

MicroBiologics

Guideline for Qualitative Food Process Controls

“QL-FPC”

Assayed Control Microorganism Challenges for Presence/Absence, Positive/Negative or Qualitative Detection Test Methods

This document is designed to serve as an example or guideline in developing a quality assurance program for microbiology Qualitative Detection Test Methods. **The guideline must be adapted to the specific demands imposed on each individual laboratory.** Several important considerations must be raised.

EZ-FPC™ (Food Process Control) Microorganisms

The EZ-FPC™ Microorganisms are lyophilized and assayed control microorganism preparations. The process design for these preparations offers a quality control challenge to measure and provide documentation that a qualitative test method performs within an anticipated range of tolerance.

The production and process design for these lyophilized microorganism preparations results in a mean assay value that falls within a range of **100 TO 990** (1.0E+02 – 9.9E+02) **CFU per pellet** for Qualitative Process Controls.

Quality control documentation includes, but is not limited to, a Certificate of Assay stating:

- a) The identity and traceability of the microorganism preparation to a reference culture
- b) The number of passages the microorganism preparation has been removed from the reference culture
- c) The mean assay value for the microorganism preparation.

Microorganism Challenges

Each qualitative food process control (QL-FPC) consists of a reference stock culture that is derived from and traceable to the American Type Culture Collection (ATCC®) or other authentic reference culture collection. Each lyophilized QL-FPC preparation contains a target microorganism at a known concentration. Examples of QL-FPC include, but are not limited to:

***Escherichia coli* O157:H7**

Listeria monocytogenes

Salmonella abaeetuba

Objective for QL-FPC

Each day that a Qualitative Detection Test Method is run, the specific QL-FPC must be performed. This regular use of QL-FPC provides evidence and leads to documentation that each Qualitative Detection Test Method continues to meet the range of tolerance for which the method was validated.

Food Sample Matrix

A review of the actual procedure will reveal that a sterile solution of non-fat dry milk (NFDM) is used as the sample matrix. The ideal situation would suggest that a QL-FPC be run with each type of food sample analyzed in the laboratory. The real situation suggests that this practice is cost-prohibitive AND it may be difficult or impossible to achieve a uniform distribution of the QL-FPC microorganism population throughout all food types.

QL-FPC Cocktails

It is not necessary to prepare, process, and run each challenge microorganism separately. When a similar Pre-Enrichment Broth is shared for more than one test method, several challenge microorganisms can be combined.

QL-FPC DIRECTIONS FOR USE**A. Preparation of 100 mL Vials of 1:10 NFDM**

1. Weigh out 10.0 grams of Non-Fat Dry Milk (NFDM).
2. Place into a screw cap vial container.
3. Add 90.0 mL of pH 7.2 Phosphate Buffer.
4. Mix thoroughly.
5. Sterilize the 1:10 NFDM vials at 121°C for 15 minutes.
6. Store the sterile 1:10 NFDM at 4°C to 8°C.

B. Preparation of Pre-Enrichment broth

1. Prepare individual 225.0 mL volumes of Pre-Enrichment Broths according to Laboratory SOP.

C. QL-FPC Processing

1. Add 25.0 mL of the 1:10 NFDM to 225.0 mL of Pre-Enrichment Broth (NFDM: PEB).
2. Incubate the NFDM: PEB at 35°C to 37°C for sixty (60) minutes.
3. Remove the appropriate EZ-FPC™ Microorganism vial(s) from refrigerated storage and allow the unopened vial(s) to equilibrate to room temperature.
Vials containing lyophilized microorganism pellets should be allowed to equilibrate to room temperature before opening. If cold vials are opened, condensation can collect in the vial. The combination of moisture and oxygen can produce toxic free radicals that can reduce the recovery of lyophilized microorganisms.
4. Place a pellet(s) of the lyophilized assayed control microorganism(s) into the NFDM: PEB.
5. IMMEDIATELY, replace the rubber plug, reseal the vial, and return the desiccant-containing vial of the remaining EZ-FPC™ Microorganism pellets to refrigerated storage.

6. Mix each QL-FPC thoroughly and incubate the seeded NFDM:PEB at 35°C to 37°C for thirty (30) minutes.
Gelatin is an integral component of the lyophilized pellet and provides its structure. This gelatin dissolves above 30°C. Prewarming the 1:10 NFDM and incubating each QNT-FPC sample at 35°C to 37°C for 30 minutes is ESSENTIAL to assure a homogenous suspension of the assayed control microorganisms.
7. Following the initial thirty (30) minute incubation and hydration, the seeded QL-FPC must be mixed thoroughly to ensure an even distribution of the challenge microorganism population. Return the seeded QL-FPC to the incubator for the remainder of the pre-enrichment step.

D. QL-FPC Analysis

1. Process and analyze each QL-FPC according to the appropriate Presence/Absence Test Method.
2. Record the test results.
The designation “Positive” or “Negative” is the test method result to be recorded. The Mean Assay value of the EZ-FPC™ Microorganism is the inoculum colony count to be recorded.
3. Pellet CFU. The stated performance and specifications for a qualitative EZ-FPC™ Microorganism is a pellet concentration of 100 to 990 (1.0E+02 – 9.9E+02) CFU per pellet.
4. Mean Assay Value. A Certificate of Assay is attached to each EZ-FPC™ Microorganism Unit-Of-Sale. The stated Mean Assay Value provides statistical documentation that the product's performance and specifications have been met.
5. Each laboratory must select the statistical analysis method most appropriate to the sample and develop a reporting system. The chart provided is just one way to portray Qualitative Food Process Control QA Results.

The statements contained herein are offered for informational purposes only and are intended to be followed only by persons having related technical skills and at their own discretion. Since conditions and manner of use are outside of our control, we make no warranties, expressed or implied, and assume no liability in connection with any use of this information.

QL-FPC Quality Assurance Test Results Illustration

|

QL-FPC Quality Assurance Test Results Illustration

QL-FPC Quality Assurance Test Results Illustration

QL-FPC Quality Assurance Test Results Illustration

QL-FPC Quality Assurance Test Results Illustration

QL-FPC Quality Assurance Test Results Illustration

QL-FPC Quality Assurance Test Results Illustration

QL-FPC Quality Assurance Test Results Illustration

QL-FPC Quality Assurance Test Results Illustration

QL-FPC Quality Assurance Test Results Illustration

QL-FPC Quality Assurance Test Results Illustration

QL-FPC Quality Assurance Test Results Illustration