PATT 2®

Personal Aseptic Technique Test

Catalog #GM7030

QI MEDICAL® INC
FDA REGISTERED | ISO CERTIFIED

For compliance with the current revision of USP <797> it is required to simulate the most challenging aseptic compounding procedures encountered by the person by replacing all the components in the CSPs with soybean-casein digest media. The simulation must capture elements that could potentially affect the sterility of the CSP, including but not limited to:

- Factors associated with the length of the process that can pose contamination risk (e.g., operator fatigue, quality of equipment)
- Number, type, and complexity of manipulations
- Number of personnel in the buffer room or SCA.

If the following procedure differs from the Standard Operating Procedure (SOP) in use, follow the procedure outlined in the SOP. Non-sterile TSB media can be prepared by starting with #GM3000, Soybean-Casein Digest. It is packaged in convenient 3 gram pouches. If you require further assistance with designing a custom personal aseptic technique test, please get in touch with your local QI Medical distributor for further assistance.

Storage: Upon receipt store at 2-25°C away from direct light. Media should not be used if there are any signs of discoloration, contamination or if expiration date has passed. Keep away from direct light, excessive heat, freezing and moisture. FOR LABORATORY USE ONLY

MATERIALS PROVIDED

- 20ml vials of TSB media
- 100ml partially filled mini-bags for added complexity
- 3ml ampules of colored TSB media
- Gummed labels included

Product conforms to United States Pharmacopeia standards

MATERIALS REQUIRED BUT NOT PROVIDED

- Sterile syringes
- Sterile needles
- Sterile wipes
- Incubator(s)

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Also available at:
www.qimedical.com

INSTRUCTIONS FOR USE

1. This procedure is one of the more complex of those the operator will be expected to perform. It consists of adding the contents of an ampule to a vial, then transferring 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 ampule, 1 GroMed partially filled minibag, and 1 GroMed 20 ml vial, each containing sterile Trypticase Soy Broth growth medium. Wipe the ampule and 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 an appropriate sized sterile needle and syringe. Remove the syringe from the pouch and place the syringe in the work space.
5. Aseptically attach a needle to the syringe.
6. Draw up contents of the ampule and inject into the GroMed vial. Shake to mix indicator dye.
7. 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.
8. Repeat procedure (#7) to closely mimic the number of units compounded under the most difficult or challenging compounding procedure.
9. * If performing a non-sterile to sterile simulation, see Instructions for Use for GroMed #GM3000.
10. Immediately inspect the final container contents for particulates, corings, and fibers. These particles should not be recorded as microbial growth.
    *Immediately following the final manipulation of the media fill test, operator shall perform surface sampling as well as gloved fingertip sample per USP 797 requirements.
11. Label the final container of TSB. Incubate in an incubator for 7 days at 20-25°C followed by 7 days at 30-35°C to detect a broad spectrum of organisms.
12. 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.
13. A positive test sample indicates that the operator has introduced microorganisms into the "product" and has failed the test.
14. All operators should be revalidated, using the above procedure. Frequency of revalidation depends upon risk level being simulated.
15. After 14 days, transfer piggyback label and enter related data in the GroMed log.