SteriTEQ™ Directions for Use

The SteriTEQ is designed to monitor the sterility of products that are compounded by hospital, clinical, and home healthcare pharmacy CSP opreratives and Nursing personnel who are required to compound sterile products.

The SteriTEQ is a highly-concentrated Trypticase-soy broth (TSB) USP growth medium. Utilizing the product as the test diluent, SteriTEQ is aseptically added to the actual product container in the amount of 5 mL per 100 mL of the final product volume to bring the entire volume to a normal, 1X TSB test solution. In this manner, the entire product is transformed into a microbiologic growth medium within its final container. Within this medium, the growth of any aerobic and facultative anaerobic microbiota, introduced as a result of compromised storage, handling, or improper compounding procedures, is promoted. Such growth will produce turbidity within the product following incubation, facilitating a simplified Pass/Fail test result by observation.

Inoculation of any product with the SteriTEQ Concentrate constitutes a “Destructive Test” of the product, rendering it unusable and a potential hazard to the patient. Once inoculated as a test subject, the end-product is isolated from the institutional product stream to be disposed of immediately following the development and documentation of the sterility test result.

General Directions for Use

A SteriTEQ vial should be assigned to each individual performing sterility monitoring. In the case of multiple tests, this vial should be handled and stored carefully as a multi-dose vial to be used only by the individual to whom it is assigned. In this manner, any 'false-positive' result introduced by others may be ruled out.

1. Assure that the SteriTEQ Concentrate is at room temperature (20 ° - 25 °C.).
   Swirl the vial for fifteen seconds, or until any sedimentation due to storage is re-dissolved.
2. Aseptically withdraw 5 mL of SteriTEQ Concentrate per 100 mL of solution to be monitored. (In cases where Large Volume Parenterals of greater than 500 mL are monitored, it is possible to aseptically reduce the volume of the LVP to 500 mL in order to conserve the test medium.
   NOTE: Great care must be exercised in eliminating and disposing of product volume in order that its sterility will not be compromised.)
3. In the manner of a routine additive, aseptically add the Concentrate to the finished product through its additive port, and mix thoroughly. Apply a tamper-evident seal to the additive port.
4. Complete and affix the test label to the test product. Do not obscure critical information on the patient label.
5. Enter the test procedure in the testing log, and place the test subject in a stable room temperature environment (20°- 25°C.). No incubator is needed.

IMPORTANT: A careful line-clearance of the compounding area should be carried out prior to, and immediately following, completion of the sterility monitoring exercise to ensure that all SteriTEQ materials and components have been removed from the compounding area, thus preventing any of these materials from entering the institutional drug stream.

Incubation and Interpretation of Results

Immediately incubate the test admixture at controlled room temperature (20 - 25 degrees C.; 68 -77 degrees F.).

Periodic examination of the test admixture(s) should be carried out at 24 hrs, 72 hrs, 1 week, and 2 weeks. Complete clarity of the test solution(s) indicates a negative test result (Pass). Turbidity (cloudiness) of the test medium or sedimentation present at any time during the incubation period constitutes a positive test result (Conditional Failure), indicating the need for additional training of the candidate in aseptic procedures. In this case, the test subject should be immediately transferred to the microbiology laboratory, and a qualified microbiologist consulted in order to subculture the test solution. If a positive subculture confirms microbiologic contamination (Confirmed Failure), the microbiologist should identify the organism(s) and render an opinion as to the likely source, or route of introduction. This will assist the Pharmacy Manager in determining the appropriate retraining or other corrective action(s). Following completion of incubation, the test subject should be disposed of immediately in the normal manner of product disposal.