PATT ™

Personal Aseptic Technique Test

Catalog #GM7020

For Low and Medium Risk Levels

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Note: Validation of high risk manipulations may require additional supplies and equipment. If necessary, modify the suggested steps to more closely simulate the most challenging aseptic manipulations performed at your pharmacy. Non-sterile TSB media can be prepared by starting with #GM3000, Soybean-Casein Digest. It is packaged in convenient 3 gram pouches.

1. This procedure is one of the more complex of those the operator will be expected to perform. It consists of adding 20 portions of a vial to a partially filled minibag.

2. Sanitize work area using standard procedures. Swab vial and bag ports according to the pharmacy's standard operating procedures.

3. Select 1 GroMed partially filled minibag, and 1 GroMed 20 ml vial, each containing sterile Trypticase Soy Broth growth medium. Wipe the injection ports of the bag and vial with a wipe dampened with IPA. If using a laminar airflow hood, place the containers at least 6 inches within the work area so as to protect the injection ports and not interrupt the clean air flow.

4. Select 20 sterile 18G x 1" needles (or smaller size as appropriate) and one sterile 3, 5, or 6cc disposable syringe. Remove the syringe from the pouch and place the syringe in the work space.

5. Aseptically attach a needle to the syringe.

6. Withdraw 1 ml of TSB from the GroMed vial and inject the TSB into the bag of sterile TSB. Change the needle. The frequent needle changes make the complexity of the procedure approach a "worst case" situation.

7. Repeat procedure (#6) 19 more times, using 19 different needles but the same syringe and receiving bag of TSB. At the end of these transfers there will be approximately 120 ml in the minibag.

Option 1: High Risk simulation, see Directions for Use for GroMed #GM3000.

Option 2: At this point in the test the complexity of the above procedure can be increased by transferring the entire contents of the GroMed minibag into another empty container. The receiving container, vial or bag, should be a frequently used size. The transfer is accomplished using gravity and a standard sterile pharmacy tubing set.

8. **Immediately** inspect the final container contents for particulates, corings, and fibers. These particles should not be recorded as microbial growth.

9. Label the final container of TSB. For compliance with USP<797>, incubate at a temperature of 20˚ - 25˚C or 30˚ - 35˚C for 14 days.

10. Examine the container of TSB daily for turbidity. If turbidity is observed, growth from microorganisms is indicated and the test is positive. If the TSB is clear, the test is negative and the operator has passed the test.

11. A positive test sample indicates that the operator has introduced microorganisms into the "product" and has failed the test.

12. All **operators** should be revalidated, using the above procedure. Frequency of revalidation depends upon risk level being simulated.

13. After 14 days, transfer piggyback label and enter related data in the GroMed log.

Q.I. Medical, Inc.
Price List

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GroMed™ LOG

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