Q.I.medical, inc

QuickTest™ System
Catalog #QT1000

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 nonvented spike on proximal end of QuickTest. Insert spike into compounder manifold (outlet).

2. Remove and save cover from distal end of QuickTest.

3. Remove protective cover from blunt connector on empty IV or TPN bag.

4. Firmly insert blunt connector into connector on distal end of QuickTest.

5. Depending upon model of compounder, either hang receiving bag on load cell hook, place on compounder scale, or on work bench. Check tubing path to eliminate kinks.

6. Operate compounder to transfer admixture through QuickTest into receiving bag.

7. Close clamp on distal end of QuickTest. Crimp tubing on receiving bag and remove blunt connector from end of QuickTest.

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.

8. Remove and discard empty source container(s) if appropriate.

9. Remove nonvented QuickTest spike from compounder manifold.

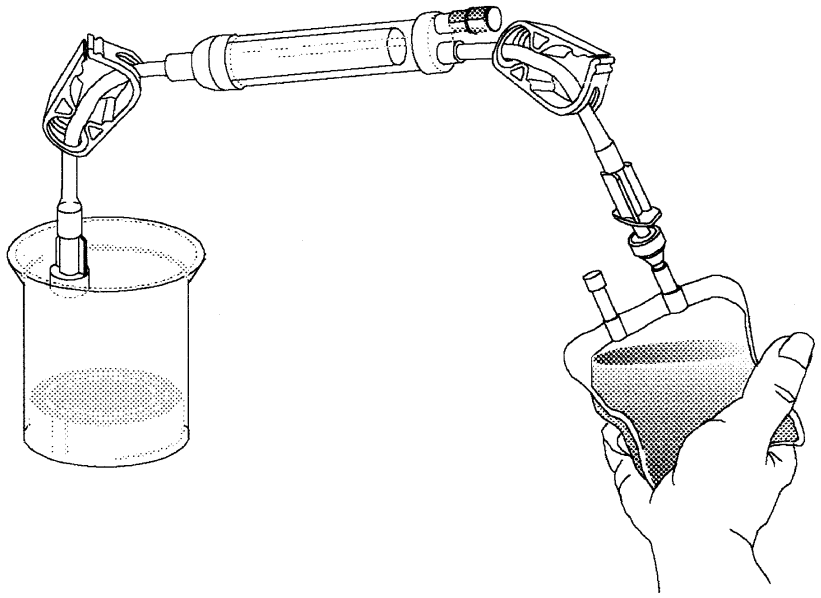
10. Insert nonvented spike on QuickTest into spike port on bag of GroMed™ growth media.

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 with media. Skip direction #12.

12. TESTING ADMIXTURES CONTAINING EMULSIONS:
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 nonvented spike. Remove and discard bag of growth media. Reattach cover on spike.

14. Reattach cover on distal connector on 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.

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Q.I. Medical, Inc.
Price List

Sterility Tests LOG

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							RESULTS		
							NEG.	POSITIVE	
Test Date	Sample #	**Prepared by**	Hood #	Solution or Process Tested	Media Lot #	Incubation Temp	Initials	Organism Identified	Comments