SteriQUOT™ Directions for Use

SteriQUOT is designed to monitor the sterility of products that are compounded by hospital, clinical, home healthcare pharmacy IV Admixtures operatives, and Nursing personnel. SteriQUOT is a 2X concentration of Trypticase-soy broth (TSB), USP. A 10-12 mL sample of the finished admixture is aseptically added to the SteriQUOT vial, and the vial is then incubated. 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 to produce turbidity within the sample following incubation.

Inoculation of any product sample into the SteriQUOT Sterility Monitor following compounding and prior to delivery to the patient constitutes a “non-destructive” test of the product, rendering the remainder of the product useable by the patient. The SteriQUOT Sterility Monitor should be isolated from the institutional product stream and should be destroyed immediately following the development of the sterility monitoring result . This will prevent the product from entering the institutional drug stream.

General Directions for Use

The SteriQUOT test vials should be handled and stored carefully as single-use vials.

1. Assure that the SteriQUOT Concentrate is at room temperature (20 ° - 25 ° C.), and swirl the
   vial for fifteen seconds.
2. From the additive port of the bag or bottle, aseptically withdraw a 10-12mL sample of the sterile admixture to be monitored.
3. Using low-pressure ('See-Saw') technique, aseptically add the monitor sample to the SteriQUOT vial in the normal manner, allowing the pressure within the vial to equalize with ambient (outside). Swirl vial gently to mix thoroughly. (Do not shake.)
4. Complete the test label affixed to the SteriQUOT monitor.
5. Enter the test procedure in the Sterility Monitoring 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 SteriQUOT 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 a probable failure in the aseptic technique of the candidate and the need for additional training of the candidate in aseptic procedures. If any turbidity or non-

resoluble sedimentation is detected, 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 Sterile Products Preceptor in determining the appropriate retraining or other corrective action(s). Following completion of incubation, the test subject should be disposed of in the normal manner of product disposal.