State of South Carolina Certification Requirements for Enterolert™ Quanti-Tray® Test Method from IDEXX for Enterococci in Water

This method is a 24-hour test for the quantification of enterococci.

To obtain certification under the South Carolina Certification Program the following documentation must be submitted in addition to the completed application and application fee prior to scheduling an on-site laboratory evaluation:

1) A Standard Operating Procedure (SOP) which outlines the procedures followed by the laboratory for the analysis of enterococci samples. No variations from the referenced method are allowed. The following items must also be addressed in the SOP:

    a) Equipment and supplies
    b) Media, reagents and standards
    c) Sample collection, preservation and storage
    d) Quality control practices and frequency of implementation

2) Documentation of start-up data that includes analytical records for at least five samples.

3) A media receipt record that documents the following:

    a) Date received
    b) Type of medium
    c) Lot number
    d) QC checks (see below). Attach all necessary documents.

Minimum Quality Control Requirements: (Each must be documented)

Each lot of Enterolert medium must be checked before use with enterococci positive, gram negative, and gram positive bacteria. Directions for performing this quality control check and recommended organisms are provided in the Enterolert Test Kit instructions.

Each lot of Enterolert medium must be checked for sterility with sterile deionized/distilled reagent water blank before use.

At least once per week a known positive control (enterococci pure culture) and sterile deionized/distilled reagent water blank must be analyzed. These quality control checks are in addition to the initial checks of the medium.

Each lot of sample containers must be checked for sterility.

The Quanti-Tray® sealer must be checked at least monthly by adding a dye (e.g., bromcresol

purple) to the water. If dye is observed outside the wells, another sealer must be obtained.

The sterility documentation from the manufacturer for each lot of Quanti-Trays must be maintained by the laboratory.

The laboratory must be certified for Temperature.

Reminders:

Marine waters must be diluted at least tenfold. These dilution procedures must be addressed in the SOP.

Use sterile deionized or distilled reagent water, **not** buffered water, for making dilutions. If reagent water is sterilized in the lab, sterilization records must be maintained.

The incubator temperature must be checked and documented at least twice daily, with at least a four hour separation between measurements. The thermometer used to determine incubation temperature must be checked against an NIST or NIST-traceable thermometer at least annually and the thermometer must be tagged with the results.

Enterolert medium must be stored in the dark at 2-30° C. If monthly quality control data are acceptable, the medium may be used until the manufacturer's expiration date.

All glassware that comes in contact with the sample must be sterile, and a sterilization record must be available unless the items are purchased presterilized.

The laboratory must have procedures to dispose of microbiological waste associated with the Enterolert test. This may be accomplished by autoclaving positive samples for thirty minutes at 121° C. A biobag or comparable product should be used to contain the used Quanti-trays during autoclaving.