solutions such as Total Parenteral Nutrition admixtures, for microbial contamination under the conditions of growth described below and for verifying aseptic technique. For use with vacuum bottles, bells, or gravity filtration of clear admixtures.

For use with any pump set with a male luer connector including:

- Acacia[™] Pump
 - Baxter[™] Repeater[™] Pump
 - HyperFormer[™] Compounder
 - PharmAssist[™] Pump
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- 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.
 - 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.

Storage and Disposal: QT System should be stored unopened at room temperature away from direct sunlight. Product can be used up to the expiration date. Dispose of any used components in accordance with State and Federal regulations.

- Materials Provided for 10 Tests:
- QuickTest[®] Device
 - 100mL TSB Bag
 - Gummed Label

INSTRUCTIONS FOR USE

NOTE: The following test procedure should be performed just before the compounder transfer set is discarded.

1. Remove and save cover from female luer lock on proximal end of QuickTest.
2. Connect QuickTest to compounder or pump outlet.
3. Remove and save cover from distal end of QuickTest.
4. Firmly attach receiving container connector to male luer connector on distal end of QuickTest.
5. Depending upon model of compounder or pump, place IV or TPN bag on compounder scale or work bench. Check tubing path to eliminate kinks.
6. Operate compounder to transfer admixture through QuickTest into receiving container.
7. Close clamp on distal end of QuickTest. Disconnect receiving container from luer connector on distal end of QuickTest.
 - A. QuickTest is not intended to filter-sterilize (cold-sterilize) contaminated solutions or admixtures made from non-sterile ingredients. Discard filtered solution and receiving container.

Instructions for use continued



Contamination tester with luer lock connector

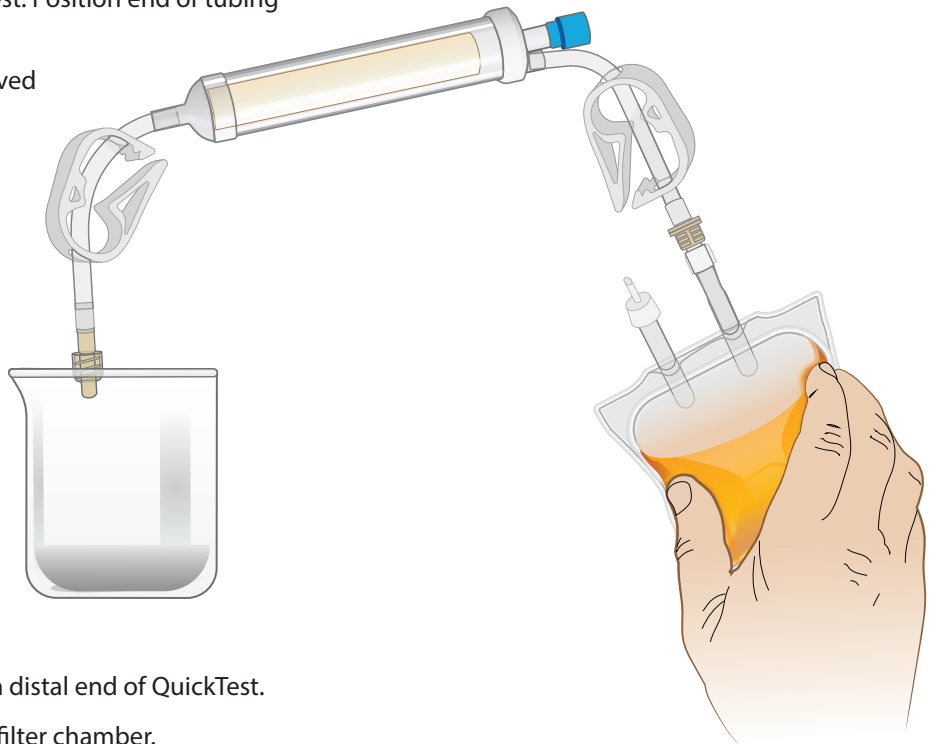
Instructions for use continued

8. Remove and discard empty source container(s) if appropriate.
9. Remove QuickTest from compounder connector.
10. Attach female luer connector on proximal end of QuickTest to male luer connector on bag of GroMed™ growth media.
 - A. The Soybean-Casein Digest Medium growth media is formulated according to UPS XXVII requirements for performing microbiological sterility tests.
11. If admixture being tested **does not** contain an emulsion, squeeze bag of growth media to fill filtered chamber. Skip instruction #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 into a clean beaker.
 - B. Most residual emulsion can be removed by rinsing with 40 - 80 cc 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 Quick-Test filter chamber.
13. Close clamp on tubing below proximal female luer connector. Remove and discard bag of growth media. Reattach cover on female luer connector.
14. Reattach cover to male luer connector on distal end of QuickTest.
15. Complete, then attach gummed label to filter chamber.
16. INCUBATION

Incubate the final containers at 20°–25° C and 30°–35° C for a minimum of 7 days at each temperature band to detect a broad spectrum of microorganisms.
17. Remove “piggy back” gummed label from QuickTest and record results in MediaFill log.
18. Discard used Quicktest filters in a safe manner.



Scan for MediaFill Log



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